Ethics Review Committee

Standard Operating Procedure Manual

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	Ethics Review Committee CINEC Campus	
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1. Purpose

The Ethics Review Committee (ERC), CINE campus is established to safeguard the rights and safety of all human subjects participating in biomedical research; and to promote standards of human research through ethical, efficient and effective review and monitoring processes in accordance with the guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL Guidelines)

2. Detailed instructions:

Scope of Responsibilities:

2.1. ERC, CINEC shall

1. provide oversight on all matters relating to ethics of research projects involving human subjects.
2. ensure that the fundamental principles of research viz. autonomy, beneficence, non-maleficence and justice are adhered to in research involving human subjects.
3. provide independent, competent, timely ethics review and monitoring of research projects involving human subjects.

2.2. The CINEC ERC shall review only research proposals submitted by students faculty staff and the ERC, accept as valid, an ethics approval given by the ERC/IRB of another institution, for the purpose of approving the commencement of a project. The ERC may review research proposals from researchers outside the CINEC provided following factors.

i. the role of the ERC in providing ethics approval and monitoring of the research

ii. the role of the institution to which the researcher is accredited in giving approval for the research to be conducted within its premises;

iii. a statement that the institution to which the researcher is accredited bears responsibility for liabilities arising from the conduct of research.

2.3. All applications will be subject to a handling fee as decided by the Board of Management of CINEC.

2.4. The CINEC ERC will review research protocols in accordance with the guidelines of the Forum of Ethics review committees in Sri Lanka (FERCSL) and ERC, shall seek advice from another ERC and/or an external reviewer if the committee lacks the expertise among its members to review specific subject or technical areas

2.5. The 'human research projects' include, but are not limited to, research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, medical records and clinical databases, as well as epidemiological, social and psychological investigations using human subjects.

2.6. CINEC ERC shall not function as a committee funding research and approving research grants

1. Purpose

To describe the membership composition of the CINEC ERC

2.Detailed instructions

2.1. The composition of the CINEC ERC shall be in accordance with the FERCSL Guidelines.

2.2. The committee will comprise ten (10) members.

2.3. Members shall be appointed to ensure that the CINEC ERC has the expertise required to assess the applications submitted to it for consideration.

2.4. Membership of the CINEC ERC will be constituted as follows:

- 2.4.1. Medical members. Both clinicians and non-clinicians will be included.
- 2.4.2 Non-medical scientists.
- 2.4.3. Legal member.
- 2.4.4. Lay members.

2.5. The committee elect its chairperson from among its members

2.6. Ethics Review Committee members shall be appointed by the CINEC research committee.

2.7. Where required, the ERC may seek advice and assistance from appropriate independent external reviewers to assist with the review of a proposal. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter

	Ethics Review Committee CINEC Campus	
	**SOP – 03 Appointment of ERC members** 2020 Version 1 Effective Date :01 September 2020	

1. Purpose

To describe the procedure for appointment of members to the ERC and their responsibilities

2. Detailed instructions

4.1. Members will be appointed by the CINEC research committee. The CINEC president will issue the letters of appointment (Annex 3) with terms of reference. Vice President, academic and research functions as an ex-officio member.

4.2. Members of the CINEC ERC may be recruited by calling applications among the internal academic staff members. Members are appointed as individuals for their knowledge and experience and not by positions held or as representatives of any organization, group or opinion. When the vacancies are advertised the academic members shall apply for the membership in the ERC.

4.3. Members shall provide a updated Curriculum Vitae (Annex 2) to the ERC and shall agree to their names and professions being made available on the CINEC website.

4.4. The letter of appointment shall include the date of appointment, length of tenure, to conduct of duties as an ERC member.

4.5. Members will be required to sign a confidentiality agreement (Annex 1) and a conflict of interest agreement upon appointment.

4.6. Upon appointment, members shall be provided with Standard Operating Procedures of the ERC, Up-to-date list of members' names and contact information and any other relevant information about the ERC's processes, procedures

4.7. Members are appointed for a period of three (03) years. Members are eligible to be reappointed for one more term consecutively to complete two terms accounting six years (06) of service.

4.8. Appointments shall allow for continuity, the development of expertise within the ERC, and the regular input of fresh ideas and approaches.

4.9. The committee shall elect its Chairperson, Vice Chairperson and Secretary from among its members already in the committee at the end of its term and inform to the CINEC research committee.

4.10. All members are encouraged and expected to attend education and training sessions.

4.11. Members may seek a leave of absence from the ERC for a period not exceeding six months

4.12. Membership will lapse if a member fails to attend three (03) consecutive meetings of the ERC without reasonable excuse/apology, unless exceptional circumstances exist. Such circumstances should be notified to the ERC in writing. In the event that membership has lapsed, the Chairperson will notify the member of such lapse of membership in writing.

4.13. Membership will lapse if a member fails to attend, in full, at least two thirds of all scheduled ERC meetings in each year, barring exceptional circumstances. Such circumstances should be notified to the ERC in writing

4.14. A member may resign from the ERC after one moth prior notice in writing with valid reasons through Chairperson, ERC. Steps shall be taken to fill the vacancy as per SOP - 03/2018, 4.2

1. Purpose

To describe the functions of members of the CINEC ERC.

2. Detailed instructions

It is the responsibility of the ERC members, to function as per SOP and TOR. The Chairperson and the Secretary of the ERC are expected to perform additional duties as detailed below

2.1. Responsibilities of a member

2.1.1 attend meetings regularly. Those who are unable to participate meetings in person, can join the meetings through videoconferencing or teleconferencing with prior notice.

2.1.2. Remain independent, impartial, and objective

2.1.3 Maintain confidentiality with regard to all matters pertaining to the ERC.

2.1.4. Disclose conflicts of interests and where a conflict exists, refrain from reviewing, and leave the room during deliberations and voting.

2.1.5 When assigned as primary reviewers;

2.1.6 Complete and handover assessment forms to the Secretary two (02) working days prior to the scheduled ERC meeting. If unable to attend, the forms should be sent to the Secretary ERC two (02) working days before the scheduled ERC meeting.

2.1.7. Lead the discussion and summarize in order to make decisions at full board meetings.

2.1.8 Decide by vote or consensus, whether to approve, request revisions, not approve or defer studies following deliberation at full board meetings.

2.1.9 Keep up-to-date with national and international research ethics and regulatory guidance.

2.1.10. Perform any other duties assigned to members according to the SOPs.

2.2. Responsibilities as the Chairperson

2.2.1.Conduct all meetings of the CINEC ERC according to the SOPs and provide guidance to ERC members and office staff.
2.2.2.Periodically review existing policies and formulate new ERC policies and guidelines in consultation with the members of ERC.
2.2.3.Review applications, progress reports, and monitor studies whenever required.

2.3 Responsibilities of Secretary

2.3.1. Organize the meetings, maintain records and arrange communications with all concerned.

2.3.2 Prepare the minutes of the meetings, attend to general correspondence with applicants and get it approved by the Chairperson before communicating with the members /applicants.

2.3.3. Ensure that membership files are current and up-to-date. Assign primary reviewers for applications in consultation with the Chairperson and co-ordinate the review process.

2.3.4. Provide guidance and supervision to the CINEC ERC office staff.
2.3.5. Classification of Protocols into various categories
2.3.6. Summarize the discussion after each protocol during the board meeting (j). review of progress reports, and monitor studies whenever required.

2.4. Lay person and legal person

(Other than the above TOR as a member they are expected to represent the public opinion and specifically review the how the author elicits the informed consent and to review the information sheet and the consent form. Legal person should review regulatory related matters along with the other ethical issues related to the study. However, they shall review the validity of the proposal as a whole.

2.5. ERC office staff

Coordinate collection and process all initial, continuing review, and study modification submissions. Maintain the electronic database of the ERC and to use database to track protocols and send reminders. Check all applications for completeness. Consult Chairperson and Secretary to schedule the ERC meeting date, agenda preparation, meeting procedure and

minutes. Prepare the meeting agenda according to the standard format in consultation with Chair and Member secretary. Reserve a place for the scheduled meeting on scheduled date and time. Make sure that the room, equipment and facilities are available in good condition for the meeting. Send the approved minutes (hard copies) to all ERC members and arrange all study related documents for subcommittee/full board meetings to be discussed. Follow strict procedures to maintain confidentiality of ERC documents. Perform any other duties assigned by the Chairperson and Secretary. Maintain training records for all ERC members.

1. Purpose

To describe the procedure for the orientation of new members of the ERC and to inform the members why training (Annex 4) is necessary and how the members should seek to attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

2. Detailed instructions

2.1. New ERC members must be provided with adequate orientation. New member orientation may include Introduction to other ERC members prior to the ERC meeting, Informal meeting with the Chairperson, Secretary and officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures.
2.2. Encourage the new members to attend the training workshops conducted by FERCSL (d). Advise the members to follow the online training program
2.3. Conducting regular training sessions along with the monthly ERC meeting on important topics in research ethics by the experienced members who are in the ERC or by past ERC members

2.4. New members will receive training in:
(a). Research Ethics and Human Subject Protection (b). Standard Operating Procedures of the committee (c). Good clinical practice

1. Purpose:

To describe the procedure for submission of new applications

New protocol submission includes initial submission of new protocols, resubmission of corrections/amendments and continuing review of approved protocols. It is the responsibility of the Secretary to receive, record, and distribute the protocols among the reviewers.

2. Detailed Instruction:

2.1. Applications must be submitted to the Secretary/ERC in the format prescribed by the ERC and shall include all necessary documents. ERC application (Annex 5) is available in the CINEC website.

2.2. Guidelines to fill the ERC applications are available in the CINEC website.

2.3. Applications should be accompanied by the following documents:

1. Covering letter written to Chairperson signed by the applicant.
2. Declaration of Applicant (Annex 06)
3. Submission Check List. (Annex 07)
4. Research Protocol (03 copies)
5. One-Page summary proposal (03 copies)
6. Information Sheet (Annex 08) and Consent Form (Annex 09) in English, and in Sinhala and Tamil where appropriate (03 copies).
7. Other relevant documents (i.e. questionnaires) in English, and in Sinhala and Tamil where appropriate (03 copies)
8. Approval letter from the relevant Board of Study for postgraduate study protocols.

9. Updated Curriculum Vitae of principal investigator and all the co- investigators as per Annex 10. In general, each CV should not be more than 2-3 pages, unless a complete CV is specifically requested for.

2.4. Supporting staff of the ERC office ensures that all required forms and documents are submitted along with the application under the supervision of the Secretary.

2.5. Upon receipt of complete protocol, supporting staff of the ERC office should issue a unique registration number and enter the protocol in to the electronic database. Format of the number should be ERC/CINEC/current year/serial number.

2.6. Document Receipt Form will be issued upon receipt of complete application along with all the necessary documents as per Annex 11.

2.7. A compressed/zipped folder containing soft copies of all the documents relevant to the application should be emailed to the ERC within 24 hours of receipt of Document Receipt Form. Subject of the email should be ERC Registration Number followed by the last name of the applicant (eg. ERC/CINEC/2020/XXX – Perera).

2.8. Upon receipt of an email from the principal investigator, all the protocols will be circulated among all ERC members via email.

2.9. A fee will be charged for applications.

2.10. Duly completed applications are accepted by the ERC office from Monday through Friday (except on public holidays) during office hours (9.00am to 4.00pm).

2.11. Deadline of applications for the regular monthly meeting shall be the close of business of the last working day of the previous month.

2.12. In the event of a public health emergency, such as the investigation of a disease outbreak or a disaster relief operation, the investigators may request a proposal to be reviewed expeditiously. In such instances, the Chairperson/Secretary may call an emergency meeting of the subcommittee/full committee to discuss such protocols.

1. Purpose

To describe the procedure of appointing independent external reviewers and their roles and responsibilities

2. Detailed instructions

Upon the advice or the recommendation of the Secretary/any other ERC member, it is the responsibility of the ERC to nominate and approve the names of the independent external reviewers to be approved by the Chairperson.

2.1. Subcommittee meets weekly on Monday and screen all the new proposals received within the previous week. Subcommittee assesses the degree of risk involved and decides the review type.

2.2. Degree of Risk

There are three levels of risk associated with human research as follows: No risk, Minimal risk, and More than Minimal Risk. Degree of risk involved in a particular research will be determined based on these risk levels. This categorization should be applied as defined in the FERCSL guidelines.

2.3. Types of review:

Based on the degree of risk, a proposal will be subjected to one of the review types

2.3.1.Exemption from review (annex 12)

No risk is associated and proposals are exempted from ethics review when there is no possibility of harm arising as a result of the conduct of the research project or when the information being collected is available from the public domain.

2.3.2. Expedited review (annex 13)

A proposal is considered for expedited review when the research procedures present no more than minimal harm to the research participants or communities. In

this case, the proposal is reviewed by the subcommittee.

2.3.3. Full committee review

All research protocols with more than minimal risk to human subjects are reviewed by two ERC members as per SOP 10, using the prescribed format (Annex 05 Part B), who present the protocol to the ERC followed by a general discussion and a consensus decision. All the member of the ERC are expected to go through such proposal and provide their comments at the discussion.

1. **Purpose:** To describe the procedure for new protocols exempted from review

   Protocols which carry less than minimal risk fall under this category. It is the responsibility of the subcommittee comprised of the Chairperson, the Secretary, and an assigned member of the ERC to grant approval for exemption.

2. **Detailed Instruction:**

   2.1. At the weekly subcommittee meeting, new proposals received within the previous week will be reviewed and the proposals with less than minimal risk will be exempted from review.

   2.2. Proposals that fulfil any of the following conditions are exempted from review

      2.2.1. Does not involve collection or use of individual level data or community level data on sensitive topics

      2.2.2. All data to be used are freely available in the public domain

      2.2.3. Research on cadavers and death certificates provided such research reveals no personally identifiable data

      2.2.4. Audits or educational practices

   2.3. Applicants whose applications qualify for exemption will be informed by the Secretary.

   2.4. Applications which are eligible for exemption from review will be submitted to the next ERC meeting for ratification of the decision of the subcommittee.

   2.5. Formal letter of exemption will be issued only after confirmation of the subcommittee's decision by the ERC (Annex 12).

1. **Purpose:** To describe the procedure for expedited review of new protocols

Protocols that carry a minimal risk to the participants or the community fall under this category. It is the responsibility of the subcommittee comprised of the Chairperson, the Secretary, and an assigned member of the ERC to grant approval.

2. Detailed Instruction:

2.1. Subcommittee meets weekly on Monday and screen all the new proposals received within the previous week. Subcommittee assesses the degree of risk involved and decides the review type.

2.2. Subcommittee may undertake expedited review of proposals with minimal risk and those on non-sensitive topics under following circumstances; when the participants are not considered a vulnerable group or the topic of research is not considered a sensitive topic

2.3. Applicants whose applications qualify for expedited review by the subcommittee will be informed by the Secretary the results.

2.4. Applications which are eligible for expedited review will be submitted to the next ERC meeting for ratification of the decision of the subcommittee.

2.5. Formal letter of approval will be issued only after the confirmation of the subcommittee's decision by the ERC (Annex 13).

1. **Purpose: To describe the procedure for full board review of new protocols**

   Protocols which carry more than minimal risk fall under this category. Proposals which were not considered for exemption nor expedited review as needing full board review also will be reviewed.

2. **Detailed Instruction:**

2.1. Subcommittee meets weekly on Monday and screen all the new proposals received within the previous week. Subcommittee assesses the degree of risk involved and decides the review type. Proposals with more than minimal risk will undergo full board review.

2.2. If proposal is not exempted nor undergone expedited review, then the subcommittee will assign primary reviewers based on their expertise. One scientific reviewer and one non-scientific reviewer will be assigned to each protocol coming under this category.

2.3. The scientific reviewers are tasked to review technical soundness and related ethical issues while the non-scientific reviewers are tasked to review the informed consent process and forms.

2.4. The Secretary prepares the proposals for primary review and circulate among the assigned reviewers. Primary reviewers will review the protocols using review forms. Based on their preference hard copies will be circulated. Soft copies of all the proposals that undergo full board review shall be emailed to all the ERC members.

2.5. Decision making: When there is a quorum, decision is arrived at by consensus. If consensus is not possible, voting is carried out. Only members who are present are allowed to participate in the voting.

2.6. External reviewer/s who are experts in the subject may be invited where necessary to offer their views, but external reviewer/s should not participate in the decision-making process.

2.7. The full board review of a research proposal will result in one of the following actions

2.7.1. Approved: The research proposal is approved as submitted. This does not preclude the Committee from sending comments for the consideration of the research team.

2.7.2. Conditional approval: If the full board approves a research proposal in principle subject to minor modifications ('Conditional Approval'), the revised project proposal submitted by the proponent will be reviewed and approved by the subcommittee. When the requirements are met, a letter of approval will be issued.

2.7.3. Revise and resubmit: The research proposal is not approved as submitted either because there is insufficient information to make a decision or the proposal is not ethically sound. However, the proposal can be resubmitted for full board review after addressing all the comments of the first review. The revised documents will be discussed in a full board meeting.

2.7.4. Reject: The research proposal is ethically or scientifically unacceptable.

1. **Purpose: To describe the procedure for assigning external/independent reviewers**

ERC will seek advice of an external reviewer when the committee lacks the expertise among its members to review specific subject/technical areas.

2. Detailed Instruction:

2.1. ERC maintains a list of external/independent reviewers who are experts in different subject areas.

2.2. Subcommittee may invite external/independent reviewers when they think the expertise within the ERC is not sufficient to evaluate a particular proposal.

2.3. ERC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.

1. **Purpose**: To describe the procedure for reporting and handling conflicts of interest of the ERC members

The purpose of this SOP is to describe the procedure for reporting and handling of conflict of interest of the ERC members. It is the responsibility of all ERC members to understand, accept and declare any conflicts of interest before the ERC meeting.

2. Detailed Instruction:

2.1. An ERC member shall inform the Chairperson/Secretary if he/she has a conflict of interest, financial or otherwise, in a project or other related matter(s) to be considered by the ERC prior to the commencement of the meeting.

2.2. The ERC will determine if this results in a conflict of interest for the member and, if so, the member will withdraw from the meeting until the ERC's consideration of the relevant matter has been completed. The member shall not be permitted to adjudicate on the research.

2.3. All declarations of conflicts of interest and the resolutions of the same shall be recorded.

1. Purpose

To provide procedures for preparation of the agenda by the Secretary.

2. Detailed instructions

2.1. The Secretary ERC will prepare an agenda for each ERC meeting.

2.2. An application will be included on the agenda for the next available ERC meeting

2.3. All complete applications with relevant documents, and all correspondence received by Secretary of ERC will be included on the agenda

2.4. The agenda and associated documents will be prepared by Secretary ERC and circulated to all ERC members.

2.5. Documentation pertaining to clarifications of previously reviewed proposals will be included on the agenda and/or tabled at the meeting.

2.6. Agenda items will include at least the following items

Confirmation of the minutes of previous meeting, Matters arising from minutes, new items, conflict of interest items any other matters and the announcement and next meeting date

1.Purpose

This SOP describes the procedure for conduct of the ERC meeting. It is the responsibility of the Chairperson and the Secretary to inform members and facilitate the conduct of regular and special meetings of the ERC.

2. Detailed instructions:

2.1. The ERC shall meet on once in two months. Dates of ERC meetings for the year shall be pre-decided and be publicly available.

2.2. Members may attend ERC meetings in person or via teleconference or video conference. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the Secretary of the ERC. The minutes should record the submission of written comments.

2.3. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least 50% + one of members are gathered including the Chairperson or Secretary and at least one non-medical member present (if possible).

2.4. If the meeting does not achieve a quorum, the Chairperson shall cancel it and the ERC will convene a meeting within ten (10) working days of the cancelled meeting.

2.5. The ERC meeting will be conducted in such a manner as to ensure confidentiality and open discussion.

2.6. The ERC may agree to the presence of visitors or observers at a meeting. Visitors or observers will be expected to sign a confidentiality agreement with the ERC and a conflict of interest declaration prior to attending the ERC meeting.

2.7. Any member of the ERC who has any conflict of interest, financial or otherwise, in a proposal or other related matter(s) considered by the ERC must declare such interest beforehand. This will be dealt with in accordance with SOP - 11.

2.8. In circumstances where reviewers cannot be present, they are expected to return the written comments of review to Chairperson/Secretary/Administrative Assistant in advance so that they can be examined before the meeting.

1. Purpose

To describe the preparation and format of minutes of a meeting of the ERC as per the quality standard form done by the Quality assurance unit in CINEC.

4. Detailed instructions

1.Purpose: To describe the procedure and format of minutes of the ERC meeting

This SOP describes the administrative procedure for preparation ,review, approval and distribution of ERC meeting minutes. It is the responsibility of the Secretary to prepare the minutes and to ensure the quality and validity of the minutes after the meeting is over. It is the responsibility of the Chairperson to review and approve the minutes sent to him by the Secretary.

2. Detailed Instruction:

2.1. The Secretary of the ERC will prepare the minutes of each meeting of the ERC as per the template given in Annex 14.

2.2. All completed applications and relevant documents received by the ERC office by the agenda closing date will be included in the agenda.

2.3. The format of the minutes will include the following items:

1. Attendance
2. Announcements/Welcome/Excuses
3. Declaration of Conflicts of interest
4. Proceedings of the previous meeting
5. Matters arising from the previous minutes

6. Training
7. New applications
8. Previously considered applications for approval
9. Amendments/extensions to approved proposals
10. Progress/Final reports of the approved proposals
11. Reports from subcommittees
12. Amendments to SOPs
13. Correspondence

2.4. The minutes should include the recording of decisions taken by the ERC as well as a summary of relevant discussions. This includes reference to views expressed in writing by absent members.

2.5. In relation to the review of new applications or amendments, the minutes shall record the ERC's decision and any requests for additional information, clarification or modification of the proposal.

2.6. In recording a decision made by the ERC, any significant dissenting view or concern will be noted in the minutes.

2.7. Declarations of conflicts of interest by any member of the ERC and the absence of the member concerned during the ERC deliberation of the relevant application will be documented.

2.8. The minutes will be produced as soon as possible following the relevant meeting and will be checked by the Chairperson for accuracy.

2.9. The minutes will be circulated among all members of the ERC as an agenda item for the next meeting. The minutes will be formally ratified at the next ERC meeting.

2.10. The confirmed and amended minutes of each meeting (with the inclusion of revisions if any) will be filed in the 'Minutes File'.

1. Purpose: To describe the procedure for the notification of ERC decisions

The purpose of this SOP is to ensure proper completion, distribution and filing of communications with investigators. It is the responsibility of all CINEC ERC members, including the Secretary and the Chairperson,

2. Detailed Instruction:

2.1. The Secretary of the ERC will prepare the ERC Decision letter two weeks after the monthly ERC meeting.

2.2. Decision letters can be collected from the CINEC ERC office two weeks after the monthly meeting

2.3. If the ERC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the principal investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/ clarification/ modification should refer to the FERCSL Guidelines or other relevant documents including legislation.

2.4. The ERC shall communicate with applicants to resolve outstanding requests for further information, clarification or modification of protocols relating to ethical issues.
2.5. Notification of ethical approval will be in writing, and will contain the following information. A standard letter will be issued, in the format set out in Annex 16.

1. Title of the project
2. Name of the principal investigator(s)

3. Unique CINEC ERC identification number

4. Version number and date of all documentation reviewed and approved by the CINEC ERC including protocols, information sheets, consent forms questionnaires etc.

5. Date of the CINEC ERC meeting at which the project was first considered and the Date of the ERC's approval, conditions of the CINEC ERC's approval, if any and the Duration of the ERC's approval

2.6. Research project may not commence until written notification of ethical approval is received and non-adherence to this requirement amounts to ethical misconduct.

2.7. Any extensions for ethics approval for conducting the research project should be requested before the expiry of the validity indicated in the previous ethics clearance approval.

2.8. If the CINEC ERC determines that a project is ethically unacceptable, the notification of the ERC"s decision will include the grounds for rejecting the project with reference to the FERCSL Guidelines or other relevant pieces of legislation. A standard rejection letter will be issued, in the format set out in Annex 17.

2.9. The status of the project shall be updated on the CINEC ERC's register of received and reviewed applications.

	Ethics Review Committee CINEC Campus	
	SOP 17 - Amendments and extensions of approved protocols 2020 Version 1 Effective Date: 01 September 2020	

1. Purpose:

To describe the procedure for the submission and CINEC ERC review of requests for amendments and extensions to approved protocols.
This SOP applies to proposals submitted to the CINEC ERC, undergoing amendments or subsequent extensions after initial approval. It is the responsibility of the Secretary to forward such requests to the ERC considering the need for expedited review or full committee review in consultation with the Chairperson.

2. Detailed Instruction:

2.1. Approval for proposed changes to approved research protocols or to the conduct of the research, including extensions to the length of CINEC ERC approval, must be sought by the principal investigator in writing.

2.2. Requests shall outline the nature of the proposed changes and/or request for extension, reason/s for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must have the changes highlighted. The request for extension must be accompanied by a current progress report of the study.

2.3. Expedited review of requests for minor amendments and extensions may be undertaken by the ERC subcommittee between scheduled meetings at the discretion of the Chairperson or the Secretary and in accordance with SOP 009, on the condition that it is ratified at the next CINEC ERC meeting.

2.4. Where an urgent protocol amendment is required for safety reasons, the Chairperson may review and approve the request. In such circumstances, the ERC will review the decision at its next meeting.

2.5. All other requests for amendments shall be reviewed by the ERC at its next meeting, provided the request has been received by the ERC office by the agenda closing date.

2.6. The CINEC ERC will report in writing to the principal investigator, advising of the ethical approval of the proposed amendment and/or request for extension and that the amended research may commence, within seven (7) working days of the meeting at which the request was considered (this may be the full CINEC ERC meeting or the subcommittee meeting).

2.7. If the ERC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required.

2.8. All reviewed and approved requests for amendments and extensions shall be recorded in the relevant protocol specific file and, where appropriate, in the ERC's register of received and reviewed applications.

	Ethics Review Committee CINEC Campus	
	SOP 18 - Appeals and complaints of review process and decisions of ERC 2020 Version 1 Effective Date: 01 September 2020	

1. **Purpose**: To describe the procedure for receiving and handling appeals or complaints regarding the ERC's review process and decisions

This SOP applies to complaints/appeals submitted to the CINEC ERC, by applicants who are not satisfied with the ERC review/decision. It is the responsibility of the Chairperson to investigate such complaints/appeals.

2. Detailed instructions

2.1. An applicant who is not satisfied with the outcome of the CINEC ERC's decision may complain to the Chairperson detailing in writing the grounds of the concern or complaint.

2.2. Appeal/complaint will be tabled at the next ERC meeting and the Chairperson will appoint a panel of three members, excluding the members who originally reviewed the protocol, to investigate the appeal/complaint.

2.3. The decision of the panel will be discussed at the subsequent CINEC ERC meeting. The decision of the ERC will be informed to the applicant within three months of the complaint.

	Ethics Review Committee CINEC Campus	
	SOP 19 - Monitoring of approved research projects 2020 Version 1 Effective Date: 01 September 2020	

1. Purpose:

To describe the procedure for monitoring research projects approved by the ERC to ensure compliance with ethical approval. The ERC will monitor approved protocols to ensure compliance with its ethical approval. The purpose of this SOP is to describe the procedure for monitoring research protocols approved by the ERC to ensure compliance with ethics approval.

2. Detailed Instruction:

2.1. The CINEC ERC shall monitor approved projects to ensure compliance with the conditions for ethical approval. In particular, the ERC shall require the investigators to provide annual progress reports (Annex 18) and a final report (Annex 19) at the completion of the study.

2.2. The ERC shall require the following information in the progress reports

1. Progress to date or outcome in the case of completed research
2. Maintenance and security of records
3. Compliance with the approved protocol
4. Compliance with conditions of approval
5. Changes related to study investigators and sources of funding

2.4. The ERC shall require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of the ethical approval of the their proposal

2.5. The CINEC ERC shall require, as a condition of approval of each project, that investigators inform the ERC, giving reasons, if the research project is discontinued before the expected date of completion.

2.6. Where the ERC is of the opinion that the research project is not being conducted in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC shall inform the principal investigator and the institution as well as any Regulatory Authority of such withdrawal of approval in writing, and recommend to the institution that the research project be discontinued, suspended, or that other necessary steps be taken.

1. Purpose:

To describe the procedure for receiving, handling and responding to complaints concerning the conduct of a project approved by the ERC.
The ERC shall receive complaints from researchers, or other interested individuals regarding the conduct of approved research projects.

2. Detailed Instruction:

2.1. Any concern or complaint received will be forwarded to the Chairperson of the ERC. The Chairperson is responsible for obtaining a written complaint stating the grounds of the concern. Upon receiving this, the ERC will be notified as soon as possible.

2.2. The ERC shall send a letter of acknowledgement to the complainant and a letter of notification to the principal investigator outlining the complaint and the mechanism for investigating (described below) the complaint.

2.3. Where the complaint concerns a serious matter within the jurisdiction of the Ministry of Health or other institution, the Chairperson shall consider referral of the complaint to the Ministry of Health or the relevant governing body.

2.4. A panel consisting of a minimum of three (03) members will be appointed by the ERC to conduct an investigation of the complaint. This panel upon completion of the investigation shall make recommendations to the ERC on the appropriate course of action. Based on the seriousness of the violation one or more of the following action will be recommended.

1. Amendments to the protocol
2. Warning and increased monitoring by the ERC
3. Suspension of the project
4. Termination of the project
5. Other appropriate action to resolve the complaint

2.5. Such action will be taken within three months of receiving a written complaint.

2.6. The complainant shall be informed of the action taken.

1. Purpose:

To describe the procedure for the process for reporting and handling of protocol deviations and violations. The purpose of this SOP is to describe how the CINEC ERC, provides instructions for taking action and maintaining records, when investigators fail to follow the procedures written in the approved protocol or fail to comply with national/ international guidelines for the conduct of human research, including those who fail to respond to the CINEC ERC requests.

2. Detailed Instruction:

2.1. The CINEC ERC shall require, as a condition of approval of each proposal, that researchers report to the ERC of any protocol deviation or violation as soon as possible but no later than one (01) calendar month of its first knowledge.

2.2. The report should include,

1. ERC reference number
2. Details of the site
3. Details of protocol deviation/violation
4. Reason(s) for deviation – patient related/investigator related/other (specify)
5. Details of reporter – Name, address, telephone number, other administrative information
6. Measures taken by the investigators to deal with the violation and to avoid future occurrences

2.3. All reported deviations and violations will be dealt with by a subcommittee consisting of Chairperson, Secretary and an assigned ERC member and will be informed to the ERC, at the next meeting

1. **Purpose**: To describe the procedure for the preparation and maintenance of records of the ERC activities. Secretary of the ERC has to prepare and maintain written/electronic records of all the ERC activities.
2. **Detailed Instruction:**

   2.1. Supporting staff of the ERC will prepare and maintain a confidential electronic and/or paper record for each application received and record the following information

   1. ERC identification number
   2. Title of the project
   3. Principal investigator(s) with contact details
   4. Name of the responsible institution or organization
   5. Date of Submission
   6. Date of review at a ERC meeting
   7. Decision/s of the ERC
   8. Terms and conditions, if any, of approval of the project and
   9. Type of approval, whether approval was by expedited review.

   2.2. The paper file shall contain a hard copy of the application, including signatures, and any relevant correspondence including that between the applicant and the ERC, all approved documents and other material used to inform potential research participants.

   2.3. All relevant records of the ERC, including applications, membership, minutes, correspondence, and progress/final reports will be kept as confidential files.

   2.4. To ensure confidentiality, all documents provided to ERC members, which are no longer required, are to be disposed of in a secure manner, such as shredding.

2.5. All records pertaining to research protocols shall be held for sufficient time to allow for future reference. The minimum period for retention will be five (5) years. Files which are no longer required for retention shall be electronically archived.

2.6. A register of all the applications received and reviewed shall be maintained in accordance with the FERCSL and other national/international guidelines.

1. **Purpose**: To describe the procedure for the process for reviewing and amending SOPs within the ERC, CINEC.

   It is the responsibility of the Secretary of the ERC to appoint the SOP subcommittee to amend the SOPs by following the same procedures, format and coding system when drafting or editing any SOP of the ERC.

2. **Detailed Instruction:**

   2.1. The Terms of reference and Standard Operating Procedures shall be reviewed at least every three years and amended as necessary.

   2.2. SOPs may be emended at any time if a need arises for such amendments 2.3. The SOPs may be amended by following the procedure below

   1. Any member of the ERC can propose an amendment to the SOPs in writing.
   2. The proposed amendment shall be submitted in writing to the Secretary to be placed in the agenda of the next available Ethics Review Committee meeting for consideration and possible adoption by at least two-thirds of the committee members present and voting. Any member unable to attend such a meeting may register their views in writing
   3. The Chairperson shall send the amendment to the President/CINEC campus for review and approval, if appropriate.
   4. The amendment shall come into effect once approved by the Director and Board of Management, CINEC.

References

1. Declaration of Helsinki (DoH) of the World Medical Association (WMA), 2013. Ethics review committee guidelines, Forum of Ethics Review Committees, Sri Lanka 2007.
2. Ethical review committee Guidelines. Sri Lanka Medical Association. Colombo.
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) E6 (R1) 1996.
4. International Ethical Guidelines for Epidemiological Studies - Prepared by the Council for International Organizations of Medical Sciences(CIOMS) 2008.
5. National Ethical Guidelines for Health Research in Nepal. Nepal Health Research Council, Nepal 2001.
6. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organization 2011. Standards Operating Procedures, Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura
7. Standard Operating Procedures, Ethics Review Committee, Faculty of Medicine, University of Colombo.
8. Standards Operating Procedures, Ethics Review Committee, Faculty of Medicine, University of Kelaniya

	Ethics Review Committee CINEC Campus	
	ANNEX 1A - Confidentiality Agreement	

This agreement is made and entered into on this .....day of ..... by and between Ethics Review Committee CINEC campus (hereinafter referred to as ERC) and ..... (holder of NIC number .....) of ..... (herein after referred to as the "member/observer/visitor/expert/consultant") WHEREAS the member/observer/visitor/expert/consultant has agreed to serve on the aforesaid ERC, and in which capacity the member/observer/visitor/expert/consultant will have access to Confidential Information in the ERC; AND WHERE AS the member/observer/visitor/expert/consultant has acknowledged and agreed that the committee has and shall continue to have sole rights to Confidential Information and has agreed to hold the same in strict confidence during and after the member/observer/visitor/expert/consultant's period of service within the ERC.

And it is hereby agreed as follows

1. Interpretation

"Confidential information" shall include all information of a confidential and proprietary nature provided or made available to the member by the ERC including but not limited to the research proposals and documents, techniques, intellectual property and processes and such other information related to the ERC but shall not include information which is or becomes publicly available other than through the faults of the member.

2. Obligations of the member/observer/visitor/expert/consultant

a. To maintain the highest degree of secrecy and keep as confidential any Confidential Information which the member/observer/visitor/expert/consultant may be granted access to, or which may be available to, or which member/observer/visitor/expert/consultant receives on behalf of the ERC or in the capacity of the member/observer/visitor/expert/consultant of the

ERC by any means and to use such Confidential Information only in duty authorized manner in the interest of the ERC and for the purpose of fulfilling functions and responsibilities arising as a member/observer/visitor/expert/consultant of the ERC.

b. Not at any time during or after service within the ERC, for any reason, disclose or permit to be disclosed any Confidential Information to any third party or to use such Confidential Information for personal use without the express prior written approval of the ERC.

c. On termination of the period of membership within the ERC, the member/ observer/visitor/expert/consultant shall return to the ERC all property, documents and papers in the member/observer/visitor/expert/consultant's possession.

d. That in the event of break of any of the conditions mentioned above, the ERC shall be entitled to injunctive relief and/or specific performance to enforce the conditions set out above.

3. Legal compulsion to disclose

In the event that the member/ observer/visitor/expert/consultant becomes legally compelled to disclose any Confidential Information, the member/ observer/visitor/expert/consultant shall give prompt notice in writing of such facts to the ERC so that ERC has an opportunity to seek a protective order or other remedy. In the event that such protective order or other appropriated remedy is not sought by the ERC or is sought but is not obtained, the member/ observer/visitor/expert/consultant will nevertheless disclose only that portion of the Confidential Information as is necessary to comply with its obligations under law and shall use reasonable endeavors to obtain any appropriate court order or other reliable assurance that Confidential treatments will be accorded to Confidential Information so disclosed.

4. **The member/ observer/visitor/expert/consultant hereby unconditionally accepts and acknowledges that having regard to the nature of the ERC and the functions and duties of the member/ observer/visitor/expert/consultant of the ERC, the member/ observer/visitor/expert/consultant considers the terms and conditions imposed herein has being fair and reasonable.**

Signature of the Member Date

Signature of the Chairperson of the ERC Date

	Ethics Review Committee CINEC Campus	
	ANNEX 1B - **Conflict of Interest Agreement**	

1. Interpretation

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in the CINEC ERC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the CINEC ERC that no member/ observer/visitor/expert/consultant may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the ERC.

The Undersigned will immediately disclose to the Chairperson of the CNEC ERC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

When a member/observer/visitor/expert/consultant has a conflict of interest, the member/ observer/visitor/expert/consultant should notify the Chairperson and may not participate in the CINEC ERC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

a) A member/observer/visitor/expert/consultant is involved in a potentially competing research program.

b) Access to funding or intellectual information may provide an unfair competitive advantage.

c) Member/ Observer/visitor/expert/consultant's personal biases may interfere with his or her impartial judgment

2. Agreement on Conflict of Interest

This agreement is made and entered into on this..... day of .....by and between Ethics Review Committee, CINEC Campus (hereinafter referred to as ERC) and ..... (holder of NIC number .....) of..... (herein after referred to as the "member/observer/visitor/expert/consultant")

Whenever I have a conflict of interest, I shall immediately inform the Chairperson and will not be present for review of the said proposal and will not to count me toward a quorum for voting.

3. The member/ observer/visitor/expert/consultant hereby unconditionally accepts and acknowledges that having regard to the nature of the ERC and the functions and duties of the member/observer/visitor/expert/consultant of the ERC the member considers the terms and conditions imposed herein has being fair and reasonable.

....

Signature of the member/observer/visitor/expert/consultant Date

....

Signature of the Chairperson of the ERC Date

	Ethics Review Committee CINEC Campus	
	ANNEX 2 - CV of ERC Members	

Personal Information			
Name		Rev/Prof/Dr/Mr/Ms	
Current Designation			
Home Address			
Contact Number			
Email address			
Educational Qualifications			
Bachelor's degree			
Postgraduate degrees			
Work Experience			
Employment	Designation	Workplace	Period
Present			
Previous 1			
Previous 2			
Previous 3			
Training in ethics			
Training 1			
Training 2			
Training 3			
Publications			

....

Date Signature of the ERC Member

	Ethics Review Committee CINEC Campus	
	ANNEX 3 - Letter of appointment	

Reference No.

Date

Name of the member

Address

Dear .....

Appointment as a Member of the Ethics Review Committee, CINEC Campus

I am pleased to inform you that you have been appointed as a member of the Ethics Review Committee of the CINEC campus for a period of three years effective from .....

The Secretary, ERC CINEC campus will provide you with the Standard Operating Procedures (SOPs) of the ERC CINEC campus with which you are expected to be familiar.

You are required to sign a confidentiality agreement on the assumption of duties.

The CINEC campus will indemnify you in respect of liabilities that may arise in the course of bona fide conduct of duties as an ERC member.

Your contributions as a member of the CINEC review committee will be greatly appreciated.

Yours sincerely,

Signature of the President

CINEC campus

	Ethics Review Committee CINEC Campus	
	ANNEX 4 - Training record	

Name of the ERC Member: Rev/Prof/Dr/Ms/Mr			
Name of the Training	Training provider	Venue	Date

	Ethics Review Committee CINEC Campus	
	ANNEX 5 - Application form for scientific and ethical review	

For Office Use Only:

Application Number: CINEC/ERC/20__/_____ Date Received: __/__/__

Name of the Applicant: Rev/Prof/Dr/Mr/Ms_____

This application should be forwarded by the principal investigator who requests ethical approval for a research project. All the co-investigators should provide signed consent to submit the application to ERC, CINEC Campus. Application guidelines are available at CINEC website. Trainees, trainers, extended faculty and staff of any recognized academic/ research/industry institute are eligible to apply for ERC approval from CINEC Campus.

Part A – Administrative Details

1. **Title of the Research Project:**
2. **Details of the Investigators:**

Title, Name, Designation and Affiliation	Role	Signature
	Principal Investigator	

3. **Contact Details of the Principal Investigator:**

3.1 Postal Address	
3.2 Email Address	
3.3 Telephone	

4. Nature of the study:

   Observational/non-interventional Clinical trial (investigator initiated)
   Research database/information system Sponsored clinical trial
   Other

5. Proposed starting (initial date of enrolment of participants) and ending (completion of data collection) dates (retrospective approval will not be given to the projects already started)

   Start Date: End Date:

6. Has the relevant Board of Study/Specialty Board approved the research project (if applicable)?

   Yes: No:
   If Yes, Board of Study/Specialty Board: Details:

7. Has ethics approval for this study been requested earlier from ERC CINEC or another ERC? (if you have received ethics approval already, please attach a copy of the approval)

   Yes: No:
   Details:

8. Funding (if any)

   Name and Address of the funding source: Amount:

9. Do you believe the proposed project has conflicts of interest?

   Yes: No: If Yes, Details:

Part B – Protocol Check List

Under each category, indicate the protocol section of the research proposal. If a particular category in not relevant to your study, indicate it as 'NA'

	Scientific validity	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Title					
2	Research problem					
3	Research questions/ hypothesis					
4	Objectives					
5	Study setting					
6	Study design					
7	Study population (giving inclusion exclusion criteria)					
8	Sample size					
9	Sampling method					
10	Measurements / variables					
11	Study instruments					
12	Procedures to ensure quality of data					
13	Plan for analysis					
14	Ethical considerations					
15	Budget (if relevant)					
16	Work plan and time frame					
17	Justification for a replication study, if your study is a replica					

	Social Value	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Benefits of the study to the community/society					
2	Plan for dissemination of study findings					
3	Scientific importance of the study					

	Risk Benefit Assessment	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Potential risks to the participants					
2	Potential benefits to the participants					
3	Justification for risks against benefits					
4	Steps taken to minimize risks					
5	Support provided to participants (medical, educational, other)					

	Participants rights and consent	Protocol pages	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Procedure for recruiting the participants					
2	Information provided to the participants					
3	Procedure for requesting informed consent					
4	Procedure for requesting proxy consent					
5	Procedure for requesting assent (subjects between 12y to 18y)					
6	Procedure for withdrawing consent					
7	Incentives provided to participants					
8	Procedure for participants to ask questions / register complaints					
9	Participants right to decline consent without losing entitled benefits					

	Confidentiality and Privacy	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Steps to ensure confidentiality of data					
2	Justification for collecting personal identification data					
3	Steps taken to ensure privacy during data collection					
4	How long data and samples will be kept					
5	Who will have access to the data					
6	Procedure for storage of data and samples					
7	Procedure for disposal of data					

	Fair participant selection and vulnerability	Protocol page/s	Reviewer Evaluation			
			Acceptable			Comments
			Yes	No	N/A	
1	Justification for selection of study population					
2	Justification for conducting the study in a vulnerable population					

	Responsibilities of the researcher	Protocol page/s	Reviewer Evaluation			
			Acceptable			Comments
			Yes	No	N/A	
1	Ethical, legal, financial issues related to the study					
2	Any conflicts of interest and how the researcher plans to manage them					
3	Permissions from relevant institutions / authorities					
4	Collaborations with the relevant stakeholder					
5	Provision of medical / psychological care to the participants					
6	Qualifications of the research team to handle the research study					

	Foreign funded studies	Protocol page/s	Reviewer Evaluation			
			Acceptable			Comments
			Yes	No	N/A	
1	Justification for conducting the study in SL					
2	Relevance of the study to SL					
3	Post research benefits to SL					
4	The sharing of intellectual property rights					
5	How the results will be conveyed to authorities in SL					

	Information Sheet / Consent Form	Section in Info. sheet consent form	Reviewer Evaluation			
			Acceptable			Comments
			Yes	No	N/A	
1	Purpose of the study					
2	Voluntary participation					
3	Duration of the study and responsibilities of the participants					
4	Potential benefits					
5	Risks, Hazards, Discomforts					
6	Incentives / Reimbursements					
7	Confidentiality					
8	Contact person for the participants					
9	Understanding of information provided by the researcher					
10	Agreement of the participant to provide information / samples					

11	Consent for dissemination of research findings					
12	Appropriate translation of the information sheet					
13	Appropriate translation of the consent form					

Decision of the reviewer:

Approved Conditional approval Approve with revisions Reject

Comments of the Reviewer:

Name of the Reviewer:
Signature of the Reviewer: _____ Date: _____

	Ethics Review Committee CINEC Campus	
	ANNEX 6 - Applicant Declaration	

Declaration

As the principal investigator of this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving humans and cadavers. I understand that if there is any significant deviation from the project as originally approved, I must submit an amendment to the ERC for approval prior to its implementation. I have submitted all significant previous decisions by this or any other ERC and /or regulatory authorities relevant to the proposed study. I declare that I am not seeking approval for a study that has already been commenced or has already been completed.

_____ _____

Signature of principal investigator Date

Full name of principal investigator: _____

	Ethics Review Committee CINEC Campus	
	ANNEX 7 - Submission check list	

Title:
Name of the Applicant: Rev/Prof/Dr/Mr/Ms

Date Received: __/__/20__

Document	**Version**	**Date**
Application form		
Detailed research proposal		
All study instruments- (questionnaires/interview guides/checklist/data extraction forms) English		
Study instruments – Sinhala / Tamil/English (if applicable)		
Information sheet – English Sinhala/ Tamil / English		
Consent forms Sinhala/ English/ Tamil		
Any other documents		
Approved letter from the relevant research committees		
Payment receipts		

	Ethics Review Committee CINEC Campus	
	ANNEX 8 - Sample information sheet	

Title of the project

I/We ‹name of principal investigator/s›, a ‹Designation› attached to ‹institute/s of affiliation› would like to invite you to take part in a research project titled ‹Non- technical Title› conducted by ‹Names of Investigators› at ‹Study Site›

1. **Purpose** - The objective/s of the study in non-technical terms
2. **Voluntary participation** - Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study, you may do so at any time.
3. **Duration, procedures of the study and participant's responsibilities**

This study will be conducted over a period of (anticipated duration of study). If you volunteer to participate in this study, we will ask you to do the following:

    1. We will ask you to take part /visit the clinic for (duration of each visit and number of visits) over the course of a total of about (expected duration of participation)
    2. You will need to ‹the procedure/s of the research including what happens at each visit in simple terms and how the participant has to take part in the study›
4. Potential benefits -Participation in this study may benefit you/others by ‹ all the actual and potential benefits -
5. Risks, hazards and discomforts - Any potential or actual risks, hazards and discomforts should be clearly defined-

6. Reimbursements -You would be paid a sum of Rs. ‹ ….› OR you will not be paid any sum of money for participating in this study
7. Termination of study participation - You may stop participating in this study at any time (with no penalty or effect on medical care or loss of benefits). Please notify the investigator as soon as you decide to withdraw your consent.
8. Confidentiality - Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published. These data will never be used in such a way that you could be identified in any way in any public presentation or publication without your express permission.
9. Clarifications -If you have questions about any of the tests / procedures or information please feel - free to ask any of the persons listed below.

   The names and contact information of investigator/s› ‹postal address, email address, telephone numbers;

   If you have any clarification, concerns, or complaints related to this research project, you may contact the Ethics Review Committee, CIINEC CAMPUS

   ERC Office Address: Ethics Review Committee, CINEC campus Malabe. (between 9am and 4pm on working days)

	Ethics Review Committee CINEC Campus	
	ANNEX 9 - Sample consent form	

Title of the Research Project
To be completed by the participant (Please tick the appropriate box)

1. Have you read the information sheet? (Please keep a copy for yourself) ☐
2. Have you had an opportunity to discuss this study and ask any questions? ☐
3. Have you had satisfactory answers to all your questions? ☐
4. Have you received enough information about the study? ☐
5. Do you understand that you are free to withdraw from the stud at any time, without having to give a reason and without affecting your future medical care? ☐
6. Sections of your medical notes, including those held by the investigators relating to your participation in this study may be examined by other research assistants. All personal details will be treated as strictly Confidential. Do you give your permission for these individuals to have access to your records? ☐
7. Have you had sufficient time to come to your decision? ☐
8. Do you agree to take part in this study? ☐

Who explained you about the study:_____

Signature of the participant:_____ Date_____

Full name:_____

To be completed by the investigator/ person obtaining consent

I have explained the study to the above participant and he/ she has indicated her willingness to take part in this study.

Signature of Investigator_____ Date:_____

Full name:_____

	Ethics Review Committee CINEC Campus	
	ANNEX 10 - CV of the applicant	

Personal Information			
Name	Rev/Prof/Dr/Ms/Mr		
Current Designation			
Home Address			
Contact Number			
Email address			
Educational/Professional Qualifications			
Bachelor's degree			
Postgraduate degrees			
Work Experience			
Employment	**Designation**	**Work place**	**Period**
Present			
Previous 1			
Previous 2			
Publications (list up to 5 most relevant to the proposed study)			
Ongoing Research Projects (other than this project)			

Date: _____ Signature of the Applicant: _____

	Ethics Review Committee CINEC Campus	
	ANNEX 11 - Document check list	

Please insert the **Title** and the **Name of the Applicant Title**:

Name of the Applicant: Rev/Prof/Dr/Mr/Ms
For Office Use Only: This check list will be filled and signed by the person who receives the application at ERC, CINEC Campus

Application Number: CINEC /ERC/20__/_____ Date Received: __/__/20__

Covering Letter	☐
Submission Check List	☐
Declaration of Applicant	☐
Application form (3 copies)	☐
One-page summary proposal (3 copies)	☐
Detailed research proposal (3 copies)	☐
All study instruments in English (questionnaires/interview guides/checklist/data extraction forms) with Sinhala and Tamil translations where relevant	☐
Information sheet in English with Sinhala and Tamil translations where relevant	☐
Consent forms in English with Sinhala and Tamil translations where relevant	☐
Any other relevant documents in English with Sinhala and Tamil translations where relevant Curriculum vitae of all investigators	☐
Approval letter from the relevant Board of Study (if applicable)	☐
Online payment receipt	☐

Received by:

_____ _____ _____

Name of the Staff Member Signature Date

	Ethics Review Committee CINEC Campus	
	ANNEX 12 - Exemption letter	

ERC Reference Number *Date*

Name of the Principal Investigator
Address of the Principal Investigator›
Dear
Name of the Principal Investigator,

Title of the Proposal

Investigators: *Names of the investigators*

Thank you for submitting the above research proposal to the ERC of the Postgraduate Institute of Medicine. I am pleased to inform you that the study was exempted from the ethics review by the ERC at its meeting held on ‹meeting date› after reviewing following documents submitted by you.

Document	Version No	Submission Date
Protocol	version	date
Information sheet	version	date
Consent form	version	date
Study Instrument	version	date

Thank you.

Yours sincerely,

Signature of the Secretary
Name of the Secretary

Secretary-ERC/CINEC

	Ethics Review Committee CINEC Campus	
	ANNEX 13 - Expedited approval letter	

ERC Reference Number *Date*

Name of the Principal Investigator
Address of the Principal Investigator›
Dear
Name of the Principal Investigator,

Title of the Proposal

Investigators: *Names of the investigators*

Thank you for submitting the above research proposal to the ERC of the Postgraduate Institute of Medicine. I am pleased to inform you that the study was exempted from the ethics review by the ERC at its meeting held on .....(meeting date) after reviewing following documents submitted by you.

Document	Version No	Submission Date
Protocol	version	date
Information sheet	version	date
Consent form	version	date
Study Instrument	version	date

The approval is valid until one year from ..... You may submit a written request for renewal/extension of the approval, along with a progress report.
Please note that you are required to inform the ERC about the following:

- Any unanticipated events involving potential risks to study subjects
- Any deviations in protocol
- Any changes to the documents listed above
- You are required to submit the final report to the ERC /CINEC with the following declaration:

  "*the research was conducted in accordance with the proposal for which approval was granted by the ERC CINEC* within three (03) months upon the completion of the study.

Thank you.

Yours sincerely,

Signature of the Secretary
Name of the Secretary

Secretary-ERC/CINEC

	Ethics Review Committee CINEC Campus	
	ANNEX 14 - Minutes of ERC meeting	

Minutes of the (Meeting No) Meeting of the CINEC ERC Committee on .....(Date) at .....(Time) at .....

Name	**Position**	**‹Year›**								
		Date Mon	Date Mon	Date Mon	Date Mon	Date Mon	Date Mon	Date Mon	Date Mon	Date
Name of the Chairperson	Chairperson									
Name of the secretory	Secretory									
Name of the member	Member									
Name of the member	Member									
Name of the member	Member									
Name of the member	Member									
Name of the member	Member									
Name of the member	Member									
Name of the member	Member									
Name of the member	Member									
Name of the member	Member									
Name of the member	Member									

P – Present **E** – Excused **V**- Virtually Participated **A** – Absent **L** – on Leave

who chaired the meeting› chaired the meeting.

Item 1 – Announcements/Welcome/Excuses announcements, welcome and excuses if any

Item 2 – Declaration of Conflict of Interest Member– ERC Ref number
Item 3 – Confirmation of the Minutes - minutes of the last meeting number, .
Item 4 – Matters arising from the Minutes - matters arising from the minutes of the last meeting
Item 5 – Training Meeting
Meeting .5.1 In-house Training -training topic, name of the member who conducted the training
Meeting No.5.2 details if any
Item 6 – New protocols
6.1. exempted protocols details.
6.2 New protocols for expedited review
6.3. New protocols for full board review

ERC No:	‹ERC Ref No.›	Date Submitted:				submission date		
Applicant	Name of the applicant							
Study Design	Type of study							
Documents	Application	Protocol	Instrument			IS/ICF		
			E	S	T	E	S	T
Version	version No	version No	version No			version No		
Internal reviewers	Name of the 1st primary reveiwer	Name of the 2nd primary reveiwer	Name of the person who review Sinhala Name of the person who review Tamil					
ERC Discussion	discussion points							
Recommendation	ERC recommendation. i.e. type of approval							
Remarks	Details if any							

Item 7 – Previous considered protocols

ERC No:	‹ERC Ref No.›	Date Submitted:	submission date
Applicant	Name of the applicant		
Study Design			

	Type of study						
Documents	Application	Protocol	Instrument			IS/ICF		
			E	S	T	E	S	T
Version	version No	version No	version No			version No		
Internal reviewers	Name of the 1st primary reveiwer	Name of the 2nd primary reveiwer	Name of the person who review Sinhala Name of the person who review Tamil					
ERC Discussion	discussion points							
Recommendation	ERC recommendation. i.e. type of approval							
Remarks	Details if any							

Item 8 – Amendments / extensions to the approved protocols
Item 9 – Progress/ final reports of approved proposals
Item 10 – reports of the subcommittees
Item 11 – Amendments to SOPs
Item 12 – Correspondence
Item 13 – any other business
Item 14 – Date time and Venue for the next meeting

	Ethics Review Committee CINEC Campus	
	ANNEX 15 - Resubmission	

RC Reference Number *Date*

Name of the Principal Investigator and the ‹Address of the Principal Investigator

Dear ..... Name of the Principal Investigator,

Title of the Proposal

Investigators: *Names of the investigators*

Thank you for submitting the above research proposal. ERC at its meeting held on ‹meeting date› reviewed the following documents submitted by you.

Document	Version No	Submission Date
Protocol	version	date
Information sheet	version	date
Consent form-	version	date
Study Instrument	version	date

The ERC has suggested following modifications prior to the consideration for approval. suggested modifications -Please resubmit the revised proposal with a covering letter, within three (03) months of this letter. Please underline all the changes in the proposal and indicate the changes in the covering letter in a table with four columns indicating reviewers comments, original wording, the responses/revisions and page numbers.

Thank you.
Yours sincerely,
Signature of the Secretary /Name of the Secretary / Secretary-ERC/CINEC

	Ethics Review Committee CINEC Campus	
	ANNEX 16 - Approval letter	

RC Reference Number *Date*

Name of the Principal Investigator and the <Address of the Principal Investigator

Dear ..... Name of the Principal Investigator,

Title of the Proposal

Investigators: *Names of the investigators*

Thank you for submitting the above research proposal. I am pleased to inform you that your study was approved by the ERC at its meeting held on .....meeting date reviewed the following documents submitted by you.

Document	Version No	Submission Date
Protocol	version	date
Information sheet	version	date
Consent form-	version	date
Study Instrument	version	date

The approval is valid until one year from the meeting date stated above. You may make a written request for renewal/extension of the validity, along with the submission of a progress report.

Please note that you are required to inform the ERC about the following:

- Any unanticipated events involving potential risks to study subjects
- Any deviations in protocol
- Any changes to the documents listed above

You are required to submit the final report to the CIINEC / ERC with the following declaration:

"*the research was conducted in accordance with the proposal for which approval was granted by the ERC of CINEC* within three (03) months upon the completion of the study.

Thank you.

Yours sincerely,

Signature of the Secretary
Name of the Secretary
Secretary ERC/CINEC

	Ethics Review Committee CINEC Campus	
	ANNEX 17 - Rejection Letter	

RC Reference Number *Date*

Name of the Principal Investigator and the <Address of the Principal Investigator

Dear ..... Name of the Principal Investigator,

Title of the Proposal

Investigators: *Names of the investigators*

Thank you for submitting the above research proposal. I regret to inform you that your study was NOT approved by the ERC at its meeting held on .....meeting date reviewed the following documents submitted by you.

Document	Version No	Submission Date
Protocol	version	date
Information sheet	version	date
Consent form-	version	date
Study Instrument	version	date

Main reason/s for the decision is/are

You may submit a new application after addressing all above comments.

Thank you
Sincerely
Signature of the Secretary
Name of the Secretary
Secretary ERC/CINEC

	Ethics Review Committee CINEC Campus	
	ANNEX 18 - Progress report	

ERC ref number	
Title	

Details of principal investigator

Name of the principal investigator	
Address of the principal investigator	
Phone number	

Details of the study

Date of approval	
Study start date	
Progress report	
Progress to the date	
Maintenance and security of records	
Compliance with approved protocol	
Protocol deviation and violations	
Publication related to data gathered in this study	
Any other	

....

Signature PI Date

Every 6 months this report should be submitted

	Ethics Review Committee CINEC Campus	
	ANNEX 19 - Final Report	

ERC ref number	
Title	

Details of principal investigator

Name of the principal investigator	
Address of the principal investigator	
Phone number	

Details of the study

Date of approval	
Study start date	
Study end date	
Number of participants	
Main finding	
Protocol deviation and violations	
Publication presentations	
Any other	

....

Signature PI Date