STANDARD OPERATING PROCEDURES

ETHICS REVIEW COMMITTEE

FACULTY OF HEALTH-CARE SCIENCES

EASTERN UNIVERSITY, SRI LANKA

VERSION: 1.0

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FACULTY OF HEALTH-CARE SCIENCES

EASTERN UNIVERSITY, SRI LANKA

2018

AUTHORS

Name and position in ERC	Signature	Date
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APPROVED BY

Name and position	Signature	Date
Dr. A. N. Arulpragasam Dean, Chairperson/ Facultyboard Faculty of Health-Care Sciences, EUSL		

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	Title: Functions of ERC
	SOP/01/18 **Effective Date: 01.02.2018**

1. **Purpose:**

   To describe the overall function and scope of responsibilities of the ERC to safeguard the dignity, rights, safety, and well-being of all actual or potential research participants, 'respect for the dignity of persons'.

2. **Scope:**

   The SOP applies to all activities under the ERC, Faculty of Health-Care Sciences, Eastern University, Sri Lanka.

3. **Responsibility:**

   It is the responsibility of the ERC, Faculty of Health-Care Sciences, Eastern University, Sri Lanka, members to read and understand and respect the rules set by ERC.

4. **Detailed functions:**

Overall function

The primary objective of the Ethics Review Committee (ERC), Faculty of health Care Sciences, Eastern university, Sri Lanka is to review the ethics of medical research involving human participants, tissue and data; and animals used in research in a medical setting. The purpose of the ERC is to safeguard the dignity, rights, safety and well-being of all actual or potential research participants and ensure that animals, if used for research, are treated humanely. This will be achieved through efficient and effective review and monitoring processes in accordance with the Guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL guidelines) and other relevant national and international legislations and guidelines.

4.1. Function of ERC

The functions of the ERC are:

a) to review proposals for research involving human subjects and animals taking care that all the cardinal principles of research viz. autonomy, beneficence, non-maleficence and justice are adhered to in research proposals.
b) to make bi-annual report to the Faculty Board of the FHCS, EUSL

4.2. The ERC, FHCS/EUSL will review all types of research proposals involving human and animal studies conducted by the following
   a) staff and students of the EUSL.
   b) research proposals submitted by other investigators from institutions/organizations that do not have a recognized ERC.

4.3. All applications will be subjected to a handling charge as decided by the Faculty Board of FHCS/EUSL

4.4. The ERC will assess proposals submitted for review in accordance with the FERCSL and other national and international guidelines and legal requirements in order to determine their ethical acceptability.

4.5. ERC, FHCS/EUSL will seek advice of another ERC and/or send the application to an external reviewer when the committee lacks the expertise among its members to review specific subject/technical areas.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Composition of membership and Functions
	SOP/02/18 **Effective Date: 01.02.2018**

1. **Purpose:**

   To describe the membership composition of the ERC

2. **Scope:**

   This SOP applies to functions of the Faculty Board, Faculty of Health-Care Sciences, Eastern University, Sri Lanka which appoints the members to the ERC, Faculty of Health-Care Sciences, Eastern University, Sri Lanka.

3. **Responsibilities:**

   It is the responsibility of the Faculty Board of Faculty of Health-Care Sciences to read and understand and act accordingly in appointing members to ERC

4. **Detailed functions:**

Composition of ERC

4.1. The composition of the ERC shall be in accordance with the FERCSL Guidelines and other relevant national and international guidelines.
4.2. The committee will comprise of at least nine (9) and not more than fifteen (15) members.
4.3. The membership will comprise of the following categories:

a) Members from FHCS/EUSL (eight)
b) Members representing the Eastern University, Sri Lanka (excluding academic members of the FHCS,two: from science/ sociology/ Siddha Medicine)
c) Scientific or medical members from institutions other than EUSL (two: A clinician/ a specialist from Public Health Sector)
d) A statistician
e) A non-scientific member
f) A person with expertise in law

4.4. The committee should strive to ensure that there is a gender balance in its composition.

4.5. 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 seven (7) members including Chairperson, Secretary or their designated members, and at least one non-medical or one non-affiliated member are present.

5. Function of Members

In additions to functions described in 5.3, the Chairperson and the Secretary of the ERC are expected to perform additional duties as detailed below:

5.1. Chairperson:

a) Conduct all meetings of the ERC according to the SOPs. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson nominated by a majority vote from the members present will conduct the meeting.
b) Provide guidance to ERC members and office staff.
c) Periodically review and formulate existing or new ERC policies and guidelines in consultation with the members of ERC.
d) Review applications if assigned.

5.2. Secretary

a) Organizing the meetings, maintaining records and communicating with all concerned.
b) Prepare the minutes of the meetings and the general correspondence with applicants and get it approved by the Chairperson before communicating with the members/applicants.
c) Ensure that membership files are current and up to date.
d) Assign primary reviewers for applications in consultation with the Chairperson and co-ordinate the review process.
e) Provide guidance and supervision to the ERC office staff.
f) Perform any other duties of the ERC assigned by the Chairperson.
g) Review applications if assigned.

5.3. All members of the ERC, FHCS/EUSL:

a) Review applications assigned to them and lead the discussion on the application at full board meetings.
b) Complete assessment form for the protocols assigned as primary reviewers prior to the meeting and hand over the completed forms to Secretary at the meeting. If unable to attend, the forms should be sent to Secretary ERC two (2) working days before the scheduled ERC meeting.
c) Perform any other duties assigned to members according to the SOPs.
d) Perform any other duties assigned by the Chairperson.
e) Lead and summarize discussions on applications.

5.4. An administrative secretary will be appointed for ERC, and in the absence such staff the functions of the office staff is handled by the Secretary/ERC

a) Coordinate and process all initial, continuing review, and study modification submissions.
b) Maintain the electronic database of the ERC.
c) Perform any other duties assigned by the Chairperson and Secretary.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Appointment of members
	SOP/03/18 **Effective Date: 01.02.2018**

1. **Purpose:**

   To describe theTerms of Reference (TOR) which provide the framework for the appointment of members and the responsibilities of members of ERC, Faculty of Health-Care Sciences, Eastern University, Sri Lanka.

2. **Scope:**
   This SOP applies to the Faculty Board and members of ERC Faculty of Health-Care Sciences, Eastern University, Sri Lanka

3. **Responsibility:**
   It is the responsibility of the ERC members and the Faculty of Health-Care Sciences to read and understand and respect the rules set by ERC of the Faculty of Health-Care Sciences, Eastern University, Sri Lanka.

4. **Detailed functions:**

4.1. Prospective members of the ERC, FHCS/EUSL may be recruited by direct approach, nomination or by advertisement. Prospective members shall be asked to provide a copy of their Curriculum Vitae. Members must agree to their names and professions being made available to the public, including being published on the ERC website.

4.2. The committee shall **elect** its Chairperson and Secretary from among its members and inform the Dean and Faculty Board for approval. An individual should have at least three years' experiences as a member of the FHCS/EUSL to be eligible to be elected to the post of Chairperson.

4.3. Upon recommendations of the ERC, the Dean and the Faculty Board will **appoint** the Chairperson and the Secretary. They will receive formal letter of appointment.

4.4. The letter of appointment (A/18/01) shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as an ERC member, the circumstances whereby membership may be terminated and the conditions of appointment.

4.5. Members will be required to sign a confidentiality statement (A/18/02) undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the ERC will be

kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the ERC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a ERC member. It's preferable to have members who already got training in ethical review.

4.6. Upon appointment, members shall be provided with the following documentation:

a) ERC Terms of Reference (TOR)
b) ERC Standard Operating Procedures (SOPs)
c) An up-to-date list of members‟ names and contact information including that of the Dean.

4.7. Duration of membership will be for a period of three years. Members are eligible for re-appointment. At the end of three (03) years the committee is reconstituted and the new committee should comprise of at least seven (05) who have a minimum of two years‟ experience as members of previous ERC‟s to maintain the expertise with the view to facilitate the efficient functioning of the ERC.

4.8. New members are expected to attend training sessions as soon as practicable after their appointment.

4.9. All members are encouraged to attend education and training sessions.

4.10. Members may seek a leave of absence from the ERC for extended periods. Steps shall be taken to fill the vacancy if this period exceeds 3 months.

4.11. Membership will lapse if a member fails to attend three (03) consecutive meetings of the ERC without reasonable excuse/apology, unless exceptional circumstances exist.

a) A valid excuse is defined as being involved in designated academic or clinical work. This should be informed to the ERC in writing prior to commencement of the ERC meeting for which the member is going to be absent.
b) The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy.

4.12. 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.

4.13. Members will be expected to participate in relevant specialised working groups as required. The Chairperson and /or Secretary will be expected to be available between meetings to participate in subcommittee meetings where required.

4.14. A member may resign from the ERC at any time upon giving notice in writing to the Chairperson/ERC and the Dean/ FHCS. The effective date

of resignation will be the date in which the resignation is formally accepted by the Faculty Board of FHCS.

4.15. Vacancies in the ERC will be filled as per SOP/03/18 – 4.1, 4.2 and 4.3.

4.16. **Orientation to new members;**

New ERC members must be provided with adequate orientation.

4.16.1. **New member orientation will include the following:**

a) Introduction to other ERC members prior to the ERC meeting.
b) Informal meeting with the Chairperson, Secretary and Officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures.
c) An opportunity to sit in on ERC meetings before their appointment takes effect.
d) Priority given to participate in training sessions.
e) New members will receive training in:
   - Research ethics and human subjects' protection
   - Standard Operating Procedures of the committee

4.16.2**. Obtaining training**

a) Members should get information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards and various media channels.
b) Members should select the ones they need and inform the secretary/secretariat.
c) Keeping the training records - Fill in the form (A/18/03) to record the training/workshop/conference activities in chronological order. A copy must be retained in the ERC office.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Selection of Independent Consultants
	SOP/04/18 **Effective Date: 01.02.2018**

1. Purpose

To provide procedures for engaging the expertise of a professional as a consultant to the ERC, FHCS/EUSL.

2. Scope

If the Chairperson or the ERC determines that a study will involve procedures or information that is not within the area of expertise of its members, they may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the ERC.

3. Responsibility

Upon the advice or recommendation of the secretariat or any ERC member, it is the responsibility of the ERC to nominate and approve the name of the special consultants to be endorsed by the Chairperson.

4. Detailed instruction

4.1. The ERC members will nominate suitable experts for external review based on expertise, availability and independence criteria at the review meeting pertaining to a specific study proposal under review.

4.2. The Secretary / Secretariat will contact the consultant and send the relevant documents for review with the confidentially agreement form and the appropriate study assessment form.

4.3. The consultant must complete and send a report to the Secretary ERC be reviewed by the ERC at the time the study is reviewed at the ERC meeting. This will be reviewed by the ERC at the time the study is reviewed.

4.4. The consultant may be invited to attend the ERC meeting, present the report and participate in the discussion if required as decided by the ERC members.

4.5. The consultation services are sought and applied in relation to a specific protocol and is not a continuous ongoing appointment/service.

4.6. The consultant will not participate in the decision making process of the proposal under review or on any other matter of ERC.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Submission Procedure for New Application
	SOP/05/18 **Effective Date: 01.02.2018**

1. **Purpose :**

   To describe the procedure for the submission of new applications

2. **Scope** :

   Protocol submission include; initial submission, resubmission of protocols with corrections/amendments and continuing review of approved protocols.

3. **Responsibility:**

   It is the responsibility of the ERC secretary /administrative assistant to receive, record and distribute the review protocol and other relevant documents received by the ERC, Faculty of Medicine, University of Peradeniya.

4. **Detailed instruction**

4.1 Applications must be submitted in the appropriate format as determined by the ERC, (A/18/04) and shall include all documentation as required by the ERC (a declaration by the applicant that all required documents have been submitted by completing and signing the application checklist). Information about the procedures for application to the ERC and the application format shall be readily available to applicants in the web site of ERC, FHCS/EUSL Applications must be submitted in the application form given by the ERC and should be accompanied by the following documents:

   a) The complete research proposal
   b) All relevant documents – in English as well as in Sinhala and Tamil where appropriate
   c) Information sheets and consent forms – in English as well as in Sinhala and Tamil where appropriate
   d) All the above documents has to be emailed to the Secretary of ERC as well.

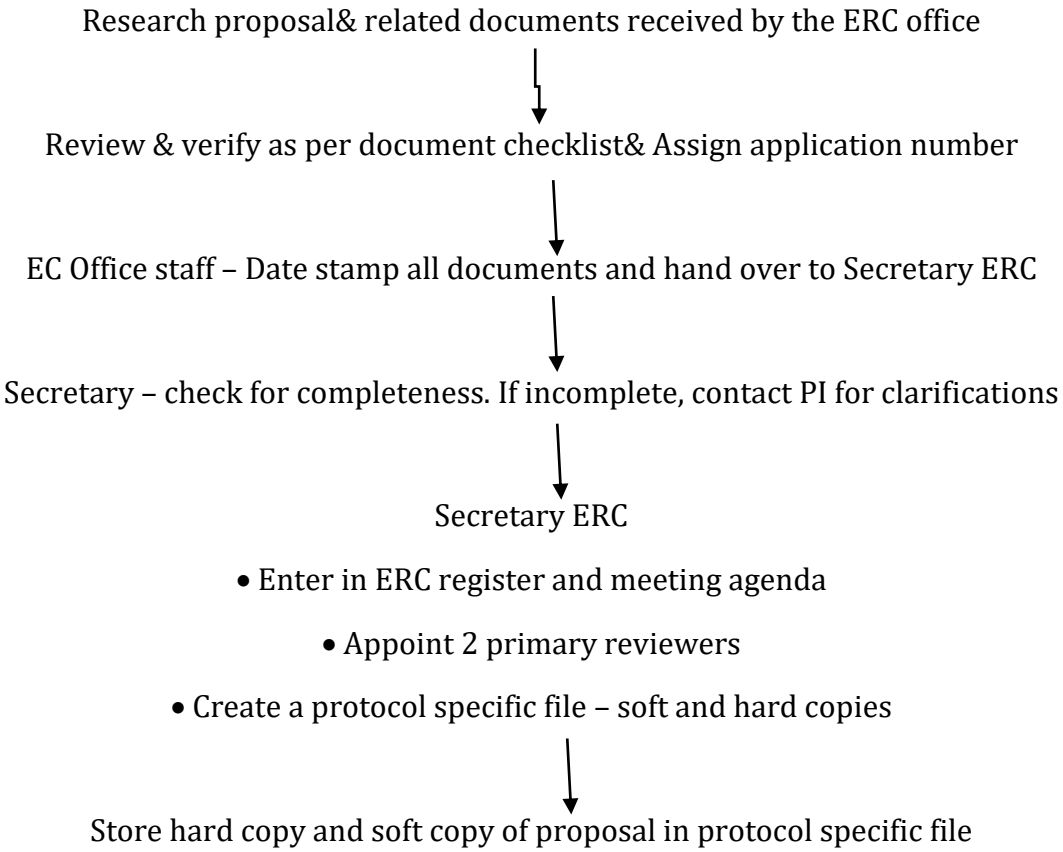
4.3. For postgraduate study proposals - Letter from the relevant postgraduate board stating that the project has been evaluated and has been found to be satisfactory for the purpose of postgraduate research.

4.4. Guidelines shall be issued by the ERC to assist applicants in the preparation of their applications, including guidance on how to determine whether application to the ERC is necessary. These will be made available in the ERC web site. (A/18/06).

4.5. All applicants will have to pay a handling charge as decided by the Faculty Board of FHCS. Handling charges for undergraduate student/FHCS proposals conducted as a direct requirement of course work will be waived at the discretion of the ERC.

4.6. All applications for ethical review must be submitted to the office of the ERC.
4.7. ERC office / Secretary will review and verify documents as per check list. Incomplete applications will be returned to applicant. Once the application is complete, ERC office will date stamp all documents.
4.8. The ERC office will issue a receipt of acknowledgement to the Principal Investigator (A/18/05).
4.9. Once a completed application has been accepted for ethics review, the ERC shall assign a unique proposal identification number to the project containing the calendar year and chronological order of applications [E/YEAR/NO]. The proposal will be added to the ERC's register of received applications. A proposal specific file will be created to file all documents relevant to the proposal.
4.10. The chairperson and the secretary will do the risk assessment and decide whether the application could be exempted from ethics review or needs an expedited review or a full committee review.
4.11. Secretary shall, in consultation with Chairperson, appoint 2 primary reviewers for each project. Primary reviewers shall include a subject expert where ever possible

Submission procedure for applications



	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Processing of applications submitted for ethical review
	SOP/06/18 **Effective Date: 01.02.2018**

1. **Purpose :**
   To describe the process of the ERC's consideration of initial applications for ethics assessment

2. **Scope:**
   This SOP applies to the review process of a study proposal submitted for the first time.

3. **Responsibility:**
   It is the responsibility of the assigned reviewers to thoroughly review the study proposals delivered to them, give their decision, observations and comments to the ERC in the study assessment form and return to the ERC office on the date due. The secretary / administrative assistant is responsible for receiving, verifying and managing the content of submission forms. In addition, the administrative assistant creates a proposal specific file, distributes the proposals and other documents and gets them reviewed by the ERC and delivers the review results to the applicants.

4. **Detailed instruction**
   4.1. The ERC will consider a new application at its next monthly meeting provided that the completed application is received.
   4.2. Each application will be assigned to TWO (02) primary reviewers, one of whom with expertise appropriate and relevant to the proposal.
   4.3. Primary reviewers would:
   a. review the application in detail prior to the meeting.
   b. submit written comments on the application (by filling and forwarding the reviewers comment form to the Secretary ERC)
   c. lead the discussion on the application at the committee meeting.
   4.4. The application will be assigned to a third reviewer who is an expertise in biostatistics to review the methodology and scientific validity.
   4.5. The application will be reviewed by all members of the ERC present at the meeting or by providing written comments in lieu of attendance.
   4.6. The ERC will assess each application in accordance with relevant national and international guidelines. The ERC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, to make an ethical assessment.
   4.7. The ERC may consider whether an advocate for any participant or group of participants should be invited to the ERC meeting to ensure informed decision-making.

4.8. Where research involves the recruitment of persons unfamiliar with the English language, the ERC will ensure that the participant information sheet and informed consent form are translated into the participant's language and/or that an interpreter is present during the discussion of the project.

4.9. Decision making process

4.9.1. The ERC, after consideration of an application at the monthly meeting, will make one of the following decisions:

a) Approved – no changes required
b) Minor clarifications needed – would be eligible for Chairperson's approval once these are done.
c) Major clarifications needed – would require an assessment by the primary reviewers and a full board review once the revisions are done.
d) Rejected -reasons will be conveyed to the applicant

4.9.2. The ERC will attempt to reach a decision concerning the ethical acceptability of a protocol by agreement. Any significant dissenting view or concern shall be noted in the minutes. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members present and reviewed the protocol and making submissions in writing in lieu of attendance, provided that the majority includes at least one non-medical person.

4.9.3. **Chairperson's approval**

For proposals which the ERC considers ethically acceptable with conditions, it may delegate the authority to review the applicant's response and give final approval to one of the following:

- Chairperson alone or
- Chairperson in oral or written consultation with one or more named members who were present at the meeting or who submitted written comments on the application.

In such circumstances, the ERC shall be informed at the next meeting of the final decision taken on its behalf and this will be ratified by the full ERC at its next meeting.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Preparation of agenda
	SOP/07/18 **Effective Date: 01.02.2018**

1. **Purpose:**

   To explain the procedures for preparation of the agenda for an ERC meeting

2. **Scope:**
   The secretary, ERC will prepare the agenda for the next meeting considering the previous minutes, new protocols and other documents pertaining to the protocols under consideration.

3. **Responsibility:**
   It is the responsibility of the secretary ERC to prepare the agenda.

4. Detailed instructions:

4.1. The Secretary of the ERC shallprepare an agenda for each ERC meeting.

4.2. The Agenda shall include the following items (but not necessarily restricted to the followings)

a) Excuses
b) Minutes of the previous meeting
c) Matters arising from the previous minutes
d) New applications
e) Conflicts of interest
f) Amendments to approved protocols
g) Previously unapproved applications
h) Reports of sub committees; (Progress Report)
i) Extensions
j) Serious adverse events
k) Correspondence
l) Any other matters
m) Date of next meeting.

4.3. The meeting agenda and associated documents shouldbe prepared by the Secretary of the ERC and circulated to all ERC members at least seven (7) calendar days prior to the next meeting.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Conduct of meetings
	SOP/08/18 **Effective Date: 01.02.2018**

1. Purpose:

To describe the format of meetings of the ERC

2. Scope:

These standard operational procedures describe the procedures for the conduct of the ERC meetings.

3. Responsibility:

It is the responsibility of the chairperson and secretary / administrative assistant to inform members and facilitate the conduct of regular and special meetings of ERC

4. Detailed instructions:

4.1. The ERC shall meet on a regular basis, which will normally be at monthly intervals. If it deems necessary, the secretary shall call special meeting in congruence with chairperson.

4.2. Members may attend ERC meetings in person.

4.3. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the Secretary of the ERC. The quorum of the meeting shall be half of the (7) members including one non-medical member.

4.4. Quorum must be present in order for the ERC to reach a final decision on any agenda item.

4.5. The Chairperson may cancel a scheduled meeting if quorum cannot be achieved. Should this occur the ERC will convene another meeting within ten (10) working days of the cancelled meeting to ensure all agenda items are taken up for discussion.

4.6. In exceptional circumstances the Chairperson shall decide to proceed with the meeting even in the absence of a quorum. In such circumstances, decisions made by the ERC must be ratified by at least one non-affiliated / lay member.

4.7. The ERC meeting will be conducted in private to ensure confidentiality and open discussion. Members will be advised of the venue in the meeting agenda.

4.8. Any member of the ERC who has the conflict of interest in any form must declare such interest beforehand.

4.9. Any member who is an applicant should leave the ERC meeting prior to the discussion on his/her application and shall re-join the discussion once the discussion on his/her application is over.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Preparation of minutes
	SOP/09/18 **Effective Date: 01.02.2018**

1. **Purpose:**

   To identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting minutes of ERC, FHCS/EUSL meetings.

2. **Scope:**

   This SOP applies to administrative process concerning the preparation of minutes for all ERC meetings.

3. **Responsibility:**

   It is the responsibility of the secretary/administrative assistant to prepare the minutes and to ensure the quality and validity of the minutes after the meeting is over. The chairperson should review and approve the minutes sent to him/her.

4. **Detailed instructions:**

   4.1. The Secretary of the ERC will prepare and maintain minutes of all meetings of the ERC.

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

   a) Attendance and Excuses;
   b) Errors and corrections indicated in the minutes of previous meeting if any.
   c) Matters arising from the previous minutes;
   d) New applications and the achieved decisions;
   e) Decisions regarding the already reviewed proposals
   f) Any other matters
   g) Close and next meeting

   4.3. The minutes should include the recording of final decisions taken by the ERC on any topic. In recording a decision made by the ERC, any significant dissenting view or concern will be noted in the minutes.

   4.4. To encourage free and open discussion and to emphasize the collegiate character of ERC deliberations, particular views shall not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded by name.

   4.5. Declarations of conflicts of interest by any member of the ERC and the absence of the member concerned during the ERC consideration of the relevant application will be recorded in the minutes.

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

4.7. The original copy of each meeting's minutes will be retained in a 'Minutes' file.

4.8. The extracts of minutes of each Committee meeting shall be forwarded to the Dean and the Faculty Board of FHCS, EUSL. The extracts will consist of the titles of the approved protocols and the names of investigators and any other decision of ERC that would need Faculty Board approval for implementation.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Notification of decisions of the ERC
	SOP/10/18 **Effective Date: 01.02.2018**

1. **Purpose :**
   To describe the procedure for the notification of decision of the ERC concerning the review of new applications.

2. **Scope**:
   This SOP applies to all communications related to the studies under review of the ERC, Faculty of Health-Care Sciences, EUSL.

3. **Responsibility:**
   It is the responsibility of all ERC members, secretariat and the chairperson conducting activities of the ERC to complete a written communication record for telephone, or interpersonal discussions related to past, present and/or future studies and/or processes involving the ERC.

4. **Detailed instructions**:

4.1. The ERC will report in writing to the principal investigator regarding the status of ethical approval of the application, within 5 working days of the meeting, unless otherwise notified.

4.2. The ERC decisions should be in the form of one of the following:

a) **Approve the proposal**
b) **Minor revisions needed**
c) **Major revisions needed**
d) **Disapproved/ reject the proposal**

4.3. If approved, any conditions stipulated should be made clear. An application shall be approved only after all outstanding requests (if any) for further information, clarification or modification has been satisfactorily resolved.

4.4. Notification of ethical approval shall be in writing, and will contain the following information:

a) the title of the proposal
b) the name of the principal investigator(s)
c) the unique ERC proposal identification number
d) the version number and date of all documentations reviewed and approved by the ERC including protocols, patient information sheets, consent forms, advertisements, questionnaires etc.
e) the date of the ERC meeting at which the proposal was first considered
f) the date of the ERC's approval
g) the conditions of the ERC's approval, if any, to which approval is subject
h) the period of validity of the ERC's approval (one year)
i) the frequency of progress reports (annual report)
j) the date of submission of the final report.

4.5. In all instances, data collection shall not commence until the written notification has been received by the applicant confirming approvaland non-adherence to this requirement amounts to ethical misconduct.

4.6. A standard ethical clearance certificate will be issued in the format (A/18/07)

4.7. If further information, clarification or modification of the proposal is required, this should be clearly stated in the letter and communicated to the PI. Wherever possible reference should be made to the FERCSL guidelines or other relevant documents or legislation to support the request.

4.8. The letter shall be in the standard format (A/18/08).

4.9. The ERC shall promote active communication with applicants to speedily resolve outstanding requests for further information, clarification or modification of proposals. It may nominate one of its members to communicate directly with the applicant (PI) or invite the applicant to attend an ERC meeting to enable verbal discussion.

4.10. If the proposal is rejected on ethical or other grounds, the letter of rejection shall include the reasons on which the decision was made with reference to the FERCSL Guidelines or other relevant documents or legislation.

4.11. The letter shall be in the standard format set out in annexure (A/18/09).

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

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Amendments and extensions to approved proposals
	SOP/11/18 **Effective Date: 01.02.2018**

1. **Purpose:**
   The purpose of this procedure is to describe how protocol amendments and extensions are managed and reviewed by the ERC.

2. **Scope**:
   This SOP applies to previously approved study protocols that require approval of amendments or extension of validity of ethical clearance. Amendments or extensions made to protocols may not be implemented until reviewed and approved by the ERC.

3. **Responsibility:**
   It is the responsibility of the secretary ERC to manage protocol amendments and extensions. Investigators may amend the content, questionnaires, and consent forms from time to time. They may request a period of extension to complete the research.

4. **Detailed instructions**

   4.1. Approval for amendments to proposals that have been approved, including changes in the manner of conduct of the research and extension of the period for which approval has been given, shall be sought by the principal investigator in writing.

   4.2. Such requests shall be in writing and include:

   a) the nature of the proposed amendments and/or reasons for the request for extension

   b) a self assessment of any ethical implications, arising as a result of amendment and /or extension

   c) all amended documents identified by revised version numbers and dates with amendments highlighted.

   4.3. All 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.

   4.4. The ERC shall report in writing to the principal investigator within five (5) working days of the scheduled meeting at which the request was considered.

   a) Approval of amendments requested shall be as in the approval letter set out in annexure (A/18/10).

b) Approval of extension of the period of validity shall state the new period for which approval has been given with dates. Standard ethical clearance certificate will be issued in the format set out in annexure; A/18/11.

4.5. 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 decision, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the FERCSL Guidelines.

4.6. If the requested amendment and/or extension is rejected, a letter of rejection stating the reasons on which the decision was made with reference to the FERCSL Guidelines or other relevant documents or legislation shall be issued.

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

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Handling of adverse events
	SOP/12/18 **Effective Date: 01.02.2018**

1. **Purpose:**
   To describe the procedure for the reporting and handling of adverse events

2. **Scope**:
   This SOP applies to all communications and actions related to a serious adverse event defined as undesirable clinical responses to an intervention, including a treatment or diagnostic procedures of studies under the approval of the ERC, FHCS, EUSL, that have resulted in harm/death of participants.

3. **Responsibility**:
   The Principal investigator should immediately report all serious adverse events in clinical trials to the ethics committee of the institution responsible for the conduct of research in accordance with the reporting conditions required by ERC.
   The Principal investigator should report all adverse events and the response to those events in the periodic and final reports for the projects.
   The chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention.

4. **Detailed instructions**

4.14.1. The ERC shall require, as a condition of approval of each proposal, that researchers immediately report Suspected Unexpected Serious Adverse Events (SUSAR) or Serious Adverse Events (SAE) to the ERC.

4.2 This requirement includes those that have occurred at other sites in the case of Multicentre Studies.

4.3 The current guidelines of the Sri Lanka Drug Regulatory Authority stipulate the following timelines for reporting such events occurring at local trial sites:

a) death or life threatening event in a patient on a trial or within 30 days off trial: report as soon as possible, but no later than **fivedays**.
b) events, other than fatal and life threatening, in a patient on a trial or within 30 days off trial: report as soon as possible, but no later than **seven days**.

4.4. Notifications of Serious Adverse Events (SAE) must be submitted in the format as set out in annexure; A/18/12 and shall include all documentation as required by the ERC. This documentation shall include as a minimum:

4.5. A summary of all SUSARs related to the same investigational product reported from all sites involved with the same protocol driven clinical trial, should be reported with a causality statement by researchers/sponsors.

4.6. Causality statement from the principal investigator shall be as to whether, in his/her opinion, the adverse event was related to the protocol or in the case of a drug/device trial, whether the adverse event was related to the study drug/device.

4.7. A statement from the principal investigator as to whether, in his/her opinion, the adverse event necessitates an amendment to the project and/or the patient information sheet/consent form.

4.8. The procedure and format for notification of adverse events to the ERC shall be readily available to investigators.

4.9. Adverse events may be reviewed by a special committee of the ERC to recommend the appropriate course of action.

4.10. The special committee shall consist of the following:

a) Chairperson ERC
b) Secretary ERC
c) Clinical pharmacologist
d) A clinician with special training /interest in the clinical discipline.

4.11. The review shall take place within one week of notification of the event. The special committee shall determine the appropriate course of action and inform the ERC of its recommendations. This may include:

a) a notation on the proposal file of the occurrence;
b) increased monitoring of the research;
c) a request for an amendment to the protocol and/or patient information sheet/consent form;
d) request for additional information (e.g. occurrence of similar events in other centres if the study is being conducted in multiple centre);
e) suspension of ethics approval; or
f) termination of ethics approval.

4.12. All adverse events reviewed by the subcommittee will be reported to the ERC at the next meeting.

4.13. The Chairperson may take a course of action as he/she feels fit in the circumstances for those adverse events deemed serious and requiring immediate attention. This may include:

a) Immediate request for additional information;
b) Immediate suspension of ethics approval;
c) Immediate termination of ethics approval.

4.14. The ERC shall inform the investigator that it has received notification of the serious or unexpected adverse event, and the course of action is necessary.

4.15. The Chairperson shall immediately notify the Chairman, Faculty board, Faculty of Health-Care Sciences, Eastern University, Sri Lanka, if a research study has been suspended or terminated because of a serious adverse event.

4.16. In the event of suspension or termination of ERC approval, the decision of the ERC will be conveyed to the following authorities:

a) Clinical Trials Registry
b) Regulatory Authority in the Ministry of Health – Sub-committee on Clinical Trials

Glossary

1. Adverse Event

Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavourable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

2. SAE (Serious Adverse Event)

The SAE is serious and should be reported when patient outcome is:

Death – Report if the patient's death is suspected as being a direct outcome of the adverse event.

Life Threatening - Report if the patient was at substantial risk of dying at time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death.

Hospitalization (initial or prolong) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event.

Disability – Report if the adverse event resulted in a significant, persistant, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activity or quality of life.

Congenital Anomaly – Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.

Requires Intervention to Prevent Permanent Impairment or Damage – Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.

3. Unexpected ADR (Adverse Drug Reaction) – Unexpected Adverse Drug reaction, the nature or severity of which is not consistent with the informed consent/ information sheets or the applicable product information.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Dealing with protocol deviations/violations
	SOP/13/18 **Effective Date: 01.02.2018**

1. **Purpose:**
   The purpose of this SOP is to describe the mechanism of receiving, handling and responding to complaints concerning the participant's rights and conduct of a research approved by the ERC

2. **Scope:**
   This SOP applies to all studies under the approval of the ERC, FHCS, EUSL.

3. **Responsibilities:**
   The ERC will require, as a condition of approval of each project, that the researchers indicate the details of the Chairperson/Secretary of ERC to receive complaints about the conduct of the research at the time of submission of the application form.

4. **Detailed instructions:**

4.1. The ERC shall require, as a condition of approval of each proposal that researchers/sponsors report to the ERC of any protocol deviation or violation as soon as possible but no later than 15 working days after its first knowledge

4.2. The report shall include the following:

a) ERC reference number
b) Details of site
c) Patient details – initials, other relevant identifier, gender, age
d) Details of protocol deviation/violation
e) Reason for deviation – patient related /investigator related / other (specify)
f) Details of reporter – Name, address, telephone number, other administrative information
g) Measures taken by the investigators to deal with the violation and to avoid future occurrences

4.3. All reported deviations and violations will be reviewed by a sub-committee and the report of the subcommittee will be submitted to the ERC for approval.

4.4. The ERC Board may decide to suspend or terminate approval of current studies or refuse to accept and review subsequent applications from the investigators cited. This decision shall be based on the category of deviations/violations (major and minor)

4.5. The chairperson notifies the ERC action in writing to the principal investigator as follows:
   a) Temporary suspension
   b) Termination of the approval of the current study
   c) Refuse to accept and review subsequent applications from the investigator cited for major violations

4.6. Make 4 copies of the notification letter signed by the chairperson and Secretary for the following purposes:
   a) original copy shall be sent to the investigator
   b) a copy to the relevant national authorities and institutes
   c) a copy to the sponsor of the study
   d) a copy in the 'noncompliance' file of the ERC

4.7. Follow up action after reasonable time.

Glossary

1.1. **Deviation/ noncompliance/ violation**

The ERC monitors whether investigators do not perform the study in compliance with the approved protocol according to the national and international guidelines and/or fail to respond to the ERC request for information/action.

1.2. **Major protocol deviations**

Major protocol deviations are deviations which affect a participant's safety, condition or status, the integrity of the study data, pose a significant risk of harm and change the balance of risks and benefits and a participant's willingness to continue participation.

If a deviation meets any of the following criteria it should be classified as major (the list is not comprehensive):

1.2.1. deviation has harmed or posed a significant or substantive risk of harm to a participant:
   a) A participant received the wrong treatment or incorrect dose.
   b) A participant met withdrawal criteria during a study but was not withdrawn.
   c) A participant received an excluded related medication.

1.2.2. The deviation compromises the scientific integrity of the study data:
   a) A participant was enrolled but does not meet the protocol's eligibility criteria
   b) Failure to treat participants per protocol procedures that specifically relate to primary efficacy outcomes (if it involves participant's safety, it meets the category above)
   c) Changing the protocol without Ethics Committee approval
   d) Inadvertent loss of samples or data

1.2.3. The deviation is a deliberate or knowing violation of ethical or regulatory policies or guidelines:
   a) Failure to obtain informed consent
   b) Falsifying research or medical records

c) Performing tests or procedures beyond the investigator's professional scope
d) Failure to follow the safety monitoring plan

1.2.4. The deviation involves serious or continuing non-compliance with institutional or regulatory policies:
a) Working under an expired professional license
b) Repeated minor deviations

1.3. **Minor protocol deviations**

Minor protocol deviations are deviations which do not affect a participant's safety, compromise the integrity of study data or affect a participant's willingness to continue taking part in the study.

Examples of minor deviations include:

a) Missing pages of a completed consent form
b) Inappropriate documentation of informed consent such as missing signatures
c) Using an expired consent form that has not changed significantly
d) Participant did not receive a copy of a signed consent form (but on discovery, a copy is given to participant)
e) Study procedure conducted out of sequence

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Monitoring of approved research projects
	SOP/14/18 **Effective Date: 01.02.2018**

1. Purpose:

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored of its performance or compliance.

2. Scope:

This SOP applies to any visit/or monitoring of any study site as stated in the ERC approved study protocol that identify the places/s where the study and/or laboratory procedures are being carried out or performed.

3. Responsibility:

It is the responsibility of the ERC, Faculty of Medicine, University of Peradeniya to perform or designate some qualified agents to perform on its behalf on site inspection of the research projects it has approved. The chairperson/secretary or the members may initiate an on site evaluation of a study site for cause or for a routine audit.

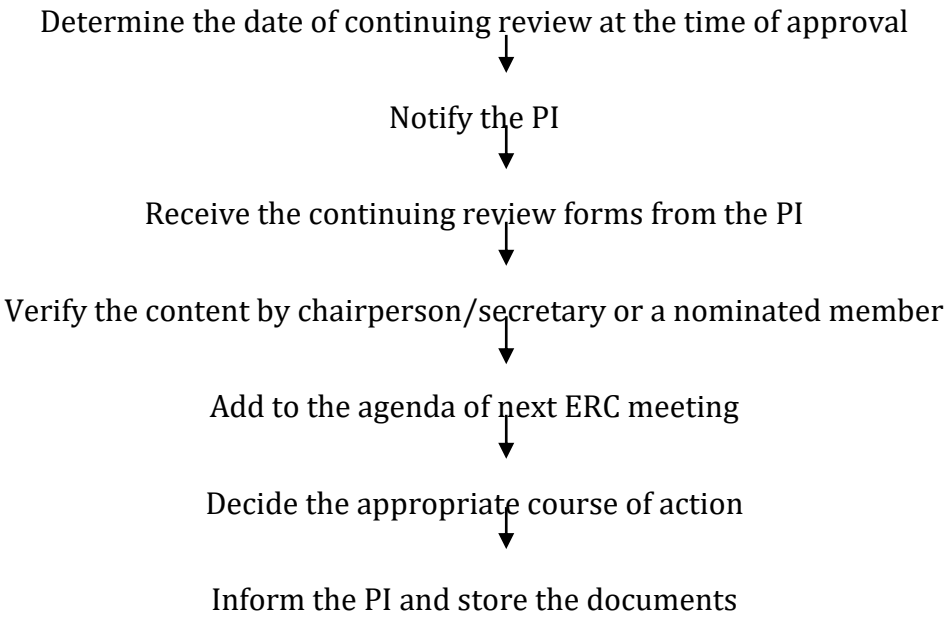
4. Detailed instructions:

4.1. The ERC will monitor approved projects to ensure compliance with its ethical approval. In doing so, it may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the ERC will require applicants to provide a report at least annually, and at the completion of the study. In the case of drug trials, the ERC shall require bi-annual reports which shall be reviewed by the ERC. Extension of ERC approval will be conditional on the submission of the progress report/s by the principal investigator. In addition the ERC could call for a progress report at any time when it is deemed necessary.

4.2. The degree of risk to participants in the research project will be the basis for determining the frequency and the type of monitoring required for approved projects.

The Principal investigator should report all adverse events and the response to those events periodically and final reports for the project.
The chairperson may take the appropriate course of action for those adverse events deemed serious and requesting immediate action.

4.3. Flow chart:



4.4. The ERC shall require the following information in the annual report:

a) progress to date or outcome in the case of completed research;
b) maintenance and security of records;
c) compliance with the approved protocol; and
d) compliance with any conditions of approval.
e) In the case of clinical trials the annual report should also include:
f) number randomized,
g) drop outs,
h) number of subjects being followed up,
i) summary of SAE, SUSAR and protocol deviations and corrective measures taken, and
j) total number randomized in other countries if applicable.

4.5. The ERC may undertake random site visits to review data and signed consent forms; and interview research participants with their prior consent to verify adherence to the approved protocol of the proposal, including:**i)**proposed changes to the protocol; **ii)**any unforeseen events that might affect continued ethical acceptability of the project; and **iii)**new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the project, or which may indicate the need for amendments to the protocol. 6. The 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. 7. Where the ERC is satisfied that circumstances have arisen which prevent a research project from 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 the Regulatory Authority in the Ministry of Health 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.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Monitoring visits to approved study sites
	SOP/15/18 **Effective Date: 01.02.2018**

1. Purpose:

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored of its performance or compliance.

2. Scope:

This SOP applies to any visit/or monitoring of any study site as stated in the ERC approved study protocol that identify the places/s where the study and/or laboratory procedures are being carried out or performed.

3. Responsibility:

It is the responsibility of the ERC, Faculty of Medicine, University of Peradeniya to perform or designate some qualified agents to perform on its behalf on site inspection of the research projects it has approved. The chairperson/secretary or the members may initiate an onsite evaluation of a study site for cause or for a routine audit.

4. Detailed instructions

4.1. As a condition of approval the principal investigators agree to visits by the ERC to the sites where the approved studies are being carried out including the laboratories used for the studies. The visits could be either to resolve any complaints or concerns regarding the conduct of a study or as a routine activity.

4.1.1.Indications for a non-routine site visits are –

a) Reports of remarkable number of serious adverse events/SUSAR
b) Reports suggesting non-compliance or suspicious conduct
c) Failure to submit progress reports/final reports
d) Valid complaint from participants

4.1.2.Preparing for a site visit

Appoint a team (two or three members) for the visit and Contact PI and agree on a mutually convenient date and time. The team members should familiarize themselves with the study protocol and progress. **During the visit** monitoring visit record should be completed during the visit to the site. The visit team should –**have checklist to**

1. ***Interview***

a) PI and other investigators
b) Study staff
c) Study participants if available

2. Review documents

a) Completed consent forms
b) Approved versions of the protocol and related documents

c) Communications with
*Regulatory authority
*Study sponsor and monitors *ERC

Observe

a) Subject recruitment
b) Follow-up visits
c) Laboratory procedures

4.1.3. After the visit

Prepare the site visit report within 2 weeks and forward the report to the ERC. The ERC shall review the report and take appropriate action. The PI will be informed about the results of the site visit by the ERC.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Complaints about the conduct of a research study
	SOP/16/18 **Effective Date: 01.02.2018**

1. Purpose:

The purpose of this SOP is to describe the mechanism of receiving, handling and responding to complaints concerning the participant's rights and conduct of a research approved by the ERC

2. Scope:

This SOP applies to all studies under the approval of the ERC, FHCS, EUSL

3. Responsibilities:

The ERC will require, as a condition of approval of each project, that the researchers indicate the details of the Chairperson/Secretary of ERC to receive complaints about the conduct of the research at the time of submission of the application form.

4. Detailed instructions:

4.1. The ERC maintains a complain register at the ERC office to receive written complaints from research participants, researchers or other interested persons about the conduct of approved research. In addition, they can post written and signed complaints to the Chairperson/Secretary of ERC directly. The contact details of the ERC should be included in the participant information sheet and consent forms. These details also available in the ERC WEB page of the Faculty.

4.2. Any complaints received by the ERC office about the conduct of research approved by the ERC should be investigated by a member appointed by the ERC. That person is responsible for obtaining details of the complaint, in writing, especially in the case of verbal complaints, including the grounds for the complaint and shall notify the Chairperson as soon as possible.

4.3. If the Chairperson considers the complaint to be of a sufficiently severe nature, he/she will bring it to the consideration of the Dean as soon as possible.

4.4. Where the complaint concerns a serious matter that lies within the authority of the Ministry of Health or other institution the Dean shall consider referral of the complaint to that body.

4.5. The Chairperson or Secretary shall send a letter of acknowledgement to the complainant and a letter of notification to the principal investigator in all cases, outlining the nature of the complaint and the mechanism for inquiring into the complaint, as set out below.

4.6. The Chairperson will inquire into the grievance and confirm its validity, or cause an inquiry by suitably qualified persons, and make a recommendation to the ERC a suitable course of action at its next meeting. If the complaint is substantiated, action may include:
   a) amendments to the proposal, including increased monitoring by the ERC;
   b) suspension of the research till counteractive action has been taken;
   c) termination of the study; or
   d) Other action to address issues raised by the complainant.

4.7. If the complainant is not satisfied with the outcome of the Chairperson's inquiry, then he/she can appeal against the decision with reasons and refer the complaint to the Dean or his/her nominee, or request that the Chairperson does so, with a request for re-appraisal.

4.8. In such an instance as in (4.7) above, the Chairperson of the ERC will provide the Dean or his/her nominee with all relevant information including:
   a) the nature of the complaint;
   b) material reviewed in the Chairperson's investigation inquiry;
   c) the results of the Chairperson's inquiry; and
   d) any other relevant documentation and pertinent information.

4.9. The chairperson of faculty board will determine whether there are sufficient grounds to review the decision of the Chairperson and if so, whether a further inquest of the complaint is justified. Where there is to be no further inquiry, the Dean will inform the complainant and the Chairperson of this.

4.10. If the chairperson of faculty board determines that there are grounds for a review of the initial inquiry, then he/she will establish a panel to consider the complaint in appeal.

4.11. The panel will include, at least, the following members:
   a) the Dean or his/her nominee, as convenor of the panel;
   b) two nominees of the faculty board (who are not members of the ERC);
   c) the ERC Chairperson or his/her nominee.

4.12. The panel will afford the ERC and the complainant the opportunity to make submissions. Where the complaint concerns the conduct of an investigator or any staff member, the panel shall also provide that person with an opportunity to make submissions.

4.13. The panel shall have access to all documents relating to the research and may interview other parties, and find internal and external expert advice, as it sees fit.

4.14. The Dean will notify the complainant, the Chairperson and the investigators (if an allegation has been made against them) of the outcome of the review in the following terms: Either the appeal is sacked and the decision of the Chairperson indorsed; or the Dean directs suitable action to be taken to resolve outstanding issues rose in the appeal.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Complaints concerning the ERC's review process and decisions
	SOP/17/18 **Effective Date: 01.02.2018**

1. **Purpose :**

   The purpose of this SOP is to describe the procedure for receiving and handling concerns or complaints from investigators about the ERC's review process.

2. **Scope:**

   This SOP applies to the conduct and actions of the ERC, FHCS, EUSL with regards to the review process of applications made.

3. **Responsibility:**

   Any concern or complaint about the ERC's review process should be directed to the attention of the chairperson of the ERC and /or Dean, FHCS, EUSL. The preliminary investigation is the responsibility of the chairperson and the Dean, Faculty of medicine, University of Peradeniya. They will decide if a further inquiry is necessary.

4. **Detailed instructions.**

4.1. Any concern or complaint about the ERC's review process should be directed to the attention of the Chairperson or Secretary of the ERC, detailing in writing the grounds of the concern or complaint.

4.2. The ERC maintains a complain register at the ERC office to receive written complaints from research participants, researchers or other interested persons about the conduct of approved research. In addition, they can post written and signed complaints to the Chairperson/Secretary of ERC directly. The contact details of the ERC should be included in the participant information sheet and consent forms. These details also available in the ERC WEB page of the Faculty.

4.3. A panel appointed by the ERC will initiate an investigation of the complaint and its validity, and make a recommendation to the ERC on the appropriate course of action. This investigation shall take no longer than two (2) weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist. The panel will make a recommendation to the ERC on the appropriate course of action at its next meeting.

4.4. If the complainant is not satisfied with the outcome of the ERC's investigation, then he/she can refer the complaint to the Dean, or request the Chairperson to do so.

4.5. The ERC will provide the Dean with all relevant information about the complaint/concern, including:
- the complaint;
- material reviewed by the investigating panel;
- the results of the investigating panel; and
- any other relevant documentation.

4.6. The Dean will determine whether there is to be a further investigation of the complaint.

4.7. If the Dean determines there is to be a further investigation, then he/she will establish a panel to consider the complaint/concern. Where there is to be no further investigation, the Dean will inform the complainant and the Chairperson of this decision.

4.8. The panel appointed by the Dean will include, at least the following members:

a) The Dean or his/her nominee, as convener of the panel.
b) Two nominees of the Dean (non-members of the ERC)

4.9. The panel will afford the ERC and the complainant the opportunity to make submissions.

4.10. The panel may review any document relating to the project. The panel may interview other parties, and seek any other internal and external expert advice. In conducting its review, the panel shall be concerned with ascertaining whether the ERC acted in accordance with the FERCSL and other relevant national/international guidelines, its terms of reference, standard operating procedures.

4.11. the Dean will notify the outcome of the complaint could be;

a) the complaint/concern being dismissed;
b) the complaint/concern being referred back to the ERC for consideration, bearing in mind the findings of the panel appointed by the Dean

4.13. The ERC should be requested to review its decision and the outcome of this review (by the ERC) will be final.

4.14. The panel may also make recommendations about the operation of the ERC including such actions as:

a) a review of the ERC's standard operating procedures; and/or other such action, as appropriate.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Handling of multi-center research
	SOP/18/18 **Effective Date: 01.02.2018**

1. **Purpose :**
   To describe the procedure for the handling by the ERC of multi-centre research

2. **Detailed instructions**:

   2.1. To facilitate the review of multi-centre research the ERC may:

   - communicate with any other ERC;
   - accept after review a scientific/technical and/or ethical assessment of the research by another ERC;
   - share its scientific/technical and/or ethical assessment of the research with another ERC.

   2.2. The ERC will take into consideration the equity aspects of benefits of the project to the participants and the community.

   2.3. Transfer of biological material abroad should be in accordance with existing laws and regulations. The ERC should act with caution to safeguard the interests of local individuals and communities and, at the same time ensure that research is not hindered. Biological samples should only be used for the purpose stated in the research proposal and not for any other purpose. The fate of the biological material after the proposed research is concluded should be clearly stated.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Record keeping
	SOP/19/18 **Effective Date: 01.02.2018**

1. **Purpose:**
   The purpose of this SOP is to identify the administrative process and provide instructions for the presentation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of ERC, Faculty of Medicine, University of Peradeniya, meetings.

2. **Scope:**
   This SOP applies to administrative process concerning the preparation of the agenda for all regular ERC, Faculty of Medicine, University of Peradeniya meetings.

3. **Responsibility:**
   It is the responsibility of the secretary ERC to prepare the agenda for the ERC meeting and to ensure the quality and validity of the minutes after the meeting is over. The chairperson should review and approve the agenda and minutes sent to him/her.

4. **Detailed instructions**

4.1. The Secretary of the ERC will prepare and maintain written records of the ERC's activities, including agendas and minutes of all meetings of the ERC.

4.2. The designated official of the ERC will prepare and maintain a confidential electronic and/or paper record for each application received and reviewed and shall record the following information:

   a) unique project identification number;
   b) name/s of principal investigator(s);
   c) name of the responsible institution or organization;
   d) title of the project;
   e) decision/s of the ERC - approval or non-approval - with date/s;
   f) approval or non-approval of any changes to the project;
   g) terms and conditions, if any, of approval of the project;
   h) action is taken by the ERC to monitor the conduct of the research.

4.3. 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.

4.4. All relevant records of the ERC, including applications, membership, minutes and correspondence, will be kept as confidential files.

4.5. 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 or via confidential disposal bins. Members who do not have access to secure disposal should leave their documents in the ERC Office for disposal.

4.6. Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention for non-clinical trial research is at least five (5) years after the date of publication or completion of the research or termination of the study. For clinical trial research, fifteen (15) years shall apply. Files which are no longer required for retention shall be electronically archived. Retention periods shall comply with relevant national guidelines and the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).

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

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Handling of conflicts of interest
	SOP/20/18 **Effective Date: 01.02.2018**

1. **Purpose:**

   The purpose of this SOP is to describe the procedure for reporting and handling of conflict of interest of the ERC members.

2. **Scope:**

   This SOP covers the agreement on conflict of interest concerning information and procedures followed by the ERC, FHCS, EUSL.

3. **Responsibility:**

   It is the responsibility of all ERC members to understand, accept and report any conflict of interest before the ERC meeting to protect the rights of study participants.

4. **Detailed instructions:**

Conflict of interest

A conflict of interest arises when a member (or members) of the EC holds interests with respect to specific applications for review that may jeopardize his/her (their) ability to provide a free and independent evaluation of the research focused on the protection of the research participants. Conflicts of interests may arise when an EC member has financial,material, institutional, or social ties to the research.

4.1. An ERC member shall, prior to the ERC meeting or as soon as practicable during the ERC meeting, inform the Chairperson if he/she has a possible conflict of interest, financial or otherwise, in any proposals or other related matter(s) to be considered by the ERC.

4.2. 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 during the ERC's consideration of the relevant matter. The member shall not be permitted to adjudicate on the proposal.

4.3. All declarations of conflict of interest and the absence of the member concerned during the deliberations will be minuted.

	Ethics Review Committee **Faculty of Health-Care Sciences** **Eastern University, Sri Lanka**
	Title: Review of Standard Operating Procedures and Terms of Reference
	SOP/21/18 **Effective Date: 01.02.2018**

1. **Purpose :**

   The purpose of this SOP is to describe the procedure for the amendment of the ERC Terms of Reference and Standard Operating Procedures within the ERC.

2. **Scope:**

   This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ERC, Faculty of Medicine, University of Peradeniya.

3. **Responsibility:**

   It is the responsibility of the chairperson and secretary to appoint a SOP team to formulate the SOPs by following the same procedure, format, and coding system when drafting or editing any SOP of the institute.

4. **Detailed instructions:**

4.1. The Standard Operating Procedures may be amended at any time if the need arises for such amendments

4.2. The Standard Operating Procedures shall be reviewed every three years and amended as necessary.

4.3. The Standard Operating Procedures may be amended by following the procedures set out below:

a) The proposed amendments must be in writing and circulated to all ERC members for their consideration.

b) The views of the members should be discussed at the next scheduled meeting of the ERC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his/her views in writing.

c) The proposed amendments shall be ratified if two thirds of the members agree to the amendments.

d) The Chairperson shall send the amendments to the Dean for review and approval of the Faculty Board

ANNEXURES

Annexure 1 (A/18/01)

Dr/Mr/……..
……..

Dear Dr. ……..,

Letter of Appointment to the Ethics Review Committee

I am pleased to inform you that you have been appointed as Secretary of the Ethics Review Committee (ERC) of Faculty of Health-Care Sciences, Eastern University, Sri Lanka for a period of three (3) years with effect from ……., as recommended by the Faculty board of Faculty of Health-Care Sciences, Eastern University, Sri Lanka at its ……. meeting held on……..

As a member of the ERC, you would be entrusted with the task of reviewing the proposals submitted for ethical approval as per the standard operating procedures of the ERC and relevant national and international guidelines.

Faculty of Health-Care Sciences, Eastern University, Sri Lanka will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. The TOR and the SOPs are attached herewith.

Please sign the attached confidentiality agreement and hand it over to the ERC office.

Yours sincerely

……..
Dean
Faculty of Health Care Sciences
Eastern University, Sri Lanka

Annexure 2 (A/18/02)

Confidentiality Agreement

This agreement is made and entered into on this ..... day of .....by and between Ethics Review Committee, Faculty of Health – Care Sciences, Eastern University, Sri Lanka (hereinafter referred to as ERC) and .....

..... (holder of NIC number.....

.....) of .....

.....(herein after referred to as the "member")

WHEREAS the member has agreed to serve on the aforesaid ERC and in which capacity the member will have access to confidential information in the ERC:

AND WHERE AS the member has acknowledged and agreed that the committee has and shall continue to have sole rights to the confidential information and has agreed to hold the same in strict confidence during and after the member'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 become publicly available other than through the faults of the member.

2. ***Obligations of the member***
   The member hereby undertakes:

   a). to maintain the highest degree of secrecy and keep as confidential any confidential information which the member may be granted access to or which may be available to or which member receives on behalf of the ERC or in the capacity of the member 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 an as member 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 for whatever reason to the ERC all property, documents and papers in the members' possessions or control relating to the inter alia of the ERC

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 becomes legally compelled to disclose any confidential information the member 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 appropriate remedy is not sought by the ERC or is sought bit is not obtained the member 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 we accorded to confidential information so disclosed.

4. ***The member hereby unconditionally accepts and acknowledges that having regard to the nature of the ERC and the functions and duties of the member of the ERC the member 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

Annexure 3 (A/18/03)

TRAINING RECORD

Training Record of ……..

ERC, FHCS, EUSL

Name of Training **Session**	**Date**	**Conducted by**

Annexure 4 (A/18/04)

ETHICS REVIEW COMMITTEE
Faculty of Health-Care Sciences
Eastern University, Sri Lanka

Application No:_____Date Received: _____

ERC Meeting date: _____Date informed: _____

Decision: _____

Names of the Reviewers:

1_____

2_____

(For office use only)

APPLICATION FORM FOR HUMAN RESEARCH

This form should be filled online and signed by the principal investigator who request ethical approval for a research project involving Human Subjects.

The spaces in this form are expendable as you type online.

When fill the application, please read the instructions carefully and ensure all necessary documents as per the document checklist are submitted.

PART I (ADMINISTRATIVE DETAILS)

1. **Title of Research Project :**

2. **Details of Principal Investigator :**

Title (Prof/Dr/Mr/Ms)& Name	
Current designation:	
Affiliation:	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

3. **Is this study a requirement for a postgraduate degree?**Yes ☐ No ☐

If yes,

Type of degree (PhD/MD/M.Phil./MSc/other.)	
Awarding of University	
Date of Registration :	

4. **Are there supervisors for this project?**Yes ☐ No ☐

If yes,give thedetails of the supervisors

Title (Prof/Dr/Mr/Ms) & Name	
Department(or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	

Phone no.:	
e-mail:	

**Please append additional pages with Supervisors names if necessary*

5. **Are there Co-investigators for this project?** Yes ☐ No ☐

If yes, give the details of the Co-Investigators

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no. :	
e-mail:	

**Please append additional pages with Co-Investigators names if necessary*

****Please note that short curriculum vitae of all investigators should be attached with the application***

6. **Location(s) where the research will be conducted :**

   6.1. Is this a multi-site study? Yes ☐ No ☐

   6.2. Specify all study sites

   If the research is to be conducted at a site, requiring administrative approval/consent (e.g., in a hospital/school),it is the responsibility of the researcher to obtain approval prior to starting the research.

Type of study sites (Hospital/Clinic/School/Community,etc.)	**Details**

7. **Has ethical approval for this study been requested from ERC / FHCS or another similar committee?**

   Yes ☐ No ☐

   If yes, give the details (names of committees and outcome of review)

   Please note that for the studies sponsored by foreign funding agencies or sponsors ethics review and approval is required from the country of the funding agency or the sponsor.

8. **Scientific review**

   Has this research proposal been subjected to scientific review by any other committee?

   (Eg: Board of study,Research committee, Higher degree committee etc.)

   Yes ☐ No ☐

   If yes, give the details (names of the committees and outcome of the review)

9. **Funding of this Project :**

Funding Status	**Name and address of funding Source(s) and Amount**
Funded	Agency : Total Budget : LKR
Applied for funding	Agency : Total Budget : LKR

10. Proposed dates of research commencement and completion that involves human participants or data for this project *†

Date of Commencement: | | Date of Completion: | |

** From initial recruitment of participants until completion of all data collection*
† Retrospective approval will not be given for projects already started or completed

11. For Clinical trials only

11.1. What phase of clinical trial is being conducted?

- Phase I ☐
- Phase II ☐
- Phase III ☐
- Phase IV (post marketing) ☐
- OTHER ☐

If OTHER specify

11.2. Have you got GCP training (Good Clinical Practice)?

Yes ☐ No ☐

**If yes, please attach a copy of GCP training certificate*

11.3. Is the clinical trial, registered inSri Lanka Clinical Trial Registry (SLCTR)?

Yes ☐ No ☐ Pending ☐

If YES, give details (name of register and registration number)

**Please attach the approval letter of clinical trial registry*

If NO, give reasons

11.4. Has this study been approved by the SCOCT (Subcommittee on clinical trials) of the Ministry of Health

Yes ☐ No ☐ Pending ☐

If YES, give details of approval number

**Please attach the supportive document*

If NO, give reasons

11.5. Data Safety Monitoring Board (only if available)

Name and Designation of Members	Role

**Please attach the curriculum vitae of all members of the DSMB.*

11.6. Details of indemnity and insurance coverage for participants, investigators and ethics committee

PART II (RESEARCH PROPOSAL)

For official use

Application No:

12. Please include the following information as given in your project proposal indicating the page number(s) relevant to each section in the corresponding box.

12.1	**Collaborative Partnership**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The collaborations you have established with institutions where the study is to be conducted	☐	☐		
2.	The collaborations you have established with community where the study is to be conducted	☐	☐		
3.	The benefits to institutions, communities, and participants in your research	☐	☐		

12.2	**Social Value**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The beneficiaries of your research and the benefit to them	☐	☐		
2.	The plan for dissemination of study findings	☐	☐		

12.3	**Scientific Validity**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The scientific importance of your study in relation to improving health care and/or knowledge on the subject.	☐	☐		
2.	The justification for a replication study, if your study is a replication study.	☐	☐		

3.	How the sample size was calculated	☐	☐		

12.4	**Confidentiality**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	How the data and sample will be obtained	☐	☐		
2.	How long data and sample will be kept	☐	☐		
3.	Justification for a collection of personal identification data	☐	☐		
4.	Who will have access to the personal data of the research participants	☐	☐		
5.	How the confidentiality of participants will be ensured	☐	☐		
6.	The procedure for data and sample storage	☐	☐		
7.	The procedure for data and sample disposal	☐	☐		

12.5	**Right of the Participants**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	Procedure for subjects to withdraw from the research at any time	☐	☐		
2.	Procedure for subjects to ask questions and register complaints	☐	☐		
3.	The contact person for research	☐	☐		

	subjects				
4.	Provision for participants to be informed of results	☐	☐		
5.	Provision to make the study product available to the study participants after research	☐	☐		

12.6	**Fair participant selection**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The justification for the selection of the study population	☐	☐		
2.	The inclusion and exclusion criteria	☐	☐		

12.7	**Responsibilities of the Researcher**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The provision of medical services to research participants	☐	☐		
2.	The provision for continuation of care after the research is completed	☐	☐		
3.	Declaration of conflicts of interests and how the investigators plan to manage the conflicts	☐	☐		
4.	The ethical/legal/social and financial issues relevant to the study	☐	☐		

12.8	**Vulnerable Populations**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	Justification for conducting the study in this population	☐	☐		

12.9	**Research funded by Foreign Agencies/Companies**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		

1.	Justification for conducting the study in Sri Lanka	☐	☐		
2.	Relevance of the study to Sri Lanka	☐	☐		
3.	Post research benefits to Sri Lanka	☐	☐		
4.	The steps taken to take to take into account cultural and social customs, practices, and taboos in Sri Lanka	☐	☐		
5.	The sharing of rights to intellectual property	☐	☐		
6.	The fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study	☐	☐		
7.	How the results of research will be conveyed to relevant authorities in Sri Lanka	☐	☐		
8.	The agreement between the sponsor/funding agency and the investigator	☐	☐	Please Attach	
9	The materials transfer agreement, if biological material is to be transferred abroad	☐	☐	Please Attach	

12.10	**Community Based Research**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The impact and relevance of the research on the community in which it is to be carried out	☐	☐		
2.	The steps taken to consult with the concerned community during the design of the research	☐	☐		
3.	The procedure used to obtain community consent	☐	☐		
4.	The contribution to capacity building of the community	☐	☐		

5.	The procedure for making available results of research to the community	☐	☐		

12.11	**Clinical Trials**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	Justification for withdrawing any therapy from participants to prepare them for the trial	☐	☐		
2.	Justification for withholding standard therapy from trial participants (eg. Control group)	☐	☐		
3.	Justification for providing care which is not the standard of care	☐	☐		
4.	Procedure for dealing with adverse events	☐	☐		
5.	Procedure for reporting adverse events	☐	☐		
6.	Provisions for safety monitoring	☐	☐		
7.	Provisions / criteria for termination of the trial	☐	☐		
8.	Provisions for making the trial drug available to participants after the trial if found to be effective	☐	☐		

12.12	**Information Sheet (IFS)/ Informed Consent Form(ICF) Check List***(The following list of sections should be included in the IFS / ICF)*	**Applicable**		**Section IFS/ICF**	**Reviewer's Comments**
		Yes	**No**		
1.	Purpose of the study	☐	☐		
2.	Voluntary participation	☐	☐		
3.	Duration, procedures of the study and participant's responsibilities	☐	☐		
4.	Potential benefits	☐	☐		
5.	Risks, hazards and discomforts	☐	☐		

6.	Reimbursements	☐	☐		
7.	Confidentiality	☐	☐		
8.	Termination of study participation	☐	☐		

12.13	**Consent**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The Procedure for initial contact of participants *	☐	☐		
2.	The Procedure for obtaining informed consent (Verbal)	☐	☐		
	The Procedure for obtaining informed consent (Written)	☐	☐		
3.	The information (written/oral) provided to participants	☐	☐		
4.	The procedure for ensuring that subject have understood the information provided	☐	☐		
5.	The Procedure for obtaining proxy consent	☐	☐		
6.	The Procedure for withdrawing consent.	☐	☐		
7.	Incentives/reward/compensation provided to participants.	☐	☐		
8.	The Procedure for re – consenting if the research protocol changes during the course of research.	☐	☐		
9.	The Procedure for consenting, if vulnerable groups/children under 18 years of age are being recruited	☐	☐		
10.	The Procedure for consenting, if children aged 12 -18 years of age being recruited. (For children aged 12 – 18 years, in addition to the	☐	☐		

	parental consent, children's assent must be sought)**				

*** Attach a copy of all posters, advertisements, flyers, and letters to be used for recruitment**

**** Attach an assent form for children aged 12 – 18 Years**

12.14	Data Collection	Applicable		Section & Page in Protocol	Reviewer's Comments
		Yes	No		
1.	The procedure to be carried out on these subjects(**details of all studyinstruments** to be used in collection of samples/blood/application of tests/administration of drugs etc,)	☐	☐		

13. Experience of Investigators with this kind of research

Please provide a brief description of previous experience with this type of research by either principal investigator or the research team or the people who will have direct contact with the participants. If there has not been previous experience, please describe how the principal investigator/research team will be trained/ prepared.

PART III (DESCRIPTION OF THE RISKS AND BENEFITS)

14. Possible Risks

14.1. Please indicate all potential risks to participants that may arise from this research.

1. Physical risks (E.g. any bodily contact or administration of any substance)Yes ☐ ☐ No

2. Psychological/emotion risks (E.g. feeling uncomfortable, embarrassed, upset) ☐ ☐ Yes No

3. Social risks (E.g. loss of status, privacy and/or reputation) Yes ☐ ☐ No

4. Legal risks (E.g. apprehension or arrest, subpoena) ☐ ☐

yes No

14.2. If yes to any of the above, please describe.

14.3. State measures employed during the procedure/study to remove or minimize these risks

15. Possible Benefits

15.1. Describe any potential direct benefits to participants from their involvement in the project

15.2. Describe any potential direct benefits to the community (e.g. capacity building)

15.3. Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

16. Compensation

16.1. Will participants receive compensation for participation?

1. Financial Yes ☐ No ☐
2. In-kind Yes ☐ No ☐
3. Other Yes ☐ No ☐

16.2. If **yes**, please provide details and justification for the amount or the value of the compensation offered.

16.3. If **No**, please explain why compensation is not possible or inappropriate.

16.4. If participants choose to withdraw, how will compensation be affected?

17. Feedback/Debriefing/Referral/After-Care

Please describe what information/feedback/services will be provided to participants and/ or communities after their participation in the project is complete.(e.g., health education, referral to clinic/hospital, etc.)

18. Do you think that the project has a Conflict of Interest?

18.1. Commercially

18.2. Financially

18.3. Intellectually

18.4. Other (Explain)

19. Does any member of the research team have any affiliation with the provider(s) of funding/ support, or a financial interest in the outcome of the research?

Yes ☐ No ☐

If yes, please explain:

20. If there is a duality of interest identified above describe the interest and state whether it constitutes a potential conflict of interest.

21. Declaration of Applicant

- As the Principal Investigator on 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 human participants.
- I understand that if there is any deviation from the project as approved I must submit an amendment to the ERC for approval prior to its implementation.
- I have submit all significant previous decisions by this or any ERC and/or regulatory authorities relevant for the proposed study.
- I declare that I am not seeking approval for a study that has already commenced or has already been completed.
- I understand that at least two months are required for ethics review and granting of ethics clearance.
- I will submit progress reports/reports of adverse events and side effects as requested by the **ERC FMS/SJP.**
- I will submit the final reports at the completion of the study.

……. **Date:**
……../……./……..
Signature of Principal Investigator

Full Name of Principal Investigator:……

22. **Consent from all Investigators**

We, the undersigned hereby confirm that we have consented to be co-investigators of the project titled.

Name	**Qualifications**	**Institutional Affiliations**	**Signature**

PART IV CHECK LIST (Please mark all documents submitted)

CHECK LIST		To be marked by the applicant	To be marked by ERC office
One copy each of the following			
1	Covering letter signed by the applicant	☐	☐
2	Letter from supervisor (If relevant)	☐	☐
3	Bank receipt	☐	☐
4	Copy of approval letter from Board of Study (for postgraduate student only)	☐	☐
5	Curriculum Vitae of all the investigators	☐	☐
6	Letter signed by all the investigators confirming their participation.	☐	☐

Four copies each of the following				
7	Completed application form		☐	☐
The following documents(where relevant)must be submitted. *They must be stapled or bound together to form 4 completes sets of documents.* *All documents must the carry the Title and Version Number as a header (E.g. Version I)*				
8.	Proposal		☐	☐
9.	Study Instruments	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
10.	Information Sheet	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
11.	Consent Forms	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
12.	Assent Forms	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
13.	Advertisement for Recruitment	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
14.	Email a complete set of all documents submitted (include of copy of your application, protocol, instruments and forms in all languages) as pdf files to erc_fhcs@esn.ac.lk at the time of submission.		☐	☐

**Your application will not be processed until all required documents are received by the ERC office.*

…….

Date:……. ……./……./……..

Signature of Principal Investigator

(E-Signatures are not accepted)

REVIEWERS' REPORT

Recommendation: Approve ☐

Reject ☐

Conditional approval (*please state the condition*) ☐

Reviewers' overall comments:

Reviewer:……..Signature:……..Date: ……

(For office use only)

Annexure 5 (A/18/01)

DOCUMENT RECEIPT CHECKLIST

For office use

Application No: ☐

This receipt will be handed over to the applicant by the ERC / FHCS member accepting the application.

The ERC confirms that the following documents were handed in by the applicant:

1. Duly filled Application form ☐
2. Covering letter signed by the applicant ☐
3. Letter from supervisor (If relevant) ☐
4. Bank receipt ☐
5. Copy of approval letter from Board of Study (for postgraduate student only) ☐
6. Approval letter to conduct the study from different institution (if relevant) ☐
7. Curriculum Vitae of all the investigators ☐
8. Letter signed by all the investigators confirming their participation. ☐
9. Project Proposal ☐
10. Study Instruments ☐
11. Information Sheet ☐
12. Consent Forms ☐
13. Assent Forms ☐
14. Advertisement for Recruitment ☐
15. Indemnity / Insurance coverage (for clinical trial) ☐
16. Summary of the proposal (Flow chart / for clinical trial) ☐
17. GCP training certificate ☐
18. Brief CVs of all investigators ☐
19. CVs of all DSMB members ☐

The application number appearing on top of this page has been assigned to this application. Please quote the number in all correspondence with the committee.

…….

……

Authorized Signatory for ERC Date

Annexure 6 (A/18/06)

Guidelines for submitting proposals to ERC of Faculty of Health-Care Sciences, Eastern University Sri Lanka Version 2 (2018)

1.List of items to be submitted

1.1. Three (3) copies of project proposal in separate files (This should include protocol, Participant information sheet, consent form and Questionnaires)

1.2. Two (2) copies of project proposal included with Participant information sheet, consent form and Questionnaires for the undergraduates of EUSL.

1.2. Duly filled application form

1.3. Twelve (12)copies of one-page summary of the study with the title

1.4. Evidence for payment (Paying voucher)

1.5. Approval letter from the relevant institution where research will be conducted (If any)

1.6. Approval letter from the relevant postgraduate institution (for Postgraduate degrees)

1.7. Supervisor's letter (for Postgraduate degrees)

1.8. Brief CVs of all investigators (maximum 2 pages)

1.9. All submitted documents except the application form and payment receipt must be emailed to the erc_fhcs@esn.ac.lk

2. For clinical trials

Apart from the above, the following documents must be submitted

2.1Investigator brochure

2.2 Clinicalrecord forms

2.3 In case of multi centered studies, listing of overseas centre(s) and ERC/IRB approval status if relevant and copies of ERC/IB approval letters from other centers

2.5 Product liability letter or insurance certificate

2.6 Patient recruitment procedures

2.7 Patient's diary cards

2.8 Justification for use of placebo (if any)

3. Resubmissions

3.1. Resubmissions

- Period of resubmission is **one month from the date of notification**.
- One copy of corrected proposal(with changes highlighted) with a covering letter

- One copy the relevant documents corrected and the version should be mentioned to all the resubmitting documents

4. Amendments and Extensions

4.1. Amendments

- Those who seek approval for any amendments in the proposal which has been previously approved by the ERC, should submit 2 copies of the amended proposal (in which the amendments should be highlighted) with a covering letter.
- The covering letter should state the nature of the proposed amendments and reasons for the request for amendment and a self-assessment of any ethical implications, arising as a result of amendment.
- The version number and date should be mentioned in each page of the proposal.

4.2. Extensions

- Those who seek approval for any extension of the period of validity of ethical clearance for a study proposal which has been previously approved by the ERC, should submit a request letter statingthe reasons for the request for extension and a self-assessment of any ethical implications, arising as a result of extension.
- Such requests should be made not later than 30 days prior to the expiry ofapproval.

5. Fees levied as processing charges

Categories	**Fees**
Non-industry sponsored research studies	LKR 3000
Industry sponsored research studies	LKR 10000
For non-Sri Lankan principal investigators	USD 100
Reviewing amendments for industry sponsored studies	LKR 2500
Post graduate degree research	LKR 3000
Undergraduate degree research of other universities	LKR 2000
If principal investigator is EUSL staff member for Non-industry sponsored research studies	LKR 1000

6. Submission of documents

Project proposals are accepted on working days (Monday – Friday, except on public holidays) from 8.30am - 4.00pmat the Department of Medical Education and Research,Faculty of Health-Care Sciences, Eastern University Sri Lanka..

7. The approval

Ethics Review Committee meet on every 3rd/4thTuesdayof each month. Proposals which are submitted before the 30th of each month before 3.00 pm will be considered in the next ERC meeting and the approval will be granted in the subsequent meetings.

If there are any deficiencies in the submitting documents, those proposals will be directed back to the principal investigatorsand will be considered by the ERC only after receiving the complete documents.

If the proposal is approved by the committee, the principal investigator will be notified through post and email.

If there is any inquiry, contact the Secretary, ERC, Departmentof Medical Education and Research, Faculty of Health-Care Sciences, Eastern University, Sri Lanka, 50, New Road,Batticaloa.Telephone 0652227026

Annexure 7 (A/18/07)

ERC Meeting date:

Name:

Application No:

Title:

I am pleased to inform you that the FMS/USJP ERC at its meeting held on ….. has granted ethical approval for your project as per details given below.

Document	**Version No**	**Date of submission**
Project proposal		
Study instrument – English		
Study instrument – Sinhala		
Study instrument – Tamil		
Participant Information sheet - English		
Participant consent forms – English		
Participant information sheet – Sinhala		
Participant consent forms – Sinhala		
Participant Information sheet - Tamil		
Participant consent forms – Tamil		

The study is approved in its presented form effective from … The approval is valid until one year from the date of sanction. You may make a written request for renewal/extension of the validity, along with the submission of annual status report. Please note that ethical approval would be revoked if any alteration is made to the project without obtaining prior written consent from the ethics review committee.

The decision was arrived at through consensus. Neither PI nor any of proposed study team members was present during the decision making of the ERC.

As the Principal Investigator you are expected to ensure that procedures performed under the project will be conducted in accordance with all relevant national and

international policies and regulations that govern research involving human participants.

Please note that this approval is subjected to the following conditions:

- Progress report to be submitted at six monthly intervals and at the completion of the study.
- All serious adverse effects should be reported to the ERC as per SOP in the prescribed form.
- In the case of clinical trials, the trial is registered in an approval Clinical Trials Registry and the registration number submitted to ERC.
- Inclusion of conduct details of the ERC nominee appointed by the ERC to receive concerns/complaints regarding your project in the information sheet. The details are given below:

  .....

  .....

In the events of any protocol amendments, ERC must be informed and the amendments should be highlighted in clear terms as follows:

a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. etc.)

b. If the amendments require a change in the consent form, the copy of revised consent form should be submitted to Ethics Committee approval.

c. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.

....

Chairperson Secretary

Annexure 8 (A/18/08)

Application No: Date:

[Name of principal investigator]

[Address of principal investigator]

Dear [Name of principal investigator],

Re : [Application No.]

Title : [Study Title]

Investigators : [Name of investigator 1]

[Name of investigator 2]

[Name of investigator 3]

Dear Prof/ Dr /Mr/Ms

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting of held on ……../……../…….. The following additional information is requested:

You are advised that you may not commence this study until final approval has been granted. Please highlight the changes made to documents to assist the Committee's checking of the amended documents. (delete if not applicable).

In order for your response to be presented at the next Ethics Review Committeemeeting, this information should be forwarded to the ERC Office by ……./……../……..

Yours sincerely,

Secretary

Ethics Review Committee

Faculty of Health-Care Sciences,

Eastern University, Sri Lanka.

Annexure 9 (A/18/09)

Application No: Date:

[Name of principal investigator]

[Address of principal investigator]

Dear [Name of principal investigator],

Re : [Application No.]

Title : [Study Title]

Investigators : [Name of investigator 1]

[Name of investigator 2]

[Name of investigator 3]

Dear Prof/ Dr /Mr/Ms

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting of held on ……../……../……..

The Committee, which operates in accordance with the relevant guidelines of theForum of Ethics Review Committees in Sri Lanka (FERCSL) has decided not toapprove your project for the following reasons:

You may discuss the ERC's review of your proposal with the chairperson or with me on an appointment.

Yours sincerely,

Secretary

Ethics Review Committee

Faculty of Health-Care Sciences,

Eastern University, Sri Lanka.

Annexure 10(A/18/10)

Application No: Date:
[Name of principal investigator]
[Address of principal investigator]

Dear [Name of principal investigator],
Re : [Application No.]
Title : [Study Title]
Investigators : [Name of investigator 1]
[Name of investigator 2]
[Name of investigator 3]

We are pleased to inform that the request made by you for the following amendment/s to the above study was considered by the Ethics Review Committee, at its meeting on [ERC meeting date] and approval was granted:
1.
2.
3.
You are requested to note the following:

- This approval is valid for one year [effective period], and the committee requests that you submit the progress and/or final report.
- This approval relates to the ethical content of the study only, and you are responsible for the following:
    - Obtaining permissions from the relevant Heads of departments for the conduct of study in their institutions and/or areas under their purview.
    - In the event of any complaints from the participants, report to the Secretary, ERC/FHCS, EUSL
- Please note that the ethical approval will be revoked if any alteration is made to the study without obtaining prior written approval from the Ethics Review Committee.

Yours Sincerely,

[Name of the Chairperson],
Chairperson,
Ethics Review Committee,
Faculty of Health-Care Sciences,
Eastern University, Sri Lanka.

Annexure 11(A/18/11)

Application No: Date:

[Name of principal investigator]

[Address of principal investigator]

Dear [Name of principal investigator],

Re : [Application No.]

Title : [Study Title]

Investigators : [Name of investigator 1]

[Name of investigator 2]

[Name of investigator 3]

We are pleased to inform that the request made by you to extend the ethical approval period from [expiry of previous approval] to complete the above study,was considered by the Ethics Review Committee, at its meeting on [ERC meeting date] and approval was granted for the extension.

You are requested to note the following:

- This approval is valid for one year [effective period], and the committee requests that you submit the progress and/or final report.
- This approval relates to the ethical content of the study only, and you are responsible for the following:
    - Obtaining permissions from the relevant Heads of departments for the conduct of study in their institutions and/or areas under their purview.
    - In the event of any complaints from the participants, report to the Secretary, ERC/FHCS, EUSL
- Please note that the ethical approval will be revoked if any alteration is made to the study without obtaining prior written approval from the Ethics Review Committee.

Yours Sincerely,

[Name of the Chairperson],

Chairperson,

Ethics Review Committee,

Faculty of Health-Care Sciences,

Eastern University, Sri Lanka.

Annexure 12(A/18/12)

Serious Adverse Event (SAE)Report

(To be filled by the principal investigator)

Principal investigator: .....
Protocol No: .....

Study Title:
.....
.....

Study Period: .....

Name of the studied medicine/device: .....

Study site: .....

Sponsor (if any) :.....

No.	Description of unexpected adverse event	Date of Event	Date start and end of treatment	sex	Age	Seriousness (Y/N)	Related to study (Y/N)	Concomitant medication	Intervention	Remarks

Causality statement:

Statement on whether adverse event necessitates an amendment to the project and/or the patient information sheet/consent form:

Any other comments :

Annexure 13(A/18/13)

STUDY ASSESSMENT FORM

Application No: ……

Mark and comment on whatever item applicable to the study

	1. Assessment of the scientific validity of the protocol	**Yes**	**No**	**NA**	**Remarks**
1.	Will the study lead to improvements in human health and/or increase the knowledge?				
2.	Is there provision for dissemination of results of the research?				
3.	Is the title reflective of the study?				
4.	Is the background information appropriate and sufficient?				
5.	Is the rationale /justification of doing the study appropriate?				
6.	Are the objectives /hypothesis of the study clear and achievable?				
7.	Is the study design appropriate to achieve the stated objectives?				
8.	Is the selection of the population and sample correct?				
9.	Is the sample size adequate?				
10.	Is the sampling technique appropriate?				
11.	Is the inclusion criteria appropriate?				
12.	Is the exclusion criteria appropriate?				
13.	Is the proposed data analysis planacceptable?				
14.	Are the selection of variables appropriate?				
	2. Ethical issues				
15.	Are the investigators' qualifications and experience competent to conduct the study?				
16.	Is the impact and relevance of the research on the community in which it is to be carried out acceptable?				
17.	Are there any conflicts of interest, including payments and other rewards?				
18.	Are any other legal/ social/ financial issues addressedadequately in the study?				
19.	Are blood/tissue samples sent abroad?				
20.	Are the biological sample storage and disposal procedures adequate?				
21.	Are the procedures to protect the confidentiality of collected data satisfactory?				
22.	Is the initial contact and recruitment of participants appropriate?				
23.	Is the process for obtaining informed consent appropriate?				
24.	Are the contents of the informed consent document clear?				
25.	Are the informed consent forms consistentin English, Tamil and Sinhala languages?				
26.	Are the contents of the information sheet appropriate and clear?				
27.	Are the information sheetsconsistentin English, Tamil and Sinhala languages?				
28.	Is thejustification for the intention to include individuals who cannot consent adequate?				

29.	Are the arrangements for obtaining proxy consent for such individuals appropriate?				
30.	Will dissent be respected?				
31.	Is the consent given voluntarily and not due to intimidation or inducement?				
32.	Is there an opportunity for the participant to ask questions regarding the research?				
33.	Is the participants' right to unconditionally withdraw from the research at any time safeguarded?				
	For interventional studies (Clinical Trials)				
34.	Have adequate provisions been made for dealing with and reporting adverse effects?				
35.	Will fresh informed consent be obtained if the procedures are changed?				
36.	Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
37.	Is there provision for the subjects to be informed of results of clinical research?				
38.	Is the medical care to be provided to the research participants during and after the research adequate?				
Vulnerable group					
39.	Can the research be equally well carried out in another less vulnerable, group?				
40.	Is there a favorable risk benefit ratio?				

Additional Comments (use separate sheet if necessary):

……

……

……

……

……

Recommendation:

The proposal;

can be approved as submitted	
can be approved conditionally, subject to the amendments indicated	
cannot be approved in the present form	

Name of Reviewer : **……..**

Signature : **……..**

Date : **……..**

Annexure 14(A/18/14)

Application No: Date:

[Name of principal investigator]

[Address of principal investigator]

Dear [Name of principal investigator],

Re : [Application No.]

Title : [Study Title]

Investigators : [Name of investigator 1]

[Name of investigator 2]

[Name of investigator 3]

The Ethics Review Committee, at its meeting on [ERC meeting date] has reviewed your application and considers it exempt from ethical clearance for the following reasons:

1. [reason 1]

2. [reason 2]

3. [reason 3]

The following documents have been reviewed by the committee:

Document	Version No.	Date
Study Protocol		
Study instrument - English		

Please note that this exemption is pertaining to the above submitted protocol and any alterations or deviations should be notified to the Ethics Review Committee.

Yours Sincerely,

[Name of the Chairperson],

Chairperson,

Ethics Review Committee,

Faculty of Health-Care Sciences,

Eastern University, Sri Lanka.

Annexure 15(A/18/15)

Format of Final report

FHCS ERC Proposal No:

Study title:

Principle investigator:

Sponsor:

Duration of study:

Started date: Completion date:

Summary of study participants:

- Target no. of participants:
- Total patients to be recruited at approved study site (ERC ceiling):
- Screened:
- Screen failures:
- Enrolled:
- Consent withdrawn: Reason:
- Withdrawn by PI: Reason:
- Active on treatment:
- Completed treatment:
- Patients on follow up:
- Patients lost to follow up:
- Any other:

No. of study arms:

Results (brief) (use extra blank sheets if more space required)

Presentation/ publication related to the data generated in this trial

SAEs at approved study centre (Total number and type)

Whether all SAEs were intimated to the ERC (Yes/ No)

Protocol deviations/ violations (Number and nature)

Conclusion:

Signature of PI and Date: