STANDARD OPERATING PROCEDURES

Sri Lanka Medical Association

Ethics Review Committee

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Ethics Review Committee
Sri Lanka Medical Association

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Background & History of SLMA and ERC

The Sri Lanka Medical Association (SLMA) is the oldest medical body in South Asia, having started life as the Ceylon Branch of the British Medical Association in 1887. The Ceylon Medical Association, as it was at the time, was incorporated as a Limited Company in 1951 and the name subsequently changed to The Sri Lanka Medical Association.

The SLMA is governed by a Council that is elected annually by the general membership at the Annual General Meeting (AGM). The Council is headed by an elected President who holds office for one year and who is not eligible for re-election. The finances of the association are overlooked by an elected treasurer; the annual accounts are subject to audit by an audit firm that is appointed annually at the AGM.

Membership in the SLMA is open to all persons registered by the Sri Lanka Medical Council under section 29—i.e. medical graduates permitted to practice medicine and surgery in Sri Lanka. The membership therefore includes all specialties, from junior grades to specialists both in the private and government sectors, as well as the Universities. SLMA is a strictly professional body with no trade union function and is apolitical. The functions of the Association are carried out through a number of standing committees and expert committees.

The Ethics Committee of the SLMA was requested by the SLMA Council to establish an Ethics Review Committee (ERC) to serve the needs of researchers who did not belong to an institution that had its own ERC. The ERC was established during 1998 and soon prepared Guidelines to regulate its work with the following objectives:

- to maintain ethical standards of practice in research, including protection of subjects of research from harm and preserving their rights;
- to provide reassurance to the public that this is done; and
- to facilitate good research.

The SLMA ERC was made a standing committee of the SLMA in 2017. Its functions are carried out in accordance with National and International guidelines and regulations.

The SLMA ERC accepts applications for review from any person who wishes to conduct biomedical (involving human subjects) or sociological research in Sri Lanka. These include medical officers attached to the Ministry of Health and the Private Sector, academics of universities and postgraduate trainees. The purpose of the ERC is to guide and support researchers in conducting their research in an ethical manner. This ensures that participants' wellbeing and safety are placed above all others when conducting research.

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DOCUMENT HISTORY

Version	Issue Date	Reason for Change
Guidelines	12 November 1998	Original guidelines finalised at the time of establishing the ERC
1.0. (draft)	22 January 2016	SOPs drafted in preparation for SIDCER survey
1.0.	23 April 2016	Minor revisions made to draft after review by ERC members. Approved by SLMA Council on 6 May 2016
1.1.	15 August 2016	Revisions made according to SIDCER survey recommendations
2.0	15th July 2019	Major revisions made according to SIDCER survey recommendation and on suggestions made by members of ERC.
2.0		Approved by SLMA Council

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 001 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Review of SOPs and Terms of Reference	**Page: 1 of 2**

1.1 Purpose

To describe the procedure for the preparation of and amendments to the Standard Operating Procedures (SOPs)of the Sri Lanka Medical Association Ethics Review Committee (SLMA ERC).

1.2 Scope

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the Sri Lanka Medical Association (SLMA) ERC.

1.3 Responsibility

It is the responsibility of the Chairperson and Secretary to appoint a SOP team to formulate the SOPs as per requirements of ERC.

1.4 Detailed instructions

1.4.1 The Standard Operating Procedures shall be reviewed at least every four years (earlier if required) and amended as necessary.

1.4.2 The Standard Operating Procedures may be amended consequent to proposals made by ERC members or the Council of the SLMA.

1.4.3 For those proposals made by an ERC member:

1.4.3.1 The proposal must be in writing and circulated to all ERC members for their consideration.

1.4.3.2 The views of the members shall be discussed at a scheduled meeting of the ERC. Any member unable to attend such a meeting may register his/her views in writing.

1.4.3.3 The proposal shall be **ratified if two thirds of the members agree** to the amendment.

1.4.3.4 The Chairperson shall send the amendment to the Council, SLMA for review and approval.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 001 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Review of SOPs and Terms of Reference	**Page: 2 of 2**

1.4.4 For those proposals made by the Council, SLMA:

1.4.4.1. The President/ Hon. Secretary, SLMA shall send the proposal in writing to the ERC. The proposal shall be circulated to all ERC members for their consideration.

1.4.4.2. The views of the members shall be discussed at a scheduled meeting of the ERC. Any member unable to attend such a meeting may register his/her views in writing.

1.4.4.3. The proposal shall be **ratified if two thirds of the members agree** to the amendment.

1.4.4.4. The decision of the ERC shall be conveyed to the Council, SLMA.

1.4.5 Items recommended for SOP

The header should contain the SOP number (number and year: 00X – 20XX), title (which should be brief but descriptive), version and effective date.

Additionally, an SOP should comprise of the following items:

1. Purpose: A concise and accurate summary of what the document is to accomplish.
2. Scope: Description of the appropriate application of the document.
3. Responsibility: Responsibility for implementing the activities mentioned in the SOP
4. Detailed instructions: Description of the activities to be performed
5. Annexures: The annexures that will be used with the SOP
   The Annexures will be coded as **A/*SOP No*/ *Annexure No*/Version No i.e. A/00X/0X/X.x)**

1.4.6 The SOPs will be reviewed, modified as necessary and ratified **if two thirds of the members agree.**

1.4.7 The final SOPs will be approved by the Council of the SLMA and the signature of the President, SLMA will signify this acceptance.

1.4.8 The approved SOPs will be accepted by the Chairperson of the SLMA ERC and will be in effect until the next revision.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 002 – 2019** **Version 2.0**
	Title: ERC function	**Effective date: 1.9.2019** **Page: 1 of 2**

2.1 Purpose

To describe the overall function and responsibilities of the Ethics Review Committee. This SOP describes the Terms of Reference (TOR) which provide the framework for the constitution, responsibilities and activities of the Sri Lanka Medical Association (SLMA) Ethics Review Committee (ERC), and applies to all activities of the SLMA ERC.

2.2 Scope

2.2.1 The primary objectives of the SLMA ERC are to protect the rights, dignity and safety of human participants used in research, to facilitate ethical research through efficient and effective review and monitoring processes, to promote ethical standards of human research and to review research in accordance with the current *Ethics Review Committee Guidelines* of the Forum of Ethics Review Committees in Sri Lanka (FERCSL Guidelines) and the latest versions of relevant national and international guidelines.

2.2.2 The SLMA ERC will entertain applications for ethical approval from researchers attached to any medical and non-medical institutions promoting or sponsoring human biomedical and sociological research. Such applicants should show qualifications and experience in the relevant field or be under the supervision of a senior researcher in the same field. Applicants may submit permission from institution not having recognised ERC when applying to ERC SLMA.

2.2.2.1 Applications <u>will not be entertained</u> for research conducted in institutions where there is an ERC recognised by the Ministry of Health, Sri Lanka

2.2.3 The Ethics Review Committee shall advise the SLMA Council on all matters relating to the ethics of research involving human participants

2.2.4 The ERC shall not undertake functions that might conflict with the above, i.e. shall not act as a research funding or grant giving committee.

2.2.5 The SLMA ERC shall not entertain any request by a clinician/s with an ethical problem relating to medical practice (not pertaining to research) as it falls outside the purview of the ERC.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 002 – 2019** **Version 2.0**
	Title: ERC function	**Effective date: 1.9.2019** **Page: 2 of 2**

2.3 Responsibility

It is the responsibility of the SLMA ERC members to read, understand and respect the rules, policies and guidelines set by the SLMA ERC.

2.4 Detailed instructions

2.4.1. All applications will be subject to a handling charge as recommended by the ERC and approved by the Council of the SLMA.

2.4.2 The SLMA ERC will provide independent, competent and timely review of the ethics of research involving human research participants. In their composition, procedures, and decision-making, the ERC needs to have independence from political, institutional, professional, and market influences. The members of the ERC also need to demonstrate competence and efficiency in their work. The ERC is responsible for carrying out the review of the proposed research before the commencement of the research and also to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision.

2.4.3. Human research projects may include, but are not limited to, research involving biological, clinical, psychological or social processes in human beings; improved methods for the provision of health services; the causes of disease; the effects of the environment on the human body; pharmaceuticals, medicines and related substances; medical devices; surgical procedures; medical radiation and imaging; and the development of new applications of health technology.

2.4.4. The term “human research participant” includes human research or clinical research involving human participants, their biological materials and/or data, such as:

i. Surveys, interviews, focus groups or ethnographic observations
ii. Review of medical records where there is access to personal information
iii. Interventional studies including psychological, physiological or medical treatment / testing
iv. Collection of data from registries, repositories or databases where personal medical information is stored and/or
v. Use of biological specimens, including cadaveric specimens

2.4.5. The ERC will assess projects submitted to it for review in accordance with the FERCSL and other national and international guidelines and legal requirements in order to determine their ethical acceptability. This shall include an examination of the scientific aspects of the proposal.

2.4.6 The ERC will review and approve projects, using the knowledge of its members and that of independent consultants when the committee lacks the expertise among its members to review specific subject areas. **(SOP 007/2.0/2019)**

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 003 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Membership composition	**Page: 1 of 2**

3.1 Purpose

To describe the membership composition of the SLMA ERC.

3.2 Scope

The SLMA ERC is composed of both scientists and non-scientists. It is independent in its reflection, advice and decisions. These standard operating procedures describe the framework for the constitution of the SLMA ERC.

3.3 Responsibility

It is the responsibility of the SLMA ERC members to read, understand and respect the rules set by the ERC.

3.4 Detailed functions

3.4.1 The composition of the SLMA ERC shall be in accordance with the FERCSL Guidelines and other relevant national and international guidelines.

3.4.2 The committee will comprise at least eleven (11) and not more than fifteen (15) members.

3.4.3 Members shall be appointed to ensure that the ERC has the expertise required to assess the applications submitted to it for consideration. The composition of the ERC shall reflect the language and cultural diversity of the country and have a gender balance.

3.4.4 Membership of the SLMA Ethics Review Committee shall be constituted as follows, wherever possible:

i. Medical members from disciplines of Basic Sciences and Clinical Specialties
ii. Non-medical scientists
iii. Legal member
iv. Non-scientist (Lay) members

3.4.5 The committee shall elect its chairperson and secretary from among its members

3.4.6 Ethics Review Committee members shall be appointed by the Council of the SLMA on the recommendation of the ERC.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 003 – 2019** **Version 2.0**
	Title: Membership composition	**Effective date: 1.9.2019** **Page: 2 of 2**

3.4.7 Whenever required, the ERC may obtain the services of appropriate experts approved by the Council, SLMA, to assist with the review of a proposal as an External Reviewer. The ERC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, or any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter. **(SOP 007/2.0/2019)**

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 004 – 2019**
	Title: Appointment of ERC members	**Version 2.0** **Effective date: 1.9.2019** **Page: 1 of 2**

4.1 Purpose

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

4.2 Scope

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for appointment of members of the SLMA ERC.

4.3 Responsibility

It is the responsibility of the ERC members and the Council members of the SLMA, to read, understand and respect the rules and responsibilities set by the SLMA ERC.

4.4 Detailed instructions

4.4.1. Members will be appointed by the Council of the SLMA. The President SLMA will issue the letters of appointment.

4.4.2. Prospective members of the SLMA ERC may be recruited by direct approach, nomination or by advertisement. Members are appointed as individuals for their knowledge and experience and not by positions held or as representatives of any organisation, group or opinion.

4.4.3. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the SLMA ERC. Members must agree to their names and professions being made available to the public, including being published on the ERC website.

4.4.4. The letter of appointment **(A/004/01/2.0)** shall include the date of appointment, length of tenure, terms of reference (TOR), 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.

4.4.5. Members will be required to sign a confidentiality agreement (**A/004/02/2.0)** and a conflict of interest agreement **(A/004/03/2.0)** 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.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 004 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Appointment of ERC members	**Page: 2 of 2**

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

i. Standard Operating Procedures of the ERC;
ii. Up-to-date list of members' names and contact information.
iii. Any other relevant information about the ERC's processes, procedures and proposals.

4.4.7. Members are appointed for a period of three years. Members may take a break after their second reappointment (i.e. 3 terms) but will be eligible for reappointment.

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

4.4.9. The committee shall elect its Chairperson and Secretary from among its members and inform the Council of the SLMA for approval. The President SLMA shall issue the letters of appointment for Chairperson and Secretary.

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

4.4.11. Members may seek a leave of absence from the ERC. The duration of leave to be granted will be considered on a case-by-case basis depending on the needs of the ERC.

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

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

4.4.14. Members will be expected to participate in relevant specialised working groups as required. The Chairperson will be expected to be available to participate in meetings when required.

4.4.15. A member may resign from the ERC at any time upon giving notice in writing through Chairperson, ERC to the President, SLMA. Steps shall be taken to fill the vacancy as per **SOP - 04/2019, 4.2**

4.5 Annexures

A/004/01/2.0, A/004/02/2.0, A/004/03/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 005 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Appointment of ERC members	**Page: 1 of 2**

5.1 Purpose

To describe the functions of members of the SLMA ERC.

5.2 Scope

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for functions of members of the SLMA ERC.

5.3 Responsibility

It is the responsibility of all members of the SLMA ERC to read and understand their functions pertaining to the SLMA ERC.

5.4 Detailed instructions

In additions to functions described in 5.4.3, the Chairperson and the Secretary of the ERC are expected to perform additional duties as detailed below:

5.4.1. 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 existing and formulate new ERC policies and guidelines in consultation with the members of ERC.
d. Review applications assigned.

5.4.2. Secretary

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

5.4.3. All members of the ERC, SLMA:

a. Review applications assigned to them and lead the discussion on the application at full board meetings.

b. Complete the 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. Lead discussions on applications which are assigned as for primary reviewers.

e. Disclose conflicting interests and where a conflict does exist with respect to a study abstain from reviewing the protocol and leave the room during discussion of and voting on the protocol.

f. Respect each other's views and the deliberative process.

h. Decide independently if the design and conduct of proposed studies will protect participants' safety, rights and welfare.

i. Remain impartial and objective when reviewing protocols.

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

k. Take part in research ethics-related continuing education.

l. Perform any other duties assigned by the Chairperson.

5.4.4 ERC Office Staff: (a designated administrative secretary will be appointed for the ERC, and in the absence of such staff, the functions of the office staff is handled by the Secretary/ERC)

a. Coordinate collection and process all initial, continuing review, and study modification submissions.

b. Maintain the electronic database of the ERC.

c. Check all applications for completeness

d. Consult chairperson/ secretary to schedule the ERC meeting date.

e. Assist secretary/ERC to prepare the meeting agenda and minutes according to the standard format

f. Reserve a place for the scheduled meeting on scheduled date and time.

g. Make sure that the room, equipment and facilities are available in good condition for the meeting.

i. Send the approved minutes to all ERC members.

j. Maintain a log book for incoming and outgoing correspondence

k. Follow strict procedures to maintain confidentiality of ERC documents.

k. Perform any other duties assigned by the Chairperson and secretary.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 006 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Training of members and staff	**Page: 1 of 1**

6.1. Purpose

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

6.2. Scope

These standard operating procedures describe the procedure of orientation of new members of the ERC, and training of all the members in the ERC.

6.3. Responsibility

It is the responsibility of new members of the ERC, to read and understand their functions as members of the SLMA ERC. It is the responsibility of all members to undergo continuing professional development.

6.4. Detailed instructions

6.4.1 New ERC members shall be provided with adequate orientation within 6 months of joining ERC. New member orientation may 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. 'Partnering' with another ERC member in the same category.
e. Priority given to participate in training sessions.

6.4.2. New members will receive training in:

a. Research Ethics and Human Subject Protection
b. Standard Operating Procedures of the committee

6.4.3. ERC Office staff will receive training in filing, documentation and archiving procedures of the ERC. Any other applicable training will be provided as required.

6.4.4 Obtaining training

1. Members should get information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards and various media channels.
2. Members should select the ones they need and inform the secretary/secretariat.
3. Keep training records of all training/workshop/conference activities in chronological order. A copy must be retained in the ERC office.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 007 – 2019**
	Title: Appointment of External Reviewers	**Version 2.0** **Effective date: 1.9.2019**
		Page: 1 of 2

7.1. Purpose

To describe the procedure of appointing External Reviewers and their roles and responsibilities

7.2. Scope

If the Chairperson in consultation with the Secretary / members of ERC determines that a study involves procedures or subject areas that are not within the area of expertise of its members, the Chairperson or the ERC may invite individuals with competence in those procedures or subject areas to assist in the review of that proposal.

7.3. Responsibility

It is the responsibility of the Chairperson, SLMA ERC in consultation with Secretary or any other ERC member to identify and appoint external reviewers.

7.4. Detailed instructions

7.4.1. The ERC shall consult any person(s) considered by the ERC to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. **Such person(s) shall not be entitled to vote on any matter**.

7.4.2. Appointment of External Reviewer(s)

7.4.2.1. External Reviewer(s) are appointed by the chairperson in accordance with the expertise needed to review the proposal and will receive a formal notice of **appointment (A/007/01/2.0).**

7.4.2.2. The letter of appointment shall include the date of appointment, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as an External Reviewer to the ERC, and the conditions of appointment.

7.4.2.3. External Reviewer(s) are appointed for the period required.

7.4.2.4. External Reviewer(s) may be remunerated.

7.4.3. Conditions of Appointment

7.4.3.1. External Reviewer (s) are appointed to the ERC under the following conditions:

a. Willingness to publicize his/her full name, profession, and affiliation;

b. All financial accountability, reimbursement for work and expenses, if any, within or related to the ERC should be recorded and made available to the public upon request.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 007 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Appointment of External Reviewers	**Page: 2 of 2**

7.4.3.2 All ERC External Reviewer(s) must sign Confidentiality agreement **(A/004/02/2.0)** and the Declaration of Conflict of Interest **(A/004/03/2.0)** regarding meeting deliberations, applications, information on research participants, and related matters

7.4.4. Responsibilities of the External Reviewer(s)

The responsibilities of the External Reviewer are to review applications assigned to them and provide written comments to be discussed at the full board meetings.

7.5 Annexures

A/007/01/2.0, A/004/02/2.0, A/004/03/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 008 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Submission procedure for applications for ethics review	**Page: 1 of 3**

8.1. Purpose

To describe the procedure for the submission of applications

8.2. Scope

Submission procedure for applications include initial submission, resubmission with corrections/amendments and continuing review of approved protocols.

8.3. Responsibility

It is the responsibility of the ERC Secretary /Administrative Assistant to receive, register and distribute the application form, research protocol and other relevant documents to primary reviewers and the members of ERC.

8.4. Flow Chart

Research protocol (proposal & related documents) received by the Administrative Assistant of the ERC as electronic and paper copies

↓

Verification done as per document checklist by the Administrative Assistant and if incomplete return to PI

↓

Date stamp all documents in the protocol

↓

Issue Document Receipt Form and register in the ERC with a registration number

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Inform Secretary ERC or designated member

↓

Secretary ERC or designated member checks for completeness; and if incomplete, inform PI to complete documentation

↓

For full board review appoint primary reviewers as 8.5.10

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 008 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Submission procedure for applications for ethics review	**Page: 2 of 3**

8.5. Detailed instructions

8.5.1 Applications must be submitted in the format prescribed by the ERC, **(A/008/01/2.0)** which will be available on the SLMA ERC web site and shall include all necessary documentation, including a declaration by the applicant that all required documents have been submitted by completing and signing the application checklist.

8.5.2 The application form should be accompanied by the following documents

i. Complete research protocol.
ii. Information Sheets and Consent Forms - in English, Sinhala and Tamil where appropriate.
iii. Other relevant documents such as questionnaires, check lists, advertisements etc. in English and relevant translations where needed

The number of copies of the above documents to be submitted (8.5.1-8.5.2) will be specified in the application form and the SLMA ERC website.

iv. Updated Curriculum Vitae (CV) of the following
   a. Principal Investigator – both electronic and paper copies
   b. Other investigators – as electronic copies
   c. The supervisor for student projects and proposals for postgraduate degrees – as electronic copies
v. For postgraduate study proposals – a letter from the relevant postgraduate institute/Board of Study stating that the research proposal has been evaluated and is satisfactory for the purpose of postgraduate research.
vi. GCP certificates of investigators for clinical trials
vii. Soft copies of all above documents (5.2.1. – 5.2.5.) should also be emailed as pdf files to <erc.slma@gmail.com>

8.5.3 A non-refundable fee, as stated in the ERC website, will be charged from all for review by the ERC. This must be paid to the SLMA office prior to submission. The charges will be revised from time to time and approved by the Council of the SLMA.

8.5.4 The ERC accepts applications from Monday to Friday during office hours. All applications submitted to the office of the ERC by close of business (3.00 p.m.) on the last working day of each month will be taken up at the scheduled ERC meeting of the following month.

8.5.5 Applications will be checked by the Administrative Assistant of the ERC using a checklist. All documents in a complete application will be date stamped while incomplete applications will be returned to the PI.

8.5.6 For complete applications, the ERC office will issue a receipt to the Principal Investigator. **(A/008/02/2.0)**.

8.5.7 Once a completed application has been accepted for ethics review, the ERC shall assign a unique identification number to the application containing the calendar year and chronological order of applications [ERC/YY- NO]. The application will be added to the ERC's register of received applications.

8.5.8 The paper copy and soft copy of protocol and all relevant documents will be stored in protocol specific file and folder (in hard drive) respectively.

8.5.9 The Secretary or a designated member of the ERC will scrutinize the applications and incomplete applications will be returned to the applicant.

8.5.10 For applications requiring full board review, the Secretary shall, in consultation with the Chairperson, appoint 2 or more primary reviewers.

8.5.11 Applications not requiring ERC review **(SOP 014/2019)** will be issued an exemption letter signed by the Chairperson of the ERC.

8.5.12 Proposals requiring expedited review **(SOP 015/2019**) may be sent to the designated experts.

8.6 Annexures

A/008/01/2.0, A/008/02/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 009 – 2019**
	Title: Preparation of agenda	**Version 2.0** **Effective date: 1.9.2019** **Page: 1 of 2**

9.1. Purpose

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

9.2. Scope

The Secretary ERC will prepare the agenda for the next meeting considering the previous minutes, new applications and documents pertaining to the applications under consideration.

9.3. Responsibility

It is the responsibility of the Secretary ERC to prepare the agenda.

9.4. Detailed instructions

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

9.4.2. An application will be included on the agenda for the next available ERC meeting, provided it is received by the relevant closing date and is complete.

9.4.3. All complete applications with relevant documents, and all correspondence received by the Secretary ERC will be included on the agenda for ERC consideration at its next meeting.

9.4.4. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting in consultation with the Chairperson.

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

9.4.6. Documentation pertaining to clarifications of previously reviewed proposals will be included on the agenda and/or tabled at the meeting if they are submitted before the stipulated deadline.

9.4.7. Agenda items will include <u>at least</u> the following items (**A/009/01/2.0):**

1. Attendance
    i. Present
    ii. Excuses
    iii. Absent
2. Conflict of interest declaration
3. Confirmation of the minutes of the previous meeting

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4. Matters arising from the minutes
5. Protocols awaiting revisions and clarifications
    i. ERC No
    ii. Month of the meeting the protocol was first discussed
    iii. Names of primary reviewers
    iv. Title of protocol – current version no.
    v. Names of PI and other investigators
    vi. Name/s of sponsors (if any)
6. New applications
    i. ERC No
    ii. Title of protocol
    iii. Principal investigator and co – investigators
    iv. Names of primary reviewers appointed
    v. Names of sponsors (if any).
7. Protocols for exemption from review
8. Protocols for expedited review
9. Amendments to approved protocols
10. Extension of ERC approval
11. Reports of serious adverse events (SAE)
12. Progress reports
13. Final reports
14. Protocol deviations, non-compliance and violations
15. Correspondence
16. FERCSL/FERCAP
17. Any other business
18. Close and date for next meeting

9.5 Annexures

A/009/01/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 010 – 2019**
	Title: Conduct of meetings	**Version 2.0** **Effective date: 1.9.2019** **Page: 1 of 2**

10.1. Purpose

To describe the conduct of meetings of the ERC

10.2. Scope

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

10.3. 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

10.4. Detailed instruction:

10.4.1. The ERC shall generally meet on a fixed day of each month. Dates of ERC meetings for the year shall be pre-decided and be publicly available.

10.4.2. The members are expected to attend ERC meetings in person. Members who are unable to attend a meeting should send a written excuse to the Secretary of the ERC. The minutes should record the submission of excuses.

10.4.3. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least five (5) members are present including the Chairperson or Secretary and at least one non-medical (i.e non-affiliated) member.

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

10.4.5. Meetings will usually continue until all agenda items have been considered. In the event that the meeting has to be concluded prior to all agenda items being considered, the ERC will reconvene within 10 working days to complete the agenda.

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

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	Title: Conduct of meetings	**Version 2.0** **Effective date: 1.9.2019** **Page: 2 of 2**

10.4.7. The ERC may agree to the presence of visitors or observers at a meeting. Visitors or observers will be expected to sign a confidentiality agreement with the ERC and a conflict of interest declaration prior to attending the ERC meeting. They will not contribute to the deliberations of the ERC.

10.4.8. Any member of the ERC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the ERC must declare such interest beforehand. This will be dealt with in accordance with **SOP - 011/2019**.

10.4.9. All deliberations will be conducted in a manner that is non offensive, unbiased, sensitive and inclusive.

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

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 011 – 2019**
	Title: Conflict of interest	**Version 2.0** **Effective date: 1.9.2019** **Page: 1 of 1**

11.1. Purpose

To describe the procedure for reporting and handling the conflict of interest of ERC members.

11.2. Scope

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

11.3. 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.

11.4. Detailed instructions

11.4.1. An ERC member shall, prior to commencing work at the ERC, submit the duly completed Conflict of Interest form to the Chairperson **(A/004/03/2.0)**

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

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

11.4.4. All declarations of conflict of interest and the resolutions of the same, such as absence of the member during the relevant discussion, will be minuted.

11.5. Annexures

A/004/03/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 012 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Initial review of ERC application	**Page: 1 of 3**

12.1. Purpose

To describe how the ERC reviews an initially submitted application.

12.2. Scope

This SOP applies to the review process of an ERC application submitted for the first time.

12.3. Responsibility

It is the responsibility of the following to carry out the assigned duties as follows.

12.3.1. Primary reviewers: Thorough review of protocol, complete the study assessment form giving observations, decision and comments and return it to ERC office on or before due date

12.3.2. Administrative officer: Sending the documents to reviewer, collecting the returned documents from the reviewer, creating and managing protocol specific file, assist the Secretary in communication with investigators

12.3.3. Secretary: Oversee the entire process and communicate the decision and comments to the applicant

12.3.4 All members of the ERC: To review all protocols to be taken up for discussion at the relevant meeting and contribute to the discussion

12.4. Detailed instructions

12.4.1. The ERC shall consider a new application at its next monthly meeting provided that the completed application is received on or before the last working day of the preceding month.

12.4.2. The Secretary shall assign each application to two (02) or more primary reviewers one with expertise appropriate and relevant to the protocol. This may include an external expert where necessary. A non-medical member will be assigned to evaluate the Information sheets and consent forms.

12.4.3. Primary reviewers shall:

a. review the application in detail prior to the meeting. He/she may contact and clarify issues with the PI if needed.

b. inform the ERC about the scientific/technical issues and ethical issues using the Protocol Assessment Form **(A/012/01/2.0)** and the ICF Assessment Form **(A/012/02/2.0)** and lead the discussion on the application at the ERC meeting.

c. whenever necessary, request the applicant to submit additional documents or a revised version of the proposal through ERC.

12.4.4 All proposals shall be circulated to all members of the ERC for review prior to the meeting. Applications will be discussed at the meeting by all members present. Written submissions made in lieu of attendance by those not present will be considered.

12.4.5 The ERC shall assess protocols submitted to it for review in accordance with the FERCSL and other national and international guidelines and with national and international laws to determine their acceptability on matters of ethics.

12.4.6 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.

12.4.7 Where research involves the recruitment of persons unfamiliar with the English language, the ERC shall ensure that the participant information sheet and informed consent form translated into the participants' language are accurate and consistent with the English version.

12.4.8 The ERC may invite an investigator to the meeting for clarification of issues in relation to the application. The applicant will be asked to leave the meeting prior to decision-making.

12.4.9 The requirement for informed consent may be waived by the ERC under the following circumstances:

a When the research design involves no more than minimal risk

b If the requirement of individual informed consent could make the conduct of the research impracticable e.g. excerpting data from participant's medical records.

12.4.10 Decision making process:
The ERC will endeavor to reach a decision concerning the ethical acceptability of a protocol by consensus. 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, provided that the majority includes at least one non-medical member. The views of those present as well as the opinion of those who reviewed the protocol and made submissions in writing in lieu of attendance will be counted

12.4.11 The ERC, after considering an application at a meeting, will make one of the following decisions:

a. **Approve the proposal** as being ethically acceptable, no changes requested

b. **Minor modifications needed** and would be eligible for chairperson's approval later once these are done.

c. **Major modifications needed** which would require full board review once the revisions are done. The ERC may assign a primary reviewer /an ERC member to discuss issues with PI to facilitate communications and subsequent resubmission process

d. **Disapprove the proposal** and reasons will be conveyed to the applicant. The files will be labelled as "closed". If the applicant resubmits a modified proposal, this will be considered as a new application.

12.4.12. Communicating the decisions of ERC to PI will be in accordance with **SOP 017/2019**

12.5 Annexures

A/0012/01/2.0, A/012/02/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 013 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Review of resubmitted protocols	**Page: 1 of 2**

13.1. Purpose

To describe how resubmitted study protocols are managed, re-reviewed and approved by the ERC.

13.2. Scope

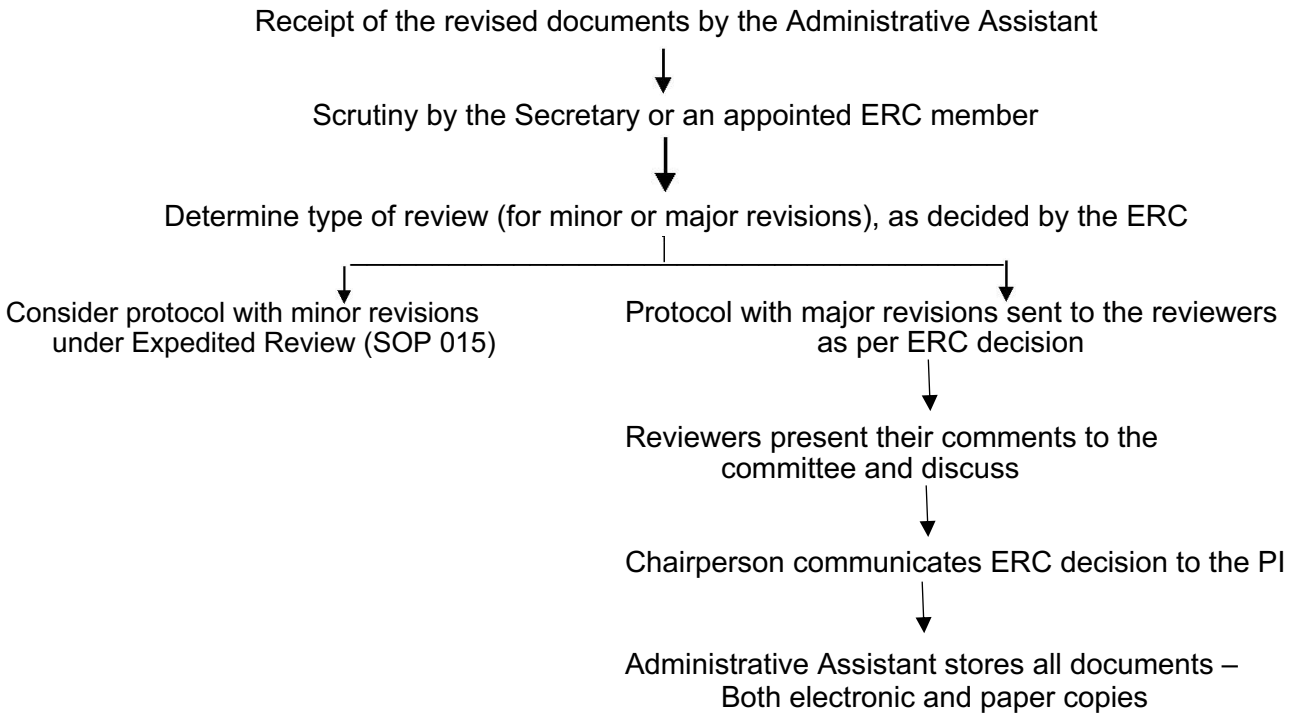
This SOP applies to study protocols that have been recommended revisions, either minor or major, during the initial review process.

13.3. Responsibility

It is the responsibility of the Secretary ERC to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol has been resubmitted for reconsideration.

a. The review of a re-submitted protocol containing minor revisions as decided at the initial review, shall be considered under expedited review (**SOP - 015/2019).**
b. The review of a re-submitted protocol containing major revisions shall be considered at a full board meeting.

13.4. Flow chart



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	Title: Review of resubmitted protocols	**Page: 2 of 2**

13.5. Detailed instructions

13.5.1. The resubmitted package should contain a table giving the corrections against the original version, revised version of the protocol and related documents such as the informed consent forms, data collection or case report forms, with appropriate version number and date.

13.5.2. The Administrative Assistant should date stamp the documents upon receiving the package.

13.5.3. The Secretary or designated member peruses the revised protocol, refers to the meeting minutes as guidance for the review and assigns those that had required minor revisions to be considered under expedited review **(SOP 015/2019).**

13.5.4. Those that had required major revisions will be resent to the primary reviewers for their observations and will undergo a full board review. The primary reviewers will present a brief oral or written summary and his/her comments to the ERC members and the Chairperson entertains discussion on the protocol revision. Further recommendations for modifications to the protocol, consent form, and any other document will be noted in the meeting minutes and communicated to the Principal Investigator.

13.5.5. All clarifications should reach the Secretary, ERC on or before a stipulated date to be considered at the monthly meeting for that month.

13.5.6. Once the revisions are accepted by the ERC, the approval will be communicated to the PI (**A/017/02/2.0)**

13.5.7. Investigators who do not respond to calls for corrections will be reminded thrice in writing and those proposals for which no response is received within 4 months of the initial review will be removed from the meeting agenda. The period may be extended upon request by a PI if the ERC considers the reasons for extension valid. The removed file will be marked as “Closed”.

13.5.8. The original completed documents along with revised documents, the completed re-review report, and assessment forms will be stored in the protocol specific file.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 014 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Exemption from review	**Page: 1 of 2**

14.1. Purpose

To describe the procedure to identify protocols which qualify for exemption from review.

14.2. Scope

This SOP applies to protocols that may be exempt from review at a full ERC meeting.

14.3. Responsibility

The Chairperson (or nominee) and the Secretary (or nominee) will assess the protocol as per check list in Annex **A/014/01/2.0.** If they find that the protocol needs to be submitted for a full board evaluation, it will be reviewed as per **SOP 012/2019.**

14.4. Detailed instructions

14.4.1 The Chairperson (or nominee) and the Secretary (or nominee) will assess the protocol as per check list in Annex A/014/01/2.0 and may exempt from review following research:

i. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular or special education instructional strategies, or (b) research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods.

ii. Educational research proposals are exempt provided <u>all</u> of the following conditions are met:

a) All of the research is conducted in a commonly accepted educational setting (e.g. school or university).
b) The research involves normal educational practices (e.g. comparison of instructional techniques).
c) The study procedures do not cause a significant deviation in time or effort from the usual educational practices at the study site.
d) The study procedures involve no increase in the level of risk or discomfort associated with routine educational practices.
e) The study procedures do not involve sensitive research areas/ topics
f) Provisions are made to ensure the existence of a non-coercive environment for students who choose not to participate.
g) The school or other institution grants written approval for the research to be conducted.

NOTE: Research involving vulnerable groups e.g children or individuals with disability, even if within 14.4.1.i or 14.4.1.ii above are not exempted from ERC review.

14.4.2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour are exempted, unless:

i. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

ii. any disclosure of the human participants' responses outside the research that could place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

NOTE: Sensitive survey research is not exempt. A sensitive survey is one that deals with sensitive or highly personal aspects of the subject's behaviour, life experiences or attitudes. Examples include substance abuse, sexual activity or attitudes, sexual abuse, criminal behaviour, sensitive demographic data, detailed health history, etc. Sensitivity will be determined on the risk to the subject in terms of a negative emotional reaction. An additional risk will be the possibility of a breach of confidentiality.

14.4.3. Taste and food quality evaluation and consumer acceptance studies are exempt:

i. if wholesome foods without additives are consumed; or

ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the relevant Sri Lanka Governmental agency.

14.4.4. A standard exemption letter will be issued, in the format set out in annexure **A/014/02/2.0**

14.4.5 A study completion report may be requested even if the protocol is exempted from review.

14.5. Annexures

A/014/01/2.0, A/014/02/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 015 – 2019**
	Title: Expedited review	**Version 2.0** **Effective date: 1.9.2019** **Page: 1 of 3**

15.1. Purpose

To describe the procedure for expedited review of research proposals.

15.2. Scope

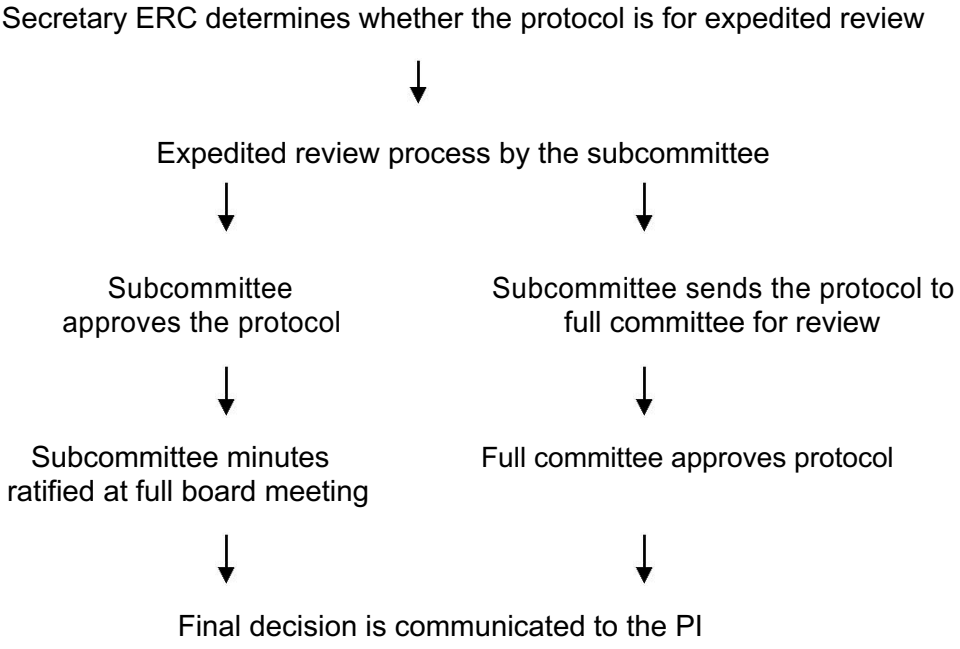
This SOP applies to

a) the initial review and approval of study proposals with minimal risk to participants
b) minor revisions to a protocol or informed consent form currently under review
c) minor protocol amendments or informed consent changes to a previously approved application

15.3. Responsibility

Expedited review shall be conducted by a subcommittee, consisting of the Chairperson, Secretary and 2 members (one medical and one non-medical), appointed as detailed in 15.5.1.

15.4. Flow chart



	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 015 – 2019**
	Title: Expedited review	**Version 2.0** **Effective date: 1.9.2019** **Page: 2 of 3**

15.5. Detailed instructions

15.5.1. Expedited review of research protocols, resubmissions or amendments to approved protocols may be undertaken between scheduled meetings. A subcommittee will be appointed for this purpose and shall consist of the Chairperson and the Secretary and two other ERC members, one medical and one non-medical. The committee will meet physically or in cyber-space for deliberations.

15.5.2. Expedited review process

15.5.2.1. The administrative assistant sends the protocols to the selected members with the assessment forms.

15.5.2.2. If the four reviewers are not in agreement, the Chairperson will refer the protocol for full board review.

15.5.2.3. Review should not take more than 2 weeks.

15.5.2.4. Inform the ERC of the proposals approved by expedited review at its regular meetings.

15.5.2.5. If any ERC member raises concern about any of the proposals presented to it as expedited review, then the proposal shall undergo full board review.

15.5.3. The Sub Committee may undertake expedited review of research protocols which carry minimal risk and research protocols on non-sensitive topics in the following circumstances:

15.5.3.1. Research involving material (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

15.5.3.2. Collection of data from voice, video, digital, or image recordings made for research purposes.

15.5.3.3. Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus groups, programme evaluation, human factors evaluation, or quality assurance methodologies where the investigator does not manipulate the participants' behaviour and the research will not involve stress to the participant.

15.5.3.4. Research previously approved by the full board ERC meeting that meet the following criteria:

a) the research permanently closed to the enrolment of new participants;
b) all participants have completed all research-related interventions;
c) the research remains active only for long-term follow-up of participants;
d) no additional risks have been identified; or where the remaining research activities are limited to data analysis.

15.5.3.5. Continuing review of research not conducted under an investigational new drug application or investigational device exemption, which was determined and documented at a full board meeting that the research involves no greater than minimal risk and no additional risks have been identified.

15.5.3.6. The requirement for informed consent may be waived by the ERC under the following circumstances:

a) When the research design involves no more than minimal risk
b) If the requirement of individual informed consent could make the conduct of the research impracticable e.g. excerpting data from participant's medical records.

15.5.4. A summary of the matters dealt with at subcommittee meetings will be included in the agenda for the next ERC meeting for ratification.

15.5.5. Research with the potential for physical or psychological harm will generally not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues and research dealing with vulnerable groups.

15.5.6. A standard approval letter/ ethical clearance certificate will be issued in the format set out in Annexure **A/015/01/2.0**

15.5.7. In the event that the Sub Committee cannot be convened, the protocols will be reviewed at a full board meeting.

15.6. Annexures

A/015/01/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 016 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Amendments to approved protocols	**Page: 1 of 1**

16.1. Purpose

To describe how protocol amendments are managed and reviewed by the ERC.

16.2. Scope

This SOP applies to previously approved study protocols that require approval of amendments. Amendments made to protocols should not be implemented until reviewed and approved by the ERC.

16.3. Responsibility

It is the responsibility of the Secretary ERC to manage protocol amendments. The Secretary ERC will forward such requests to the ERC considering the need for Chairpersons review or full committee review in consultation with the Chairperson.

16.4. Detailed instructions

16.4.1. The principal investigator may seek approval for amendments to proposals that have been approved, including changes in the manner of conduct of the research. Such requests shall be in writing and include:

16.4.1.1. details of the nature of the proposed amendments;

16.4.1.2. an assessment of the ethical implications, if any, that arise as a result of the amendment;

16.4.1.3. a set of documents incorporating the amendments, identified by revised version numbers and dates. The amendments should be highlighted/ given as a table with previously approved and proposed changes.

16.4.2. 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:

16.4.2.1. Major amendments shall be reviewed by primary reviewers of the original protocol whenever possible and will be discussed at the full board meeting.

16.4.2.2. Minor amendments shall be dealt with in accordance with expedited review (**SOP 015/2019**) provided that its decisions are ratified at the next scheduled ERC meeting.

16.4.3. The ERC shall communicate the decision to the Principal Investigator within seven (7) working days of the scheduled ERC meeting at which the request was considered.

16.4.3.1. Approval of amendments requested shall be as in the approval letter (**A/016/01/2.0)**

16.4.3.2. If clarifications are needed the investigator will be requested to submit the relevant details to be considered at the next ERC meeting

16.5. Annexure

A/016/01/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 017 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Communication of decisions of the ERC	**Page: 1 of 2**

17.1. Purpose

To describe the procedure for the notification of decisions of the ERC concerning the review of new applications

17.2. Scope

This SOP applies to all communications related to the studies under review of the SLMA ERC.

17.3. Responsibility

It is the responsibility of

a) all ERC members to complete a written communication record of any discussions they have with the PIs related to the protocols they have been assigned to review to the Secretary ERC
b) the Secretary/ERC to prepare a written communication record based on the discussion held at the ERC meeting, comments sent by absent ERC members and communications of telephone, or interpersonal discussions that have been conducted by all the members of the ERC with the relevant principal investigator.

17.4. Detailed instructions

17.4.1. Decisions of the ERC with regard to all applications discussed will be conveyed in writing, to the principal investigator, within ten (10) working days of the monthly meeting unless notified otherwise.

17.4.2. If the ERC determines that further information, clarification or modification is required for the consideration of a proposal, the correspondence to the principal investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where necessary, requests for additional information/clarification/modification should refer to the FERCSL Guidelines or other relevant documents including legislation. A standard letter will be issued, in the format set out in **A/017/01/2.0 - 017/1**

17.4.3. The ERC shall promote active communication with applicants to speedily resolve outstanding requests for further information, clarification or modification of protocols. The ERC 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. The contents of these discussions will be documented in the minutes and protocol files.

17.4.4. A proposal shall be approved only after all outstanding requests (if any) for further information, clarifications or modifications have been satisfactorily resolved.

17.4.5. If approved, any conditions stipulated should be made clear.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 017 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Communication of decisions of the ERC	**Page: 2 of 2**

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

a. the unique ERC application identification number
b. the title of the proposal
c. the name of the principal investigator(s)
d. names of collaborating investigators with affiliations
e. site/s of study
f. the version number and date of all documents reviewed and approved by the ERC including clinical protocols, patient information sheets, consent forms, advertisements, questionnaires, and other relevant documents etc.
g. the date of the ERC's approval (i.e. the ERC meeting date on which the protocol was approved)
i. the conditions, if any, to which the ERC approval is subject
j. the period of validity of the ERC's approval
k. the need to report SAE/ protocol deviations/violations/non-compliance
l. the frequency of progress of reports
m. instructions for final report to be submitted

17.4.7. A standard approval letter will be issued, in the format set out in **A/017/02/2.0** within 14 days of the meeting.

17.4.8. If the ERC determines that a proposal is disapproved on ethical or scientific grounds, the communication of the ERC's decision will include the reason for disapproval of the proposal with reference to relevant guidelines and/or other relevant legislation. A standard letter will be issued, in the format set out in **A/017/03/2.0**

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

17.5. Annexures

A/017/01/2.0, A/017/02/2.0, A/017/03/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 018 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Handling of serious adverse events	**Page: 1 of 2**

18.1. Purpose

To describe the procedure for the reporting and handling of serious adverse events.

18.2. Scope

This SOP applies to all communications and actions related to all adverse events as defined in the glossary, occurring in studies under the approval of the SLMA ERC.

18.3. Responsibility

The Principal Investigator shall immediately report all adverse events in clinical trials to the SLMA ERC in accordance with the reporting conditions required by the SLMA ERC. The Principal Investigator shall report all adverse events and the response to those events in the periodic and final reports for the proposals. The Chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention.

18.4. Detailed instructions

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

18.4.2. This requirement includes those that have occurred at other sites in the case of multi-centre studies.

18.4.3. Reporting time frame: The following time frames for reporting such events occurring at local trial sites, should be adhered to:

4.3.1. Fatal or life-threatening unexpected reactions occurring in a patient on a trial or within 30 days off trial: report as soon as possible, but no later than seven (7) days.

4.3.2. All other serious unexpected reactions, 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 fifteen (15) days.

4.3.3. Or some other time frame as required by Sri Lankan Regulations, if any.

18.4.4. Notifications of Suspected Unexpected Serious Adverse Reactions (SUSAR) and Serious Adverse Events (SAE) must be submitted in the format as set out in **A/018/01/2.0** and shall include all the documentation required by the ERC. These documents shall include at least:

18.4.4.1. A statement from the Principal Investigator 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;

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

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

18.4.6. Adverse events shall be reviewed by a special committee of the ERC (or Clinical Trials Committee) appointed to review such events, which shall determine the appropriate course of action.

18.4.6.1. The special committee shall consist of the following:

- Chairperson ERC
- Secretary ERC
- A clinical pharmacologist
- A clinician with special training / interest in the clinical discipline.

18.4.8. 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. These may include:

18.4.8.1. a notation on the proposal file of the occurrence
18.4.8.2. increased monitoring of the research
18.4.8.3. a request for an amendment to the protocol and/or patient information sheet / consent form
18.4.8.4. suspension of ethics approval or
18.4.8.5. revoke ethics approval

18.4.9. The Chairperson may take a course of action appropriate in the circumstances for those adverse events deemed serious and requiring immediate attention. This may include:

18.4.9.1. Referral to the Clinical Trials Evaluation Committee (CTEC) of the National Medicines Regulatory Authority (NMRA)
18.4.9.2. Immediate request for additional information
18.4.9.3. Immediate suspension of ethics approval
18.4.9.4. Immediate revoking of ethics approval

18.4.10. All adverse events reviewed under this section and the recommendations of the special committee shall be reported to the ERC at the next meeting.

18.4.11. The ERC shall inform the investigator that it has received notification of the serious adverse event, and the course of action it has deemed necessary to take.

18.4.12. The Chairperson shall immediately inform the President and Council of the Sri Lanka Medical Association if a research study has been suspended or ethics approval revoked because of a serious adverse event.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 019 – 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Monitoring of approved research protocols	**Page: 1 of 3**

19.1. Purpose

To describe the procedure for monitoring research studies approved by the ERC to ensure compliance with ethics approval

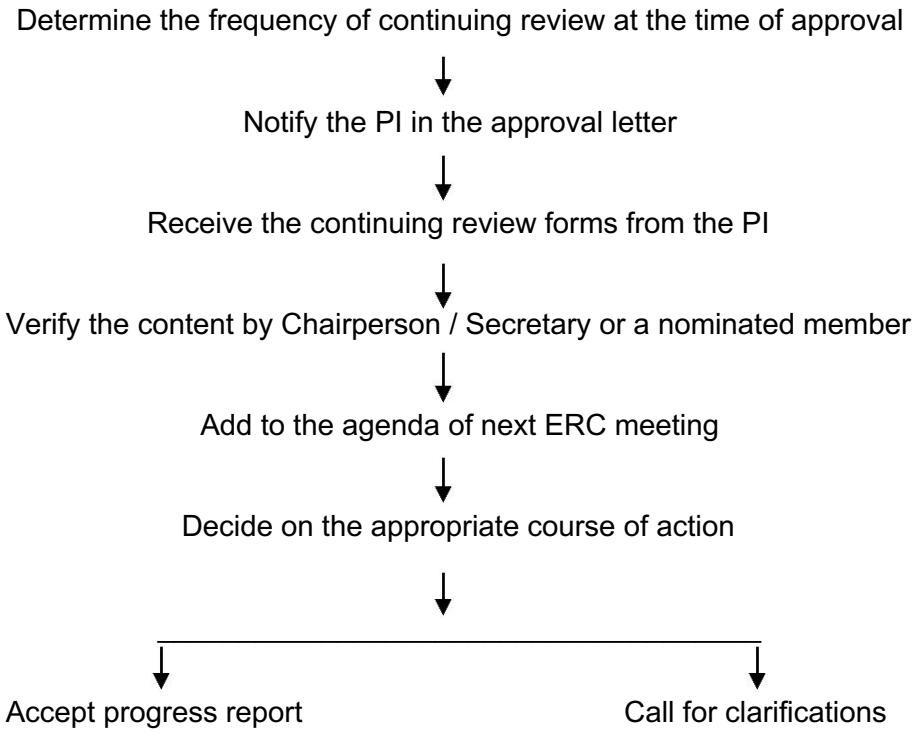
19.2. Scope

This SOP applies to all studies under the approval of the SLMA ERC.

19.3. Responsibility

The Principal Investigator (PI) should send periodic progress reports to SLMA ERC. The frequency of reports will be decided by the ERC depending on the nature and duration of the study. The PI should send the final report to the ERC at the completion of study.

19.4. Flow chart



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19.5. Detailed instructions

19.5.1. The ERC shall monitor approved research studies to ensure compliance with its approval.

19.5.2. The ERC may request, at any time, information on any relevant aspects of the study and discuss any issue of relevance with the researchers.

19.5.3. The ERC will require applicants (PI) to provide periodic progress reports annually, or more frequently depending on the risk, and a final report at the conclusion of the study. **(A/019/01/2.0, A/019/02/2.0)**

19.5.4. In the case of clinical trials, the ERC shall require six monthly reports which shall be reviewed by the special subcommittee (or the Clinical Trials Sub-committee). The progress reports shall contain at least the following information:

19.5.4.1. progress to date or outcome in the case of completed research
19.5.4.2. statements regarding maintenance and security of records
19.5.4.3. statements supporting compliance with the approved protocol
19.5.4.4. statements supporting compliance with any conditions of approval

Extension of approval for a further period will be subject to the Principal Investigator submitting progress reports as called for in the letter of approval.

19.5.5. In determining the frequency and type of monitoring required for approved studies, the ERC will give consideration to the degree of risk to participants in the research. The ERC may adopt those measures it considers appropriate for monitoring, such as:

19.5.5.1. written reports;
19.5.5.2. random inspections of research sites, data and signed consent forms etc.
19.5.5.3. interviews, with their prior consent, of research participants.

19.5.6. The ERC shall require, as a condition of approval of each proposal, that investigators immediately report anything which might warrant review of the ethical approval of the protocol, including:

19.5.6.1. proposed changes in the protocol;
19.5.6.2. any unforeseen events that might affect continued ethical acceptability of the study; and
19.5.6.3. new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.

19.5.7. Should the ERC become aware, on good grounds, of circumstances that have arisen which prevent a research study from being conducted in accordance with the approved protocol, the ERC may revoke approval. In such circumstances, the ERC shall inform the Principal Investigator and the institution of such revoking of approval in writing and recommend to the institution that the research study be discontinued or suspended, or that other necessary steps be taken.

19.6. Annexures

A/019/01/2.0, A/019/02/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 020 – 2019** **Version 2.0** **Effective date: 1.9.2019** **Page: 1 of 1**
	Title: Protocol Deviation/Protocol Violation/ Non-compliance	

20.1. Purpose

To provide instructions for taking action and maintaining records that identify investigators/ institutes who fail to follow the procedures written in the approved protocol or comply with national/international guidelines for the conduct of human research, including those who fail to respond to the SLMA ERC requests.

20.2. Scope

This SOP applies to all research protocols approved by the SLMA ERC, involving human subjects.

20.3. Responsibility

It is the responsibility of the Secretary to receive any non-compliance/deviation/violation reports and place them on the agenda of the meeting. It is the responsibility of the ERC to review and take action on these reports.

20.4. Detailed instructions

20.4.1. Ensure that the issues as well as the details of non-compliance/violation/deviation involving research investigators are included in the agenda of the ERC meeting.

20.4.2. Maintain a file that identifies investigators who are found to be non-compliant with national and international regulations or who fail to follow protocol approval stipulations or fail to respond to the ERC request for information or action.

20.4.3. The ERC may decide to suspend or withdraw approval of current studies or refuse to accept and review subsequent applications from the investigators cited.

20.4.4. The Chairperson notifies the decision of the ERC in writing to the investigator as follows:

20.4.4.1. Temporary suspension

20.4.4.2. Revoke the approval given for the current study

20.4.4.3. Refusal to accept and review subsequent applications from the investigator cited for

a. major violations without informing the ERC

b. those that have had too many protocol deviations

20.4.5. Make 4 copies of the notification letter signed by the Chairperson and Secretary; original copy to the investigator, a copy to the relevant national authorities and institutes, third copy to the sponsor of the study, the last copy in the ‘non-compliance’ file of the ERC

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 021– 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Site monitoring visits	**Page: 1 of 2**

21.1. Purpose

To provide procedures as to when and how a study site should be visited and monitored on its performance or compliance.

21.2. Scope

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

21.3. Responsibility

It is the responsibility of the SLMA ERC to perform 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.

21.4. Detailed instructions

21.4.1. Selection of the study site is based on following criteria:

- 21.4.1.1. New study sites
- 21.4.1.2. Reports of remarkable events
- 21.4.1.3. Number of studies carried out at the study site
- 21.4.1.4. Frequency of protocol submission for ERC review
- 21.4.1.5. Noncompliance or suspicious conduct
- 21.4.1.6. Frequently fail to submit progress reports/final reports

21.4.2. Before the visit

- 21.4.2.1. Contact the site and notify them about the visit
- 21.4.2.2. Make appropriate travel arrangements
- 21.4.2.3. Review the ERC files at the office and make appropriate notes

21.4.3. During the visit

- 21.4.3.1. Use the “Checklist for a Site Monitoring Visit” form **(AF/17 - 20/1.1)**
- 21.4.3.2. The ERC members will
  - review the informed consent forms
  - review randomly the subject files to ensure that the subjects are signing the correct informed consent forms
  - observe the laboratory and other facilities for the study
  - obtain immediate feed back

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	Title: Site monitoring visits	**Page: 2 of 2**

21.4.4. After the visit

21.4.4.1. write a report within 2 weeks

21.4.4.2. forward a copy of the site visit report to the 'site monitoring file' for full board review

21.4.4.3. send a copy of the report to the Principal Investigator

21.5. Annexure

A/021/01/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 022– 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Premature termination of an approved study	**Page: 1 of 2**

22.1. Purpose

To describe how the ERC manages the termination of a research study. Protocols are usually terminated

a) at the recommendation of the ERC based on serious adverse events, protocol deviation, non-compliance, protocol violation and violation of national and international regulations.
b) by the principle investigator/sponsor

22.2. Scope

This SOP applies to any study approved by the SLMA ERC that is being terminated before its scheduled completion.

22.3. Responsibility

a) It is the responsibility of the ERC Chairperson to terminate any study that the ERC has previously approved when the benefit or safety of the study participants is doubtful or at risk. The Secretary is responsible for management of the termination process.
b) It is the responsibility of the Principal Investigator to inform the ERC of inability to proceed / premature termination of the approved study, giving reasons.

22.4. Detailed instructions

22.4.1 Premature Termination by ERC

22.4.1.1. Receive recommendation for study termination.

i. Receive recommendations and comments from ERC members, sponsor or other authorized bodies (e.g. DSMB) for study protocol termination.
ii. Request Principal Investigator to prepare 'Study Termination Memorandum' and the original continuing review application form.
iii. Administrative Assistant to initial and date the documents upon receipt.

22.4.1.2. Review and discuss the termination process.

i. Administrative Assistant shall notify the Chairperson regarding the recommendation for study protocol termination within a day.
ii. Chairperson reviews the results, reasons and accrual data.
iii. Chairperson calls for an emergency meeting within 5 working days to discuss the recommendation.
iv. Chairperson signs and dates the continuing review application form in acknowledgement and approval of the termination.

22.4.1.3. Notify the Principal Investigator of the decision of ERC within 7 working days of the ERC receiving the recommendation to terminate.

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	Title: Premature termination of an approved study	**Page: 2 of 2**

22.4.1.4 Keep the original versions of the request memorandum for termination and the continuing review application form in the protocol file. Store the protocol documents for 5 years.

22.4.2 Premature Termination by Principal Investigator

22.4.2.1. Receive study termination notification from the Principal Investigator
22.4.2.2. Request Principal Investigator to prepare 'Study Termination Memorandum' and the original continuing review application form .
22.4.2.3. Review and discuss the reasons for termination and take appropriate action.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 023– 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Minutes of meetings	**Page: 1 of 3**

23.1. Purpose

To describe the preparation and format of minutes of a meeting of the SLMA ERC.

23.2. Scope

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

23.3. Responsibility

It is the responsibility of the Secretary to prepare the minutes and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson shall review and approve the minutes sent to him/her.

23.4. Detailed instructions

23.4.1. The Secretary of the ERC shall prepare and maintain minutes of all meetings.

23.4.2. The format of the minutes shall include at least the following items **(A/023/01/2.0)**

1. Attendance of members:
   1.1 Present
   1.2 Excuses
   1.3 Absent
2. Conflict of Interest
3. Confirmation of the minutes of previous meeting
4. Matters arising from minutes
5. Protocols awaiting revisions and clarifications
   a) ERC No
   b) Month of the meeting the protocol was first discussed
   c) Names of primary reviewers and others for specific areas to be reviewed i.e. Statistics, ICF etc.
   d) Title of protocol – current version no. (*Indicate if title has been changed from original)*
   e) Names of PI and other investigators
   f) Sponsors if any
   g) Observations (administrative/ scientific/ ethical) and discussion
   h) Decision
6. New applications
   a) ERC No
   b) Title of protocol
   c) Principal investigator and co – investigators
   d) Names of primary reviewers and other reviewers for specific areas to be reviewed i.e. Statistics, ICF etc.

e) Names of sponsors (if any)
f) Observations (administrative/ scientific/ ethical) and discussion
g) Decision

7. Protocols for exemption from review
8. Protocols for expedited review
9. Amendments to approved protocols
10. Extension of ERC approval
11. Reports of serious adverse events (SAE)
12. Continuing review
    i. Progress reports
    ii. Final reports
13. Protocol deviations, non-compliance and violations
14. Correspondence
15. FERCSL/FERCAP
16. Any other business
17. Close and date for next meeting

23.4.3. The minutes should include the recording of decisions taken by the ERC as well as a summary of relevant discussion, including dissenting views. This includes reference to views expressed in writing by absent members.

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

23.4.5. In recording a decision on a proposal, any significant dissenting view or concern will be noted in the minutes.

23.4.6. 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.

23.4.7. 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 minuted **(SOP - 011/2019).**

23.4.8. Secretary shall prepare minutes within 2 weeks of meeting and shall be counter signed by the Chairperson for accuracy.

23.4.9. The minutes shall be circulated to all ERC members at least one week before the date of meeting. All members shall be given the opportunity to seek amendments to the minutes prior to their confirmation

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	Title: Minutes of meeting	**Page: 3 of 3**

23.4.10. The original copy of each meeting's confirmed minutes shall be retained in a 'Minutes' file.

23.4.11. The extracts of minutes of each committee meeting shall be forwarded to the Council of the SLMA. The extracts will consist of the following

a) titles of the protocols discussed / approved/rejected/ exempted and removed from the agenda
b) the names of the principal investigators of the protocols
c) any other activities of the ERC which the SLMA Council need to be informed
d) decisions of the ERC that would need Council approval for implementation.
e) A copy of the report shall be filed separately in the ERC office

23.4.12. Extracts of the minutes will be filed in the relevant protocol file.

23.5 Annexures

A/023/01/2.0

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 024– 2019** **Version 2.0** **Effective date: 1.9.2019** **Page: 1 of 3**
	Title: Complaints about the conduct of a research project	

24.1. Purpose

To describe the mechanism for receiving, handling and responding to complaints concerning the participant's rights and the conduct of research approved by the ERC

24.2. Scope

This SOP applies to all studies under the approval of the SLMA ERC.

24.3. Responsibilities

Complaints shall be received by the Chairperson or the Secretary. Their names and contact details shall be included in the participant information sheet and consent forms.

24.4. Detailed instructions

24.4.1. The ERC maintains a complaints 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 signed complaints to the ERC directly. The contact details of the ERC shall be included in the participant information sheet and consent forms. These details shall also be available in the ERC WEB page of the SLMA.

24.4.2. Any complaints received by the ERC about the conduct of research approved by the ERC shall 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.

24.4.3. If the Chairperson considers the complaint to be of a sufficiently serious nature, he/she shall bring it to the attention of the President SLMA as soon as possible.

24.4.4. Where the complaint concerns a serious matter that lies within the jurisdiction of the Ministry of Health or other institution, the President, SLMA shall consider referral of the complaint to that body.

24.4.5. 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.

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21.4.6. The Chairperson will inquire into the complaint and confirm its validity, or cause an inquiry by suitably qualified persons, and recommend a suitable course of action to the ERC at its next meeting. The investigation will take no longer than 4 weeks from the time of notification of the complaint, unless exceptional circumstances exist. Both the complainant and the PI will be given an opportunity to make submissions. Where the complaint concerns the conduct of any other person the ERC will also provide that person with an opportunity to make submissions.

21.4.7. If the complaint is substantiated, action may include:

24.4.7.1. increased monitoring by the ERC as to whether investigators are adhering strictly to the approved protocol;

24.4.7.2. suspension of the research till remedial action has been taken;

24.4.7.3. termination of the study; or

24.4.7.4. any other action to address issues raised by the complainant.

21.4.8. 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 President, SLMA or his/her nominee, or request that the Chairperson does so, with a request for re-appraisal.

21.4.9. In such an instance as in (4.8) above, the Chairperson of the ERC will provide the President/SLMA or his/her nominee with all relevant information including:

24.4.9.1. the nature of the complaint

24.4.9.2. material reviewed in the Chairperson's investigation inquiry

24.4.9.3. the results of the Chairperson's inquiry

24.4.9.4. any other relevant documentation and pertinent information

24.4.10. The President/SLMA will determine whether there are sufficient grounds to review the decision of the Chairperson and if so, whether a further inquiry of the complaint is warranted. Where there is to be no further inquiry, the President will inform the complainant and the Chairperson of this.

24.4.11. If the President/SLMA 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.

24.4.12. The panel shall consist of 5 -7 suitably qualified persons and shall include the following members:

24.4.12.1. President/SLMA or his/her nominee, as convenor of the panel

24.4.12.2. two nominees of the Council, SLMA (who are not members of the ERC)

24.4.12.3. ERC Chairperson or his/her nominee

24.4.13. 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.

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

24.4.15. The President, SLMA 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 dismissed and the decision of the Chairperson upheld; or the President directs suitable action to be taken to resolve outstanding issues that arose in the appeal.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 025– 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Complaints about the conduct of a research project	**Page: 1 of 2**

25.1. Purpose

To describe the procedure for receiving and handling concerns or complaints from investigators about the ERC's review process

25.2. Scope

This SOP applies to the conduct and actions of the SLMA ERC with regard to the review process of applications submitted.

25.3. 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 the President, Sri Lanka Medical Association. The preliminary investigation is the responsibility of the Chairperson and the President, SLMA. They will decide if a further inquiry is necessary.

25.4. Detailed instructions

25.4.1. Any concern or complaint about the ERC's review process should be directed to the attention of the Chairperson of the ERC, detailing, in writing, the grounds of the concern or complaint. Complaints may also be made to the President, SLMA.

25.4.2. The Chairperson will inform the President as soon as possible of any complaints received by him/her. The President will inform the Chairperson as soon as possible of any complaints received by him/her. The President will send a letter of acknowledgement to the complainant, outlining the following mechanism.

25.4.3. The Chairperson or nominee will investigate the complaint and its validity and make a recommendation to the ERC at its next meeting on the appropriate course of action, which shall be communicated to the complainant.

25.4.4. If the complainant is not satisfied with the outcome of the ERC investigation, then he/she can appeal to the President/SLMA against the ERC determination of the complaint.

25.4.5. The Chairperson of the ERC will provide the President with all relevant information about the complaint/concern, including:

25.4.5.1. the complaint;
25.4.5.2. material reviewed in the Chairperson's or the nominee's investigation
25.4.5.3. the results of the Chairperson's or the nominee's investigation and
25.4.5.4. any other relevant documentation.

25.4.6. The President will determine whether there is to be a further investigation of the complaint.

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	Title: Complaints about the conduct of a research project	**Page: 2 of 2**

25.4.7. If the President determines there is to be a further investigation, then he/she will establish an Appeal Panel to review the complaint and ERC decision.

25.4.8. The Appeal Panel shall consist of 3-5 suitably qualified persons, and shall include the following members:

25.4.8.1. the President/SLMA or his/her nominee, as convenor of the panel.

25.4.8.2. two nominees of the President/SLMA (not members of the ERC).

25.4.9. The panel will ask the ERC and the complainant to make submissions.

25.4.10. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external expertise. In conducting its review, the panel shall be concerned with ascertaining whether the ERC acted in accordance with its Standard Operating Procedures, the Terms of Reference, as well as FERCSL Guidelines, or otherwise acted in an unfair or biased manner.

25.4.11. The President will notify the complainant and the ERC of the outcome of the investigation. The outcomes of this process may include:

25.4.11.1. the appeal is dismissed.

25.4.11.2. the appeal is referred back to the ERC for consideration, bearing in mind the findings of the panel.

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

25.4.12.1. a review of the Terms of Reference and Standard Operating Procedures;

25.4.12.2. a review of the ERC's membership

25.4.12.3. any other action, as appropriate.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 026– 2019** **Version 2.0** **Effective date: 1.9.2019**
	Title: Record keeping	**Page: 1 of 2**

26.1. Purpose

To describe the procedures for the preparation and maintenance of records of the ERC's activities

26.2. Scope

This SOP applies to administrative processes concerning the maintenance of records of activities of the SLMA ERC.

26.3. Responsibility

It is the responsibility of the Secretary ERC to oversee the work of the Administrative Assistant or other staff and to ensure that all records of the SLMA ERC (both paper and electronic) are in order.

26.4. Detailed instructions

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

26.4.2. The Administrative Assistant of the ERC will prepare and maintain a confidential electronic and paper record for each application received and reviewed and shall record the following information:

i. date of receiving the original application and subsequent documents.
ii. the unique project identification number
iii. the principal investigator(s)
iv. the name of the responsible institution or organisation
v. the title of the project
vi. the date of review at a ERC meeting and the decision(s) taken at this meeting
vii. the decision of the ERC with date
viii. the approval or non-approval of any changes to the project
ix. the terms and conditions, if any, of approval of the project
x. the type of approval given

26.4.3. 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.

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	Title: Record keeping	**Version 2.0** **Effective date: 1.9.2019** **Page: 2 of 2**

26.4.4. The soft copies of all relevant documents will be stored in the internal and external hard drives

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

26.4.6. 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.

26.4.7. All records pertaining to research protocols shall be held for sufficient time to allow for future reference. The minimum period for retention will be five (5) years or in accordance with national or sponsor requirements, whichever is longer.

26.4.8. Files which are no longer required for retention shall be electronically archived prior to shredding under a folder named “Secure deleted”. A separate register shall be maintained regarding all the shredded documents.

26.4.9. A register of all the applications received and reviewed shall be maintained.

	Ethics Review Committee **Sri Lanka Medical Association**	**SOP 027– 2019**
	Title: ERC reporting requirements	**Version 2.0** **Effective date: 1.9.2019** **Page: 1 of 2**

27.1. Purpose

To describe the mandatory reports of the ERC, their contents and distribution.

27.2. Scope

This SOP applies to

i. minutes of meetings, annual reports, Standard Operating Procedures and membership of the SLMA ERC.
ii. Reports that must be sent to the Ministry of Health and other regulatory bodies as per National regulations

27.3. Responsibility

It is the responsibility of the Secretary ERC to forward a summary of the minutes and any other communication to the Council of the Sri Lanka Medical Association and other national regulatory bodies on behalf of the ERC.

27.4. Detailed instructions

27.4.1. The minutes of every ERC meeting, in summary form, (title of proposal, names of investigators, study site, decision etc.) shall be forwarded to the Council of SLMA.

27.4.2. The ERC shall provide an annual report to the Council of the SLMA at the end of each calendar year on its progress, including;

27.4.2.1. Membership changes
27.4.2.2. Number of meetings
27.4.2.3. Number of proposals reviewed, approved, rejected or abandoned
27.4.2.4. Monitoring procedures for ethical aspects of research in progress
27.4.2.5. Description of any complaints received and their outcome
27.4.2.6. Description of any research where ethical approval has been withdrawn and reasons for withdrawal of approval and general issues raised

27.4.3. Any information requested by National regulatory bodies with regard to protocols approved by the SLMA ERC will be submitted to them upon request.

27.4.4. The ERC Standard Operational Procedures and membership will be available upon request to the general public and shall be posted on the website.

27.4.5. A ledger account for ERC shall be maintained by the SLMA and shall be reviewed by the ERC annually.

GLOSSARY

Active Study File: Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the SLMA ERC.

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.

Adverse Drug Reaction: In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase “responses to a medicinal product” means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

Advice: Non-binding considerations adjoined to a decision intended to provide ethical assistance to those involved in the research.

Agenda: A list of things to be done; a program of business for the meeting

Amended protocol document: A set documents consisting of amended parts and related documents of the protocol, previously approved by the ERC. In the course of the study, the PI may decide to make changes in the protocol.

Applicant: A qualified researcher undertaking the scientific and ethical responsibility for a research project, either on his/her own behalf or on behalf of an organization/firm, seeking a decision from an ethics committee through formal application.

Benefit: A favourable consequence arising from a study, for example the demonstration that a vaccine is effective in a randomized controlled trial or the identification of a workplace hazard in an observational study.

Bioethics: A field of ethical enquiry that examines ethical issues and dilemmas arising from health, health care, and research involving humans.

Case Report Form: A form on which individual patient data required by the trial protocol are recorded.

Closed Study File: The study which is completed or terminated or discontinued or suspended or not initiated is considered to be closed.

Compensation: That which is given in recompense, as an equivalent rendered, or remuneration.

Community: A community is a group of people understood as having a certain identity due to the sharing of common interests or to a shared proximity. A community may be identified as a group of people living in the same village, town, or country and, thus, sharing geographical proximity. A community may be otherwise identified as a group of people sharing a common set of values, a common set of interests, or a common disease.

Confidentiality: The obligation to keep information secret unless its disclosure has been appropriately authorized by the person concerned or, in extraordinary circumstances, by the appropriate authorities.

Conflict of interest (COI): A conflict of interest arises when a member (or members) of the ERC 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 ERC member has financial, material, institutional, or social ties to the research.

Consent form: An easily understandable written document that documents a potential participant's consent to be involved in research and describes the rights of an enrolled research participant.

Decision: The response, (positive, conditional or negative), by an ERC to an application following the review in which the position of the ERC on the ethical validity of the proposed study is stated.

Deviation: Any instance in which the current approved ERC SOP cannot be or has not been followed

Document: A document may be of any form, e.g., paper, electronic mail, faxes, audio or videotape etc.

Ethical guidelines: Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice.

ERC, SLMA: Ethics Review Committee, Sri Lanka Medical Association

Expedited review: Review by the ERC Chairperson or a designated voting member or group of voting members rather than by the entire ERC, of research which involves no more than minimal risk.

FERCSL: Forum of Ethical Review Committees in Sri Lanka

Final report: An obligatory review of study activities presented as a written report to the SLMAERC after the last subject has completed all visits and all adverse experiences have been brought to appropriate resolution.

Historical file: A document file which was effectively used in the past and presently became obsolete or expired, but still had to be kept in a file for reference purposes.

Informed consent: Is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.

Investigator: A qualified scientist who undertakes scientific and ethical responsibility, either on his/her own behalf or on behalf of an organization/firm, for the ethical and scientific integrity of a research project at a specific site or group of sites. In some instances, a coordinating or principal investigator may be appointed as the responsible leader of a team of sub-investigators

Inactive study files: Supporting and approved documents, records containing communication and correspondence with the investigator, and reports that correspond to each study approved by the SLMA ERC for which a final report has been reviewed and accepted.

Independent consultant: A non-member reviewer appointed to review, where additional or specialized expertise is needed to review a specific protocol.

Master files: Original copies of documents such as SOPs, guidelines, instruction manuals with real signatures of preparers, reviewers and authorized persons are systematically stored in secured cabinets with limited access.

Medical Device: A medical device is any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-ocular lenses, and orthopaedic pins. Medical devices also include diagnostic aids such as reagents and test kids for in vitro diagnosis of disease and other conditions, (e.g. pregnancy).

Meeting: Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.

Minutes: The official record of events, activities, and actions taken on agenda items presented to a duly constituted (quorum present) independent committee meeting.

Multi-site research: A clinical trial conducted according to a single protocol but at more thanone site, and, therefore, carried out by more than one investigator.

Monitoring visits: Visits undertaken by the ERC or its representatives to the study sites to assess how well the selected investigators and the institutions are conducting research, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the study. Normally monitoring visit will be arranged in advance with the principal investigators.

Personal data: Data that relate to a living person and contain personally identifying information.

Principal investigator (PI): The main researcher overseeing or conducting the research process.

Privacy: The state or condition of being alone, undisturbed, or free from public attention, as a matter of choice or right; seclusion; freedom from interference or intrusion; absence or avoidance of publicity or display; secrecy, concealment, discretion; protection from public knowledge or availability.

Protocol: A document that provides the background, rationale, and objective(s) of a biomedical research project and describes its design, methodology, and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol.

Protocol amendment: A written description of a change to, or formal clarification of an approved protocol.

Protocol deviation/non-compliance/violation: Where investigators do not perform the study in compliance with the approved protocol, FERCSL or international guidelines, relevant regulations and/or fail to respond to the ERC's request for information/action.

Progress Report: An ongoing review of each investigator's study activities presented as a written report.

Quorum: A quorum is the minimum number of members that must be present to constitute a valid meeting where decisions can be taken concerning submissions put forward for ethical review. A meeting is quorate when a quorum is present.

Reimburse: Payment of expenses incurred.

Researcher: A person who engages in the methodical and systematic investigation of hypotheses with the goal of contributing to new knowledge.

Research ethics committee (REC) (also known as ethical review board [ERB], ethical review committee [ERC], human research ethics committee [HREC], institutional review board [IRB]): Group of individuals who undertake the ethical review of research protocols involving humans, applying agreed ethical principles.

Research participant: An individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated.

Research involving human participants: Any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge in which human beings: (1) are exposed to manipulation, intervention, observation or other interaction with investigators, either directly or through alteration of their environment; or (2) become individually identifiable through investigators' collection, preparation or use of biological material or medical or other records.

Revision: Requirement by the research ethics committee to alter the protocol in some way prior to approval or additional review by the committee.

Risk: The probability that an event, favourable or adverse, will occur within a defined time interval. Although often contrasted to *benefit* (as in a "risk/ benefit ratio"), the term "potential harm" is better for that context, leaving "risk" in its formal epidemiological sense to express the probability of a (typically adverse) event or outcome.

Standard Operating Procedure (SOP): The Standard Operating Procedure provides clear, unambiguous, detailed, written instructions, in a certain format, describing all activities and actions undertaken by an organization to achieve uniformity of the performances of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.

Serious Adverse Events (SAEs)
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, persistent, 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.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a research project.

SUSARS: Suspected, unexpected serious adverse reactions

Terms of Reference (TOR): The scope and limitations of an activity

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

Voluntary: (1) Performed or done of one's own free will, impulse, or choice; not constrained, prompted, or suggested by another; (2) free of coercion, duress, or undue inducement. Used in the health and disability care and research contexts to refer to a consumer's or participant's decision to receive health or disability care or to participate (or continue to participate) in a research activity.

Vulnerable (research) participants: Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. They may have insufficient power, intelligence, education, resources, strength, and other needed attributes to protect their own interests, and may be more likely to be subjected to coercion and undue influence.

Workshop: A group of people engaged in study or work on a creative project or subject

Waiver: Process of declaring some or all of the elements of informed consent as inessential.

REFERENCES

1. Declaration of Helsinki (DoH), World Medical Assembly (WMA), 2013

2. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organization, 2011

3. International Ethical Guidelines for Epidemiological Studies, prepared by the Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO). Geneva, 2009.

4. International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.

5. SIDCER Survey Standard Operating Procedures, approved version, 2010

6. Ethics Review Committee Guidelines, A FERCSL Operational guidelines for Committees that review Biomedical Research Projects, Forum of Ethics Review Committees, Sri Lanka, 2018

7. Standards and operational guidance for ethics review of health-related research with human participants.WHO. Geneva. 2011

8. ICH Harmonised Guideline - integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). 2016

9. Code of Conduct for Health Research in Sri Lanka, Ministry of Health, 2018

10. National guidelines for Establishment and Functioning of Ethics Review Committees in Healthcare Institutions, Ministry of Health, Sri Lanka, 2013

11. Guidelines for the conduct of clinical trials in Sri Lanka, National Medicines Regulatory Authority Version 3, 2019

ANNEXURES

Annexure: **(A/004/01/2.0)**

Letter of Appointment for members

Date:

<<Name>>
<<Address>>

Dear ……..,

Appointment to the Ethics Review Committee

I am pleased to inform you that you have been appointed as a member of the Ethics Review Committee of the Sri Lanka Medical Association (ERC SLMA) for a period of three (3) years effective from ……. ……

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

As a member of the ERC you are expected to:

a. Review applications assigned to them and lead the discussion on the application at full board meetings.
b. Complete the assessment form for the protocols assigned as primary reviewers
    i. 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. Lead discussions on applications which are assigned as for primary reviewers.
e. Disclose conflicting interests and where a conflict does exist with respect to a study abstain from reviewing the protocol and leave the room during discussion of and voting on the protocol.
f. Respect each other's views and the deliberative process.
g. Decide independently if the design and conduct of proposed studies will protect participants' safety, rights and welfare.
h. Remain impartial and objective when reviewing protocols.
i. Keep up-to-date with national and international research ethics and regulatory guidance.
j. Take part in research ethics-related continuing education.
k. Perform any other duties assigned by the Chairperson.

As a member of the ERC SLMA The Sri Lanka Medical Association will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. An electronic copy of the SOPs of the ERC will be emailed to you.

Please sign the attached acceptance, confidentiality and conflict of interest agreement and hand it over to the ERC office.

Yours sincerely

……..
President, Sri Lanka Medical Association

Annexure: **(A/004/02/2.0)**

Confidentiality Agreement Form

Sri Lanka Medical Association Ethics Review Committee

CONFIDENTIALITY AGREEMENT FORM

Date:……

Name: ……

☐ ERC Member

☐ Other (specify position) _____

1. By signing this document, I understand and agree that the information and documentation that I will be exposed to during and related to my participation with the activities of the Sri Lanka Medical Association Ethics Review Committee (SLMA ERC) is strictly confidential.
2. I will not disclose any information, knowledge, procedures or activities of research proposals submitted to the SLMA ERC, or the decisions of the ERC, including clarifications regarding any Conflict of Interest of a Member of the ERC involved in a research study that the EC considers confidential without appropriate authorization, to any person outside the review process, or use such information for unauthorized purposes.
3. I agree that I will not copy or take any documentation or written information from the ERC without permission from the ERC Chair.

I understand and agree that this confidentiality agreement continues despite the end of my affiliation with the SLMA ERC.

……

Signature

……

Signature Chairperson, SLMA ERC

and Date

Annexure: **(A/004/03/2.0)**

Conflict of Interest Declaration

Sri Lanka Medical Association Ethics Review Committee

CONFLICT OF INTEREST DECLARATION

Date _____

Name: _____

Position of person giving Statement:

☐ ERC Member

☐ Other (specify position) _____

I understand that a member of Sri Lanka Medical Association Ethics Review Committee (SLMA ERC) is required to abstain from participating in an initial or continuing review for a project in which the member has a conflicting interest (SOP 011-2019/2.0)
Examples of conflict of interest cases may include any of the following:

1. A member is an investigator, or a supervisor of the investigator of the protocol
2. A member is involved in a potentially competing research program.
3. A member is an employee of a drug company sponsoring the research
4. Any other perceived conflict of interest, including financial considerations

By signing this document, I acknowledge that I have read the statement on conflict of interest and that I will notify the ERC of any potential conflict of interest I may have on a protocol-by-protocol basis.

……
Signature

……
Signature of Chairperson SLMA ERC & Date

Annexure: **(A/007/01/2.0)**

Confidentiality Agreement Form

Sri Lanka Medical Association Ethics Review Committee

Letter of Appointment – External Reviewer

Date:

<<Name>>

<<Designation/ address>>

Dear ……..,

Appointment as an External Reviewer to the Ethics Review Committee, Sri Lanka Medical Association

I am pleased to inform you that you have been appointed as an External Reviewer to the Ethics Review Committee of the Sri Lanka Medical Association for the scientific evaluation of the protocol/s titled
……
……..

As an External reviewer, you are expected to provide a scientific review of the above protocol/s but will not be involved in the decision making process of the ERC and will have no voting rights in the deliberations of the said protocol.

Sri Lanka Medical Association will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties.

Please sign the attached confidentiality agreement and conflict of interest declaration and hand them over to the SLMA ERC office, along with your review report. The relevant documents and the reviewer guide are enclosed for your information.

With best regards,

Yours sincerely

……..
Chairperson

Annexure: **(A/008/01/2.0)**

Ethics Review Application Form and Check List

ETHICS REVIEW COMMITTEE
Sri Lanka Medical Association
No 6, Wijerama Mawatha, Colombo 7

Office use only

Application No: ……/…….. **Date received:** ____/____/_____

Version: ……..

Name of Applicant: (Prof/Dr/Mr/Ms) …….

APPLICATION FORM – HUMAN RESEARCH

This form should be filled **online** and **signed** by the principal investigator who requests ethical approval for a research project involving **human subjects**. All entries should be typed and hand written forms will not be accepted. No cages should be left blank.

The spaces in this form are expandable as you type.

Please read the **instructions to applicants carefully when completing the application** and ensure all relevant 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 **AND** name and address of institution where the applicant is attached:	
Highest educational qualification of applicant:	
Mailing address:	
Phone No for contact:	e-mail:

3. Is this study a requirement for a postgraduate degree/requirement by PGIM for Board certification ? Yes ☐ No ☐

3.1 Have you already registered for this degree ? Yes ☐ No ☐

Type of degree (MSc/PhD/MD/MS/other):
Awarding University:

Date of registration:	Date of protocol approval by Board of Study:	Letter annexed ☐

Please append letter of approval from Board of Study of University/PGIM

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

4.1 Details of Supervisors:

Title:	Name:
Institutional affiliations:	
Highest educational qualification:	
Mailing address:	
Phone:	e-mail:
Title:	Name:
Institutional affiliation:	
Highest educational qualification:	
Mailing address:	
Phone:	e-mail:

Please append additional pages with Supervisors' names if necessary

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

Title:	Name:
Institutional affiliations:	
Highest educational qualification:	
Mailing address:	
Phone:	e-mail:

Title:	Name:
Institutional affiliation:	

Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Please append additional pages with co-investigators' names if necessary

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 project.

Type of site (hospital/clinic/school/community, etc.)	Details

7. Other Research Ethics Committee approval(s)

7.1 Has any other REC approved this project? Yes ☐ No ☐

If Yes, please attach a copy of the approval letter.

8. Funding of this project

Funding status	Source and amount
Funded ☐	Agency: Total Budget: SLR
Applied for funding ☐	Agency: Total Budget: SLR
Unfunded ☐ If unfunded, please explain why no funding is needed:	

9. For Clinical Trials only

9.1 What is the phase of the clinical trial that is being conducted?

Phase I ☐

Phase II ☐

Phase III ☐

Phase IV (post marketing) ☐

Other ☐

If OTHER specify:

9.2 Is it a multicentre trial?

Yes ☐ No ☐

If yes, list the other trial sites

Please attach ethics approval from the sponsoring country or country of the overseas Principal Investigator (if any)

9.3 Is the clinical trial registered with a clinical trials registry?

Yes ☐ No ☐ Pending ☐

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

If No, give reasons

9.4 *Has this study been approved by the SCOCT (Subcommittee on Clinical Trials) at the Ministry of Health?*

Yes ☐ No ☐ Pending ☐

If yes, give details of Approval Number

If No, give reasons

9.5 Data Safety Monitoring Board (only if available)

Name and Designation of Members*	Role

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

9.6 Details of indemnity and insurance coverage for participants, investigators and ethics

committee

9.7 Evidence of GCP training of ALL investigators – Attached/ not attached (delete inapplicable)

PART II (Research Proposal)

10. Project start and end dates

Estimated start date that involves human participants or data:

Estimated completion date of involvement of human participants or data for this project:

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

11.1 Collaborative partnership		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The collaborations you have established with institutions where the study is to be conducted	☐	☐	
2.	The collaborations you have established with the community where the study is to be conducted	☐	☐	
3.	The benefits to institutions, communities, and participants in your research	☐	☐	
11.2 Social Value		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The beneficiaries of your research and the benefit to them	☐	☐	
2.	The plan for dissemination of study findings	☐	☐	

11.3. Scientific Validity		**Applicable**		**Section in Protocol & page**
		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	☐	☐	

11.4 Confidentiality		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	How the data and samples will be obtained	☐	☐	
2.	How long data and samples will be kept	☐	☐	
3.	Justification for 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	☐	☐	

11.5 Rights of the participants		**Applicable**		**Section in Protocol & page**
		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.	Provisions for participants to be informed of results	☐	☐	
5.	Provision to make the study product available to the study participants after research	☐	☐	

11.6 Fair participant selection	**Applicable**		**Section in Protocol & page**
	Yes	**No**	

1.	The justification for the selection of the study population	☐	☐	
2.	The inclusion and exclusion criteria	☐	☐	

11.7 Responsibilities of the researcher		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The provision of medical services to research participants with special reference to research/trial related injuries	☐	☐	
2.	The provisions 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.	☐	☐	

11.8 Vulnerable populations		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	Justification for conducting the study in this population	☐	☐	

11.9 Research funded by foreign agencies/companies		**Applicable**		**Section in Protocol & page**
		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 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

11.10 Community based research		**Applicable**		**Section in Protocol & page**
		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	☐	☐	

11.11 Clinical trials		**Applicable**		**Section in Protocol & page**
		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 (e.g. 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.	Measure in place for management of trial related injuries	☐	☐	

8.	Provisions/criteria for termination of the trial	☐	☐	
9.	Previsions for making the trial drug available to participants after the trial if found to be effective	☐	☐	

11.12 Information Sheet (IFS)/Informed Consent Form (ICF) Check List (List the sections in IFS/ICF where you have dealt with the following)		**Section in IFS/ICF**
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	

11.13 Consent		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The procedure for initial contact of participants*	☐	☐	
2.	The procedure for obtaining informed consent			
	Verbal	☐	☐	
	Written	☐	☐	
3.	The information (written/oral) provided to participants	☐	☐	
4.	The procedure for ensuring that subjects have understood the information provided	☐	☐	
3.	The procedure for obtaining proxy consent	☐	☐	
4.	The procedure for withdrawing consent	☐	☐	
5.	Incentives/rewards/compensation provided to participants	☐	☐	
6.	The procedure for re-consenting if the research	☐	☐	

	protocol changes during the course of research			
7.	The procedure for consenting if vulnerable groups / children under 18 years of age being recruited	☐	☐	
8.	The procedure for consenting if children aged 12 - 18 years of age being recruited. (for children aged 12-18 years, in addition to parental consent, children's assent must be sought)**	☐	☐	
9.	If waiver of consent indicated, give justification	☐	☐	

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

**** Please attach an Assent Form for children aged 12-18 years**

12. Data Collection

12.1 What is the procedure to be carried out on these subjects (give **details of all study instruments** to be used, collection of samples/blood/application of tests/administration of drugs etc, in detail).

Page number/s	
Section/s	

13. Experience of Investigators with this type of research

13.1 Please provide a brief description of previous experience with this type of research by (i) the Principal Investigator, (ii) the research team and (iii) 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:

(i) Physical risks (e.g. any bodily contact or administration of any substance): Yes ☐ No ☐

(ii) Psychological/emotional risks (feeling uncomfortable, embarrassed, upset): Yes ☐ No ☐

(iii) Social risks (e.g. loss of status, privacy and/or reputation): Yes ☐ No ☐

(iv) 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

- Describe any potential direct benefits to participants from their involvement in the project
- Describe any potential direct benefits to the community (e.g., capacity building)
- 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?

Financial Yes ☐ No ☐ In-kind Yes ☐ No ☐
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 have a conflict of interest with regard to this protocol?

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

1. 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/animal participants.
2. I understand that if there is any deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation.
3. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study.
4. I declare that I am not seeking approval for a study that has already commenced or has already been completed.
5. I understand that at least two months are required for ethics review and granting of ethics clearance.
6. I will submit progress reports/reports of adverse events and side effects as requested by the ERC SLMA.

……..

Signature of Principal Investigator Date: ___ /____/_____

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

---

23. To be filled by SLMA Office:

Processing charge of Rs 3000/-,Rs 10,000/-, Rs 25,000/-, UDS 1000 received (delete inapplicable)

Receipt no:……..

Serial No: ERC……/……..

……..

Signature SLMA ERC Administrative Assistants

24. CHECK LIST (Please mark all documents submitted)

One copy each of the following		**To be marked by the applicant**	**To be marked by ERC office**
1.	Covering letter signed by the applicant		
2.	Letter from supervisor (if relevant)		
3.	Copy of approval letter from Board of Study (*for postgraduate students only*)		
4.	Curriculum Vitae of all investigators as e copies		
5.	Curriculum Vitae of Principal Investigator as a paper copy		
6.	In the case of clinical trials, evidence of GCP training (GCP training certificate) of all investigators		
7.	Letter signed by all investigators confirming their participation		
The following documents (where relevant) must be submitted. They must be stapled or bound together to form **four (4) complete sets** of documents. All documents must carry the date and version number as a header/footer.			
8.	Proposal (*postgraduate students must submit a copy identical to that approved by the board of study*)		
9.	Study instruments		
10.	Information Sheet **English**		
	Sinhala		
	Tamil		
11.	Consent Forms **English**		
	Sinhala		
	Tamil		
12.	Assent Forms **English**		
	Sinhala		
	Tamil		
13.	Advertisement for recruitment **English**		
	Sinhala		
	Tamil		
14.	**Four copies** of the Application Form		
15.	Email a complete set of all documents submitted (include one copy of your application, protocol, instruments and forms in **all languages)** as *pdf* files to <erc.slma@gmail.com> at the time of submission		

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

……..

Signature of Principal Investigator Date: ___ /____/_____

Annexure: **(A/008/02/2.0)**

Document Receipt Form

Document Receipt Form

Ethics Review Committee, Sri Lanka Medical Association

Protocol No: Version:		Date of submission:
Type of submission:	1. Initial review 2. Resubmission 3. Continuing review of approved protocol	4. Protocol amendments 5. Final report
Received by:		
Date of received:		
This proposal will be considered by the ERC at its meeting on ……/……../2016 Administrative Assistant SLMA, ERC Date		

Annexure: **(A/009/01/2.0)**

Template for the Agenda

Date:

To: All members of the ERC-SLMA

Dear Sir/Madam

NOTICE OF MEETING

The ……. meeting of the ERC will be held on (Friday) …….. at 9.30 am in the Council Room of the SLMA, 6, Wijerama Mawatha, Colombo 7. Your presence will be greatly appreciated.

Please note that you have been appointed as a primary reviewer for the projects mentioned. The check lists for the review process are attached. As a primary reviewer, you are expected to submit written comments of your evaluation o the Secretary, ERC. If you are unable to attend the ERC meeting, please send your comments to Secretary ERC, to enable these to be taken up at the meeting.

Prof ……., Chair	
Prof ……., Secretary	ERC YY-XXX
Dr ……., Member	
Dr ……., Member	

AGENDA

1. Attendance
2. Conflict of interest declaration
3. Confirmation of the minutes of the previous meeting
4. Matters arising from the minutes
5. Protocols awaiting revisions and clarifications
6. New applications
7. Protocols for exemption from review
8. Protocols for expedited review
9. Amendments to approved protocols
10. Extension of ERC approval;
11. Reports of serious adverse events (SAE)
12. Progress reports
    a. Final reports
    b. Protocol deviations, non-compliance and violations
13. Correspondence
14. FERCSL/FERCAP
15. Any other business
16. Close and date for next meeting

…….
Secretary
SLMA ERC

Annexure: **(A/012/01/2.0)**

Protocol Assessment Form, Version 2.3.

Ethics Review Committee

SRI LANKA MEDICAL ASSOCIATION

PROTOCOL ASSESSMENT FORM – FOR RESEARCH INVOLVING HUMANS

Instructions to reviewers:

1. Sections 1 - 6 should be filled for ALL protocols.
2. Section 7 - additional section applicable only for externally sponsored studies
3. Section 8 - additional section applicable only for clinical trials
4. Section 9 - additional section applicable only for Community based research
5. Assessment of ICF should be done for ALL protocols.
6. Please type your review, sign and send to Secretary ERC on or before due date.

NB. Additional comments to be given at the end of form

Application Number:			Date reviewed (D/M/Y):		
Reviewer's Name:			Signature:		
Title of Protocol					
1. Scientific validity / technical issues		**Yes**	**No**	**NA**	**Comments**
1	Is the title reflective of the study?				
2	Are general and specific objectives clearly stated?				
3	Is the study design appropriate to achieve the stated objectives?				
4	Are inclusion and exclusion criteria of the study population appropriate to achieve the given objectives?				
5	Is the study process clear?				
6	Is the sample size adequate?				
7	Is the sampling technique appropriate?				

8.	Is the study instrument valid for achieving the stated objectives?				
9	Are the statistics used appropriate?				
10	Is there a plausible data analysis plan?				
11	Has the budget been submitted? Is it appropriate?				

Ethical Issues

2. Social/scientific value		**Yes**	**No**	**NA**	**Comments**
1	Will the study lead to improvements in human health and wellbeing or increase knowledge?				
2	Does the literature review provide adequate information to justify the study?				
3	Is there provision for dissemination of results (reporting and publishing) of the research?				
4	Are there any conflicts of interest, including payments and other rewards?				

3. Fair subject selection		**Yes**	**No**	**NA**	**Comments**
1	Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?				
2	Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				
3	Are selection criteria based on science and not on convenience?				
4	Does the selection of subjects favour any group?				
5	Is the initial contact and recruitment appropriate?				

6	Is the research conducted on vulnerable individuals or groups?				
****** If research is to be carried out in vulnerable groups, assess the following: (a-g)**					
a	Can the research be carried out equally well in another, less vulnerable, group?				
b	Will the study result in new knowledge relevant to the health needs of this population?				
c	Is the procedure for obtaining (proxy) consent adequate?				
d	Will the subject's withdrawal from the research due to refusal (dissent) be always upheld?				
e	Is there a favourable risk-benefit ratio?				
f	Is the medical and psychological support adequate?				
g	Will the benefit of the research be made reasonably available to this group?				

4. Risk - benefit assessment			**Yes**	**No**	**NA**	**Comments**
1	Is the need for human participants justified?					
2		Are the inclusion criteria appropriate?				
3		Are the exclusion criteria appropriate?				
4		Is recruitment of participants voluntary and non-coercive?				
5		Is the intervention to be used in the research acceptable?				
6	Are the risks and benefits assessment by the investigator acceptable?					

7	Are the facilities at the site adequate to support the study? If not, have the investigators made acceptable alternate arrangements?				
8	Are the non routine facilities offered funded by the project or not?				
9	Have provision been made for treatment of study-related injuries and if so are they adequate?				
10	Are the provisions for medical/psychosocial support adequate?				
11	Have adequate provisions been made for safety monitoring and termination of the research project?				
12	Is there provision for the subjects to be informed of the results of clinical research?				
13	If biological samples are being collected, is the fate of the sample mentioned and appropriate?				
14	In your opinion, are the risks involved minor, minimal or major? Are they acceptable?				
15	Are qualifications and experience of the participating investigators appropriate? **(Check CVs)**				

5. Respect for participants					
Informed consent		**Yes**	**No**	**NA**	**Comments**
1	Is the process for obtaining informed consent appropriate (written/verbal)?				
2	Are the participants competent?				
3	Is the justification for the intention to include individuals who cannot consent appropriate?				
4	If participants are not competent, is the procedure for obtaining proxy consent appropriate?				

5	Will dissent be respected?				
6	Are incentives offered and if so do you approve those offered?				
7	Will fresh informed consent be obtained if the procedures are changed during the research?				
8	Does it qualify for waiver?				

6. Confidentiality (check both protocol and ICF)		**Yes**	**No**	**NA**	**Comments**
1	Will the researcher collect only the minimum Information / samples required to fulfill the study objectives?				
2	Is the privacy of the research participant safeguarded?				
3	Is the place for data collection appropriate?				
4	Are data/sample storage and disposal procedures adequate?				

7. For externally sponsored research		**Yes**	**No**	**NA**	**Comments**
1	Is there a local collaborator?				
2	Has the research project been approved by an ERC/ IRB in the sponsoring country?				
3	Is the research also being carried out in the sponsor's country?				
4	Is the justification for the research to be carried out in Sri Lanka and not in the sponsoring country adequate?				
5	Is the research relevant to Sri Lanka?				
6	Are the post-research benefits to the country acceptable?				

7	For any trial drug or device, is it registered in the country of origin?				
8	Are relevant local laws/regulations/guidelines of each country adhered to?				
9	Is the research responsive to cultural/social differences?				
10	Are the provisions for intellectual property sharing fair?				
11	If the data/biological samples are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights? i.e. material transfer agreement				
12	Is there provision for results of research to be conveyed to relevant authorities in Sri Lanka?				
13	Are any conflicts of interest resolved?				
14	Is there a written agreement between the collaborators?				

8. For clinical trials – i.e. any research that has an intervention		**Yes**	**No**	**NA**	**Comments**
1	Have sufficient information been provided about the investigational product?				
2	Have adequate animal toxicity and teratogenicity trials been carried out? **(Check the background and justification sections)**				
3	Is there sufficient justification for using a control arm?				
4	Are there any plans to withdraw or withhold standard therapy for the purpose of research				

	and if so is such action justified?				
5	Is the treatment given to control group appropriate?				
6	Is the standard of care the best available locally?				
7	Are all participants treated equally?				
8	Is the site including support staff, facilities and emergency procedures adequate?				
9	Have provisions been made for treatment of study-related injuries and if so are they adequate?				
10	Is there provision for compensation (where applicable) and if so is it adequate?				
11	Have adequate provisions been made for dealing with and reporting adverse effects?				
12	Have provisions been made for the continuing care of those that withdraw consent and if so is it adequate?				
13	Is there a possibility of an intervention being available to the population/trial participants if found effective?(i.e. post-trial access)				
14	Are the criteria for termination of the trial detailed?				
15	Is there provision for insurance of trial participants? If yes, is it adequate?				
16	If it is a multicentre trial, are all centres following the same protocol?				

1. For community based / observational / qualitative research		**Yes**	**No**	**NA**	**Comments**
1	Are the impact and relevance of the research on the community in which it is to be carried out acceptable?				
2	Has the concerned community been consulted during the design of the study?				

3	Is community consent obtained?				
4	Is individual consent obtained?				
5	Is the privacy of the participants safeguarded?				
6	If the intervention is shown to be beneficial will the researcher/ sponsor continue to provide it to the participants after conclusion of the study?				
7	Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the population?				
8	Does the research contribute to capacity building of the community?				
9	Will the results of the research be made available to the concerned community?				

Decision: **Approved** ☐

Minor modifications needed ☐

Major modifications needed ☐

Disapproved ☐

Any other comments (Append extra sheets as needed)

Annexure: (A/012/02/2.0)
ICF Assessment Form, Version 1.1.

Ethics Review Committee

SRI LANKA MEDICAL ASSOCIATION
ICF ASSESSMENT FORM

Application Number:		**Date reviewed (D/M/Y):**			
Reviewer's Name:		**Signature:**			
Informed Consent Forms		**Yes**	**No**	**NA**	**Comments**
1	Are the written and oral information to be given to the research participants appropriate, adequate and complete?				
2	Is the language used in information sheets clear and understandable? N.B. Check the use of scientific words.				
3	Is there a statement to the effect that the participation in the research is voluntary?				
4	Are translations of all forms consistent and accurate?				
5	Is there an opportunity for the participant to ask questions regarding the research?				
6	Are there provisions for the participant to withdraw unconditionally from the research without penalty or loss of care?				
7	If biological samples are being collected, are the participants informed about - What is being collected - What tests will be done with them - Whether they will be stored for future studies - If stored for how long and what is expected to be done with samples				
8	Consent Form – has the participant consented for all procedures planned? e.g. Immediate activities of study, storing of samples, recording of interviews etc.				
9	Is Assent Form provided adequate?				
10	Are contact details of PI and other appropriate investigators for site given in the information sheet?				
11	Are there provisions for study participants to make complaints if needed? e.g. ERC contact details				

Annexure: (A/014/01/2.0)
Check List for Exemption from Review

Check List for Protocols Exempted from Review
Ethics Review Committee, Sri Lanka Medical Association

		YES	NO	COMMENTS
1	Audits of educational practices/programmes that are conducted with the approval of the head of the institution/department			
2	Research on regular or special education instructional strategies			
3	Research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods			
4	Research on immortalized cell lines			
6	Research on microbes cultured in the laboratory provided such research reveals no identifying personal data			
7	Analysis of data freely available in public domain			
8	Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe			
If YES to any of the above, check:				
1	Does the research involve vulnerable groups?			
2	Does the research involve interviews?			
3	Does the research involve observation of public behavior or minors and the researcher participates in the activities being observed			
4	Does the survey deals with sensitive or highly personal aspects of the subject's behaviour, life experiences or attitudes? (sensitive surveys) e.g. substance abuse, criminal behaviour, sexual activity/attitude, sexual abuse etc			
5	Does the data provide identification of subjects?			
6	Would the information if disclosed outside research reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?			
If NO to ALL of the above → Exempt from review				

…… ……

Chairperson, ERC, SLMA Secretary, ERC, SLMA

Annexure: (A/014/02/2.0)
Standard Letter for Exemption from Review

Exemption from Ethics Review
Ethics Review Committee, Sri Lanka Medical Association

Date:

Protocol No:	Date of Submission :
Protocol Title :	
Protocol version no and date:	
Name of the PI:	
Address:	

Dear Prof/ Dr/Mr/Ms

Thank you for submitting the above research proposal. This proposal is exempt from ethics review.

Please note that
1. No changes to above protocol/any related documents can be made without prior ERC approval.
2. A study completion report must be submitted to ERC.
3. This approval is subjected to ratification by full board of ERC.

Yours sincerely,

Chairperson
Ethics Review Committee

Annexure: (A/015/01/2.0)
Standard Letter for Approval for Expedited Review

Letter of approval for Expedited Review
Ethics Review Committee, Sri Lanka Medical Association

«date»

«Name_and_Address»
«Salutation»

Re: Proposal No «Proposal_No» - " Proposal_Title "

Thank you for submitting the above research proposal, which was considered by the Subcommittee for Expedited Review of the Ethics Review Committee, at its meeting of«Date_of_Meeting».

Approval is granted to proceed. This approval for expedited review is dependent on ratification by full board meeting on «Date_of_Meeting».

This approval relates to the following:
.[insert details of approved documents]

Please note the following:
This approval is valid for one year from ……. and the Committee requires that you furnish it with «period» reports on the study's progress.

You are responsible for negotiating individual arrangements with the Heads of service departments in those situations where the use of their resources is involved.

Yours sincerely,

«name»
Chairperson
Ethics Review Committee
Sri Lanka Medical Association

Annexure: (A/016/01/2.0)
Standard Letter for Approval of Amendments to Proposal

Letter for Approval of Amendments to Protocols
Ethics Review Committee, Sri Lanka Medical Association

«Date»
«Name and Address»

Dear……
Re: Protocol No «Proposal_No» - " Proposal_Title "
(Version No of all documents approved by ERC with dates)
(Name of PI)

The Ethics Review Committee, at its meeting of …….. considered your letter dated…… and gave its approval for the following amendments.

1. ……..
2. ……..

This approval is subject to the following conditions: (delete if inapplicable)

1. ……[insert details of conditions]

The approval is effective from …….. and is valid for a period of 1 year.

Yours sincerely,

Chairperson
Ethics Review Committee
SLMA

Annexure : (A/017/01/2.0)
Standard Letter for Requesting Additional Information

Requesting Additional Information
Ethics Review Committee, Sri Lanka Medical Association

Date:

Protocol No:	Date of Submission :
Protocol Title:	
Name of the PI:	
Address:	

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 decision was taken.

Approved	☐
Minor modifications needed	☐
Major modifications needed	☐
Disapproved	☐

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 by attaching a table giving the original and revised items side by side, 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 Committee meeting, this information should be forwarded to the ERC Office by ……./……./…….

Yours sincerely,

Chairperson
Ethics Review Committee
Sri Lanka Medical Association

Annexure: (A/017/02/2.0)
Ethical Clearance Certificate

ETHICAL CLEARANCE CERTIFICATE
Ethics Review Committee, Sri Lanka Medical Association

«Date»
«Name_and_Address»

Dear…….
Re: Proposal No «Proposal_No» - " Proposal_Title "
Name(s) of Principal Investigator(s), Co-investigators, Supervisors

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting of «Date_of_Meeting». We are pleased to inform you that the SLMA ERC has granted ethical approval for the above proposal effective from «date_ month_ year» as per details given below.

The following documents were reviewed and approved:
«insert details of approved documents, version number and date of all documentation received, reviewed and approved by the ERC, including Clinical Proposals, Patient Information Sheets and Consent Forms (in each language), Advertisements, Questionnaires, etc;»

We affirm that none of the study team members were present during the decision-making process of the ERC.
This approval is valid for one year from the date of sanction and the Committee requires that you furnish it with «period» progress reports on the study and a final report at the completion of the study, using the appropriate forms of the SLMA ERC. Please report to the ERC any serious adverse events that may occur, in keeping with applicable national regulations and guidelines. If an extension for the period of study is required, it will depend on the progress report submitted and the reason for extension.

Please note that ethical approval will be revoked if any alteration is made to the research proposal without obtaining prior written consent from 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 regulations and guidelines that govern research involving human participants.

You are also responsible for negotiating individual arrangements with the heads of service departments in those situations where the use of their resources is involved, or if appropriate, registering the study with a Clinical Trials Registry.

Yours sincerely,

«name»
Chairperson
Ethics Review Committee

Annexure : (A/017/03/2.0)
Letter for Disapproval of an Application

Date:

Disapproval of Application
Ethics Review Committee, Sri Lanka Medical Association

Protocol No:	Date of Submission:
Protocol Title:	
Name of the PI:	
Address:	

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 the Forum of Ethics Review Committees in Sri Lanka (FERCSL) and the International Conference on Harmonization Good Clinical Practice (ICH GCP), has decided not to approve your project for the following reasons:
(List each reason separately. Each reason must refer to the relevant paragraph/s of the FERCSL Guidelines, relevant legislation or other applicable guidelines]

1.
2.
3.

Should you wish to discuss the ERC's review of your proposal please contact me (on the telephone number or email address listed below) or the Secretary, «name», on «details».

Yours sincerely,

«name»
Chairperson
Ethics Review Committee
Sri Lanka Medical Association

Annexure: (A/018/01/2.0)
Notification of Serious Adverse Event

NOTIFICATION OF SERIOUS ADVERSE EVENTS

Date:

Secretary
Ethics Review Committee,
Sri Lanka Medical Association
6, Wijerama Mawatha,
Colombo7

Re: Notification of Serious Adverse Event (SAE)

Please bring the following serious adverse event report to the attention of the Ethics Review Committee.

ERC Proposal No:
Sponsor Proposal No:
SAE Identification Number:
Patient Identification No:
Description of SAE :
Outcome:

Study Drug/Device:

Relationship to Study Drug: Unlikely Possible Probable Definite

Requires alteration to:
Information for Participants: No Yes (if yes, revised copy attached)
Participant Consent Form : No Yes (if yes, revised copy attached)
Proposal l:No Yes (if yes, revised copy attached)

Principal Investigator's Comments -

Yours sincerely

«name»
Principal Investigator

Annexure: (A/019/01/2.0)
Continuing Review Form

Continuing Review Form (six monthly / annually)
Ethics Review Committee, Sri Lanka Medical Association

Protocol Number:		
Principal Investigator:		
Telephone No:	Email:	
Protocol Title:		
Date of approval:	Date of study commencement:	No of reviews undergone:
Period of reporting: From…… to …….		
Number of participants enrolled		
Number of participants who withdrew		
Number of participants lost to follow-up		
Summary of SAEs during the reporting period:		
A summary of any complaints about the research during the reporting period:		
A summary of protocol deviations/violations during the reporting period:		
A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last ERC review.		
Signature of PI		Date

Annexure: (A/019/02/2.0)
Standard Form for Final Report

FINAL REPORT
Ethics Review Committee, Sri Lanka Medical Association

Protocol No:	Assigned No:
Protocol Title:	
Principal Investigator :	
Phone No:	E mail Address:
Sponsor's Name:	
Address:	
Phone No:	E mail address:
Date of study commencement:	Date of study completion:
Study site(s):	
Total number of study participants:	
Number of study arms:	
Objective(s):	
Study materials and method:	
Study dose(s):	
Duration of the study:	
Treatment form:	
Adverse events:	
Results and Conclusions:	
Any ethical issues encountered and action/s taken	
Publications, if any	
Signature of PI:	Date:

Annexure: (A/021/01/2.0)
Checklist for a Site Monitoring Visit

Checklist for a Site Monitoring Visit
Ethics Review Committee, Sri Lanka Medical Association

Protocol No.:	Date of visit:
Study Title:	
Name of the Principal Investigator:	
Phone:	Name of the Sponsor:
Address:	Address of the Sponsor:
Total number of subjects expected: □ yes □ No	Total number of subjects enrolled:
Are site facilities appropriate? □ yes □ No	Comments:
Are informed consent up to date? □ yes □ No	Comments:
Any adverse event found? □ yes □ No	Comments:
Ant protocol non-compliance/violence? □ yes □ No	Comments:
Are all case records forms up to date? □ yes □ No	Comments:
Are storage of data and investigating products locked? □ yes □ No	Comments:
How well are participants protected? □ Good □ Fair □ Poor	Comments:
Any outstanding tasks or results of visits? □ yes □ No	Details:
Duration of visit:……hours.	Starting from:
Names and signatures of the ERC members conducting site visit	
Date:	

Annexure: (A/023/01/2.0)
Template for the Minutes

MINUTES OF THE SLMA ETHICS REVIEW COMMITTEE (ERC)

Minutes of the …… meeting of the SLMA ERC held on …….. at ……
The meeting was chaired by ……..

1. Attendance of members:
   - 1.1 Present
   - 1.2 Excuses
   - 1.3 Absent
2. Conflict of Interest
3. Confirmation of the minutes of previous meeting
4. Matters arising from minutes
5. Protocols awaiting revisions and clarifications
   a) ERC No
   b) Month of the meeting the protocol was first discussed
   c) Names of primary reviewers and others for specific areas to be reviewed i.e. Statistics, ICF etc.
   d) Title of protocol – current version no. (*Indicate if title has been changed from original)*
   e) Names of PI and other investigators
   f) Sponsors if any
   g) Observations (administrative/ scientific/ ethical) and discussion
   h) Decision
6. New applications
   a) ERC No
   b) Title of protocol
   c) Principal investigator and co – investigators
   d) Names of primary reviewers and other reviewers for specific areas to be reviewed i.e. Statistics, ICF etc.
   e) Names of sponsors (if any)
   f) Observations (administrative/ scientific/ ethical) and discussion
   g) Decision
7. Protocols for exemption from review
8. Protocols for expedited review
9. Amendments to approved protocols
10. Extension of ERC approval
11. Reports of serious adverse events (SAE)
12. Continuing review
    - iii. Progress reports
    - iv. Final reports
13. Protocol deviations, non-compliance and violations
14. Correspondence
15. FERCSL/FERCAP
16. Any other business
17. Close and date for next meeting

Secretary, ERC SLMA
Date