Standard Operating Procedures
(Version 5.0)

Ethics Review Committee

Faculty of Medicine

University of Colombo

Standard Operating Procedures
Ethics Review Committee, Faculty of Medicine, University of Colombo

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Editors

Professor Priyanga Ranasinghe	–	Chairperson, ERC
Dr. Ashwini de Abrew	–	Co-Secretary, ERC
Dr. Yamuna Rajapakse	–	Co-Secretary, ERC
Dr. Chiranthi Liyanage	–	Member, ERC
Ms. Yanithra Kumaraguru	–	Member, ERC

Internal Review (Members, ERC)

Dr. Asela Anthony
Dr. Joel Arudchelvam
Dr. Sriyakanthi Beneragama
Dr. Umayal Branavan
Dr. Prasad Chathurangana
Dr. Vihara Dassanayake
Dr. Sajith Edirisinghe
Ms. Kumudini Hettiarachchi
Dr. Anuradha Herath
Dr. Kavindu Hewa Geeganage
Dr. Kapila Jayarathna
Dr. Nishani Lucas
Dr. Sanmugeswaran Pathmanesan
Professor Kamal Perera
Professor Chathuranga Ranasinghe
Dr. Neesha Rockwood
Professor Sanjeewa Senevirathne
Dr. Ahalyaa Sivashangar
Professor Tharanga Thoradeniya
Professor Dakshitha Wickramasinghe
Dr. Manu Wimalachandra

External Review

Professor RMMK Rathnayaka
Head/Department of Pharmacology and Secretary/Ethics Review Committee
Faculty of Medicine,
Sabaragamuwa University of Sri Lanka

Approved by

Ethics Review Committee	–	21st August 2025
Faculty Board	–	09th September 2025

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Annexures

List of Abbreviations

ADR	–	Adverse Drug Reaction
AE	–	Adverse Event
ARWSC	–	Animal Research and Welfare Subcommittee
CIOMS	–	Council for International Organizations of Medical Sciences
CTSC	–	Clinical Trials Subcommittee
ERC	–	Ethics Review Committee
FERCSL	–	Forum of Ethics Review Committees in Sri Lanka
FERCAP	–	Forum for Ethical Review Committees in Asia and the Western Pacific
GCP	–	Good Clinical Practice
ICH	–	International Council for Harmonisation
MOU	–	Memorandum of Understanding
MTA	–	Material Transfer Agreement
PI	–	Principal Investigator
SAE	–	Serious Adverse Event
SIDCER	–	Strategic Initiative for Developing Capacity in Ethical Review
SOP	–	Standard Operating Procedure
SUSAR	–	Suspected Unexpected Serious Adverse Reaction
TOR	–	Terms of Reference

Reference Number	**SOP 001**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Function**
Purpose	**To describe the objective, scope and responsibilities of the Ethics Review Committee (ERC)**
Scope	**Applies to all ethics review and oversight activities of the ERC for research involving humans, animals, tissues, or data conducted within or affiliated to the University of Colombo**
Responsibility	**It is the responsibility of the ERC members to read, understand and respect the rules, policies and guidelines set by the ERC**

DETAILED INSTRUCTIONS

1.1. OBJECTIVE

The Ethics Review Committee (ERC) shall protect the physical, mental and social welfare, rights, dignity and safety of human participants and animals in research, facilitate ethical research through efficient and effective review and monitoring in accordance with the Guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL) and relevant national and international guidelines and promote ethical standards of human and animal research.

1.2. SCOPE

a) To provide independent, competent and timely review of and approval of the ethics of research projects involving humans and animals, that include health related variables/outcomes.
b) To provide oversight, monitoring* and advice on the ethics of approved research projects involving humans and animals.
c) To describe the principles and procedures that govern research projects involving humans and animals including those on tissues, genetic material and/or personal records.
d) To promote and support ethics training for researchers conducting studies involving humans and animals.

*Monitoring projects approved by the ERC shall be conducted in accordance with SOP 021

1.3. RESPONSIBILITIES

a) The ERC shall review only applications submitted by student/s and/or staff of the University of Colombo or where the study setting is the University of Colombo, except as provided hereunder:

   i. The ERC may accept as valid, an ethics approval given by the ERC of another local institution, for the purpose of approving the commencement of a project, where the study setting is the University of Colombo.

ii. The ERC may review applications from researchers outside the University of Colombo provided a valid and current Memorandum of Understanding (MoU) between the University of Colombo and the institution to which the researcher is accredited exists. Such MoU shall define:

- The role of the ERC in providing ethics approval and monitoring of the research; and
- The role of the institution to which the researcher is accredited in giving approval for the research to be conducted within its premises; and
- A statement indemnifying the Faculty of Medicine, University of Colombo from responsibility for liabilities that may arise from the ethics review conducted by the ERC; and
- A statement that the institution to which the researcher is accredited bears responsibility for liabilities arising from the conduct of the research.

b) The ERC shall assess applications 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 research ethics. This shall include an examination of the scientific aspects of the proposal.

c) Th ERC shall engage in research ethics education and capacity building, including the review of undergraduate and postgraduate research projects, conducted as part of academic curricula of the University of Colombo.

Reference Number	**SOP 002**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Membership**
Purpose	**To describe the membership of the ERC**
Scope	**Expected composition of committee**
Responsibility	**It is the responsibility of the Chairperson and the Committee to ensure that the composition of ERC membership conforms to this SOP**

DETAILED INSTRUCTIONS

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

2.2. Members shall be appointed to ensure the ERC has the technical expertise required to assess the applications submitted to it for consideration.

2.3. The composition of the ERC shall be diverse in gender, language and ethnicity.

2.4. Members are expected to have a reasonable knowledge of the Sri Lankan social and cultural context

2.5. The membership shall comprise of medical and non-medical as well as institutional (Faculty of Medicine, University of Colombo) and non-institutional personnel, including clinicians, lay person(s) conversant with social values and persons with expertise in a) basic medical sciences, b) law, c) philosophy/social science and d) public health research/statistics.

2.6. The committee should include at least one medical member who is not affiliated to the institution.

Reference Number	**SOP 003**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Appointment and responsibilities of members/staff**
Purpose	**To describe the procedure for appointment of members/staff to the ERC and the responsibilities of members/staff**
Scope	**Outlines the procedures for appointment of members and staff of the ERC and defines their respectively roles, duties and operational responsibilities in the conduct of ERC functions**
Responsibility	**It is the responsibility of the Chairperson and the Committee to ensure that the appointment of members/staff takes place in accordance with this SOP. It is the responsibility of the members/staff to comply with their respective terms of reference**

DETAILED INSTRUCTIONS

3.1. Members will be appointed by the Faculty Board, on the recommendation of the ERC.

3.2. The letters of appointment will be issued by the Dean, Faculty of Medicine, University of Colombo.

3.3. A Chairperson and two Joint Secretaries will be nominated by the ERC, from among its members, and the names will be submitted to the Faculty Board for approval. Upon approval by the Faculty Board, the Dean, Faculty of Medicine, University of Colombo will issue the letters of appointment.

3.4. The Chairperson of the ERC will have a minimum of one terms' prior experience as a member of the ERC

3.5. Vacancies in the ERC will be advertised by the Dean. Applications should include curriculum vitae. A selection committee, consisting of the Chairperson and at least two other ERC members nominated by the membership, shall interview the applicants, consult the ERC and make a recommendation to the Dean and the Faculty Board. The ERC may also invite suitable persons to serve on the ERC at its discretion.

3.6. Prospective members may be invited to attend a meeting of the ERC as observers, consequent to signing a confidentiality agreement.

3.7. Members are appointed in their individual capacity for their knowledge and experience and not by designation, or as representatives of any organization, group or opinion.

3.8. Letters of appointment (A/003/01/5.0) shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as an ERC member, the circumstances whereby membership may be terminated and the conditions of appointment.

3.9. Members shall agree to their name and profession being made available to the public, including being published on the ERC website.

3.10. Members/Staff will be required to sign a confidentiality agreement (A/003/02/5.0) and a declaration of integrity (A/003/03/5.0) upon appointment, stating inter alia, that all matters of which he/she becomes aware during the course of his/her 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/staff.

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

a) Terms of Reference of the ERC

b) Standard Operating Procedures of the ERC

c) Up-to-date list of members' names and contact information including that of the Dean

d) Current FERCSL Guidelines on Ethical Conduct in Human Research

e) Any relevant previous reports on the ERC's activities and

f) Any other relevant information about the ERC's processes, procedures and proposals

3.12. All members are appointed for a period of three years, renewable at the discretion of the Dean and the Faculty Board. Members who wish to be reappointed shall make a written request to the Dean through the Chairperson of the ERC.

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

3.14. All members are required to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by the ERC.

3.15. Members shall not be remunerated. Members may be reimbursed for legitimate expenses incurred in attending ERC meetings, such as travelling and parking expenses, upon request.

3.16. Members may seek a leave of absence from the ERC for a period not exceeding six months, subject to approval by the ERC

3.17. Membership will lapse if a member fails to attend three consecutive meetings of the ERC without reasonable excuse/apology, unless exceptional circumstances exist. Such reasons should be notified in writing to the ERC, which shall decide if membership shall lapse or not. In the event that membership has lapsed, the Chairperson will notify the member in writing of such lapse of membership.

3.18. Membership will lapse if a member fails to attend, in full, at least two thirds of all scheduled ERC meetings in a given calendar year, barring approved excuses and exceptional circumstances. Such circumstances should be notified to the ERC in writing. In such circumstances, the ERC shall decide if membership has lapsed or not considering the facts

notified. In the event that membership has lapsed, the Chairperson will notify the member in writing of such lapse of membership.

3.19. If a member's membership lapses due to failure to attend as stipulated in the attendance policy above, the letter of membership or service completion will be issued only for the time period of active service, excluding the period of absence.

3.20. Members will be expected to participate in relevant specialised working groups/sub-committees as required. The Chairperson will be expected to be available to participate in meetings of such groups when required.

3.21. A member may resign from the ERC at any time upon giving notice in writing. Steps shall be taken to fill the vacancy.

3.22. The responsibilities of ERC officials are as follows:

a) Chairperson

I. Preside over ERC meetings and ensure quorum and adherence to agenda.

II. Guide discussions to ensure reviews are conducted in a fair, objective and timely manner.

III. Provide final sign-off on decisions, letters, and minutes on behalf of the ERC.

IV. Ensure compliance with SOPs, international guidelines (e.g. ICH-GCP, CIOMS), and national regulations.

V. Liaise with external stakeholders, including regulators and sponsors, when necessary.

VI. Oversee training and capacity building of ERC members.

VII. Lead the ERC during accreditation or compliance reviews (e.g. SIDCER/FERCAP).

VIII. Declare any conflicts of interest and recuse themselves when appropriate.

b) Joint Secretaries

i. Coordinate and schedule ERC meetings with the assistance of administrative staff.

ii. Receive and screen submissions for completeness and eligibility.

iii. Maintain accurate documentation including study protocols, reviewer forms, meeting minutes, and correspondence, with the assistance of administrative staff.

iv. Draft and issue approval letters, queries, or rejections based on ERC decisions, with the assistance of administrative staff.

v. Keep the application tracking system up to date, with the assistance of administrative staff.

vi. Maintain the confidentiality and security of ERC documents.

vii. Assist the Chairperson in meeting preparation and communication, with the assistance of administrative staff.

viii. Facilitate communication between investigators and the ERC, with the assistance of administrative staff.

ix. Declare any conflicts of interest and recuse themselves when appropriate.

c) Members

i. Review assigned applications and lead the discussion of such applications during the meeting.

ii. Attend ERC meetings regularly and contribute to deliberations.

iii. Function in the Executive Committee of the ERC and/or other sub-committee/technical committees, when required.

iv. Declare any conflicts of interest and recuse themselves when appropriate.

v. Maintain confidentiality of all documents and discussions.

vi. Stay updated on research ethics guidelines and attend training sessions.

vii. Uphold the principles of independence, integrity, and scientific/ethical rigor.

d) ERC Office Staff

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

ii. Compose letters to researchers, relaying specific ERC requests and follow-up.

iii. Coordinate electronic distribution of applications and related documents received for review.

iv. Coordinate and process all ERC Adverse Event Reporting (i.e. on-site/off-site Adverse Events)

v. Maintain the electronic database of the ERC

vi. Perform any other duties assigned by the Chairperson and Secretary

3.23. Executive Committee: The Chairperson, one of the Secretaries and one other ERC member appointed by the ERC, in rotation shall constitute the Executive Committee. A summary of the matters dealt with at Executive Committee meetings must be included in the agenda for the next ERC meeting. The functions of the Executive Committee will include the following:

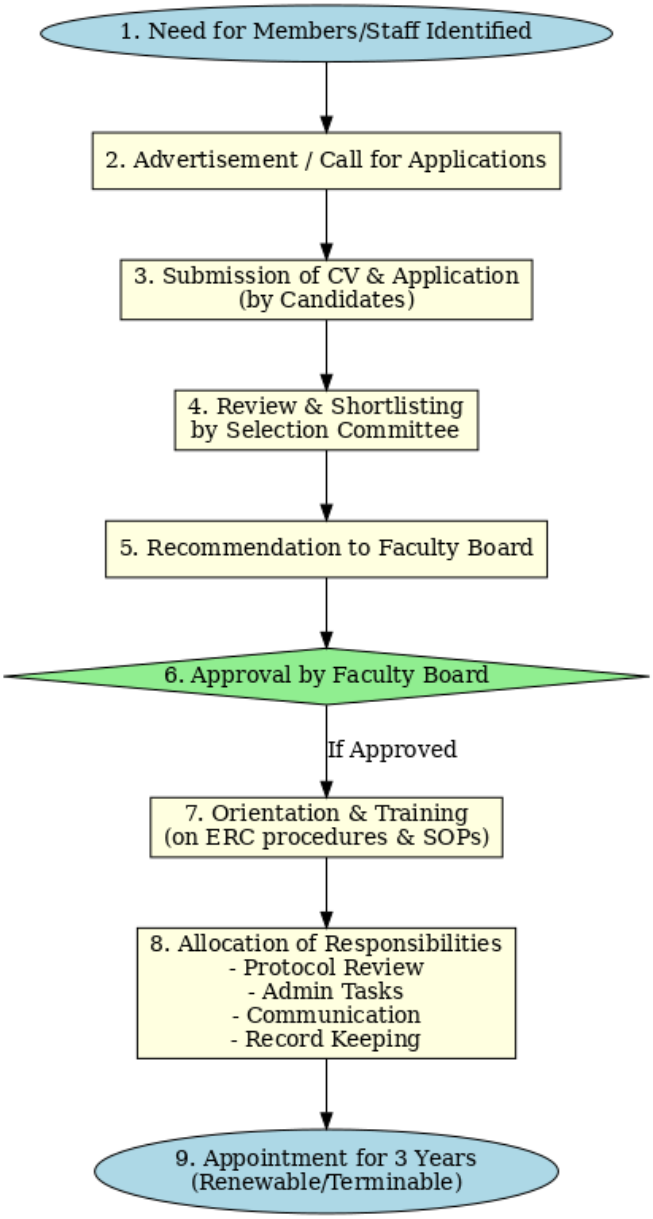
i. Identification of research applications which qualify for expedited review under relevant SOP.

ii. Expedited review of research projects may be undertaken between scheduled meetings, by any two members of the Executive Committee. They may seek advice

from other ERC members or suitably qualified experts, as appropriate, before reaching a decision. The decision of this review must be tabled for ratification at the next ERC meeting.

iii. The Executive Committee may consider other items of business that are considered to be of minimal risk to participants such as minor revisions to protocols, appropriate adverse events, project reports, annual/final reports, extension requests, minor amendments and the like.

WORKFLOW



ANNEXURES: A/003/01/5.0; A/003/02/5.0; A/003/03/5.0

Reference Number	**SOP 004(a)**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Appointment and responsibilities of the Clinical Trials Subcommittee (CTSC)**
Purpose	**To describe the procedure for appointment of members to the CTSC and the responsibilities of members of the CTSC**
Scope	**Outlines the procedures for appointment of members of the CTSC and defines their respectively roles, duties and operational responsibilities in the conduct of CTSC functions**
Responsibility	**It is the responsibility of the Chairpersons and members of the ERC and CTSC to ensure that the appointment of members takes place in accordance with this SOP. It is the responsibility of the members of CTSC to comply with their respective terms of reference**

DETAILED INSTRUCTIONS

4(a).1 The CTSC will provide technical advice to the ERC on the scientific and safety aspects of applications involving clinical trials, including preliminary stages leading up to development and piloting of the intervention(s), where relevant.

4(a).2 The CTSC will review modifications to ongoing research under in its jurisdiction and will undertake regular review of submitted progress and safety reports. The CTSC will also undertake review of clinical trials in instances where it is deemed necessary by the main ERC.

4(a).3 The CTSC will comprise of members, both medical and non-medical, and co-opted external experts, as required. The subcommittee may also invite suitable persons to advise the subcommittees, at their discretion.

4(a).4 Members of the CTSC shall be nominated by the Chairperson ERC following consultation with the ERC and CTSC. Members of the CTSC will be appointed by the Faculty Board. The letters of appointment will be issued by the Dean.

4(a).5 The Chair and Secretary of the CTSC will be selected from among the membership of CTSC by the ERC. The Chair/CTSC will have a minimum of one term's prior experience as a member of the CTSC. Chair and Secretary shall be approved by the Faculty Board. The letters of appointment will be issued by the Dean.

4(a).6 The Chairperson and the Secretary from the CTSC shall be members of the ERC. In the event they are unable to attend the ERC meeting, they may nominate a suitable member/s to attend the meeting.

4(a).7 Members are appointed in their individual capacity for their knowledge and experience and not by designation, or as representatives of any organization, group or opinion.

4(a).8 The letter of appointment (A/003/01/5.0) shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as a CTSC member, the circumstances whereby membership may be terminated and the conditions of appointment.

4(a).9 Members shall agree to their name and profession being made available to the public, including being published on the ERC website.

4(a).10 Members will be required to sign a confidentiality agreement (A/003/02/5.0) and a declaration of integrity (A/003/03/5.0) upon appointment, stating inter alia, that all matters of which he/she becomes aware during the course of his/her work on the CTSC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the CTSC 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 member.

4(a).11 Upon appointment, members shall be provided with the following documentation:

a) Terms of Reference of the CTSC

b) Standard Operating Procedures of the CTSC and ERC

c) Up-to-date list of subcommittee members' names and contact information

d) Current FERCSL Guidelines on Ethical Conduct in Human Research

e) Any relevant previous reports on the CTSC/ERC's activities and

f) Any other relevant information about the CTSC/ERC's processes, procedures and proposals

4(a).12 Members are appointed for a period of three years, renewable at the discretion of the Dean and the Faculty Board. Members who wish to be reappointed shall make a written request to the Dean through the Chairpersons of the CTSC and ERC.

4(a).13 A member may apply for resignation from the CTSC at any time upon giving notice in writing. The CTSC may decide to accept or decline the request, depending on the state of completion of tasks designated to the member. Once resignation is accepted, steps shall be taken to fill the vacancy.

4(a).14 Any member who has absented him/herself without a valid excuse from three consecutive meetings will cease to be a member of the CTSC.

4(a).15 The responsibilities CTSC ERC officials are as follows:

a) Chairperson

I. Preside over CTSC meetings and ensure quorum and adherence to the agenda.

II. Guide discussions to ensure scientific, ethical, and welfare issues are appropriately considered.

III. Ensure compliance with national regulations and international guidelines (e.g. GCP, CPCSEA, ARRIVE).

IV. Sign final recommendations and review documents submitted to the main ERC.

V. Support training and awareness activities on clinical trial ethics for the membership of the CTSC

VI. Serve as the spokesperson for the subcommittee where necessary.

VII. Declare any conflicts of interest and recuse themselves when appropriate.

b) Secretary

i. Schedule and organize CTSC meetings and distribute relevant materials, with the assistance of administrative staff.

ii. Maintain accurate records of submissions and meeting minutes, including discussions, decisions, and recommendations, with the assistance of administrative staff.

iii. Communicate with investigators to request clarifications, revisions, or additional information, with the assistance of administrative staff.

iv. Ensure secure and confidential handling of proposals and related documentation.

v. Assist the Chairperson in follow-up communications and coordination with the main ERC, with the assistance of administrative staff.

vi. Track timelines and ensure that reviews and responses occur within stipulated timeframes.

vii. Declare any conflicts of interest and recuse themselves when appropriate.

c) Members

i. Review assigned applications thoroughly before meetings.

ii. Attend meetings regularly and provide expert input during deliberations.

iii. Declare any conflicts of interest and recuse when appropriate.

iv. Maintain confidentiality of all documents and discussions.

v. Apply relevant ethical and regulatory frameworks in evaluating applications.

vi. Participate in ongoing training in clinical trial ethics.

4(a).16 The CTSC will maintain detailed minutes of its meetings and will submit a technical report on each application submitted to it by the ERC.

4(a).17 The ERC will take into account the technical report of the CTSC when taking a decision to grant ethics approval to an application. However, the final decision on an application will be taken by the full ERC at a convened ERC meeting.

ANNEXURES: A/003/01/5.0; A/003/02/5.0; A/003/03/5.0

Reference Number	**SOP 004(b)**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Appointment and responsibilities of the Animal Research and Welfare Subcommittee (ARWSC)**
Purpose	**To describe the procedure for appointment of members to the ARWSC and the responsibilities of members of the ARWSC**
Scope	**Outlines the procedures for appointment of members of the ARWSC and defines their respectively roles, duties and operational responsibilities in the conduct of ARWSC functions**
Responsibility	**It is the responsibility of the Chairpersons and members of the ERC and ARWSC to ensure that the appointment of members takes place in accordance with this SOP. It is the responsibility of the members of ARWSC to comply with their respective terms of reference**

DETAILED INSTRUCTIONS

4(b).1 The Animal Research and Welfare Subcommittee (AWRSC) provides technical advice to the ERC on the ethical, scientific and safety aspects of protocols involving the use of animals for scientific research and/or educational purposes. The primary responsibility of the AWRSC is to ensure, on behalf of the Faculty, that all care and use of animals is conducted in compliance with the principles, outlined in the current SALLAS Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka. The AWRSC will review modifications to ongoing research under in its jurisdiction and will undertake regular review of submitted progress reports.

4(b).2 The AWRSC will comprise of at least four persons, including a separate person from each of the following categories whenever possible:

Category A: a person with qualifications in veterinary science who is registered as a veterinary surgeon with the Sri Lanka Veterinary Council

Category B: Head of Animal House or a suitably qualified person with substantial experience in the use of animals for scientific purposes and/or with commitment to furthering the welfare of animals

Category C: a suitably qualified person with substantial experience in the use of animals for scientific purposes and/or with commitment to furthering the welfare of animals, who is not employed by the institution

Category D: a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities and not fitting into any other category

The AWRSC may also invite suitable persons to advise the subcommittee, at their discretion.

4(b).3 The Chairperson and the Secretary from the AWRSC should be members of the ERC. In the event they are unable to attend the ERC meeting, they may nominate a suitable member/s to attend the meeting.

4(b).4 Members of the AWRSC will be appointed by the Faculty Board, on the recommendation of the ERC.

4(b).5 The Chairperson and the Secretary will be nominated by the subcommittee from among its members and the names submitted to the Faculty Board for approval.

4(b).6 The letters of appointment will be issued by the Dean, Faculty of Medicine, University of Colombo.

4(b).7 The Chair and Secretary of the AWRSC will be selected from among the membership of AWRSC/ ERC by the ERC. The Chair will have a minimum of one term's prior experience as a member of the AWRSC/ ERC .

4(b).8 Vacancies in the AWRSC will be advertised by the Dean. Applications should include curriculum vitae. A selection committee, consisting of the Chairperson and at least two other ERC members nominated by the membership, shall interview the applicants, consult the ERC and make a recommendation to the Dean and the Faculty Board. The ERC may also invite suitable persons to serve on the AWESC at its discretion.

4(b).9 The letter of appointment (A/003/01/5.0) shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as an AWRSC member, the circumstances whereby membership may be terminated and the conditions of appointment.

4(b).10 Prospective members may be invited to attend a meeting of the AWRSC as observers, consequent to signing a confidentiality agreement.

4(b).11 Members are appointed in their individual capacity for their knowledge and experience and not by designation, or as representatives of any organization, group or opinion.

4(b).12 Members shall agree to their name and profession being made available to the public, including being published on the ERC website.

4(b).13 Members will be required to sign a confidentiality agreement (A/003/02/5.0) and a declaration of integrity (A/003/03/5.0) upon appointment, stating inter alia, that all matters of which he/she becomes aware during the course of his/her work on the AWRSC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the AWRSC 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 member.

4(b).14 Upon appointment, members shall be provided with the following documentation:

a) Terms of Reference of the ARWSC
b) Standard Operating Procedures of the ARWSC and ERC

c) Up-to-date list of subcommittee members' names and contact information
d) Current SALLAS Guidelines on Ethical Conduct in Animal Research
e) Any relevant previous reports on the ARWSC/ERC's activities and
f) Any other relevant information about the ARWSC/ERC's processes, procedures and proposals

4(b).15 Members are appointed for a period of three years, renewable at the discretion of the Dean and the Faculty Board. Members who wish to be reappointed shall make a written request to the Dean.

4(b).16 A member may resign from the AWRSC at any time upon giving notice in writing, to the AWRSC chairperson. The Chairperson will then inform the ERC chairperson, and steps shall be taken to fill the vacancy.

4(b).17 Appointments shall allow for continuity, the development of expertise within the ERC, and the regular input of fresh ideas and approaches.

4(b).18 All members are required to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by the ERC.

4(b).19 The responsibilities ARWSC ERC officials are as follows:

a) Chairperson

I. Preside over ARWSC meetings and ensure quorum and adherence to the agenda.
II. Guide discussions to ensure scientific, ethical, and welfare issues are appropriately considered.
III. Ensure compliance with national regulations and international guidelines (e.g. GCP, CPCSEA, ARRIVE).
IV. Sign final recommendations and review documents submitted to the main ERC.
V. Support training and awareness activities on animal research ethics and welfare, for the membership of the ARWSC.
VI. Serve as the spokesperson for the subcommittee where necessary.
VII. Declare any conflicts of interest and recuse themselves when appropriate.

b) Secretary

i. Coordinate and schedule ARWSC meetings and distribute relevant materials, with the assistance of administrative staff.
ii. Maintain accurate records of submissions and meeting minutes, including discussions, decisions, and recommendations, with the assistance of administrative staff.
iii. Communicate with investigators to request clarifications, revisions, or additional information, with the assistance of administrative staff.

iv. Ensure secure and confidential handling of applications and related documentation.

v. Assist the Chairperson in follow-up communications and coordination with the main ERC, with the assistance of administrative staff.

vi. Track timelines and ensure that reviews and responses occur within stipulated timeframes.

vii. Declare any conflicts of interest and recuse themselves when appropriate.

c) Members

i. Review assigned applications thoroughly before meetings.

ii. Attend meetings regularly and provide expert input during deliberations.

iii. Declare any conflicts of interest and recuse when appropriate.

iv. Maintain confidentiality of all documents and discussions.

v. Apply relevant ethical and regulatory frameworks in evaluating proposals.

vi. Participate in ongoing training in animal research ethics.

vii. Function in the main ERC/ technical committees when required

viii. Uphold the principles of independence, integrity, and scientific/ethical rigor

4(b).20 The AWRSC will maintain detailed minutes of its meetings and will submit a technical report and recommendations to the ERC on each protocol submitted to it. The AWRSC will meet at least quarterly to review their duties and responsibilities even if there are no protocols for review.

4(b).21 Any member who has absented him/herself without a valid excuse from three consecutive meetings will cease to be a member of the ARWSC.

ANNEXURES: A/003/01/5.0; A/003/02/5.0; A/003/03/5.0

Reference Number	**SOP 005**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Orientation and training of new members**
Purpose	**To describe the procedure for the orientation and training of new members**
Scope	**Outlines the procedures for providing orientation and training for members newly appointed to the ERC**
Responsibility	**It is the responsibility of the Chairperson, Secretaries and experienced members of the ERC and staff to ensure that adequate orientation and training are provided to newly appointed members to the ERC.**

DETAILED INSTRUCTIONS

5.1. New ERC members shall be provided with adequate orientation.

5.2. New member orientation will include the following:

a) Introduction to other ERC members prior to the ERC meeting.

b) Provision of an orientation package, including, relevant national/international guidelines, SOPs and TOR.

c) Informal meeting with the Chairperson and Secretary/Officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures.

d) An opportunity, if required, to sit in on ERC meetings before their appointment takes effect.

e) 'Partnering' with another ERC member in the same category.

5.3. New members will receive training in:

a) Research ethics review.

b) Standard Operating Procedures of the ERC.

c) Non-scientific members will be given an understanding of medical terminology and research methodology sufficient to enable them to participate intelligently in the committee's discussions.

5.4. New members may be required to observe proceedings or be partnered with another ERC member for review process for a maximum of three meetings /applications before undertaking independent ethics review.

Reference Number	**SOP 006**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Handling of conflicts of interest**
Purpose	**To describe the procedure for the handling of conflicts of interest of members of the ERC or a designated technical/sub-committee of the ERC**
Scope	**Outlines the procedures for identification, declaration, management and documentation of actual, potential or perceived conflicts of interest of members while functioning as a member of the ERC, or a designated technical/sub-committee of the ERC**
Responsibility	**It is the responsibility of the members of the ERC or designated technical/sub-committee of the ERC to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

6.1. An individual shall, as soon as practicable prior to or during a meeting, inform the Chairperson of the meeting, if he/she has a conflict of interest, in relation to an application or other related matter(s) to be considered.

6.2. The ERC/relevant technical/sub-committee will determine if this results in a conflict of interest for the member and, if so the member will withdraw from the meeting until consideration of the relevant matter is complete. The member shall not be permitted to adjudicate on the relevant application.

6.3. In the event of the Chairperson of the ERC or any technical /sub-committee has a conflict of interest, the discussion and decision making related to the relevant application shall be temporarily chaired by another member of the relevant committee, appointed by consensus of the membership.

6.4. All declarations and determinations of conflict of interest and the withdrawal of the member concerned during discussion of the relevant application will be recorded in the minute.

6.5. The letter of ethics approval will record the withdrawal of the member/s of the committee who were determined to have a conflict of interest.

6.6. a) Definition of conflict of interest: A conflict of interest shall be taken to mean a financial or non-financial interest or other opportunity for personal benefit of an individual or his/her immediate family that may exert a substantial influence on the individual's professional judgment in exercising any institutional duty or responsibility, including the review of research.

b) Examples of conflicting interest: Conflicts of interest shall include, but not be limited to, the following:

I. Participation in a project, either as an investigator or part of the research team.

II. Supervision of a project, in any academic or professional capacity.

III. Financial interest in a project.

IV. Personal relationship to investigator (either spouse/partner, children or close family members)

V. Fiduciary relationship to sponsor (For example, where the ERC member serves on the company's board of directors).

VI. Other nonfinancial interests that may conflict with the ability to review objectively.

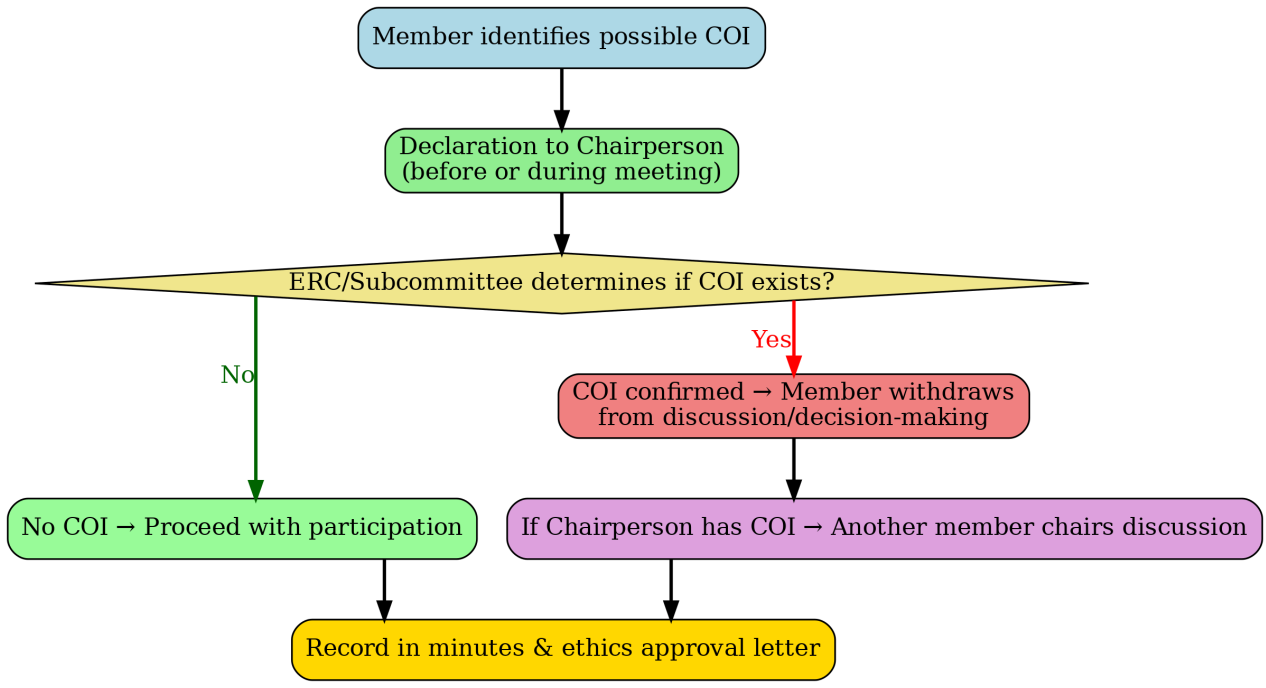
VII. Where the ERC member is in direct competition with the investigator for limited resources, funding, sponsorship, or research subjects.

VIII. Where the ERC member is considered a personal or professional adversary of the investigators.

IX. Any other reason for which the ERC member believes he or she has a conflicting interest with the research.

6.7. In the event an individual with a conflict of interest was present during deliberations and decision making of an application, the course of action shall be determined by the committee, considering factors, including the significance of the conflict of interest and the influence individual concerned may have had on the decision taken. Such course of action may include re-review of the application and/or its status of approval.

WORKFLOW



Reference Number	**SOP 007**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Submission and processing of new applications**
Purpose	**To describe the procedure for the submission and processing of new applications**
Scope	**Outlines the procedures for submission, receipt, initial screening, and allocation of all new research applications submitted to the ERC for ethics review**
Responsibility	**It is the responsibility of ERC office to ensure applications are received, and documented, while the executive committee is responsible for screening, and allocating for review in compliance with this SOP**

DETAILED INSTRUCTIONS

7.1. Applications which fall within the scope of the ERC, described in SOP 001, shall be accepted for review. For applications that do not meet this requirement, the applicant will be notified of the same in writing.

7.2. Applications must be submitted in the format prescribed by the ERC (A/007/01/5.0) and shall include all necessary documentation (A/007/02/5.0). A checklist, to be completed and signed by the principal investigator is included for this purpose. A signed copy of the completed checklist confirming receipt of the application and all supporting documents will be handed over to the applicant, signed by ERC office (A/007/03/5.0).

7.3. A unique application number will be allocated for complete application by the ERC office and shall be in the format of EC/YY/Number, where the number is sequential in order of receipt. Such applications will be added to the ERC's register.

7.4. For undergraduate research reviewed by a sub-committee see SOP 12.

7.5. Incomplete applications, including the non-submission of all relevant soft-copies of the application shall not be accepted by the ERC office for further processing.

7.6. Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study.

7.7. Information relating to the format and procedure for application for ethics review shall be readily available to applicants. Guidelines shall be issued by the ERC to assist applicants in the preparation of their applications, including guidance on how to determine whether ethics review is necessary.

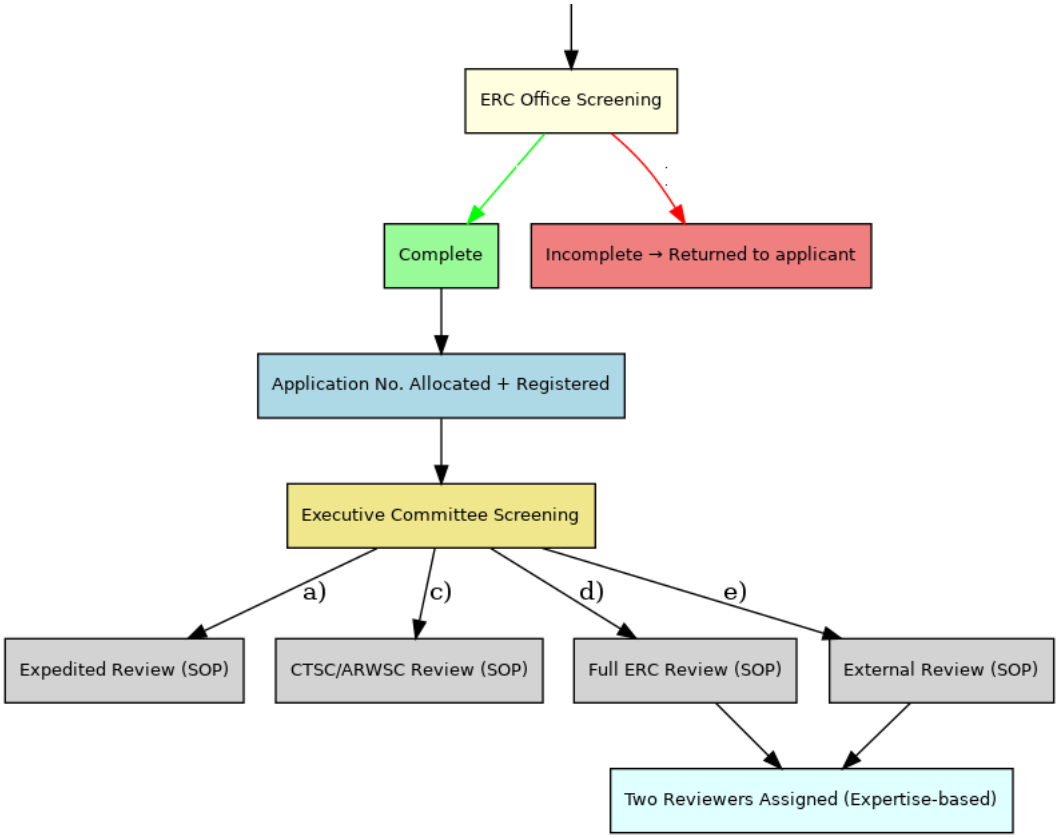
7.8. A non-refundable fee will be charged for applications submitted for review by the ERC. However, this may be waived at the discretion of the ERC. The fee structure for applications shall be readily available to prospective applicants. Fees shall be revised from time-to-time by the ERC, with the approval of the faculty board.

7.9. All applications for ethics review must be submitted to the office of the ERC by close of business on the relevant closing date. The closing date for applications shall usually be the last working day of the month preceding the relevant monthly ERC meeting. Such applications will be included in the agenda of the next available ERC meeting. Information about the closing date shall be readily available to prospective applicants.

7.10. All accepted application for the month, are screened by the Executive Committee on the first working day of the subsequent month, and processed, where the applications may be subject to a) expedited review (SOP 009), b) fast-track review (SOP 010), c) allocation for review by CTSC/ARWSC or d) full review by members of the ERC (SOP 008) and/or e) external review (SOP 011).

7.11. In relation 7.10d or 7.10e above the Executive committee shall identify two suitable reviewers based on their subject expertise deemed appropriate and relevant to the application.

WORKFLOW



ANNEXURES: A/007/01/5.0; A/007/02/5.0; A/007/03/5.0

Reference Number	**SOP 008**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Full review of applications by members of the ERC**
Purpose	**To describe the process followed by ERC in conducting a full ethics review of submitted research applications**
Scope	**Outlines the procedures followed by ERC in conducting a full ethics review of submitted research applications**
Responsibility	**It is the responsibility of the ERC members to review applications thoroughly and providing independent, objective, and timely assessments in line with ethical guidelines to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

8.1. If an application is allocated for full review by the Executive Committee, such applications shall be sent to two principal reviewers with expertise deemed appropriate and relevant to the proposal, who would:

a) review the application in detail prior to the meeting; and

b) submit written comments in the structured format (A/008/01/5.0) and

c) lead the discussion on the application at the ERC meeting.

8.2. All information sheets/consent forms shall be reviewed by a lay member, who would:

a) review them in detail prior to the meeting; and

b) submit written comments in the structured format (A/008/02/5.0) and

c) lead the discussion on the information sheet/consent forms at the ERC meeting.

8.3. The ERC will assess projects submitted for review in accordance with FERCSL and other national and international guidelines and any relevant national and international laws to determine their acceptability on matters of ethics. The ERC must ensure that it is sufficiently informed on all aspects of a research, including its scientific validity, to make an assessment. The ERC will deal with multi-centre research applications in accordance with SOP 013.

8.4. Under exceptional circumstances the ERC may request the applicant or a nominee to be present at an ERC meeting for clarification of issues in relation to their application. The applicant shall be present only for the duration of such clarifications and shall leave the meeting prior to ERC deliberation and decision-making concerning the application.

8.5. The ERC may invite a member of an advocacy group representing the interests of the participants to the meeting to clarify relevant issues.

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

a) Approve the proposal;

b) Require modification of the proposal - major revisions or minor revisions

c) Reject the proposal

8.7. The ERC shall attempt to reach all decisions by consensus. If a unanimous decision cannot be reached, the decision shall be by agreement of two-thirds of those present at the meeting, provided it includes at least one lay-member.

8.8. For applications requiring revisions (major/minor) a letter containing point-by-point responses to ERC comments in the stipulated format (SOP 020), along with all other revised documents should be submitted by the applicant for re-consideration by the ERC.

8.9. If no response is received from the applicant within two months of notification of the decisions, such applications shall be removed from the agenda, and any subsequent submissions on the same project will be considered as a new application.

8.10. For applications requiring minor revisions, the authority to review an applicant's responses and grant final approval is delegated to the Executive Committee. The ERC shall be informed at the next meeting of the final decision taken on its behalf by the Executive Committee

8.11. For applications requiring major revisions, the revised proposal, along with all other revised documents shall be reviewed by the original two reviewers, with subsequent discussion at the next full ERC meeting.

8.12. For all applications requiring revisions (major/minor), one of the following decisions will be made, and reviewed as per clauses 8.7-8.11 above

a) Approve the proposal;

b) Require modification of the proposal - major revisions or minor revisions

c) Reject the proposal

WORKFLOW

ANNEXURES: A/008/01/5.0; A/008/02/5.0

Reference Number	**SOP 009**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Expedited Review**
Purpose	**To describe the criteria and procedure for expedited review of research applications**
Scope	**Applies to all research applications submitted to the ERC that involve no more than minimal risk to participants, do not include sensitive topics or vulnerable populations, and fulfils the eligibility criteria outlined below**
Responsibility	**It is the responsibility of the Executive Committee to conduct expedited review of eligible research proposals in compliance with this SOP**

DETAILED INSTRUCTIONS

9.1. The Executive Committee may consider a research application for expedited review if it meets one or more of the following criteria:

a) Research conducted in established or commonly accepted educational settings, involving standard educational practices, where there is no deviation from normal educational methods or increase in risk or discomfort to participants. Such proposals may include observational studies on instructional strategies or evaluations of teaching methods, curricula, or classroom management techniques. However, the procedures must not cause significant deviation in time or effort from routine practices, must not involve sensitive topics, and must ensure a non-coercive environment for student participants. Written approval must be obtained from the educational institution concerned. Research involving children or individuals living with disabilities shall not be eligible for expedited review under this category.

b) Research involving the use of validated educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behaviour, provided that the information obtained is recorded in a manner that does not identify participants directly or through linked identifiers, and any disclosure of responses would not place the participants at risk of any harm, including but not limited to, criminal or civil liability, or damage their financial standing, employability, or reputation. Surveys on sensitive topics including but not limited to, sexual behaviours or attitudes, substance use, criminal behaviours, or other highly personal matters, shall not be eligible for expedited review under this category.

c) Research involving existing data, documents, or records that are publicly available or have been recorded in a manner that precludes identification of the individuals involved, provided that the data were collected/intended to be used for non-commercial purposes and the risk of participant identification is minimal

d) Research involving secondary use of previously collected biological specimens, provided that the material was collected/intended to be used for non-commercial purposes, risk of participant identification is minimal, and the collection has been for routine clinical purposes and/or with consent for further analysis where relevant.

e) Research involving collection of minimal risk data about individual or group characteristics or behaviours, including but not limited to studies on perception, cognition, motivation, language, communication, cultural beliefs or practices, and social behaviours, using methods such as interviews, surveys, oral history, focus groups, program evaluation, or quality assurance assessments, where there is no manipulation of behaviour and the research methods do not induce stress or discomfort to the participant.

f) Taste and food quality evaluation or consumer acceptance studies may be considered for expedited review where the food consumed is either wholesome and without additives, and contains ingredients approved for consumption by the relevant government agency and is at or below the level found to be safe.

g) Studies designed to examine public benefit or service programmes (e.g. audits), including changes/improvements/alternatives to such service programmes, conducted primarily for service provision, where prior institutional or departmental approval has been granted.

h) Research proposals involving non-invasive collection of biological specimens, or similar low-risk activities may be eligible if the protocol poses no risk of harm to participants and is not intended for commercial product development.

i) Vector studies with no involvement of human participants.

9.2. Research proposals that involve more than minimal risk, including but not limited to clinical trials, research involving invasive procedures, psychological discomfort, sensitive personal or cultural issues or studies involving vulnerable populations (such as children, pregnant women, individuals with cognitive impairments, or those unable to provide informed consent) shall not be considered under this SOP.

9.3. If the Executive Committee considers that the research may compromise the ethical principles of respect for persons, beneficence or justice or raise concerns about scientific validity or integrity, the protocol must be submitted for full review by the ERC.

9.4. The Executive Committee shall meet on the first working day of the month to examine all new applications received during the preceding month. The Committee shall determine whether any protocols qualify for expedited review in accordance with the eligibility criteria above.

9.5. Protocols qualifying for expedited review shall be reviewed using the standard form for expedited review (A/009/01/5.0), and decisions shall be documented accordingly. If the Executive Committee determines that clarifications or minor modifications are required, the

Principal Investigator (PI) will be notified. Approval shall be granted after addressing such modifications to the satisfaction of the Executive Committee.

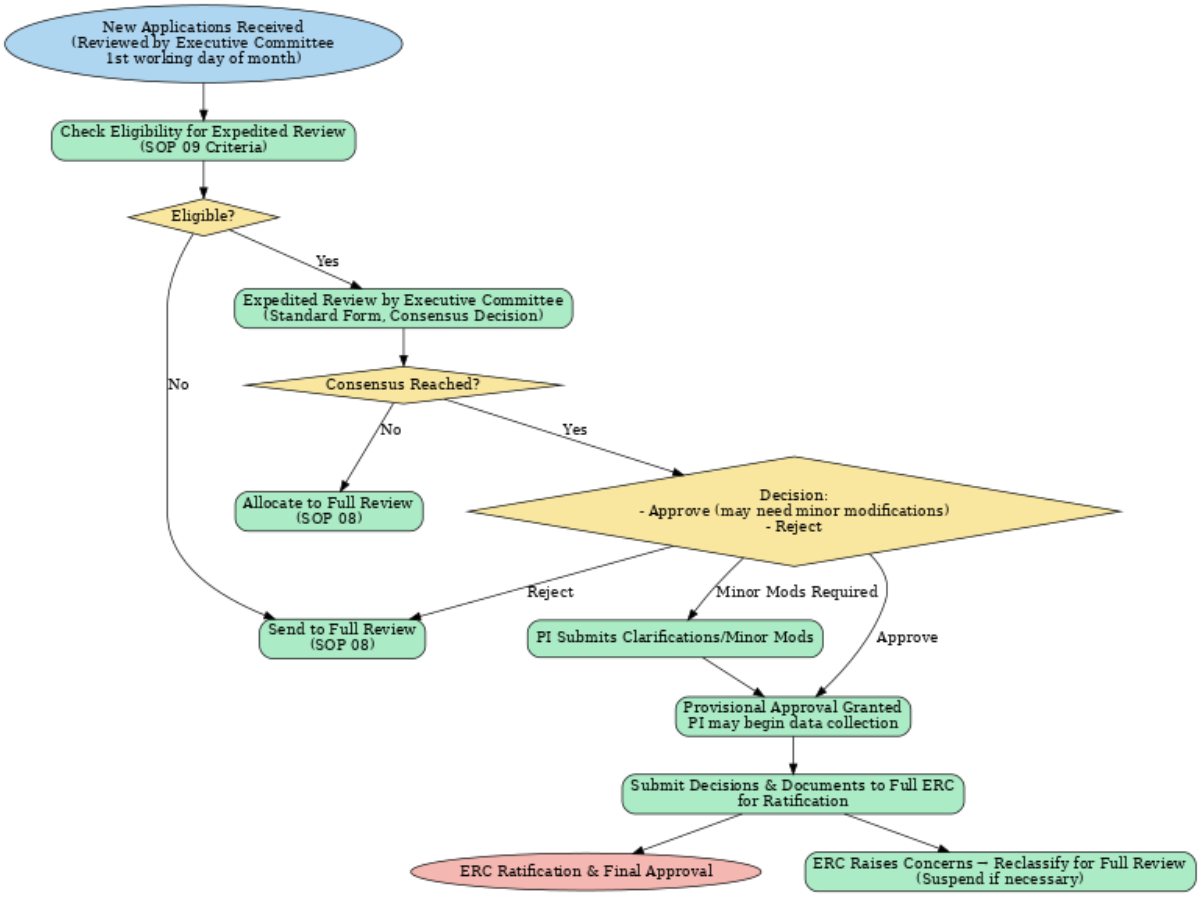
9.6. Expedited review and provisional approval by the Executive Committee shall be by consensus agreement. In situations where consensus agreement cannot be reached, such applications shall be allocated for full review as per SOP 008

9.7. A letter of expedited review and provisional approval (A/009/02/5.0) shall be issued once such modifications have been submitted and deemed acceptable. The PI shall be informed that data collection may begin following receipt of this provisional approval, pending final ratification by the full ERC.

9.8. All such decisions, review forms, and letters of approval shall be submitted to the ERC for ratification and final approval at its next scheduled meeting. A formal letter of final approval will be issued only after such ratification.

9.9. In the event that valid scientific or ethical concerns regarding a protocol reviewed under this SOP arises during the full ERC meeting, the study may be reclassified for full review as per SOP 008, and the PI shall be informed accordingly. This may include suspension of research activities until full review, if deemed necessary by the full ERC.

WORKFLOW



ANNEXURES: A/009/01/5.0; A/009/02/5.0

Reference Number	**SOP 010**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Fast-Track Review**
Purpose	**To describe the criteria and procedure for fast-track review of research proposals**
Scope	**Outlines the procedures for submission, receipt, initial screening, and allocation of all research applications submitted to the ERC for fast-track review**
Responsibility	**It is the responsibility of ERC office to ensure applications are received, and documented, while the executive committee is responsible for screening, and allocating for review in compliance with this SOP**

DETAILED INSTRUCTIONS

10.1. The Committee may consider suitable applications for fast-track review, strictly limited to situations where it is necessary to commence a research project as early as possible due entirely to the circumstances related to the research question/s and the appropriate research methods of the project under consideration. This will relate to sudden, unforeseen situations that arise in the community (e.g., natural disasters, human-made disasters, infectious disease epidemics) and where the research study must commence with minimal delay if the research question is to be answered and the research methods are to be applied.

10.2. Applications for fast-track review must comply with all requirements stipulated in SOP 007.

10.3. Applications so prepared may be submitted via e-mail, addressed to the official e-mail address of the Committee. In the email covering note, the principal investigator must specifically request for consideration of the application under the fast-track review. The relevant application fee paid and hard copies of the application need to be submitted to the ERC office as soon as feasible.

10.4. If the Executive Committee upon receiving such an application decides that the application is not suitable for fast-track review, the principal investigator will be informed forthwith, by email.

10.5. The Executive Committee, upon being satisfied of its suitability for consideration for fast-track review and will determine whether the applications may be subject to expedited review (SOP 009), allocation for review by CTSC/ARWSC or review by members of the ERC and/or suitable external reviewers (SOP 011).

10.6. Expedited review (SOP 009): If the Executive Committee decides to expedite review or exempt from review, with or without comments for revision, this decision will be conveyed to the principal investigator forthwith, by email.

10.7. Full review:

a) If the Executive Committee decides to submit the application for full review, it will identify two main reviewers, with relevant subject expertise. The full application will be emailed to all members of the Committee, including the identified two main reviewers. This shall be done within one working day of the receipt of the application.

b) Each of the two main reviewers will be required to submit his/her observations by email to the full Committee in the prescribed format (A/008/01/5.0), within five working days of the receipt of the application by email.

c) Any members of the Committee who wish to submit observations will submit them by email within two working days of the circulation of the observations of the two main reviewers.

10.8. Clinical trials:

a) Chairperson / CTSC should be consulted before deciding the trial is suitable for fast-track review.

b) If the project is a clinical trial, it will be forwarded by a Joint-Secretary/ERC to the Secretary of the Clinical Trials Subcommittee (CTSC) for appropriate action.

c) The Secretary/CTSC with the concurrence of the Chairperson of the CTSC will identify two main reviewers for the application from within the CTSC. The application will be forwarded to all members of the ERC and CTSC, including the two identified main reviewers, forthwith.

d) The two main reviewers will submit their observations to the CTSC by email within ten working days.

e) The Secretary/CTSC will cause the CTSC members to come to a consensus decision by email communication, within two working days. This consensus will be submitted to a Joint-Secretary/ERC forthwith. These observations will then be forwarded by the said Joint-Secretary/ERC to the ERC forthwith.

f) The full ERC will then consider the application overall, including comments sent by the CTSC. Each member will submit his/her observations within two working days of the receipt by email of the comments of the CTSC.

10.9. After the completion of the two days available for ERC members to send in their comments (in the case of both 10.8 and 10.8 above), a Joint-Secretary/ERC will collate all comments received from members of the ERC and submit it to the Executive Committee for the final decision. The Executive Committee may consult ERC members for further guidance, in those situations where there is no consensus decision.

10.10. This decision will be communicated as per any ERC application: i.e., whether approved, requires revision, or rejected; if requiring revision, whether major or minor.

10.11. A Joint-Secretary/ERC will then convey the final decision to the principal investigator in the standard format, via email, within one day of the decision being made.

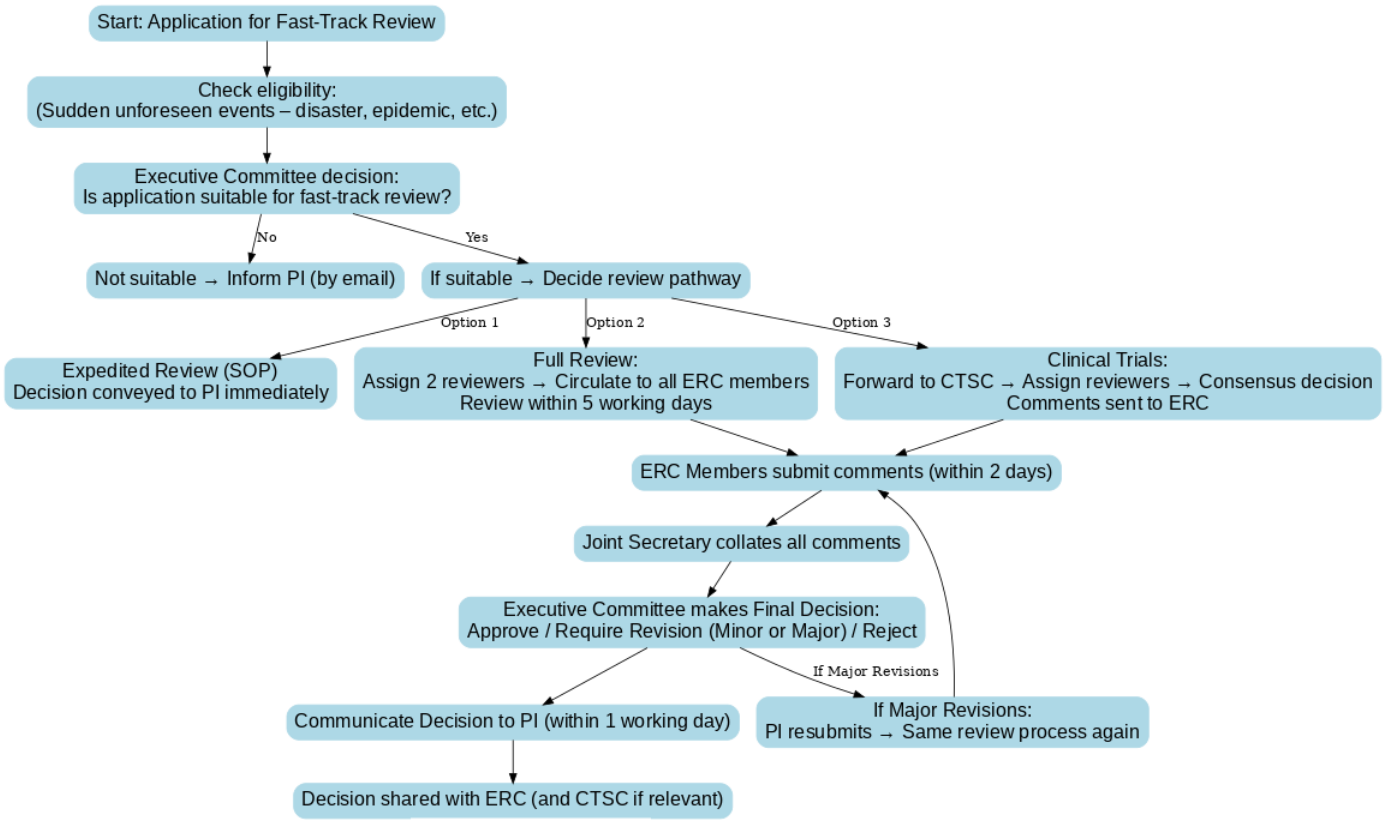
10.12. However, throughout this process, the Joint-Secretaries of the ERC and/or the CTSC will ensure that the application or comments received will not be emailed to any member of the ERC or CTSC who is an investigator in the application or has any other reason due to a conflict of interest to be unsuitable to take part in the review discussion.

10.13. When the final decision is made and conveyed to the principal investigator, it will also be conveyed by email to all members of the ERC and, if relevant, the CTSC.

10.14. In the event of major revision, once the revised version of the protocol is received, this too will be processed in the same manner as for the initial application described above.

10.15. If PI does not send his/her responses within 14 working days, revisions submitted thereafter will be processed as per major/minor revisions of standard ERC proposals.

WORKFLOW



ANNEXURE: A/008/01/5.0

Reference Number	**SOP 011**
Last Revised	**August 2025**
Version	**5.0**
Subject	**External Review**
Purpose	**To describe the criteria and procedure for External Review of applications and the procedure to appoint External Reviewers and their roles and responsibilities**
Scope	**Outlines the procedures for the appointment, roles, and responsibilities of external reviewers engaged by the ERC or its sub-committees to provide expert advice on applications requiring additional expertise not available in-house.**
Responsibility	**It is the responsibility of the Chairpersons and members of the ERC and/or relevant sub-committees to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

11.1. The ERC or a relevant technical/sub-committee shall be free to consult any person(s) considered by it to be qualified to provide advice and assistance in the review of any application, *inter alia* if expertise in that particular area is considered inadequate in-house, provided that such person(s) have no conflict of interest and signs an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.

11.2. Appointment of the External Reviewer(s)

a) External Reviewer(s) who possess/es the necessary expertise to review the application will be appointed by the ERC and/or technical/sub-committee such as the CTSC/ARWSC with approval from the ERC and will receive a letter of appointment, with the relevant terms of reference.

b) The letter of appointment shall include 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 and the conditions of appointment.

c) External Reviewer(s) shall not be remunerated but may be reimbursed for legitimate expenses incurred in attending ERC meetings, upon request.

d) The appointment of the external reviewer shall be documented in the minute at the relevant ERC and/or technical/sub-committee meeting.

11.3. Conditions of Appointment: External Reviewer(s) shall agree to;

a) Review application/s assigned to him/her and provide written comments and be present and lead the discussion on the application at the ERC meeting and/or technical/sub-committee such as the CTSC/ARWSC meeting if required.

b) Declare his/her full name, profession, and affiliation.

c) Permit disclosure of documents pertaining to reimbursements by the ERC.

d) Sign a Confidentiality Agreement pertaining to deliberations at meetings, applications, research participants and related matters.

e) Sign a Declaration of Conflict of Interest (SOP 006).

Reference Number	**SOP 012**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Ethics review of undergraduate research projects conducted as part of academic curricula of the University of Colombo**
Purpose	**To describe the procedure for the submission and processing of applications for ethics review of undergraduate research projects conducted as part of academic curricula of the University of Colombo**
Scope	**Outlines the procedures for submission, review, and decision-making process for undergraduate research applications submitted to the ERC through relevant academic streams**
Responsibility	**It is the responsibility of Chairperson and the appointed sub-committees to ensure ethics review of all undergraduate research applications are processed in compliance with this SOP**

DETAILED INSTRUCTIONS

12.1. Undergraduate research applications must be submitted through the relevant academic stream (e.g., Community Medicine Stream for MBBS undergraduate research projects). Applications should include all required documentation as per ERC guidelines (SOP 007).

12.2. Upon the request of the relevant stream responsible for administration of the undergraduate research projects, the ERC shall appoint a sub-committee comprising:

a) One or more ERC member(s) and

b) One or more academic representative(s) from the relevant stream and

c) Other experts if deemed appropriate

The composition of the sub-committee shall be approved by the ERC and recorded in the minutes.

12.3. Members of the sub-committee are bound by ERC policies on confidentiality and declaration of conflicts of interest. Each member shall sign the standard ERC Confidentiality Agreement and COI Declaration before commencing review.

12.4. Application will be allocated for review to members of the appointed sub-committee by an academic representative from the relevant stream

12.5. The sub-committee shall convene to discuss all submitted applications, where the discussion shall be led by the reviewer. Decision for each proposal may be one of the following:

a) Approved

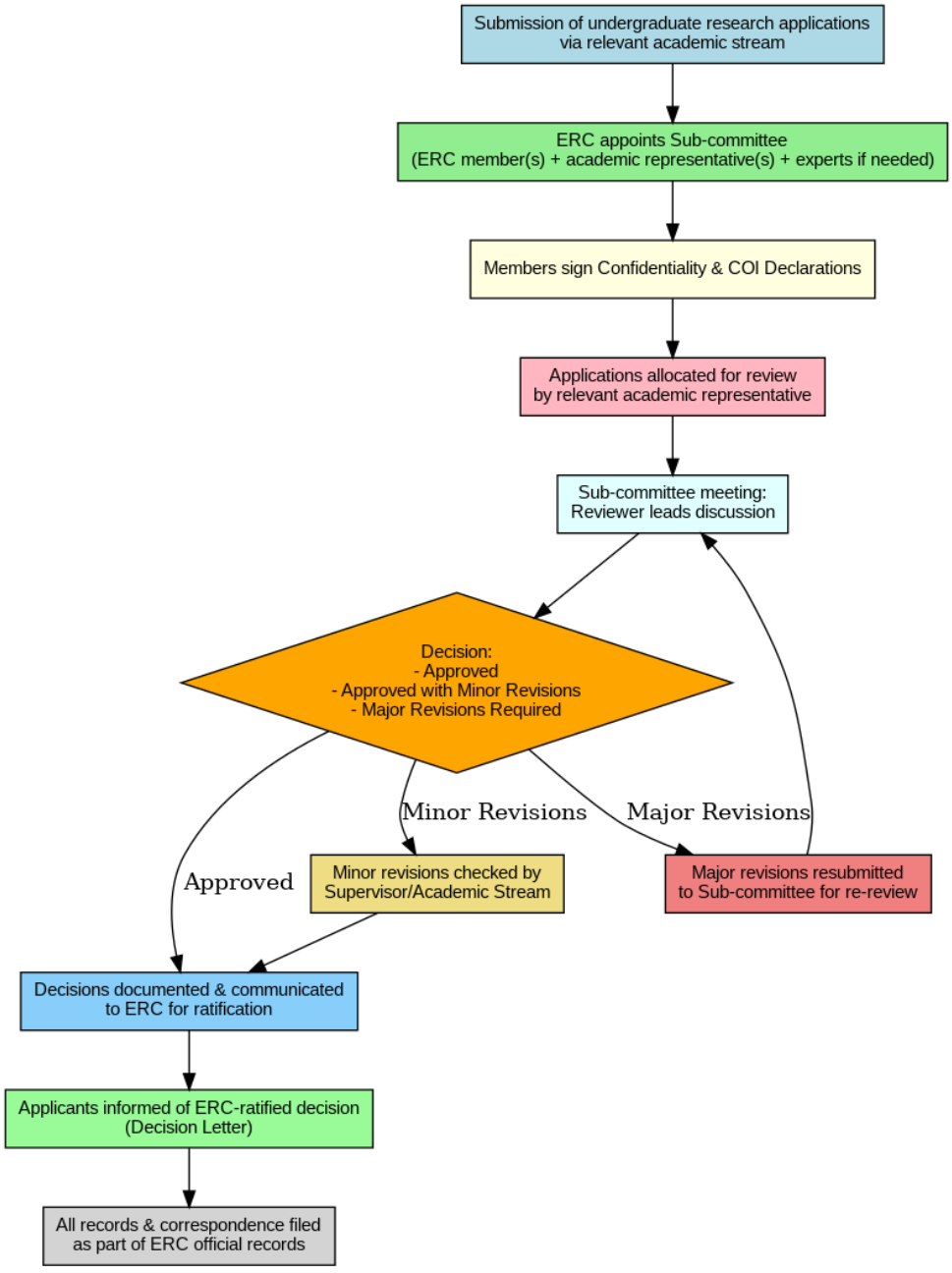
b) Approved with minor revisions: minor changes requested, review of revisions delegated to the research supervisor/relevant research stream.

c) Major revisions required: proposal is returned to applicant for substantial changes; revised submission is re-reviewed by the sub-committee and undergo the same process for review as described above.

12.6. The decisions of the sub-committee shall be documented and communicated to the ERC for formal ratification at the next full ERC meeting. Applicants shall be informed of the ERC-ratified decision in writing (A/012/01/1.0).

12.7. All documentation, minutes of sub-committee meetings, and correspondence with applicants shall be filed as part of the ERC's official records.

WORKFLOW



ANNEXURES: A/012/01/1.0

Reference Number	**SOP 013**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Handling of multi-centre research and research funded by foreign agencies or industry**
Purpose	**To describe the procedure for the handling by the ERC of multi-centre research and research funded by foreign agencies or industry**
Scope	**Outlines the procedures for ethics review of multi-centre research and research funded by foreign agencies or industry, submitted to the ERC**
Responsibility	**It is the responsibility of the Chairpersons and members of the ERC to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

13.1. Research projects designed to be conducted in a number of centres (multi-centre studies in different communities or countries) should be conducted in identical ways at each centre. Any site-specific modifications should be approved by the ERC. The research project submitted to the ERC for review shall indicate all site-specific information, pertaining to the study sites in Sri Lanka, including but not limited to, study centres used, facilities available, personnel involved, monitoring, insurance if applicable and training offered to investigators.

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

a) communicate with any other ERC;

b) consider a scientific/technical and/or ethical assessment of the research by another ERC;

c) share its scientific/technical and/or ethical assessment of the research with another ERC

13.3. The term ‘research funded by foreign agencies/industry’ refers to research wholly or partly sponsored/financed and wholly or partly carried out by an external non-Sri Lankan entity including but not limited to public/private/academic/governmental/non-governmental/corporate entity.

13.4. For such research projects,

a) A local collaborator/co-investigator, responsible for the conduct of the research component in Sri Lanka is essential.

b) A written agreement regarding sample/data ownership, publication strategy (including issues such as authorship and the right of the Sri Lankan collaborator to publish data pertaining to Sri Lanka), and intellectual property rights should be in place.

c) The research protocol should also have been submitted for ethics and scientific clearance in the country of the sponsoring organisation and the ethical standards applied in Sri Lanka should be comparable to those of the country of the sponsoring organisation

d) The ERC shall take into consideration whether the goals of the research are relevant to the health needs and priorities of Sri Lanka and whether any benefits of research are shared.

e) In the case of clinical trials, the ERC shall consider post-trial access of the product at an affordable cost to the public of Sri Lanka and/or the participants, if the investigational medicinal product is proven to be efficacious and safe based on the trial results. The ERC may stipulate post-trial access requirements in granting approval.

f) The ERC should ascertain whether the research conforms to the culture and practices of Sri Lanka.

g) Transfer of biological material abroad should be in accordance with existing laws and regulations and as per the material transfer agreement (MTA) approved by the ERC. The ERC shall act with caution to safeguard the interests of local individuals and communities and, at the same time, ensure that research is not hindered. Biological samples shall only be used for the purpose stated in the research proposal and not for any other purpose. The management of the biological material after the conclusion of the proposed research should be clearly stated

h) There should be provisions in the research proposal to ensure that important research findings are conveyed to the appropriate authorities in Sri Lanka.

Reference Number	**SOP 014**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Preparation of agenda and annexures**
Purpose	**To describe the process and format of agenda for an ERC meeting**
Scope	**Outlines the procedures for the preparation and formatting of the agenda and annexures for ERC meetings**
Responsibility	**It is the responsibility of the Joint Secretaries and ERC Staff to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

14.1. The Joint Secretaries of the ERC will prepare an agenda for each ERC meeting, with the assistance of ERC staff.

14.2. All complete applications together with relevant documents and all relevant correspondence received by the Secretary of the ERC by the stipulated deadline will be included on the agenda for ERC consideration at its next meeting. The stipulated deadline for new applications shall be 12 noon of the last working day of the previous month.

14.3. The meeting agenda and associated documents will be prepared by the Joint Secretaries of the ERC and circulated to all ERC members at least three (3) calendar days prior to the next meeting.

14.4. Documentation received after the closing date may be included in the agenda and/or tabled at the meeting at the discretion of the Executive Committee, or they shall be included in the agenda of the immediate next ERC meeting.

14.5. Agenda will include the following items:

a) Confirmation of Minutes

b) Matters Arising from Minutes

c) Declaration of Conflicts of Interests by ERC Members

d) Announcements / Welcome / In-house Training

e) Clinical Trials Sub Committee (CTSC)

f) Animal Research and Welfare Sub Committee (ARWSC)

g) Interim/Final Reports of Approved Protocols

h) Protocols Previously Considered by Full ERC, Referred to the Executive Committee for Approval

i) Protocols Previously Considered by the Full ERC Approval by the Full ERC

j) Approved Protocols for amendments by the Full ERC

k) Approved Protocols for amendments by the Executive Committee

l) Correspondence Regarding Approved protocols

m) Approved Protocols for extension of Approval Period by the Executive Committee

n) Approved Protocols for extension of Approval Period by the Full ERC

o) New Protocols Exempt from Review

p) New Protocols Granted Expedited Review

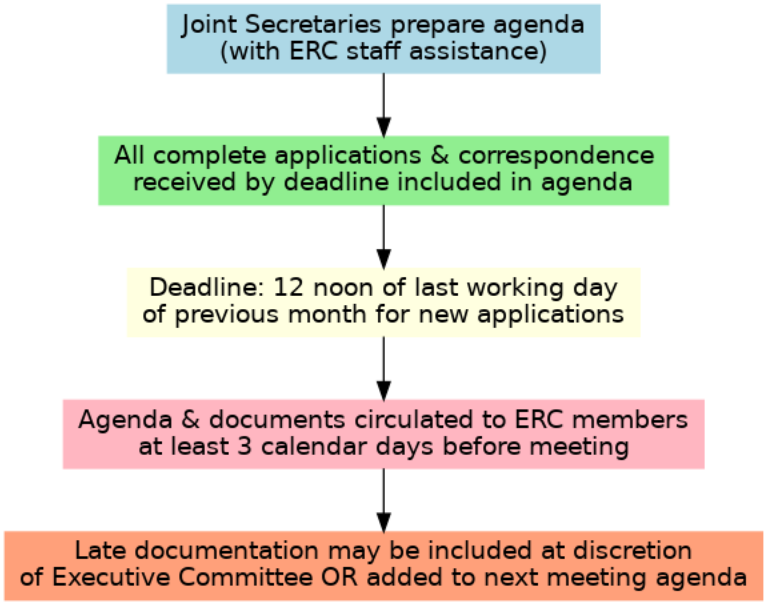
q) New Protocols for Full ERC Review

r) Any other business

s) Financial statement for the previous year (February meeting)

t) Annual report for the previous year (February meeting)

WORKFLOW



Reference Number	**SOP 015(a)**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Preparation of agenda and annexures CTSC meeting**
Purpose	**To describe the process and format of agenda for an CTSC meeting**
Scope	**Outlines the procedures for the preparation and formatting of the agenda and annexures for CTSC meetings**
Responsibility	**It is the responsibility of the CTSC Secretary and ERC Staff to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

15(a).1. The Secretary of the CTSC will prepare an agenda for each CTSC meeting, with the assistance of ERC staff.

15(a).2. All complete applications together with relevant documents and all relevant correspondence received by the secretary of the CTSC by the stipulated deadline will be included on the agenda for CTSC consideration at its next meeting.

15(a).3. The stipulated deadline for new applications shall be 12 noon of the last working day of the previous month. The stipulated deadline for, “applications under review” would be 7 calendar days prior to the date of the next CTSC meeting. The stipulated deadline for protocol amendments, progress reports and other forms of correspondence would be 4 calendar days prior to the next CTSC meeting.

15(a).4. The meeting agenda and associated documents will be prepared by the secretary of the CTSC and circulated to all CTSC members at least three (3) calendar days prior to the next meeting.

15(a).5. Documentation received after the closing date may be included in the agenda and/or tabled at the meeting at the discretion of the Chairperson/CTSC, or they shall be included in the agenda of the immediate next ERC meeting.

15(a).6. Agenda will include the following items:

a) Confirmation of Minutes

b) Declaration of conflicts of Interests by CTSC Members

c) Announcements / Welcome / Excuses

d) Matters Arising from Minutes

e) Protocols previously considered but unapproved by CTSC, for consideration of newer version.

f) New protocols for review

g) Approved protocols for amendments by the CTSC

h) Interim/Final Reports of approved Protocols

i) Approved protocols for extension of approval period by the CTSC

j) Correspondence regarding approved protocols

k) Any other business

Reference Number	**SOP 015(b)**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Preparation of agenda and annexures ARWSC meeting**
Purpose	**To describe the process and format of agenda for an RWSCC meeting**
Scope	**Outlines the procedures for the preparation and formatting of the agenda and annexures for ARWSC meetings**
Responsibility	**It is the responsibility of the ARWSC Secretary and ERC Staff to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

15(b).1. The Secretary of the ARWSC will prepare an agenda for each ARWSC meeting, with the assistance of ERC staff.

15(b).2. All complete applications together with relevant documents and all relevant correspondence received by the secretary of the ARWSC by the stipulated deadline will be included on the agenda for ARWSC consideration at its next meeting.

15(b).3. The stipulated deadline for new applications shall be 12 noon of the last working day of the previous month. The stipulated deadline for, “applications under review” would be 7 days prior to the date of the next ARWSC meeting. The stipulated deadline for protocol amendments, progress reports and other forms of correspondence would be 4 calendar days prior to the next ARWSC meeting.

15(b).4. The meeting agenda and associated documents will be prepared by the secretary of the ARWSC and circulated to all ARWSC members at least three (3) calendar days prior to the next meeting.

15(b).5. Documentation received after the closing date may be included in the agenda and/or tabled at the meeting at the discretion of the Chairperson/ARWSC, or they shall be included in the agenda of the immediate next ARWSC meeting.

15(b).6. Agenda will include the following items:

a) Confirmation of Minutes

b) Declaration of conflicts of Interests by ARWSC Members

c) Announcements / Welcome / Excuses

d) Matters Arising from Minutes

e) Protocols previously considered but unapproved by ARWSC, for consideration of newer version.

f) New protocols for review

g) Approved protocols for amendments by the ARWSC

h) Interim/Final Reports of approved Protocols

i) Approved protocols for extension of approval period by the ARWSC

j) Correspondence regarding approved protocols

k) Any other business

Reference Number	**SOP 016**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Conduct of ERC meetings**
Purpose	**To describe the format and conduct of meetings of the ERC**
Scope	**Outlines the procedures for the conduct of ERC meetings**
Responsibility	**It is the responsibility of the Chairperson to conduct the meetings, while the Joint-Secretaries are responsible for ensuring logistical arrangements and accurate documentation to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

16.1. The ERC shall meet on a monthly basis. Dates of ERC meetings for the year shall be pre-decided and be publicly available.

16.2. The meeting will be presided over by the Chairperson, and in their absence a *pro tem* Chairperson will be nominated by the members.

16.3. Members will attend ERC meetings in person. In special circumstances the meeting may be conducted as a virtual meeting. Members who are unable to attend a meeting should send an excuse in writing to a Joint Secretary of the ERC. The minutes should record the submission of excuses.

16.4. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least 50% +1 members, including the Chairperson, one Joint Secretary and at least one medical and one lay member, are present. To calculate the 50%, the members from whom valid excuses have been received will be excluded. In discussions where one or more members excuse themselves from the meeting due to conflicts of interest, the quorum shall be re-calculated as above.

16.5. If the meeting does not achieve quorum, the Chairperson may cancel the scheduled meeting. Should this occur, the ERC will convene within ten (10) working days of the cancelled meeting. However, in exceptional circumstances the Chairperson may proceed in the absence of the quorum. In such circumstances, decisions made by the ERC must be ratified by at least one lay member.

16.6. Meetings will 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 ten (10) working days to complete the agenda.

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

16.8. Notwithstanding clause 16.7, the ERC may agree to the presence of visitors or observers at a meeting. Such observers/visitors should sign a confidentiality agreement.

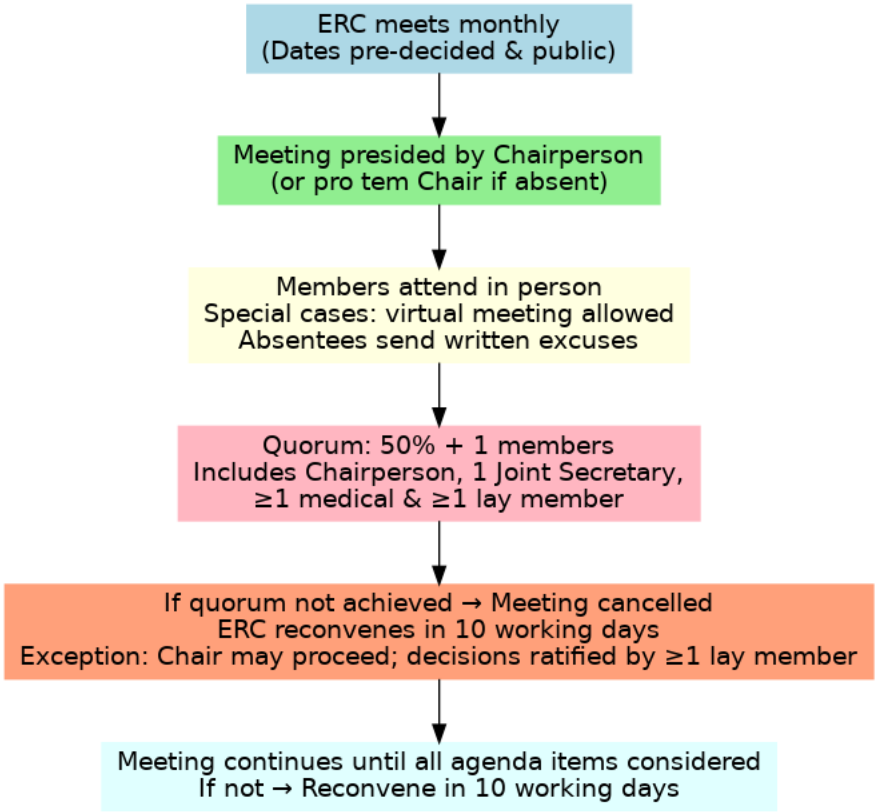
16.9. Any member of the ERC who has any interest, financial or otherwise, in an application or other related matter(s) considered by the ERC must declare such an interest beforehand. This will be dealt with in accordance with SOP 006.

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

16.11. At least one primary reviewer is expected to be present at the meeting, to lead the discussion. In circumstances where one/both reviewers cannot be present, they must inform the Chairperson/a Joint Secretary and provide a written review to be tabled at the meeting.

16.12. Members who cannot be present, may provide written comments to a Joint Secretary regarding any agenda items. These will be tabled at the meeting.

WORKFLOW



Reference Number	**SOP 017(a)**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Conduct of meetings - CTSC**
Purpose	**To describe the format and conduct of meetings of the CTSC**
Scope	**Outlines the procedures for the conduct of CTSC meetings.**
Responsibility	**It is the responsibility of the Chairperson of the CTSC to conduct the meetings, while the CTSC Secretary is responsible for ensuring logistical arrangements and accurate documentation to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

17(b).1. The CTSC shall meet on monthly basis. Dates of CTSC meetings for the year shall be pre-decided and made available to all committee members.

17(b).2. The meeting will be presided over by the Chairperson/CTSC, and in their absence a *pro tem* chairperson will be nominated by the members.

17(b).3. Members will attend CTSC meetings in person. In special circumstances the meeting may be conducted as a virtual meeting. Members who are unable to attend a meeting should send an excuse in writing to the secretary before the meeting. The minutes should record the submission of excuses.

17(b).4. A quorum must be present in order for the CTSC to reach a final decision on any agenda item. A quorum shall exist when at least 50% +1 members, including the chairperson, secretary is present. To calculate the 50%, the members from whom valid excuses have been received will be excluded when calculating the denominator. In discussions where one or more members excuse themselves from the meeting due to conflicts of interest, the quorum shall be re-calculated as above.

17(b).5. If the meeting does not achieve quorum, the Chairperson/CTSC may cancel the scheduled meeting. Should this occur, the CTSC will convene as a physical or virtual meeting within 2 working days of the cancelled meeting. However, in exceptional circumstances the chairperson may proceed in the absence of the quorum.

17(b).6. Meetings will 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 CTSC will reconvene as a physical or virtual meeting within 2 working days to complete the agenda.

17(b).7. The CTSC meeting will be conducted in such a manner as to ensure confidentiality and open discussion.

17(b).8. Notwithstanding paragraph 7, the CTSC may agree to the presence of visitors or observers at a meeting. Such observers/visitors should sign a confidentiality agreement.

17(b).9. Any member of the CTSC who has any conflict of interest, financial or otherwise, in an application or other related matter(s) considered by the CTSC must declare such a conflict of interest beforehand. This will be dealt with in accordance with SOP 006.

17(b).10. All deliberations will be conducted in a manner that is non-offensive, unbiased, sensitive and inclusive.

17(b).11. At least one primary reviewer is expected to be present at the meeting, to lead the discussion. In circumstances where one/both reviewers cannot be present, they must inform the Chairperson/CTSC or Secretary/CTSC and provide a written review to be tabled at the meeting.

17(b).12. Members who cannot be present, may provide written comments to the secretary regarding any agenda items. These will be tabled at the meeting.

17(b).13. Attendance at meetings - A minimum physical attendance requirement of 6 of 12 meetings per year and not more than two consecutive absences (without excuses) from meetings is required. If any member fails to fulfil the above requirements, they will cease to be part of the CTSC.

Reference Number	**SOP 017(b)**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Conduct of meetings - ARWSC**
Purpose	**To describe the format and conduct of meetings of the ARWSC**
Scope	**Outlines the procedures for the conduct of ARWSC meetings.**
Responsibility	**It is the responsibility of the Chairperson of the ARWSC to conduct the meetings, while the ARWSC Secretary is responsible for ensuring logistical arrangements and accurate documentation to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

17(b).1. The ARWSC shall meet as and when required, depending on submissions received (e.g., new protocols, progress reports, amendments, or other matters requiring review).

17(b).2. The meeting will be presided over by the Chairperson/ARWSC, and in their absence, a pro tem chairperson will be nominated by the members present.

17(b).3. Members are expected to attend ARWSC meetings in person. In special circumstances, the meeting may be conducted virtually. Members who are unable to attend should provide an excuse in writing to the Secretary/ARWSC before the meeting. The submission of excuses will be recorded in the minutes.

17(b).4. A quorum must be present for the ARWSC to reach a final decision on any agenda item. A quorum shall exist when at least the Chairperson/ARWSC, Secretary/ARWSC, and at least one other member, are present.

17(b).5. If quorum is not achieved, the meeting may be rescheduled. In exceptional circumstances, the Chairperson/ARWSC may proceed in the absence of quorum.

17(b).6. Meetings will continue until all agenda items have been considered. If all items cannot be completed in one sitting, the ARWSC will reconvene within 10 working days (or as soon as feasible) to complete the agenda.

17(b).7. Meetings will be conducted in a manner that ensures confidentiality and open discussion.

17(b).8. The ARWSC may agree to the presence of visitors or observers at a meeting. Such observers/visitors must sign a confidentiality agreement.

17(b).9. Any member of the ARWSC who has an interest, financial or otherwise, in a submission under review must declare such interest beforehand. This will be dealt with in accordance with SOP 006.

17(b).10. All deliberations will be conducted in a manner that is respectful, unbiased, sensitive, and inclusive.

17(b).11. Members unable to attend may provide written comments to the Secretary/ARWSC on any agenda items. These will be tabled at the meeting.

Reference Number	**SOP 018**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Minutes of ERC meetings**
Purpose	**To describe the preparation and format of minutes of a meeting of the ERC**
Scope	**Outlines the procedures for preparing, formatting and maintaining minutes of ERC meetings**
Responsibility	**It is the responsibility of the ERC Joint Secretaries to accurately record, prepare, and archive the minutes, in consultation with the Chairperson to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

18.1. The Joint Secretaries of the ERC will prepare and maintain minutes of all meetings.

18.2. The format of the minutes will include and not be limited to the following items:

a) Members Present/Excused/Absent

b) Confirmation of Minutes

c) Matters Arising from Minutes

d) Declaration of Conflicts of Interests by ERC Members

e) Announcements / Welcome / In-house Training

f) Clinical Trials Sub Committee (CTSC)

g) Animal Research and Welfare Sub Committee (ARWSC)

h) Interim/Final Reports of Approved Protocols

i) Protocols Previously Considered by Full ERC, Referred to the Executive Committee for Approval

j) Protocols Previously Considered by the Full ERC Approval by the Full ERC

k) Approved Protocols for amendments by the Full ERC

l) Approved Protocols for amendments by the Executive Committee

m) Correspondence Regarding Approved protocols

n) Approved Protocols for extension of Approval Period by Executive Committee

o) Approved Protocols for extension of Approval Period by the Full ERC

p) New Protocols Exempt from Review

q) New Protocols Granted Expedited Review

r) New Protocols for Full ERC Review

s) Any other business

18.3. The minutes should include a record of decisions taken by the ERC and a summary of any relevant discussion. This may include views expressed by those not present at the meeting, any requests for additional information, clarification or modification of the proposal and any significant dissenting view or concerns.

18.4. Specific views shall not be attributed to individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded and where such recordings are deemed necessary by the ERC.

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

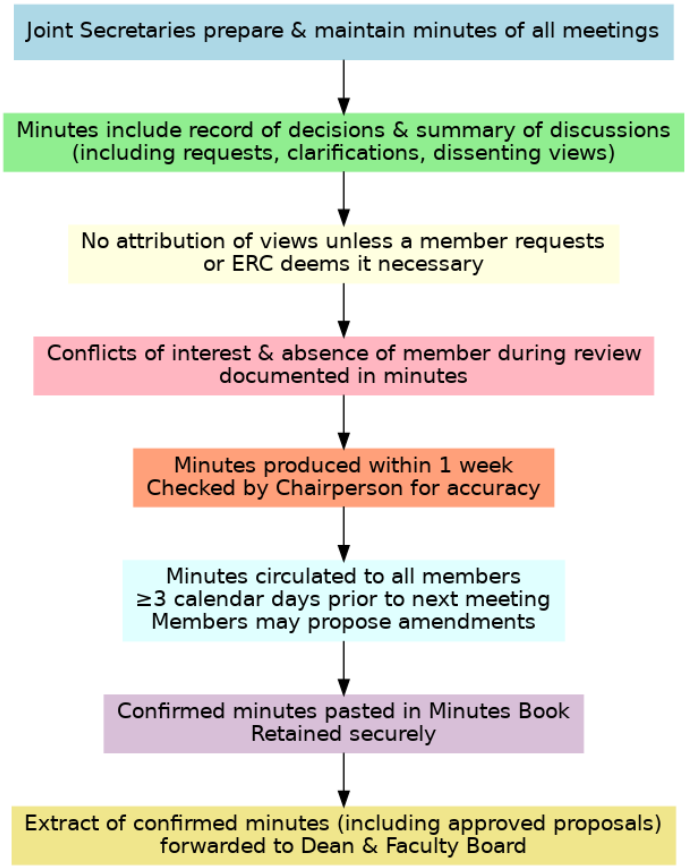
18.6. Minutes will be produced within one week of the meeting and will be checked by the Chairperson for accuracy.

18.7. The minutes will be circulated to all members of the ERC three (03) calendar days prior to the next ERC meeting. All members will be given the opportunity to propose amendments to the minutes prior to their confirmation.

18.8. Confirmed minutes of each meeting will be pasted in a Minutes Book and retained securely.

18.9. An extract of the confirmed minutes of each meeting, including a list of approved proposals shall be forwarded to the Dean and the Faculty Board for their information/approval.

WORKFLOW



Reference Number	**SOP 019(a)**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Minutes of meetings - CTSC**
Purpose	**To describe the preparation and format of minutes of a meeting of the CTSC**
Scope	**Outlines the procedures for preparing, formatting, and maintaining minutes of CTSC meetings**
Responsibility	**It is the responsibility of the CTSC Secretary to accurately record, prepare, and archive the minutes, in consultation with the CTSC Chairperson to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

19(a).1. The Secretary/CTSC will prepare and maintain minutes of all meetings.

19(a).2. The format of the minutes will include and not be limited to the following items:

a) Attendance - Present/Excused/Absent
b) Declaration of Conflicts of Interests by Members
c) Matters Arising from Minutes
    a. Correspondence regarding approved protocols
    b. Any other business
d) Applications under review
    - New applications
    - Revised proposals
e) Approved protocols for extension of approval period by the CTSC
f) Approved protocols for amendments by the CTSC
g) Interim/Final Reports of approved Protocols
h) Correspondence regarding approved protocols
i) Any other business

19(a).3. The minutes should include a record of decisions taken by the CTSC and a summary of any relevant discussion. This may include views expressed by those not present at the meeting, any requests for additional information, clarification or modification of the proposal and any significant dissenting view or concerns.

19(a).4. Specific views shall not be attributed to individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded and where such recordings are deemed necessary by the CTSC.

19(a).5. Declarations of conflicts of interest by any member of the CTSC and the absence of the member concerned during the consideration of the relevant application will be documented in the minutes.

19(a).6. Minutes will be produced within 24 hours of the meeting and shared with the committee members via email. The committee will be allowed a further 24 hours for to comment on its accuracy and confirmation.

19(a).7. An extract of the confirmed minutes of the monthly meeting will be submitted to the main ERC committee for discussion.

19(a).8. Any changes/suggestions that were suggested at the main ERC will be included under “matters arising from minutes” at the next CTSC meeting.

19(a).9. The confirmed minutes of each meeting will be pasted in a Minutes Book and retained securely.

Reference Number	**SOP 019(b)**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Minutes of meetings - ARWSC**
Purpose	**To describe the preparation and format of minutes of a meeting of the ARWSC**
Scope	**Outlines the procedures for preparing, formatting, and maintaining minutes of ARWSC meetings**
Responsibility	**It is the responsibility of the ARWSC Secretary to accurately record, prepare, and archive the minutes, in consultation with the ARWSC Chairperson to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

19(a).1. The Secretary/ARWSC will prepare and maintain minutes of all meetings.

19(a).2. The format of the minutes will include and not be limited to the following items:

a) Attendance - Present/Excused/Absent
b) Declaration of Conflicts of Interests by Members
c) Matters Arising from Minutes
    a. Correspondence regarding approved protocols
    b. Any other business
d) Applications under review
e) New applications
f) Revised proposals
g) Approved protocols for extension of approval period by the ARWSC
h) Approved protocols for amendments by the ARWSC
i) Interim/Final Reports of approved Protocols
j) Correspondence regarding approved protocols
k) Any other business

19(a).3. The minutes should include a record of decisions taken by the ARWSC and a summary of any relevant discussion. This may include views expressed by those not present at the meeting, any requests for additional information, clarification or modification of the proposal and any significant dissenting view or concerns.

19(a).4. Specific views shall not be attributed to individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded and where such recordings are deemed necessary by the ARWSC.

19(a).5. Declarations of conflicts of interest by any member of the ARWSC and the absence of the member concerned during the consideration of the relevant application will be documented in the minutes.

19(a).6. Minutes will be produced within 24 hours of the meeting and shared with the committee members via email. The committee will be allowed a further 24 hours for to comment on its accuracy and confirmation.

19(a).7. An extract of the confirmed minutes of the monthly meeting will be submitted to the main ERC committee for discussion.

19(a).8. Any changes/suggestions that were suggested at the main ERC will be included under “matters arising from minutes” at the next ARWSC meeting.

Reference Number	**SOP 020**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Notification of decisions of the ERC for new applications**
Purpose	**To describe the procedure for the notification of decisions of the ERC concerning the review of new applications**
Scope	**Outlines the procedures for communicating the ERC's decisions on newly submitted research application**
Responsibility	**It is the responsibility of the ERC Joint Secretaries with assistance from the ERC Staff to prepare and dispatch decision letters to applicants, with approval from the ERC Chairperson**

DETAILED INSTRUCTIONS

20.1. The decisions of the ERC with regard to new applications shall be conveyed in writing to the applicant within five (5) working days after such a decision has been taken barring exceptional circumstances. This letter shall include requests for clarifications and/or amendments.

20.2. The ERC decisions shall take one of the following forms:

a) Approved

b) Requires minor revisions

c) Requires major revisions

d) Rejected

20.3. Where revisions are required details of such revisions should be conveyed to the applicant. Wherever possible, reference should be made to the FERCSL Guidelines or other relevant documents or legislation to support the request.

a) The ERC should promote active communication with applicants to speedily resolve outstanding requests for revisions. The ERC may nominate one of its members to communicate directly with the Principal Investigator or under exceptional circumstances request the Principal Investigator or a nominee to attend the ERC meeting.

b) The letter requesting revisions shall be in the standard format set out (A/020/01/5.0 or A/020/02/5.0)

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

20.5. The approval letter shall be in writing and shall contain the following information:

a) The title of the project;

b) The name of the principal investigator(s);

c) The unique ERC protocol identification number;

d) The version number and date of all documents reviewed and approved by the ERC including protocols, patient information sheets, consent forms, advertisements, questionnaires etc

e) The date of the ERC meeting at which the proposal was first considered;

f) The date of the ERC's approval;

g) The conditions, if any, to which approval is subject;

h) Responsibility of the investigator to notify the ERC of any amendments to the protocol

i) Responsibility of the investigator to notify the ERC of any SAE

j) The period of validity of the ERC's approval

k) The frequency of progress reports

l) The date of submission of the final report

20.6. Research shall not commence until notification has been received by the applicant confirming approval.

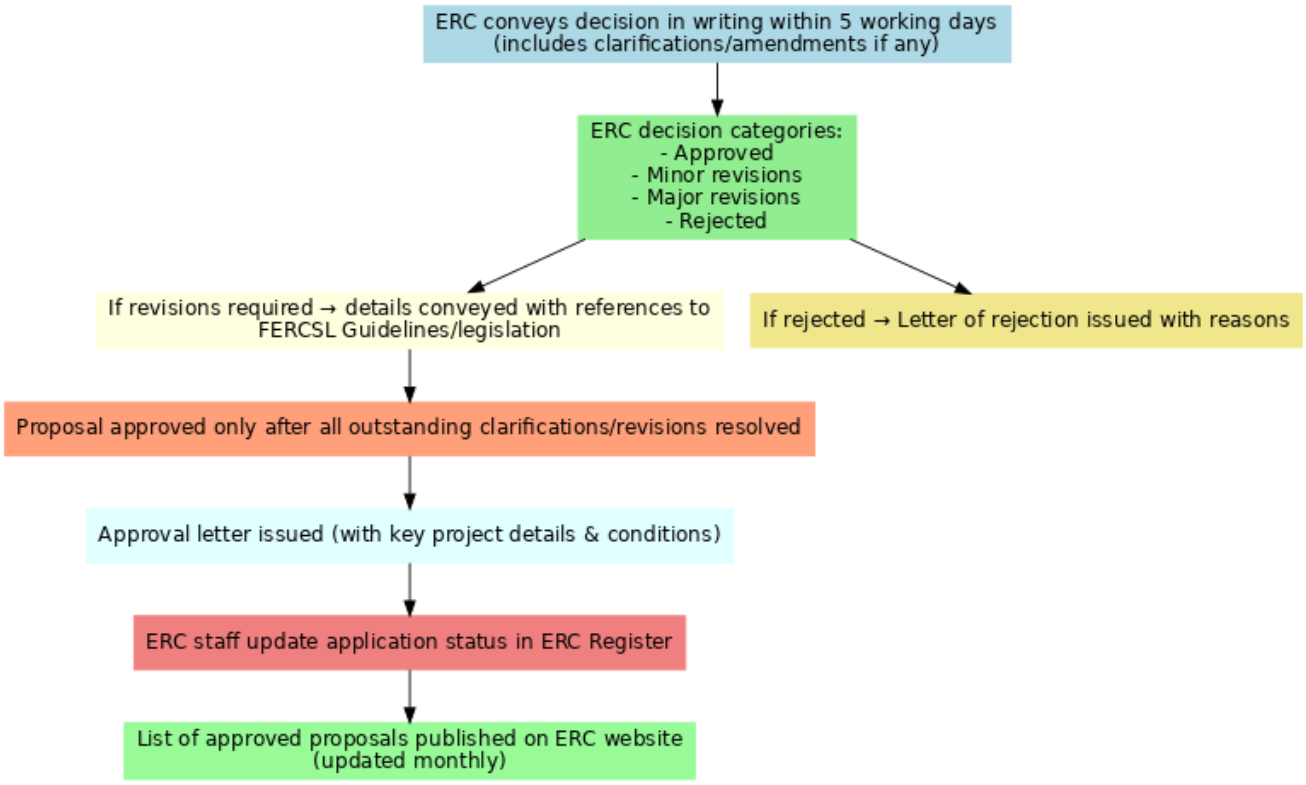
20.7. A standard approval letter shall be issued in the format set out (A/020/03/5.0 or A/020/04/5.0)

20.8. If the proposal is rejected on ethical or other grounds, the letter of rejection shall include the reasons on which the decision was made. The letter of rejection shall be in the standard format set out (A/020/05/5.0)

20.9. The status of the application shall be updated in the ERC's register, by the ERC Office Staff.

20.10. A list of approved proposals shall be included in the ERC website and updated on a monthly basis.

WORKFLOW



ANNEXURES: A/020/01/5.0; A/020/02/5.0; A/020/03/5.0; A/020/04/5.0; A/020/05/5.0

Reference Number	**SOP 021**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Monitoring of approved research projects**
Purpose	**To describe the procedure for monitoring research projects approved by the ERC to ensure compliance with ethics approval**
Scope	**Outlines the procedures for procedures for monitoring research projects approved by the ERC, including submission and review of progress/final reports and amendments**
Responsibility	**It is the responsibility of the Principal Investigator to submit timely reports and notify the ERC of any amendments/adverse events. The ERC Executive Committee and relevant subcommittees (CTSC/ARWSC) are responsible for review, while ERC staff handle receipt, tracking, and record keeping under the oversight of the Chairperson in compliance with this SOP**

DETAILED INSTRUCTIONS

21.1. The ERC shall monitor approved research projects to ensure compliance with its approval.

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

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

a) Written reports (annual progress / final report) ;

b) Random inspections of research sites, data and signed consent forms etc

c) Interviews, of research participants, with their prior consent

21.4. For all approved project submission of annual progress reports (except clinical trial) and a final report at the conclusion of the study, by the PI is mandatory. In the case of clinical trials, the ERC shall require quarterly reports, in addition to the final report.

21.5. Progress/final reports of clinical trials / animal research shall be reviewed initially by the relevant sub-committee (CTSC/ARWSC) with subsequent reporting to the ERC.

21.6. The progress / final reports shall contain the following information, submitted in the stipulated format (A/021/01/5.0 or A/021/02/5.0):

a) progress to date or outcome in the case of completed research;

b) statements regarding maintenance and security of records;

c) statements supporting compliance with the approved protocol;

d) statements supporting compliance with any conditions of approval

21.7. If the study continues for a period beyond one year, the PI is required to furnish an annual progress report for the year and an application for the extension of approval by a further year.

21.8. The progress / final reports will be reviewed and approved by the Executive Committee and will be tabled at the meeting of the main committee for any further queries and ratification of approval.

21.9. If a PI has three or more research proposals in which the progress reports and/or final reports have lapsed in this manner, no further applications for ethics review shall be entertained from the same PI.

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

a. proposed changes in the project;

b. any unforeseen events that might affect continued ethical acceptability of the study; and

c. new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the study, or which may indicate the need for amendments to the protocol.

21.11. The ERC shall require, as a condition of approval of each application, that investigators inform the ERC, giving reasons, if the research study is discontinued before expected completion.

21.12. Where the ERC is satisfied that circumstances have arisen which prevents a research study from being conducted in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC shall inform the principal investigator and the institution of such withdrawal of approval in writing (A/021/03/5.0) and recommend that the research study be discontinued or suspended, together with other necessary steps be taken.

ANNEXURES: A/021/01/5.0; A/021/02/5.0; A/021/03/5.0

Reference Number	**SOP 022**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Amendments and extensions to approved projects**
Purpose	**To describe the procedure for the submission and ERC review of amendments and extensions to approved projects**
Scope	**Outlines the procedures for submission, receipt, initial screening, and review of all research applications for amendments and extensions of approved project, submitted to the ERC**
Responsibility	**It is the responsibility of ERC office to ensure applications are received, and documented, while the Executive Committee is responsible for screening, and allocating for review (if required) in compliance with this SOP**

DETAILED INSTRUCTIONS

22.1. The principal investigator may seek approval for amendments to a project that has been approved, including changes in the manner of conducting the research, and/or extensions to the period for which approval has been given, on/before the lapse of such approval. Such requests shall be in writing and include:

a) details of the nature of the proposed amendments given as a table with previous approved and propose changes with reasons, and/or reasons for request for extension, accompanied by an up-to-date progress report in the standard format (A/021/01/5.0 or A/021/02/5.0);

b) an assessment of the ethical implications, if any, that arise as a result of the amendment or extension;

c) a set of documents incorporating the amendments identified by revised version numbers and dates. The amendments should be highlighted.

22.2. The PI is required to furnish a duly completed application for extension along with an annual progress for each year as long as the study continues. If no such application is made by the due date (which is the final date of ethics approval in force), the ERC approval lapses automatically.

22.3. In circumstance where the submission is made within one month of the due date (which is the final date of ethics approval in force) the ERC may consider such applications for extension. For such applications the PI should provide evidence to the statisfcation of the ERC that no protocol deviations and/or participant recruitement has not taken place after the lapse of ERC approval. The extension granted for such projects shall be one year from the date of extension application.

22.4. If the request for extension is delayed more than 1 month beyond the due date (which is the final date of ethics approval in force), the PI will be required to submit the project as a

new application as per SOP 007, should he/she wishes to resume the study.

22.5. All requests for amendments and/or extensions shall be reviewed by the ERC at its next meeting, provided the duly completed request has been received by the ERC office by the stipulated deadline.

22.6. The ERC Executive Committee may undertake expedited review of requests for minor amendments between scheduled meetings at the discretion of the Chairperson and in accordance with SOP 009, provided that its decisions are ratified at the next scheduled ERC meeting;

22.7. The ERC shall report in writing to the principal investigator within five (5) working days of the meeting at which the request was considered (the scheduled ERC meeting or the Executive Committee meeting as the case may be).

a) Approval of amendments requested shall be as in the approval letter set out (A/022/01/5.0)

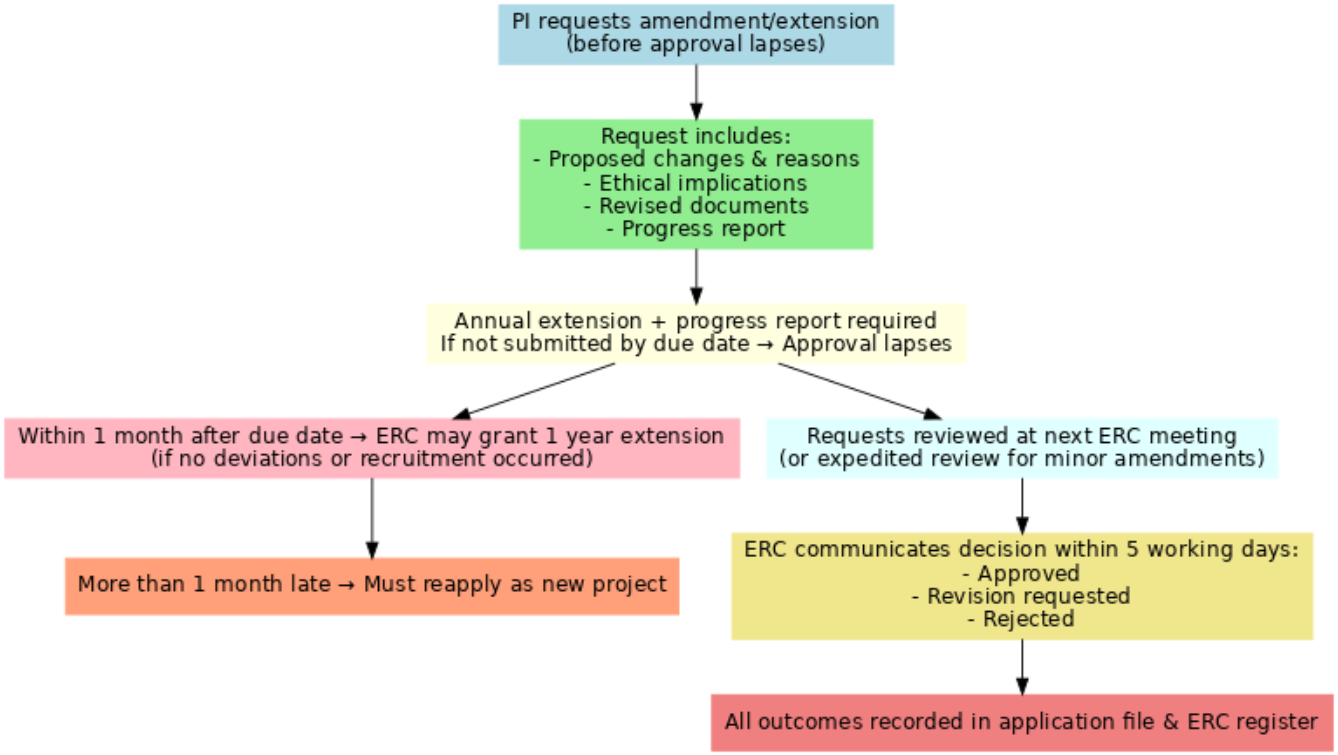
b) Approval of extension of the period of validity shall state the new period for which approval has been given with dates. This letter shall be in the format set out (A/022/02/5.0)

22.8. If the ERC finds that further information, clarification or modification is required for the consideration of the request for amendment or extension, the applicant should be so informed with reasons and the information requested should be clearly set out. Wherever possible, requests for additional information/clarification/modification should refer to the FERCSL Guidelines or relevant pieces of legislation. The letter shall be in the format as set out in (A/020/01/5.0 or A/020/02/5.0)

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

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

WORKFLOW



ANNEXURES: A/020/01/5.0; A/020/02/5.0; A/021/01/5.0; A/021/02/5.0; A/022/01/5.0; A/022/02/5.0

Reference Number	**SOP 023**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Management of Premature Termination/Suspension/Discontinuation**
Purpose	**To describe the procedure for terminating a study, either due to serious non-compliance or regulatory breaches, or at the request of the Principal Investigator/Sponsor**
Scope	**Applies to all research studies approved by the ERC, covering circumstances and procedures for termination** **The ERC is responsible**
Responsibility	**It is the responsibility of the ERC to review circumstances leading to termination and ensuring appropriate action. Principal Investigators/Sponsors are responsible for notifying the ERC of voluntary termination and providing the required documentation, in compliance with this SOP**

DETAILED INSTRUCTIONS

23.1. Premature Termination of a study can be initiated by the ERC or by the Principal Investigator

23.2. The following procedure shall be followed when the termination is initiated by the ERC

a) Receive Recommendation

i. The ERC may receive recommendations for study termination from: ERC members, Sponsor or Authorized bodies (e.g., DSMB)

ii. The PI will be requested to submit a Study Termination Memorandum.

iii. The ERC Office Staff shall initial and date the documents upon receipt.

b) Review and Discussion

i. The ERC Office Staff shall notify the Chairperson within 1 working day of receiving the recommendation.

ii. The Chairperson reviews results, reasons, and accrual data.

iii. The Chairperson convenes an emergency ERC meeting within 5 working days to discuss the recommendation.

c) Decision and Documentation: The ERC shall notify the PI of its decision within 7 working days of receiving the recommendation to terminate.

d) Record Keeping

i. The Study Termination Memorandum and decision shall be filed in the protocol file.

ii. Protocol documents shall be securely stored for 5 years.

23.3. The following procedure shall be followed when the termination is initiated by the Principal Investigator

a) Notification: The PI shall notify the ERC in writing of the decision to terminate the study.

b) Submission of Documentation: The PI shall submit a Study Termination Memorandum.

c) Review by ERC

   i. The ERC reviews the PI's notification and supporting documents.

   ii. The ERC discusses the reasons for termination at its next scheduled meeting or an emergency meeting if required.

d) Decision and Action: The ERC may;

   i. Accept the termination with acknowledgement, or

   ii. Request further clarification or supporting data, or

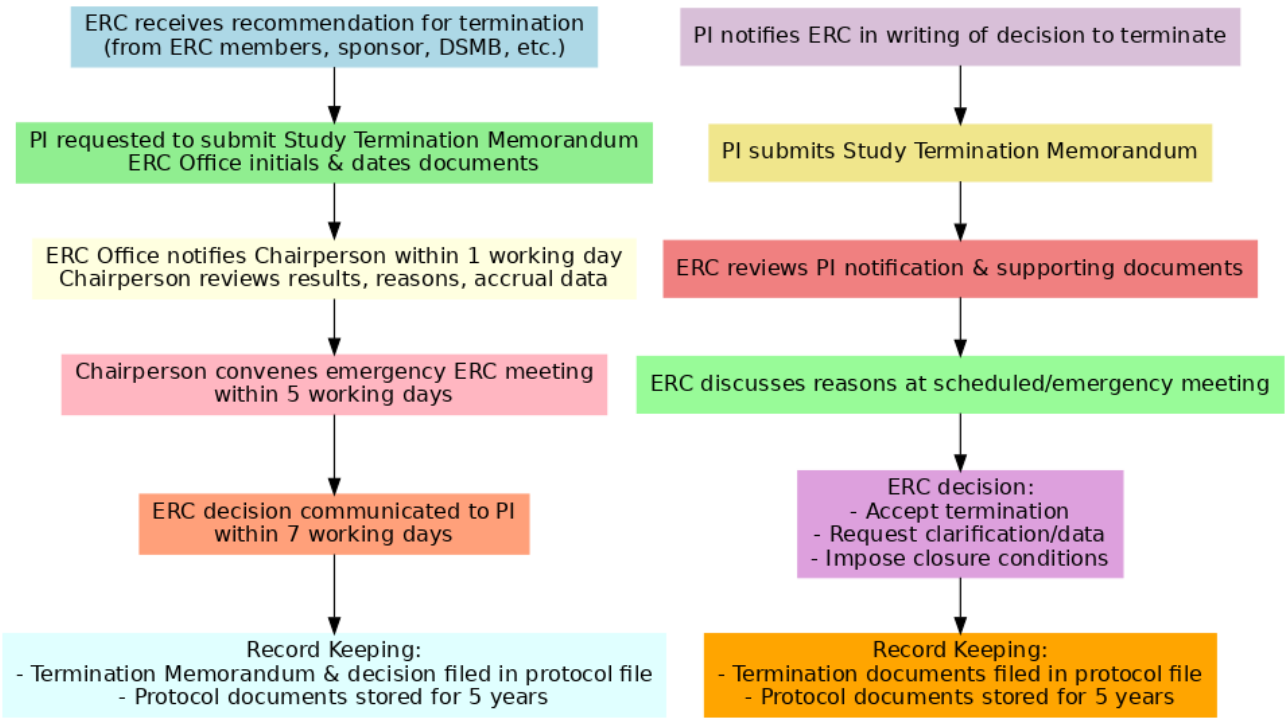
   iii. Impose conditions for study closure.

e) Record Keeping

   i. The ERC office shall file all submitted termination documents in the protocol file.

   ii. Protocol documents shall be retained for 5 years.

WORKFLOW



Reference Number	**SOP 024**
Last Revised	**August 2025**
Version	**1.0**
Subject	**Review of Protocol Deviations/Violations/Waiver/Non-Compliance**
Purpose	**To describe the procedure for documenting and taking action against investigators or institutions that fail to adhere to approved protocols, ethical guidelines, in accordance with national and international standards for human research**
Scope	**Outlines the procedures for submission, receipt, initial screening, and review of all research applications for amendments and extensions of approved project, submitted to the ERC**
Responsibility	**It is the responsibility of ERC office to ensure applications are received, and documented, while the Executive Committee is responsible for screening, and allocating for review (if required) in compliance with this SOP**

DETAILED INSTRUCTIONS

24.1. All issues of noncompliance, violations, or deviations by investigators must be included in the agenda of the ERC meeting for formal discussion and decision-making.

24.2. The ERC Office Staff shall maintain a Non-compliance File containing:

a) Names of investigators found to be non-compliant.

b) Nature and details of violations (e.g., protocol deviations, failure to follow stipulations, or non-response to ERC requests).

c) Relevant correspondence and evidence.

24.3. During the ERC meeting, members will review the case and may decide on one or more of the following actions:

a) Temporary Suspension – pause approval until corrective measures are taken.

b) Revocation of Approval – withdraw approval for the ongoing study.

c) Refusal of Future Application – decline to accept or review subsequent applications from the investigator, in cases of, Major violations conducted without informing the ERC or Excessive protocol deviations.

24.4. The ERC Chairperson shall notify the investigator in writing of the decision. The letter must clearly state the nature of noncompliance and the specific action taken.

24.5. Notification must be documented as follows:

a) Original copy: Sent to the Investigator

b) Copy 1: Sent to the relevant National Authorities and Institutes

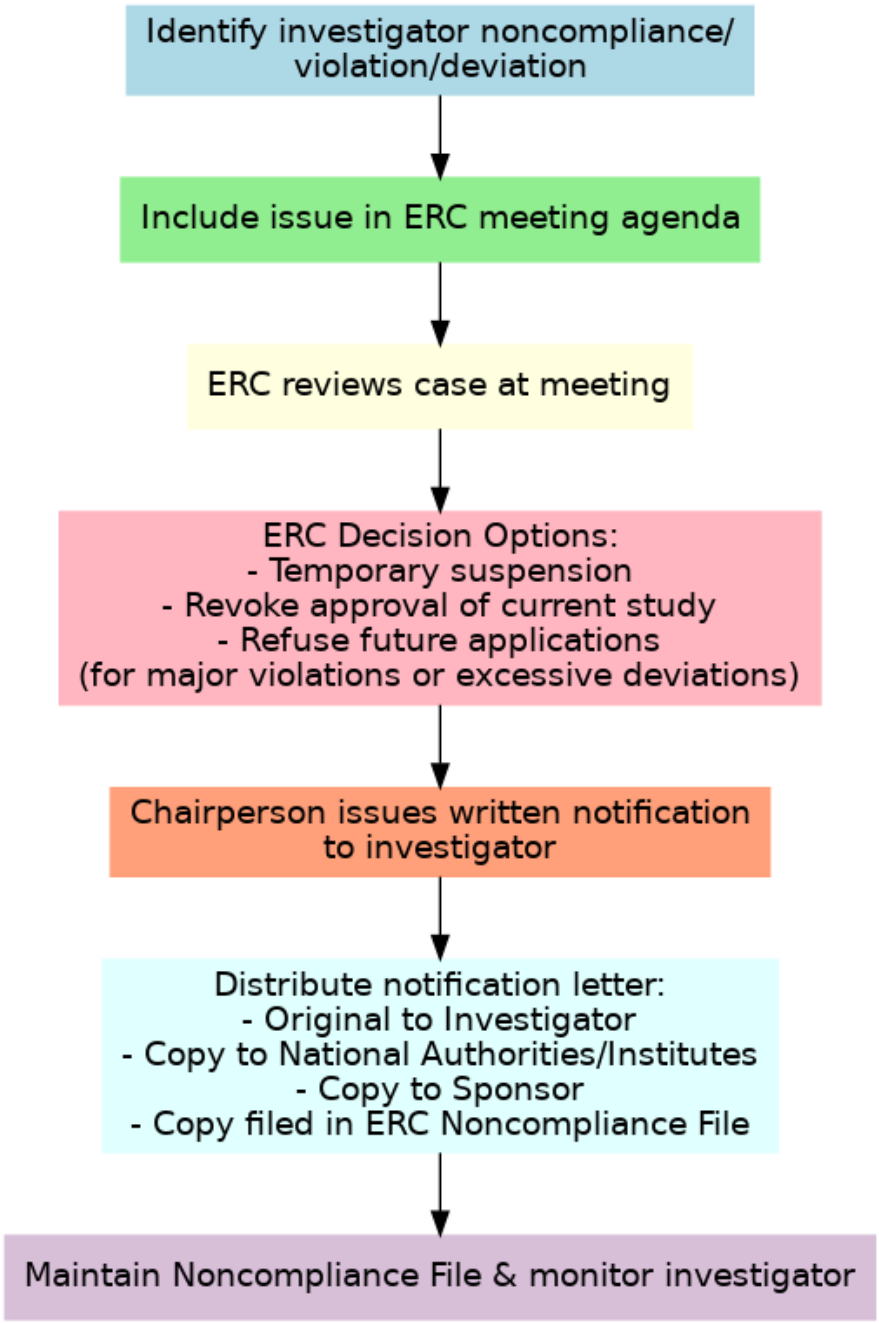
c) Copy 2: Sent to the Sponsor of the Study (if applicable)

d) Copy 3: Filed in the ERC's official Noncompliance File

24.6. The ERC will monitor compliance following the notification.

24.7. Repeated or unresolved noncompliance may result in escalation, including permanent restrictions on investigator submissions.

WORKFLOW



Reference Number	**SOP 025**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Handling of Suspected Unexpected Serious Adverse Reactions (SUSAR) or Serious Adverse Events (SAE)**
Purpose	**To describe the procedure for reporting and handling of SUSARs and SAEs**
Scope	**Outlines the procedures for timely identification, documentation, assessment, reporting and follow-up of SUSARs and SAEs in compliance with applicable regulatory and ethics requirements**
Responsibility	**It is the responsibility of the ERC Joint Secretaries and ERC Office Staff to receive, record and track these reports and ensuring that the ERC reviews and responds appropriately. The ERC and CTSC are responsible for evaluating the safety information and making decisions regarding the continuation, modification, or termination of the study based on the reported events in compliance with this SOP**

DETAILED INSTRUCTIONS

25.1. Suspected Unexpected Serious Adverse Reactions (SUSAR) or Serious Adverse Events (SAE) should be reported to the ERC.

a) This requirement includes those that have occurred at other sites in the case of Multi Centre Studies.

b) The current guidelines of the National Medicinal Regulatory Authority (NMRA) of Sri Lanka stipulate the following timelines for reporting such events occurring at local trial sites:

i. fatal or life-threatening event in a patient on a trial or within 30 days off trial: report as soon as possible, but no later than seven calendar days.

ii. events, other than fatal and life threatening, in a patient on a trial or within 30 days off trial: report as soon as possible, but no later than fifteen calendar days.

25.2. Notifications of SUSARs and SAEs must be submitted in the format as set out (A/025/01/5.0) and shall include all the documents required. These documents shall include at least:

a) 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;

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

c) *Evaluation report of the Data and Safety Monitoring Board appointed as per the approved protocol

*this may not be available if the SUSAR/SAE is reported immediately, in that case these should be submitted before the given deadlines

25.2. Other safety issues requiring expedited reporting to the ERC: These qualify for expedited reporting where they might materially alter the current benefit-risk assessment of an investigational medicinal product or that would be sufficient to consider changes in the investigational medicinal products administration or in the overall conduct of the trial, such as:

a) an increase in the rate of occurrence or a qualitative change of an expected serious adverse reaction, which is judged to be clinically important

b) post-study SUSARs that occur after the patient has completed a clinical trial and are reported by the investigator to the sponsor

c) new events related to the conduct of the trial or the development of the investigational medicinal products and likely to affect the safety of the subjects, such as:

I. a serious adverse event which could be associated with the trial procedures, and which could modify the conduct of the trial,

II. a significant hazard to the subject population such as lack of efficacy of an investigational medicinal product used for the treatment of a life-threatening disease,

III. a major safety finding from a newly completed animal study (such as carcinogenicity)

IV. any anticipated end or temporally halt of a trial for safety reasons and conducted with the same investigational medicinal products in another country by the same sponsor,

d) recommendations of the Data and Safety Monitoring Board, if any, where relevant for the safety of the subjects

25.3. Upon receipt of a SUSAR/SAE report, the ERC Office shall immediately forward the communication and all relevant documents to the following individuals: (1) Chairperson and Joint Secretaries of the ERC (2) Chairperson and Secretary of the clinical trial subcommittee (CTSC).

25.4. After reviewing the submitted documentation and, consulting with the individuals listed above, the Chairperson of the ERC shall, within three working (3) days, initiate one or more of the following actions**.** The Principal Investigator (PI) shall confirm agreement within three (3) days (if applicable):

a) Acknowledge receipt of the report and accompanying documents

b) Request additional information or clarification, if required

c) Temporarily suspend recruitment of new participants, if deemed necessary

d) Impose immediate suspension of ethics approval, if warranted

e) Notify the National Medicines Regulatory Authority (NMRA)

f) Constitute a special committee for further review

g) Refer the matter to the next scheduled CTSC meeting

h) Take any other action deemed appropriate under the circumstances

25.5. Subsequently, these reports shall be reviewed by a "special/subcommittee" of the CTSC within one week of notification of the event. Secretary/CTSC will convene this meeting. All the relevant information shall be shared with the members of the special committee before the meeting

25.6. The special committee shall consist of the following

a) Chairperson CTSC

b) Secretary CTSC

c) A clinical/academic pharmacologist

d) A clinical/academic pharmacist (if applicable)

e) A member with special training / interest in the clinical discipline

25.7. The special subcommittee of the CTSC shall recommend one or more of the following courses of action to the Executive Committee of ERC, not later than 2 days of the meeting

a) Immediate request for additional information**

b) Immediate suspension of ethics approval

c) Immediate termination of ethics approval

d) a notation on the proposal file of the occurrence

e) increased monitoring of the research

f) a request for an amendment to the protocol and/or patient information sheet / consent form

g) any other action deemed appropriate under the circumstances

**PI should be given a maximum of three days to provide the additional information, once received the process will take the same course as given above

25.8. The above recommendations shall be sent to the PI within 3 working days of the review meeting. Agreement of the PI with the decision of the ERC to be received within 3 working days of sending the decision. PI can subsequently notify the actions taken based on agreed decisions

25.9. Minor adverse events may be reviewed by the CTSC at its routine monthly meeting and an appropriate course of action should be determined with the consultation of the executive committee of ERC. This may include:

a) a notation on the proposal file of the occurrence;

b) increased monitoring of the research;

c) a request for an amendment to the protocol and/or patient information sheet/consent form;

d) suspension of ethics approval; or

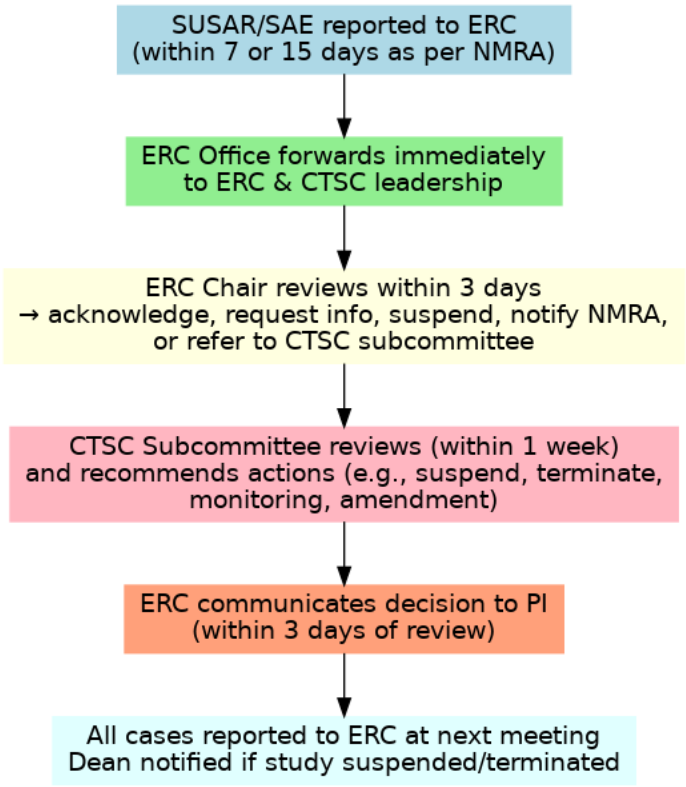
e) termination of ethics approval.

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

25.11. The ERC will inform the investigator that it has received notification of the SUSAR or SAE, and the course of action it has deemed necessary.

25.12. The Chairperson of ERC will immediately notify the Dean (or nominee) if a research study has been suspended or terminated because of a SUSAR or SAE.

WORKFLOW



ANNEXURES: A/025/01/5.0

Reference Number	**SOP 026**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Appeals and Complaints concerning the ERC review process**
Purpose	**To describe the procedure for receiving and handling appeals or complaints from investigators about the review process or functions of the ERC**
Scope	**Outlines the procedures regarding the receipt, documentation, and resolution of appeals or complaints related to the ERC's review process.**
Responsibility	**It is the responsibility of the ERC Chairperson to address appeals or complaints in a fair and timely manner, with support from the ERC Joint Secretaries and, if necessary, consultation with the full committee to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

26.1. Any appeals, concern or complaint about the ERC's review process should be directed to the attention of the Chairperson of the ERC in the standard format (A/026/01/5.0) detailing in writing the grounds of the appeal, concern or complaint.

26.2. A panel consisting of the executive committee and two reviewers will review the documents, considering the grounds of the appeal and

a) Dismiss the appeal and uphold the original decision of the ERC or

b) Call for a fresh review

26.3. All complaints received by the Chairperson ERC shall be notified to the Dean. Complaints may also be made directly to the Dean using the same standard format, at which point the Dean may notify the Chairperson ERC of the complaint (A/026/01/5.0).

26.4. Upon receipt of such complaint, the Dean shall determine whether the complaint requires further investigation, based on its validity, the mandate and SOPs of the ERC.

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

26.6. The panel will include, at least, the following members:

a) The Dean or his/her nominee, as convenor of the panel and

b) Two nominees of the Dean, and where the complaint concerns the rejection of an application, at least one such nominee should be an expert in the relevant area of study.

The members nominated to the panel shall not be members of the ERC or any persons affiliated with the project concerned.

26.7. The panel shall convene within 14 days of appointment and will afford the ERC and the complainant the opportunity to make submissions in writing, prior to such meeting.

26.8. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external experts. In conducting its review, the panel shall be concerned with ascertaining whether the ERC acted in accordance with the FERCSL Guidelines, its mandate and its Standard Operating Procedures.

26.9. The panels' decision shall be documented by/be formally informed to the Dean. The Dean will notify the complainant and the ERC of the outcome of the investigation. The outcomes of the investigation may include:

a) The complaint is dismissed, and no further action is needed.

b) The complaint is accepted but no remedial action is possible.

c) The complaint is accepted, and remedial action is needed.

26.10. The panel may make recommendations about the remedial action that is needed and also recommendations to modify the operation of the ERC including actions such as:

a) re-evaluation of a proposal for ethics approval

b) a review of the Standard Operating Procedures;

c) a review of the ERC's membership

d) remedial action in relation to a member of the ERC/CTSC/ARWSC or a designated sub-committee

ANNEXURES: A/026/01/5.0

Reference Number	**SOP 027**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Complaints about the conduct of a research project approved by the ERC**
Purpose	**To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of research approved by the ERC**
Scope	**Outlines the procedures regarding the receipt, documentation, and resolution of complaints related to research approved by the ERC**
Responsibility	**It is the responsibility of the ERC Chairperson to address complaints in a fair and timely manner, with support from the ERC Secretary and, if necessary, consultation with the full committee to ensure compliance with this SOP**

DETAILED INSTRUCTIONS

27.1. The ERC office, Chairperson or Joint Secretaries shall accept complaints from research participants, researchers, or other interested persons about the conduct of approved research.

27.2. Such complaints may be submitted via email, post, telephone and/or in-person.

27.3. Relevant contact information of the ERC must be included in the participant information sheet of all approved research projects. In addition, procedures for complaints shall be clearly stated in the ERC website.

27.4. The Joint Secretaries are 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.

27.5. If the ERC considers the complaint to be of a sufficiently serious nature, the Chairperson will bring it to the attention of the Dean as soon as possible.

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

27.7. The Chairperson or Joint Secretaries 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. The results of such an enquiry shall be conveyed to the complainant and the PI in a timely manner.

27.8. The Chairperson will inquire into the complaint and confirm its validity.

27.9. If a complaint is found valid, the Chairperson shall appoint an incident review committee to investigate the complaint. The committee will include, at least, the following members:

a) The Chairperson or his/her nominee and

b) A Joint Secretary as convenor of the committee and

c) One nominee of the ERC with expertise in the relevant area of study.

27.10. The investigation will take no longer than 4 weeks from the time of notification of concern/complaint unless exceptional circumstances exist. Both the complainant and PI will be given an opportunity to make submissions.

27.11. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external experts. In conducting its review, the panel shall be concerned with ascertaining whether the ERC acted in accordance with the FERCSL Guidelines, its mandate and its Standard Operating Procedures.

27.12. The Committees decision is informed to the ERC. The final recommendation of the ERC may include:

a) amendments to the proposal, including increased monitoring by the ERC;

b) suspension of the research till remedial action has been taken;

c) termination of the study; or

d) other action to address issues raised by the complainant.

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

27.14. In such an instance as in 11.13 above, the Chairperson of the ERC will provide the Dean or his/her nominee with all relevant information including:

a) the nature of the complaint;

b) material reviewed in the committee's investigation inquiry;

c) the results committee's inquiry; and

d) any other relevant documentation and pertinent information.

27.15. The Dean 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 Dean will inform the complainant and the Chairperson of this.

27.16. If the Dean 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. The panel will include, at least, the following members:

a) the Dean or his/her nominee, as convenor of the panel;

b) two nominees of the Dean (who are not members of the ERC);

c) the ERC Chairperson or his/her nominee.

27.17. 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.

27.18. 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.

27.19. Either the appeal is dismissed and the decision of the Chairperson upheld; or the Dean directs suitable action to be taken to resolve outstanding issues raised in the appeal.

Reference Number	**SOP 028**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Record keeping**
Purpose	**To describe the procedure for the preparation and maintenance of records of the ERC's activities**
Scope	**Outlines the procedures for systematic preparation, storage, retrieval, and archiving of all records related to ERC activities.**
Responsibility	**It is the responsibility of the ERC Joint-Secretaries and ERC Office Staff to prepare, maintain, and securely store records, while the Chairperson has overall responsibility for ensuring compliance with this SOP**

DETAILED INSTRUCTIONS

28.1. The Joint Secretaries of the ERC will prepare and maintain written records of the ERC's activities, including agendas and minutes of all meetings of the ERC, with the help of the ERC Office staff

28.2. A designated ERC Office Staff member will prepare and maintain a confidential electronic and/or paper record for each application received. This record shall contain a copy of the application, including signatures, all submitted documents, and any relevant correspondence including that between the applicant and the ERC, all approved documents and other material used to inform potential research participants.

28.3. In addition, a designated ERC Office Staff member shall maintain a confidential electronic and/or paper register of all the applications received and reviewed in accordance with the FERCSL Guidelines. This register shall contain the following information:

a) the unique project identification number;

b) the principal investigator(s);

c) the name of the responsible institution or organisation;

d) the title of the project;

e) whether the proposal was given expedited approval with date;

f) the ethics approval or non-approval with date;

g) the terms and conditions, if any, of approval of the project;

h) the approval or non-approval of any amendments/extensions to the project; and

i) action, if any, taken by the ERC to monitor the conduct of the research.

28.4. All relevant records of the ERC, including applications, membership, minutes and correspondence, will be maintained as confidential files/secure electronic storage.

28.5. To ensure confidentiality, hard copies of documents, which are no longer required, are to be disposed of in a secure manner, such as shredding or via confidential disposal bins.

28.6. All records pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention will be three (3) years after completion of the study. Files which are no longer required for retention shall be electronically archived. Retention periods shall comply with relevant national guidelines and the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).

Reference Number	**SOP 029**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Reporting**
Purpose	**To describe the mandatory reports of the ERC, their contents and distribution**
Scope	**Outlines the procedures preparing and distributing mandatory reports of the ERC, in compliance with institutional requirements**
Responsibility	**It is the responsibility of ERC Joint-Secretaries and ERC Office Staff to prepare and maintain the reports, while the ERC Chairperson is responsible for ensuring timely submission and distribution in compliance with this SOP**

DETAILED INSTRUCTIONS

29.1. An extract of the confirmed minutes of each meeting, including a list of approved proposals shall be forwarded to the Dean and the Faculty Board for their information/approval.

29.2. The ERC shall submit an annual report to the Faculty Board through the Dean at the end of every calendar year on its activities, including:

a) membership/membership changes;

b) number of meetings;

c) number of proposals reviewed, approved and rejected;

d) monitoring procedures for ethical aspects of research in progress and any problems encountered by the ERC in undertaking its monitoring role;

e) description of any complaints received and their outcome;

f) description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval; and

g) any other relevant issues arisen

29.3. The ERC shall maintain records of all financial transactions and summary of accounts prepared by the Bursar shall be reviewed by the ERC annually (February Meeting).

29.4. The ERC Terms of Reference, Standard Operating Procedures, a list of approved applications on a monthly basis and membership information shall be available in the public domain.

Reference Number	**SOP 030**
Last Revised	**August 2025**
Version	**5.0**
Subject	**Review of Terms of Reference and Standard Operating Procedures**
Purpose	**To describe the procedure for the amendment of the ERC Terms of Reference and Standard Operating Procedures**
Scope	**Outlines the procedures for periodic review, revision, and approval of the ERC Terms of Reference (ToR) and Standard Operating Procedures (SOPs) to ensures that these documents remain current, accurate, and aligned with national/international guidelines and institutional requirements**
Responsibility	**It is the responsibility of the ERC Chairperson to initiate and oversee the review process of the ToR and SOPs. The ERC Joint Secretaries are responsible for maintaining updated records of all approved versions and ensuring proper dissemination in compliance with this SOP**

DETAILED INSTRUCTIONS

30.1. The Terms of Reference (TOR) and Standard Operating Procedures (SOPs) shall be reviewed by the ERC at least every five years and amended as necessary. Any amendments shall be ratified if two thirds of the members agree to the amendment, with subsequent submission to faculty board for review and approval.

30.2. The TOR and SOPs may also be amended consequent to proposals made by ERC members or the Faculty Board.

30.3. For those proposals made by an ERC member:

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

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

c) The proposal shall be ratified if two thirds of the members agree to the amendment.

d) The Chairperson shall send the amendment to Faculty Board for review and approval.

30.4. For those proposals made by the Faculty Board:

a) The Dean shall send the proposal in writing to the ERC

b) The proposal shall be circulated to all ERC members for their consideration.

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

d) The proposal shall be ratified if two thirds of the members agree to the amendment.

e) The Chairperson shall send the decision of the ERC to the Faculty Board for review and approval.

30.5. For items recommended for SOP, the header should contain the SOP number, subject, version and revised date. Additionally, an SOP should comprise of the following items:

a) Purpose: A concise and accurate summary of what the document is to accomplish.

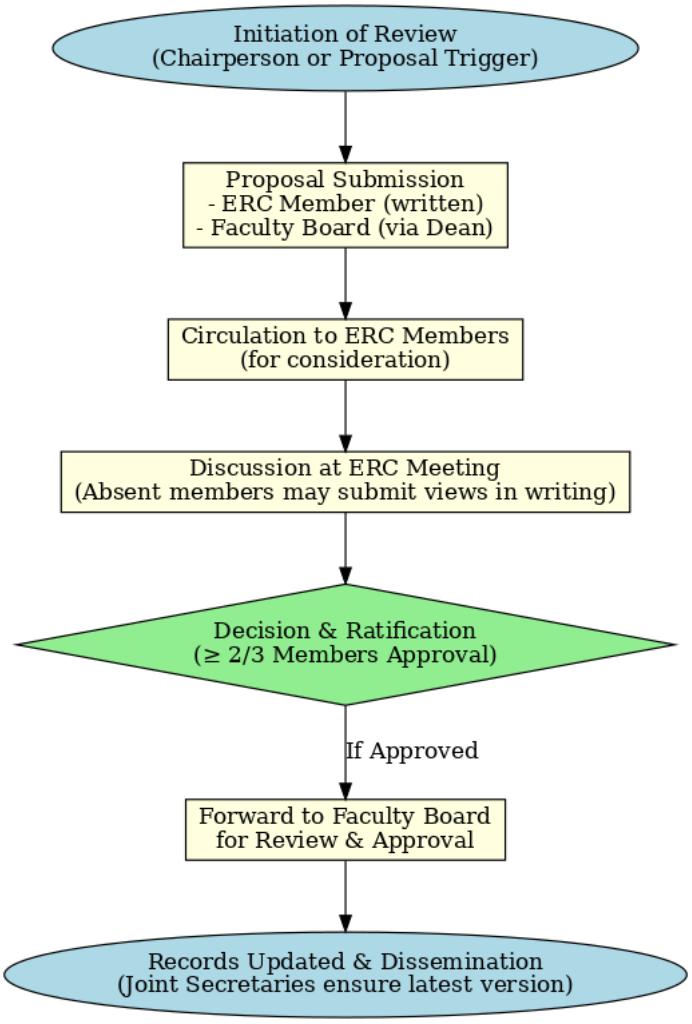
b) Scope: Description of the appropriate application of the document.

c) Responsibility: Responsibility for implementing the activities mentioned in the SOP

d) Detailed instructions: Description of the activities to be performed

e) Annexures: The annexures that will be used with the SOP. The Annexures will be coded as SOP A/No/Annexure No/Version No (e.g. A/001/01/1.0)

WORKFLOW



ANNEXURES

Annexure: A/003/01/5.0 (Letter of Appointment)

Dr. Prof

Department of,

Faculty of Medicine

University of Colombo

Dear Sir/Madam,

Appointment to the Ethics Review Committee

We are pleased to inform you that you have been appointed as a member of the ERC/CTSC/Animal Research and Welfare Subcommittee of the Ethics Review Committee of the Faculty of Medicine, University of Colombo with effect from..... for a period of.....

As a member of the committee you would be entrusted with the task of: **INCLUDE SPECIFIC TOR FROM SOP**

Please find the following documents attached:

1. Standard Operating Proceedures (SOP) of the ERC
2. Terms of Reference (TOR) of the ERC
3. Confidentiality Agreement
4. Terms of appointment of the members (See SOP 003 and TOR 7.3)
5. Conditions of appointment of the members (See TOR 7.4)
6. Current FERCSL Guidelines on Ethical Conduct in Human Research
7. National Guidelines for the Protection of Animals used in Research
8. List of names of members and contact information of the ERC

The Faculty of Medicine, University of Colombo will provide you indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. Please refer SOP and TOR on the ERC meeting attendance responsibilities and general responsibilites as an ERC member.

Please sign the attached confidentiality agreement and hand it over to the ERC office. Please provide a copy of your CV to be filed.

Thank You,

Yours Sincerely,

Prof.

Dean

Faculty of Medicine

University of Colombo

Dear Sir / Madam,

Acceptance of the Appointment

I hereby acknowledge and accept the appointment by the **Faculty of Medicine, University of Colombo** as a **Member** of the Ethics Review Committee, Faculty of Medicine, University of Colombo for the period……through ……..

Signature: .....

Name : .....

Date : .....

Annexure: A/003/02/5.0 (Confidentiality Agreement)

Ethics Review Committee, Faculty of Medicine, University of Colombo

Confidentiality Agreement

This Agreement is made and entered into on this ……day of ……by and between Ethics Review Committee, Faculty of Medicine, University of Colombo (hereinafter ERC) and …….. (Holder of NIC number ……..) Of ……

…….. (Hereinafter referred to as the "member")

WHEREAS the member has agreed to serve on the aforesaid ERC and in which capacity the member will have access to Confidential Information in the ERC;

AND WHEREAS the Member has acknowledged and agreed that the committee has and shall continue to have sole rights to the Confidential Information and has agreed to hold the same in strict confidence during and after the member's period of service within the ERC.

And it is hereby agreed as follows

1. Interpretation

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

2. Obligations of the member

   The member hereby undertakes:

   a. to maintain the highest degree of secrecy and keep as confidential any Confidential Information which the member may be granted access to, or which may be available to, or which member receives on behalf of the ERC or in the capacity of a member of the ERC by any means and to use such Confidential Information only in duty authorized manner in the interest of the ERC and from the purpose of fulfilling functions and responsibilities arising as a member of the ERC.

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

   c. on termination of the period of membership within the ERC, for whatever reason to return to the ERC all property, documents and papers in the members possessions or control relating to *inter alia* of the ERC

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

3. Legal compulsion to disclose

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

4. The member hereby unconditionally accepts and acknowledges that having regard to the nature of the ERC and the functions and duties of the member of the ERC the member considers the terms and conditions imposed herein as being fair and reasonable.

Signature of the member: ……..

Date: ……

Signature of the Chairperson of the ERC: …….

Date: …….

Annexure: A/003/03/5.0 (Declaration of Integrity)

DECLARATION OF INTEGRITY

[This Declaration is to be signed by every member of the Ethics Review Committee of the Faculty of Medicine, University of Colombo (ERC), upon appointment to such committee.

This Declaration governs issues relating to confidentiality of all matters dealt with by the ERC, any conflicts of interest that may arise during a member's tenure on the ERC, and other matters related to the integrity and honesty of the member.]

DECLARATION BY MEMBER:

I,……(Name)……OF……(Address) ……
HEREBY UNDERTAKE THAT:

1. I shall not disclose in any manner whatsoever, any part of the proceedings, discussions or decisions conducted and /or made by the ERC relating to any proposal that is submitted to it.
2. I shall declare my interest in any proposal that is submitted to the ERC for ethics approval, where I have acted in any capacity whatsoever, including but not limited to the post of Consultant, Scientific Advisor, Investigator, Researcher, Director, Board Member or Shareholder of a Funding Agency, or where I have any other interest in such proposal.
3. I have not been subject to any criminal conviction or any disciplinary action, both in my personal capacity as well as my professional capacity, which would prejudice my integrity and standing as a member of the ERC.

Signature:

Date:

Annexure: A/007/01/5.0 (Application for Ethics Review)

Faculty of Medicine, University of Colombo
Application for Ethics Review (Part I) – Basic Information

for official use

Application No:		Date Received:	/ /
Reviewed By:		ERC Meeting Date:	/ /
Decision:		Date Informed:	/ /

1. Title of Project

2. Investigators

Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study and who will appear as co-authors in any publication arising out of the study.

Declaration by Investigators - We, the undersigned, hereby confirm that we have consented to be co-investigators of the study. We further confirm that we have read the full study proposal and are in agreement with all the details submitted therein. Any potential conflicts of interest (CoI), where relevant, have been declared under Section 10 of this application for all investigators

Name with Title	Qualifications	Designation & Affiliation	Role	Signature
			Principal Investigator	

Please note that a short curriculum vitae of all investigators should be attached to the application.

3. Contact Details of the Principal Investigator

Address:	
Telephone numbers (including mobile):	
Fax number:	
Email address:	

4. Funding

Funding status	Applicable		Source and Amount	
	Yes	No		
Funded	☐	☐	Agency:	Total Budget: LKR
Applied for funding	☐	☐	Agency:	Total Budget: LKR
Not funded	☐	☐	Reason:	

5. Study Overview

5.1. Start Date*‡ _____ End Date*‡ _____

5.2. Study Type (Mark all applicable)

Epidemiological Study	☐
Survey / Audit	☐
Clinical Trial	☐
Community-Based Research	☐
Case Study / Case Series	☐
Qualitative study	☐
Health Systems Research	☐
Implementation Research	☐
Complementary and Alternative Medicine (CAM) Research	☐
Experimental Study (Non-clinical / Laboratory-based)	☐
Other (Please Specify)	

5.3. Multi-center Study: Yes ☐ No ☐

5.4. Details of Study Setting(s)

Type (e.g. hospital)	Details (e.g. NHSL)

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

‡Retrospective approval will not be given for projects already started or completed.

6. Has ethics approval for this study been requested earlier from Colombo/ERC or another similar committee?

Yes ☐ No ☐

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

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

7. Scientific review - Has this research proposal been subjected to scientific review by any other committee

Yes ☐ No ☐

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

8. Is this study a requirement for an undergraduate (e.g. MBBS/BSc) or postgraduate degree (e.g.

MSc/MD/PhD/MSc)

Yes ☐ No ☐

If yes, give details (name of degree and status of registration with the relevant degree e.g. registered, applied)

9. Clinical trials

9.1. What phase clinical trial 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 ☐

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

9.4. Data Safety Monitoring Board (only if available)

Name and Designation of Members	Role

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

9.5. Details of Indemnity and Insurance coverage for participants, investigators and ethics committee

10. Conflict of Interest (please declare for all investigators)

10.1. Do you believe this project has a Conflict of Interest:

Commercially

Financially

Intellectually

Other (explain):

10.2. 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:

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

Faculty of Medicine, University of Colombo
Ethics Review Application (Part II) - Protocol Checklist

for official use

Application No: ☐☐☐☐☐☐☐☐☐☐

1. Title of Protocol

2. Name of Principal Investigator

3. A List of Documents Submitted for Review

Title of Document	Version	Date

4. Protocol Checklist

Please indicate the following:

4.1. Collaborative partnership		**Applicable**		**Protocol Section Number**
		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	☐	☐	

4.2. Social Value		**Applicable**		**Protocol Section Number**
		Yes	**No**	
1.	The beneficiaries of your research and the nature of the benefit to them	☐	☐	
2.	The plan for dissemination of study findings	☐	☐	

4.3. Scientific Validity		**Applicable**		**Protocol Section Number**
		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	☐	☐	

4.4. Assessment of Risks/Benefits		Applicable		Protocol Section Number
		Yes	No	
1.	The risks to research subjects (physical/psychological/social/legal/etc.)	☐	☐	
2.	Benefits to research subjects	☐	☐	
3.	Steps taken to minimize risks	☐	☐	
4.	Steps taken to enhance benefits	☐	☐	
5.	Justification of the potential benefits against the risks	☐	☐	
6.	Support provided to the research participants (medical, psychological and other)	☐	☐	
7.	Any compensation provided to participants for participation (e.g. financial, in-kind, other)	☐	☐	

4.5. Consent		Applicable		Protocol Section Number
		Yes	No	
1.	The information (written/oral) provided to the community	☐	☐	
2.	The procedure for initial contact of participants (Attach a copy of all posters, advertisements, flyers, and letters, to be used for recruitment)	☐	☐	
3.	The information (written/oral) provided to participants	☐	☐	
4.	The procedure for obtaining informed consent	☐	☐	
5.	The procedure for ensuring that participants have understood the information provided	☐	☐	
6.	The procedure for obtaining proxy consent	☐	☐	
7.	The procedure for obtaining assent (12-18 year old children)	☐	☐	
8.	The procedure for consenting if the child reaches consenting age during the study	☐	☐	
9.	The procedure for consenting if the participant acquires capacity to give consent during the study	☐	☐	
10.	The procedure for re-consenting if data or specimens that have been collected are to be used for other research projects that may be in the same (Extended Consent) or a different (Unspecified Consent) field of study	☐	☐	
11.	The procedure for withdrawing consent	☐	☐	
12.	The justification for waiver of consent or waiver of written consent	☐	☐	
13.	Incentives/rewards/compensation/reimbursement provided or not provided to participants and their accompanying persons	☐	☐	
14.	The procedure for re-consenting if the research protocol changes during the course of research	☐	☐	

4.6. Confidentiality		Applicable		Protocol Section Number
		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.	Persons who will have access to the personal data of 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	☐	☐	

4.7. Rights of the participants		**Applicable**		**Protocol Section Number**
		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.	Provisions to make the study product available to the study participants after research	☐	☐	

4.8. Fair participant selection		**Applicable**		**Protocol Section Number**
		Yes	**No**	
1.	Justification for the selection of the study population	☐	☐	
2.	Inclusion and exclusion criteria	☐	☐	

4.9. Responsibilities of the researcher		**Applicable**		**Protocol Section Number**
		Yes	**No**	
1.	Provision of medical services to research participants	☐	☐	
2.	Provisions for continuation of care after the research is completed	☐	☐	
3.	Declaration of conflicts of interest and how the investigators plan to manage the conflicts	☐	☐	
4.	The ethical/legal/social and financial issues relevant to the study.	☐	☐	

4.10. Vulnerable populations		**Applicable**		**Protocol Section Number**
		Yes	**No**	
1.	Justification for conducting the study in this population	☐	☐	

4.11. Research funded by foreign agencies/companies		**Applicable**		**Protocol Section Number**
		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.	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

4.12. Community based research		**Applicable**		**Section in Protocol**
		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	☐	☐	

4.12. Clinical trials		**Applicable**		**Section in Protocol**
		Yes	**No**	
1.	Justification for withdrawing any therapy from participants as preparation 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.	Provisions/criteria for termination of the trial	☐	☐	
8.	Measures in place for management of trial related injuries	☐	☐	
9.	Previsions for making the trial drug available to participants after the trial, if found to be effective	☐	☐	

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

Annexure: A/007/02/5.0 (Document Checklist)

Faculty of Medicine, University of Colombo
Application for Ethics Review – Document Checklist

for official use

Application No: ☐☐☐☐☐☐☐☐☐☐

Application Checklist

I declare that I have attached the following documents (Please tick the check box and confirm):

1. Application Form: Part I [1 copy] ☐
2. Application Form: Part II [1 copy] ☐
3. The complete research protocol including a section on ethics considerations [1 copy] ☐
4. Information sheet for research participants (Should be provided in all three languages – Sinhala, Tamil, and English - if the participant is being interviewed or is filling up the form). [1 copy each] ☐
5. Consent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [1 copy each] ☐
6. Assent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [1 copy each] ☐
7. Data collection booklets/forms/questionnaires. (Should be provided in all three languages – Sinhala, Tamil, and English) [1 copy] ☐
8. Indemnity/Insurance coverage (required for clinical trials) ☐
9. Clinical Trials Contract (required for clinical trials) [1 copy] ☐
10. Summary and flowchart (required for clinical trials) [1 copy] ☐
11. Certificate of GCP training for at least one member of the research study [1 copy] ☐
12. Materials Transfer Agreement (required for all research involving transfer of biological samples abroad) [1 copy] ☐
13. Ethics approval from sponsoring country or country of the overseas investigator (if any) ☐
14. Brief curriculum vitae (maximum 3 pages per investigator) of all investigators [1 copy] ☐
15. Brief curriculum vitae (maximum 3 pages per member) of all DSMB members [1 copy] ☐
16. Agree to submit soft copies of all documents after receiving the ERC reference number ☐
17. A receipt for the appropriate payment to the accounts department ☐

I confirm that this application is complete and that the study has not yet commenced. I understand that the ERC requires up to two months for review and that clearance will not be granted retrospectively. I will report any adverse events, progress, or deviations from the approved protocol and seek prior ERC approval for any amendments. I have disclosed all relevant prior decisions from this or other ERCs/regulatory bodies. I will ensure the study is conducted in accordance with applicable national and international research ethics guidelines.

…… ……

Signature of Principal Investigator Date

Annexure: A/007/03/5.0 (Document Receipt Checklist)

Faculty of Medicine, University of Colombo
Application for Ethics Review – Document Receipt Checklist

for official use

Application No: ☐☐☐☐☐☐☐☐☐☐

THIS WILL BE FILLED AND HANDED OVER TO THE APPLICANT BY THE

ERC STAFF MEMBER ACCEPTING THE APPLICATION

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

1. Application Form: Part I [1 copy] ☐
2. Application Form: Part II [1 copy] ☐
3. The complete research protocol including a section on ethics considerations [1 copy] ☐
4. Information sheet for research participants (Should be provided in all three languages – Sinhala, Tamil, and English - if the participant is being interviewed or is filling up the form). [1 copy each] ☐
5. Consent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [1 copy each] ☐
6. Assent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [1 copy each] ☐
7. Data collection booklets/forms/questionnaires. (Should be provided in all three languages – Sinhala, Tamil, and English) [1 copy] ☐
8. Indemnity/Insurance coverage (required for clinical trials) ☐
9. Clinical Trials Contract (required for clinical trials) [1 copy] ☐
10. Summary and flowchart (required for clinical trials) [1 copy] ☐
11. Certificate of GCP training for at least one member of the research study [1 copy] ☐
12. Materials Transfer Agreement (required for all research involving transfer of biological samples abroad) [1 copy] ☐
13. Ethics approval from sponsoring country or country of the overseas investigator (if any) ☐
14. Brief curriculum vitae (maximum 3 pages per investigator) of all investigators [1 copy] ☐
15. Brief curriculum vitae (maximum 3 pages per member) of all DSMB members [1 copy] ☐
16. Agree to submit soft copies of all documents after receiving the ERC reference number ☐
17. A receipt for the appropriate payment to the accounts department ☐

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

Please see the website of the ERC – https://med.cmb.ac.lk/erc/ for the standard operating procedures of the committee.

…… ……

Authorized Signatory for ERC Date

Annexure: A/008/01/5.0 (Review Format)

Faculty of Medicine, University of Colombo

Ethics Evaluation Form

Application No:											Date Reviewed:			/			/			
Reviewed By:											ERC Meeting Date:			/			/			
Decision: (office use)											Date Informed:			/			/			

Reviewer Instructions
1. Complete Sections 2.1 to 2.5 for all protocols.
2. Section 2.6.1 should be completed only for sponsored studies.
3. Section 2.6.2. is applicable only to clinical trials and to be completed in addition to other sections.
4. Section 2.6.3. applies to non-clinical trial studies (e.g., community-based, observational, or qualitative research) and to be completed in addition to other sections.

11. Title of Project

12. Reviewer Checklist

2.1. Technical Issues

2.1.1 Justification/Scientific Value		**Yes**	**No**	**N/A**
1.	Clearly stated scientific importance/justifications	☐	☐	☐
2.	Literature review provides adequate information to justify the study	☐	☐	☐
3.	Justification provided for a replication study, if applicable	☐	☐	☐

Comments

2.1.2 Scientific Validity		**Yes**	**No**	**N/A**
1.	Title accurately reflects the scope and focus of the study	☐	☐	☐
2.	General and specific objectives clearly defined	☐	☐	☐
3.	Selected study design suitable for addressing the stated objectives	☐	☐	☐

4.	Inclusion/exclusion criteria appropriate to meet study's objectives	☐	☐	☐
5.	Methodology/process of the study clearly described	☐	☐	☐
6.	Proposed sample size sufficient to achieve reliable results	☐	☐	☐
7.	Sampling method appropriate for the study population	☐	☐	☐
8.	Study instrument appropriate and validated for the intended objectives	☐	☐	☐
9.	Proposed statistical methods suitable for the data and objectives	☐	☐	☐
10.	Clear and feasible data analysis plan	☐	☐	☐
11.	Budget provided, and is reasonable and justified	☐	☐	☐

Comments

2.2. Ethical Issues

2.2.1. Social Value		**Yes**	**No**	**N/A**
1.	Beneficiaries of the research and the benefit to them clearly explained	☐	☐	☐
2.	Study leads to improvements in human health and wellbeing or increase knowledge	☐	☐	☐
3.	Plan for dissemination of study findings explained	☐	☐	☐
4.	Provision for the subjects to be informed of the results of clinical research	☐	☐	☐

Comments

2.2.2. Assessment of Risks/Benefits		**Yes**	**No**	**N/A**
1.	Risks to research subjects (physical/ psychological/social/legal/etc) stated	☐	☐	☐
2.	The benefits to research subjects explained	☐	☐	☐
3.	Appropriate steps taken to minimize risks	☐	☐	☐
4.	Steps taken to enhance benefits	☐	☐	☐
5.	Clear justification of the potential benefits against the risks provided	☐	☐	☐
6.	Facilities at site(s) adequate to support study	☐	☐	☐
7.	Is only the minimum information/samples required to fulfil objective being collected	☐	☐	☐
8.	Non-routine facilities/care offered, funded by the project?	☐	☐	☐
9.	Support provided to the research participants (medical,	☐	☐	☐

	psychological and other) described			
10.	Any compensation provided to participants for participation (e.g. financial, in-kind, other)	☐	☐	☐
11.	Have provision been made for treatment of study-related injuries and if so, are they adequate	☐	☐	☐
12.	Qualifications/experience of investigators appropriate	☐	☐	☐

Comments

2.2.3. Fair participant selection		**Yes**	**No**	**N/A**
1.	The justification for the selection of the study population clearly described, and based on scientific objectives	☐	☐	☐
2.	The inclusion and exclusion criteria is appropriate, and minimises risks and maximises benefits, with burden of research equitably distributed	☐	☐	☐
3.	Selection of subjects favour any special groups	☐	☐	☐
4.	The study is conducted in vulnerable individuals/groups (Please also complete section 2.2.4. below)	☐	☐	☐

Comments

2.2.4. Vulnerable populations		**Yes**	**No**	**N/A**
1.	Justification for conducting the study in this population, clearly described	☐	☐	☐
2.	Procedure for obtaining consent/proxy consent satisfactory	☐	☐	☐
3.	Favourable risk-benefit ratio	☐	☐	☐
4.	Adequate medical and/or psychological support provided	☐	☐	☐

Comments

2.2.5 Rights of the participants		**Yes**	**No**	**N/A**
1.	Procedure for subjects to withdraw from the research at any time explained	☐	☐	☐
2.	Procedure for subjects to ask questions and register complaints explained	☐	☐	☐
3.	The contact person for research subjects provided	☐	☐	☐
4.	Provisions for participants to be informed of results are made	☐	☐	☐
5.	Provision are made to make the study product available to the study participants after research	☐	☐	☐

Comments

	2.2.6 Responsibilities of the researcher	Yes	No	N/A
1.	The provision of medical services to research participants are explained	☐	☐	☐
2.	The provisions for continuation of care after the research is completed described	☐	☐	☐
3.	Declaration of conflicts of interests and how the investigators plan to manage the conflicts described	☐	☐	☐
4.	The ethical/legal/social and financial issues relevant to the study clearly addressed	☐	☐	☐

Comments

	2.2.7. Confidentiality	Yes	No	N/A
1.	How the data and/or samples will be obtained explained	☐	☐	☐
2.	How long data and/or samples will be kept described	☐	☐	☐
3.	Justification for collection of personal identification data provided	☐	☐	☐
4.	Who will have access to personal data of research participants clearly described	☐	☐	☐
5.	How the confidentiality/privacy of participants will be ensured described	☐	☐	☐
6.	Location/place of data collection is appropriate	☐	☐	☐
7.	Procedure for data/sample storage adequate	☐	☐	☐
8.	Procedure for data/sample disposal adequate	☐	☐	☐

Comments

	2.2.8. Consent	Yes	No	N/A
1.	The procedure for initial contact of participants appropriate (Review all posters, advertisements, flyers, and letters, to be used for recruitment)	☐	☐	☐
2.	The information (written/oral) provided to the participants adequate and clear	☐	☐	☐
3.	The procedure for ensuring that participants have understood the information provided described	☐	☐	☐
4.	The procedure for obtaining informed consent voluntary and non-coercive	☐	☐	☐
5.	The procedure for obtaining proxy consent appropriate (if applicable)	☐	☐	☐

6.	The procedure for obtaining assent (12–18-year-old children) appropriate	☐	☐	☐
7.	The procedure for consenting if the participant acquires capacity to give consent during the study explained	☐	☐	☐
8.	The procedure for re-consenting if data or specimens that have been collected are to be used for other research projects that may be in the same (Extended Consent) or a different (Unspecified Consent) field of study is described	☐	☐	☐
9.	The procedure for withdrawing consent is described and clear	☐	☐	☐
10.	Justification provided for waiver of consent or waiver of written consent	☐	☐	☐
11.	Any incentives/rewards/compensation/ reimbursement provided or not provided to participants and their accompanying persons, and if so are they appropriate	☐	☐	☐
12.	The procedure for re-consenting if the research protocol changes during the course of research explained	☐	☐	☐

Comments

2.3. Information Sheets

		Yes	No	N/A
1.	The information (written/oral) provided to the participants clear and complete	☐	☐	☐
2.	Language used in the information sheet clear and understandable	☐	☐	☐
3.	Voluntary participation clearly explained	☐	☐	☐
4.	Translation of all forms consistent and accurate	☐	☐	☐
5.	Opportunity for participants to ask questions	☐	☐	☐
6.	Provisions for withdrawal unconditional without penalty and loss of care	☐	☐	☐
7.	Duration, procedures of the study and participant's responsibilities clearly explained	☐	☐	☐
8.	Potential benefits, risks, hazards and/or discomforts clearly explained	☐	☐	☐
9.	Reimbursements provided clear and not coercive	☐	☐	☐
10.	If biological samples are collected, participants informed about collection, tests, storing, duration and/or transfer aboard	☐	☐	☐
11.	Contact details of PI and other investigators given	☐	☐	☐
12.	ERC contact details provided, with provisions for participants to make complaints	☐	☐	☐

Comments

2.4. Consent Forms

		Yes	No	N/A
1.	Participant consented to all procedures planned (e.g. storing of samples, transfer abroad, etc)	☐	☐	☐
2.	Assent form clear and satisfactory	☐	☐	☐

Comments

2.5. Questionnaires/Data Collection Instrument

		Yes	No	N/A
1.	The questions are relevant to the study objectives	☐	☐	☐
2.	The language used is simple, clear, and understandable to the target population	☐	☐	☐
3.	The questionnaire has been validated or pre-tested (if applicable)	☐	☐	☐
4.	The questionnaire avoid leading, offensive, or sensitive questions unless justified	☐	☐	☐
5.	Cultural appropriateness considered in the content and wording	☐	☐	☐
6.	Length of the questionnaire reasonable and not burdensome to participants	☐	☐	☐
7.	If translated, is the translation accurate and appropriate for the local context	☐	☐	☐
8.	A clear plan for how the questionnaire data will be collected (e.g., interviewer-administered, self-administered)	☐	☐	☐
9.	Privacy and confidentiality considerations adequately addressed in the design and administration of the questionnaire	☐	☐	☐

Comments

2.6. Study Specific Ethical Considerations

2.6.1 Research funded by foreign agencies/companies		**Yes**	**No**	**N/A**
1.	There is an appropriate local collaborator	☐	☐	☐
2.	ERC/IRB approval being obtained in sponsoring country	☐	☐	☐
3.	The study also carried out in sponsor's country	☐	☐	☐
4.	Drug/device registered in country of origin (for clinical trials)	☐	☐	☐
5.	Clear justification for conducting the study in Sri Lanka	☐	☐	☐
6.	Relevance of the study to Sri Lanka explained	☐	☐	☐
7.	Post research benefits to Sri Lanka explained	☐	☐	☐

8.	Steps are taken to take into account cultural and social customs, practices, and taboos in Sri Lanka	☐	☐	☐
9.	Sharing of rights to intellectual property described	☐	☐	☐
10.	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	☐	☐	☐
11.	The results of research will be conveyed to relevant authorities in Sri Lanka	☐	☐	☐
12.	Potential conflicts of interest involved, described	☐	☐	☐
13.	The agreement between the sponsor/funding agency and the investigator included	☐	☐	☐
14.	The materials transfer agreement, if biological material is to be transferred abroad included	☐	☐	☐

Comments

2.6.2 Clinical trials		**Yes**	**No**	**N/A**
1.	Intervention to be used in the research acceptable	☐	☐	☐
2.	Sufficient information provided about investigational product	☐	☐	☐
3.	Clear justification for withdrawing any therapy from participants to prepare them for the trial (if any)	☐	☐	☐
4.	Clear justification for withholding standard therapy from trial participants (e.g. control group)	☐	☐	☐
5.	Clear justification for providing care which is not the standard of care	☐	☐	☐
6.	Procedure for dealing with adverse events clear and satisfactory	☐	☐	☐
7.	Procedure for reporting adverse events clear and satisfactory	☐	☐	☐
8.	Provisions for safety monitoring clear and satisfactory	☐	☐	☐
9.	Site including support staff, facilities and emergency procedures adequate	☐	☐	☐
10.	Provision of compensation (where applicable) and adequate	☐	☐	☐
11.	Provision of insurance to participants and adequate	☐	☐	☐
12.	Provisions/criteria for termination of the trial clear and satisfactory	☐	☐	☐
13.	Measure in place for management of trial related injuries	☐	☐	☐
14.	Provisions for making the trial drug available to participants after the trial if found to be effective	☐	☐	☐

Comments

2.6.3 Community based research		Yes	No	N/A
1.	Impact and relevance of the research on the community in which it is to be carried out acceptable	☐	☐	☐
2.	Steps taken to consult with concerned community during design of the research	☐	☐	☐
3.	Procedure used to obtain community consent adequate	☐	☐	☐
4.	Any contribution to capacity building of the community	☐	☐	☐
5.	Procedure for making available results of research to the community described	☐	☐	☐

Comments

Reviewer Recommendation:

Approved	☐
Minor Revision	☐
Major Revision	☐
Rejection	☐

Comments to ERC

2.1. Technical Issues

Justification/Scientific Value:

Scientific Validity:

2.2. Ethical Issues

Social Value:

Assessment of Risks/Benefits:

Fair participant selection:

Vulnerable populations:

Rights of the participants:

Responsibilities of the researcher:

Confidentiality:

Consent:

2.3. Information Sheets:

2.4. Consent Forms:

2.5. Questionnaires/Data Collection Instrument:

2.6. Study Specific Ethical Considerations

Research funded by foreign agencies/companies:

Clinical trials:

Community based research:

Reviewer Name:

Signature and Date:

Annexure: A/008/02/5.0 (Review Format – IFS/Consent Forms by Lay Members)

EC Number: **Reviewer:**

Title:

Information Sheet check list	**Section IFS**	**Review check list (S)**	**Review check list (T)**	**Review check list (E)**
List the sections in IFS where you have dealt with the following:	IFS			
1. Purpose of the study	1			
2. Voluntary participation	2			
3. Duration, procedures of the study and Participant's responsibilities	3			
4. Potential benefits	4			
5. Risks, hazards and discomforts	5			
6. Reimbursements	6			
7. Confidentiality	7			
8. Termination of study participation	8			

Consent form (CF) check list	**Section CF**	**Review check list**
Consent form in Q & A format		
Any other		

Other Comments	**Sections IFS/CF**	**Other Comments**
All documents typed		
In simple language		
Consistency between translations		

Annexure: A/009/01/5.0 (Expedited Review Format)

Expedited Review Form – Executive Committee

Application No: Date of Meeting:

Expedited Review SOP applicable:

Reviewer 1:

Name:

Comments:

Reviewer 2:

Name:

Comments:

Final Decision:

☐ Approved

☐ Approved with Minor Revisions

Revisions:

☐ Rejected

Reason/s:

☐ Forwarded to the Main Committee

Reason/s:

Signature 1:

Signature 2:

Annexure: A/009/02/5.0 (Expedited Approval Letter)

REFERENCE: EC-……

Date

Name,

Designation,

Address

Dear ……,

RE : Protocol EC-……

Title : ……..

Thank you for submitting the above research proposal, which was considered for expedited review by the Executive Committee of the Ethics Review Committee (ERC) on …….

The Committee determined that the protocol qualified for expedited review as per SOP 009, and has granted provisional ethics approval subject to ratification by the full ERC at its next scheduled meeting on …….

This provisional approval relates to the following documents reviewed and accepted:

- Research Proposal (Version …….)
- Information Sheets (Version …….)
- Consent Forms (Version …….)
- Data Sheets/Questionnaires (Version …….)

You are informed that data collection may commence immediately following receipt of this letter. Please note, however, that this approval will be subject to final ratification by the full ERC, and a full approval letter issued accordingly. In the event that valid scientific or ethical concerns arise during this meeting, the study may be reclassified for full review under SOP 008. The ERC may require modifications, or in exceptional circumstances, suspend the study pending further review in such circumstances.

Thank You,

Yours Sincerely,

Chairperson
Ethics Review Committee
Faculty of Medicine, University of Colombo

Annexure: A/012/01/1.0 (Undergraduate Letter)

REFERENCE:

DATE

NAME

DESIGNATION

ADDRESS

Dear Mr/Ms.,

ERC Application No :

Project Title :

Investigators :

Supervisor :

I wish to inform you that the above mentioned project was reviewed as a _____ Stream student research project, by a sub-committee appointed by the Ethics Review Committee Faculty of Medicine, University of Colombo on _____. Approval is granted to proceed.

This approval relates to the following:

- Research Proposal (Version …….)
- Information Sheets (Version ……..)
- Consent Forms (Version ……..)
- Data Sheets/Questionnaires (Version ……..)

The decision of the sub-committee was approved by the Ethics Review Committee at its meeting held on _____.

Thank You,

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine,

University of Colombo

Annexure: A/020/01/5.0 (Revise Letter)

EC-……..- (Title)

Dear ……**,**

Thank you for submitting the above protocol for ethics review. It was considered by the ERC at its meeting on …… and the following concerns were documented:

Recommendation: ……. revisions

Kindly submit the **highlight amended documents as Version ……** to the ERC office **at least 10 days before the next meeting***. (**Next ERC meeting – ……**)

Further, please note that all suggested changes have to be incorporated into the protocol, questionnaire etc. as appropriate.

In addition, please provide a cover letter which summaries the responses to each numbered comment in a table format, as shown below;

Number	ERC Comment	PI Response	Document/Page Number with Change
1.			

(1 set of amended documents should be submitted along with a soft copy. *ERC meetings are held on every third Thursday of the month)

Thank You,

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine

University of Colombo

Annexure: A/020/02/5.0 (Revise Letter – Clinical Trials)

REFERENCE: …….

Date

Name,

Designation,

Address

Dear ……..,

EC-……..- (Title)

Thank you for submitting the above proposal which was considered by the Clinical Trials Sub Committee (CTSC) at its meeting on ……., and the recommendations of the CTSC were endorsed by the Ethics Review Committee at its meeting held on …….

The committee, which operates in accordance with the relevant guidelines of the Forum of Ethics Review Committee in Sri Lanka (FERCSL) and the International Conference on Harmonisation of Good Clinical Practice (ICH GCP) documented the following concerns:

Recommendation: ……. revision

Kindly submit the responses to all the above concerns one by one in a **Table format (Should be in MS word format)** (see below for an example**) and incorporate the amendments (shown as highlighted sentences or paragraphs) in the relevant research documents (protocol, information sheet, consent form, questionnaire, etc.) labeled as Version ……. to the ERC office.

Responses Table (Should be in MS Word) **, with the cover letter and 1 set of amended documents should be submitted along with soft copies.

***The date of the next CTSC meeting is on …….. If you would like version 2.0 of your proposal to be taken up for discussion at this meeting please ensure your response reaches the ERC office 7 days prior to the said date.**

Thank You,

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine

University of Colombo

** Responses Table

Comments from the ERC	Responses from the PI	Amendments (indicate the page numbers where the amendments are done in the relevant documents)

Annexure: A/020/03/5.0 (Approval Letter)

REFERENCE: EC-……

Date

Name,

Designation,

Address

Dear ……,

RE : Protocol EC-……

Title : ……..

Investigators : ……..

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting on ……. Approval is granted to proceed.

This approval relates to the following:

- Research Proposal (Version …….)
- Information Sheets (Version ……..)
- Consent Forms (Version ……..)
- Data Sheets/Questionnaires (Version ……..)

The following members of the ERC were present at the meeting:

…….

You are asked to note the following,

- This approval is valid for one year from the date of issue of this letter, and the committee requires that you furnish a final report once the study is concluded.
- If the study is continued for a period beyond one year, you are required to furnish an annual progress report for the year and an application for the extension of approval by a further year. The ERC will issue such extension after consideration of the progress report and any other information it may require from you for this purpose.

- Progress reports and final reports should be submitted in the recommended template, which can be downloaded from the ERC web page of the Faculty of Medicine, University of Colombo website.
- In similar manner, you are required to furnish a progress report and an application for the extension of approval for each subsequent year as long as the study is continued. If no such application is made or extension of approval given, the ethics clearance lapses automatically once the current year of approval is finished.
- If the progress report and/or the final report is/are delayed more than one month beyond the due date (which is the final date of ethics approval in force), approval for the study will lapse and you will be required to furnish a new application should you wish to resume or continue the study.
- If a PI has three or more research proposals in which the progress reports and/or final reports have lapsed in this manner, no further applications for ethics review shall be entertained from such PI.
- It is the responsibility of the PI to notify the ERC of any amendments to the protocol

This approval relates to the ethical content of this study only, and you are responsible for the following:

- Negotiating individual arrangements with the heads of service departments in those situations where the use of their resources is involved.
- If appropriate, informing the study sponsor that the membership and procedures of the Faculty of Medicine, University of Colombo, Ethics Review Committee comply with appropriate guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL).
- You are advised to obtain all necessary regulatory approvals and administrative or institutional permissions necessary to conduct the study.

Thank You,

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine

University of Colombo

Annexure: A/020/04/5.0 (Approval Letter – Clinical Trials)

REFERENCE: EC-……

Date

Name,

Designation,

Address

Dear ……,

RE : Protocol EC-……

Title : ……..

Investigators : ……..

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting on …….. Approval is granted to proceed.

This approval relates to the following:

- Research Proposal (Version …….)
- Information Sheets (Version ……..)
- Consent Forms (Version ……..)
- Data Sheets/Questionnaires (Version ……..)

The following members of the ERC were present at the meeting:

……..

You are asked to note the following,

- **You are requested to submit an early progress report at the conclusion of pre-testing and pilot testing of the intervention.**
- If there is any change in the intervention, you have to seek ERC approval for the amended intervention (a new version of the proposal had to be submitted)
- This approval is valid for one year, and the committee requires that you furnish a progress/final report at the end of one year.

- Suspected Unexpected Serious Adverse Reactions (SUSAR) and Serious Adverse Events (SAE) should be reported to the ERC.
- Both the progress report template and the format for reporting SUSAR/SAE can be downloaded from the ERC web page of the Faculty of Medicine, University of Colombo website.
- You are requested to submit a copy of the invoice of payment for premium insurance coverage for study participants to cover study related injuries as soon as possible
- This approval relates to the ethical content of this study only, and you are responsible for the following:
    - Negotiating individual arrangements with the heads of service departments in those situations where the use of their resources is involved.
    - If appropriate, informing the study sponsor that the membership and procedures of the Faculty of Medicine, University of Colombo Ethics Review Committee comply with appropriate guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL).
    - You are advised to obtain all necessary regulatory approvals and administrative or institutional permissions necessary to conduct the study.

Kindly note that all clinical trials must be registered with a clinical trials registry before commencing the trial.

Thank You

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine

University of Colombo

Annexure: A/020/05/5.0 (Rejection Letter)

REFERENCE: EC-……

Date

Name,

Designation,

Address

Dear ……,

EC-……: ……

Thank you for submitting the above proposal, which was considered by the Ethics Review Committee at its meeting 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 Harmonisation of Good Clinical Practice (ICH-GCP), has decided not to accept the proposal for review in its present form. Several fundamental issues were identified, including:

Given the above concerns, the proposal cannot be considered further in its current form. Should you wish to proceed, we kindly request that you undertake the necessary revisions and re-submit the study as a new application. Thank you for your understanding.

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine

University of Colombo

Annexure: A/021/01/5.0 (Annual Progress/Final Report to ERC)

ANNUAL PROGRESS / FINAL REPORT TO ERC (Version 5.0)

To be completed in typescript and submitted by the Principal Investigator (PI).

1. Details of PI

Name:	
Address:	
Telephone:	
E-mail:	

2. Details of study

Full title of study:	
Protocol number:	
Date of ERC approval:	
Is this an Annual Progress Report or a Final Report	
Duration for which the report is provided (Reporting Period)	

3. Progress of the Study to Date

4. Ethical Issues

Maintenance and security of records	
Compliance with approved protocol	

Any changes to the protocol including any planned for the next year	
Any unforeseen events that might affect continued ethical acceptability of the project	
Any new information which may have an impact on continued ethical acceptability of the project	

5. Declaration

Signature of Principal Investigator:	
Print name:	
Date of submission:	

Annexure: A/021/02/5.0 (Annual Progress/Final Report to ERC – Clinical Trials)

CLINICAL TRIAL OF AN INVESTIGATIONAL MEDICINAL PRODUCT (CTIMP)

PROGRESS/FINAL REPORT TO ERC (Version 5.0)

To be completed in typescript and submitted by the Principal Investigator (PI).

1. Details of PI

Name:	
Address:	
Telephone:	
E-mail:	
Fax:	

2. Details of study

Full title of study:	
Protocol number:	
Date of ERC approval:	
Sponsor(if any):	

3. Commencement and termination dates

Has the study started in Sri Lanka	***Yes / No***
If yes, what was the actual start date in Sri Lanka?	
If no, what are the reasons for the study not commencing? What is the expected start date?	
Has the study finished?	***Yes / No***

If no, what is the expected completion date? *If you expect the study to overrun the planned completion date this should be notified to the ERC for information.*	
If you do not expect the study to be completed, give reason(s)	

4. Registration

Is the study registered on a publically accessible database? (Registration of clinical trials is a requirement by the ERC)	Yes / No
If yes, please provide the name of the database and the registration number Database: Registration number:	
If no: a. What is the reason for non-registration? b. What are your intentions for registration?	

5. Site information

Number of research sites proposed in original application: Number of research sites recruited to date:	
Do you plan to increase the total number of sites proposed for the study? *The addition of any new sites not listed in the original applications to the ERC should be notified in writing*	***Yes / No***

6. Recruitment of participants

Recruitment status:	pending/ recruiting/ recruitment complete/ recruitment suspended / recruitment
Number assessed for eligibility:	
Number recruited and randomized:	
Number allocated to each intervention/arm:	
Losses/exclusions after randomization:	

** In the case of international trials, please provide separate figures for Sri Lankan and non-Sri Lankan participants.*

Have there been any serious difficulties in recruiting participants?	***Yes / No***
If yes, give details:	

7. Safety reports

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in Sri Lanka?	**Yes / No**
Have these SUSARs been notified to the ERC within 7 days for fatal/life threatening events and 15days for other events? *If no, please arrange urgently and give reasons for late notification.*	***Yes / No***
Has the Annual Safety Report (ASR) been submitted?	***Yes / No / Not yet due***
When is the next ASR due?	

8. Amendments

Have any substantial amendments been made to the trial during the year?	Yes / No
If yes, please give details and the date and amendment number for each substantial amendment made.	

9. Trial output

Summary of Interim/Final data (if available): Publications: (Please attach a scanned copy or link to paper)	
Presentations of results at scientific meetings: (Please attach a scanned copy or link to abstract)	

10. Serious breaches of the protocol or Good Clinical Practice

Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year?	Yes / No
If yes, please give the date of each notification to the ERC.	

11. Other issues

Are there any other developments in the trial that you wish to report to the Committee?	*Yes / No*
Are there any ethical issues on which further advice is required? *If yes to either, please attach separate statement with details.*	*Yes / No*

12. Declaration

Signature of Principal Investigator:	
Print name:	
Date of submission:	

Annexure: A/021/03/5.0 (Withdrawal Letter)

REFERENCE: EC-……

Date

Name,

Designation,

Address

Dear ……..,

EC-……: ……

The Ethics Review Committee of the Faculty of Medicine, University of Colombo, considered the above project at its meeting held on …….

Following review, the Committee has determined that circumstances have arisen which prevent the research from being conducted in accordance with the approved protocol and conditions of approval. In particular, the Committee noted the following issues:

- ……
- ……

In view of the above, the Ethics Review Committee has decided to withdraw approval for the conduct of this study. Accordingly, the research study must be discontinued/suspended with immediate effect.

The Committee further recommends that you and your institution take any additional steps necessary to ensure the protection of study participants and proper handling of collected data and materials.

Thank you for your cooperation.

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine

University of Colombo

Annexure: A/022/01/5.0 (Amendment Letter)

REFERENCE: EC-……

Date

Name,

Designation,

Address

Dear ……,

RE : Protocol EC-……

Title : ……..

The request made by you for the following amendments of the above study was considered by the Executive Committee of the Ethics Review Committee, at its meeting on …….. and approval was granted:

Thank You,

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine

University of Colombo

Annexure: A/022/02/5.0 (Extension Letter)

REFERENCE: EC-……

Date

Name,

Designation,

Address

Dear ……,

RE : Protocol EC-……

Title : ……..

Investigators : …….

The request made by you to extend the ethics approval period from …… in order to complete your research, was considered by the Executive Committee of the Ethics Review Committee at its meeting on …… and approval was granted for this extension.

You are asked to note the following,

- This approval is valid for one year from the date of issue of this letter, and the committee requires that you furnish a final report once the study is concluded.
- If the study is continued for a period beyond one year, you are required to furnish an annual progress report for the year and an application for the extension of approval by a further year. The ERC will issue such extension after consideration of the progress report and any other information it may require from you for this purpose.
- Progress reports and final reports should be submitted in the recommended template, which can be downloaded from the ERC web page of the Faculty of Medicine, University of Colombo website.
- In similar manner, you are required to furnish a progress report and an application for the extension of approval for each subsequent year as long as the study is continued. If no

such application is made or extension of approval given, the ethics clearance lapses automatically once the current year of approval is finished.

- If the progress report and/or the final report is/are delayed more than one month beyond the due date (which is the final date of ethics approval in force), approval for the study will lapse and you will be required to furnish a new application should you wish to resume or continue the study.
- If a PI has three or more research proposals in which the progress reports and/or final reports have lapsed in this manner, no further applications for ethics review shall be entertained from such PI.

This approval relates to the ethical content of this study only, and you are responsible for the following:

- Negotiating individual arrangements with the heads of service departments in those situations where the use of their resources is involved.
- If appropriate, informing the study sponsor that the membership and procedures of the Faculty of Medicine, University of Colombo Ethics Review Committee comply with appropriate guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL).
- You are advised to obtain all necessary regulatory approvals and administrative or institutional permissions necessary to conduct the study.

Thank You,

Yours Sincerely,

Chairperson

Ethics Review Committee

Faculty of Medicine

University of Colombo

Annexure: A/025/01/5.0 (SUSAR/SAE Report)

Data Elements for Suspected Unexpected Serious Adverse Reaction (SUSAR) / Serious Adverse Event (SAE) report (Version 5.0)

1. ERC protocol number:

2. Subject's details:

- Sponsor's subject identification number
- Initials, if applicable
- Gender
- Age and/or date of birth
- Weight
- Height

3. Suspected investigational medicinal product(s):

- Name of the investigational medicinal product or brand name as reported
- International non-proprietary name (INN)
- Batch number
- Indication(s) for which suspect investigational medicinal product was prescribed or tested
- Dosage form and strength
- Daily dose and regimen (specify units e.g. mg, ml, mg/kg)
- Route of administration
- Starting date and time of day
- Stopping date and time, or duration of treatment
- Unblinding: yes/no/not applicable; results:

∗ Investigator's causality assessment

∗ Sponsor's causality assessment

∗ Comments, if relevant (e.g. causality assessment if the sponsor disagrees with the reporter; concomitant medications suspected to play a role in the reactions directly or by interaction; indication treated with suspect drug(s).

4. Other treatment(s):

- For concomitant medicinal products (including non prescription/OTC medicinal products) and non-medicinal product therapies provide the same information as listed above for the suspected investigational medicinal product.

5. Details of suspected Adverse Drug Reaction(s):

- Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious should be given. In addition to a description of the

reported signs and symptoms, whenever possible attempts should be made to establish a specific diagnosis for the reaction,

- Setting (e.g. hospital, out-patient clinic, home, nursing home),

- Outcome: information on recovery and any sequelae; what specific tests and/or treatment may have been required and their results; for a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction should be provided. Any autopsy or other post-mortem findings (including a coroner's report) should also be provided when available,

- Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse, family history, findings from special investigations.

6. Details on reporter of event/suspected adverse reactions:

- Name,

- Address,

- Telephone number,

- Email address

- Profession (speciality).

7. Administrative and Sponsor details:

- Date of this report,

- Source of report: from a clinical trial, from the literature (provide copy), spontaneous, other,

- Date event report was first received by sponsor,

- Country in which reaction occurred,

- Type of report filed to authorities: initial or follow-up (first, second, etc),

- Name and address of sponsor/manufacturer/company,

- Name, address, telephone number and fax number of contact person in reporting sponsor,

- Case reference number (sponsor's/manufacturer's identification number for the case) (this number must be the same for the initial and follow-up reports on the same

Annexure: A/026/01/5.0 (Complaints Format)

Complaint / Appeal Submission Form

1. Reference Details

- ERC Reference Number of the project (if applicable): ……
- Title of the research proposal/project: ……
- Principal Investigator: ……
- Date of ERC decision/action under appeal/complaint: ……

2. Complainant / Appellant Information

- Name: ……
- Designation: ……
- Institution / Department: ……
- Address: ……
- Telephone: ……
- Email: ……

3. Nature of Submission (please tick):

☐ Appeal against ERC decision

☐ Complaint regarding ERC review process

☐ Concern regarding ERC member conduct

☐ Other (please specify): ……

4. Grounds of Appeal / Complaint (attach additional sheets if necessary):

……
……
……

5. Supporting Documents Attached (list):

1. ……
2. ……
3. ……

6. Declaration

I hereby declare that the information provided in this form is accurate and complete to the best of my knowledge.

Name: ……

Signature: ……

Date: ……

For Office Use Only

- Date of receipt: ……
- Received by: …… (ERC staff)
- Action taken / Forwarded to: ……
- Reference No. assigned: ……