STANDARD OPERATING PROCEDURES

Ethics Review Committee

Faculty of Medicine

University of Kelaniya

Sri Lanka

Version 5

April 2023

Document History

Version	History	Date
Draft version	Developed by ERC	2007-2010
Draft version1	Finalized by ERC	2011
Version1	Approved by Faculty Board, Faculty of Medicine, University of Kelaniya	2013
Draft version2	ERC	2015
Version 2	Approved by Faculty Board, Faculty of Medicine, University of Kelaniya	2016
Draft version 3	ERC	2017
Version 3	Approved by Faculty Board, Faculty of Medicine, University of Kelaniya	February 2018
Draft version 4	ERC	September 2018
SOP version 4	Approved by Faculty Board, Faculty of Medicine, University of Kelaniya	December 2018
Draft version 5	ERC	November 2022
SOP version 5	Approved by the Faculty Board, Faculty of Medicine, University of Kelaniya	April 2023

Standard Operating Procedures- Version 5, Ethics Review Committee, Faculty of Medicine, University of Kelaniya, Sri Lanka

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SOP version 5

Date of Acceptance: 6th April 2023.

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ERC-SC - Ethics Review Committee - Subcommittee

CIOMS - Council for International Organizations of Medical Sciences

CTR - Clinical Trial Registry

ERC - Ethics Review Committee

FERCSL - Forum of Ethics Review Committees in Sri Lanka

FM/UoK - Faculty of Medicine, University of Kelaniya, Sri Lanka

GCP - Good Clinical Practice

HBM - Human Biological Material

ICF - Informed Consent Form

PI - Principal Investigator

PIS - Participant Information Sheet

SAE - Serious Adverse Events

SOP - Standard Operating Procedures

SUSAR - Suspected Unexpected Serious Adverse Reaction

1.1 Purpose

To describe the functions and responsibilities of the Ethics Review Committee (ERC) of Faculty of Medicine, University of Kelaniya (FM/UoK). This SOP provides the terms of reference (TOR) for the constitution, responsibilities and activities of ERC, FM/UoK.

1.2 Scope

1.2.1 To safeguard the rights, dignity, safety and wellbeing of humans participating in biomedical research. This will be achieved through independent, competent and timely review and monitoring of human research projects with regard to their ethical acceptability and scientific merit.

1.2.2 To provide guidance, direction and advice, when needed, to researchers carrying out research projects involving human subjects.

1.3 Responsibility

It is the responsibility of the members of the ERC, FM/UoK to read, understand and respect the rules and guidelines set by ERC, FM/UoK.

1.4 Detailed instructions

1.4.1 The ERC, FM/UoK shall review proposals of health related research, involving human research participants.

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

1.4.3 ERC, FM/UoK shall entertain applications for ethical approval of research proposals from thefollowing categories:

1. Staff and students of the University of Kelaniya
2. Members of the extended faculty of the FM, UoK which consists of consultants at the North Colombo Teaching Hospital (NCTH) and institutions affiliated to UoK
3. Research proposals involving patients of nearby hospitals and people of the localcommunity
4. Industry sponsored intervention/observational studies

1.4.4 All applications for ethical approval will be subject to a review fee as recommended by the ERC and approved by the Management Committee, FM/UoK.

1.4.5 The ERC will assess projects submitted to it for review in accordance with the FERCSL and other national and international guidelines and Sri Lankan legal requirements in order to determine theirethical acceptability and scientific merit.

1.4.6 Accountability

1. ERC shall report to Faculty Board (FB), FM/UoK on all matters relating to the ethics of research involving human participants.
2. A copy of confirmed minutes shall be sent to the Dean and a list of approved research protocols shall be sent to the Faculty Board.
3. ERC shall maintain a financial record and provide an annual budget to the Management Committee, FM/UoK.
4. All financial transactions of the ERC shall be handled by the Finance Department of FM/UoK and be audited as per the state financial regulations.

2.1 Purpose

To describe the membership composition of the ERC, FM/UoK.

2.2 Scope

Members shall be appointed to ensure that the ERC has the expertise required to assess the applications submitted to it for consideration. The composition of the ERC shall be diverse in language, culture and gender. This SOP describe the TOR for composition of ERC, FM/UoK.

2.3 Responsibility

The composition of the ERC should enable independent, competent and timely review.

2.4 Detailed instructions

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

2.4.2 The committee will comprise a minimum of 11 and a maximum of 25 members.

2.4.3 The membership should be representative in terms of academic disciplines, research interests, age and gender.

2.4.4 The membership will comprise of the following categories:

1. Affiliated members – both medical (clinical and non-clinical) and non-medical members from permanent staff of the FM/UoK.
2. Non-affiliated members – Members who are not from the permanent staff of the FM/UoK.
3. A lay person conversant with social values.
4. A lawyer.

2.4.5 Number of members from categories 2, 3 and 4 should be a minimum of one from each and a maximum of 5 in total.

2.4.6 A quorum must be present in order for the ERC to reach a final decision on any agenda item. Aquorum shall exist when at least half plus one of number of existing members are present.

2.4.7 Where required, the ERC may seek advice and assistance from appropriate independent consultants to assist with the review of a proposal. However, the ERC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, or any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to sign a confidentiality agreement and shall not be entitled to vote on any matter.

3.1 Purpose

To describe procedures for appointing members to the ERC of FM/UoK.

3.2 Scope

This SOP describes the TOR and procedures for appointing the ERC members.

3.3 Responsibility

Dean of the FM/UoK appoints ERC members, approved by the Faculty Board according to the composition of the ERC as described in the SOP.

3.4 Detailed instructions

3.4.1 Members are appointed as individuals rather than in a representative capacity.

3.4.2 Members of the ERC may be recruited by nomination or by advertisement. Prospective members shall be asked to provide a copy of their curriculum vitae to the Dean of the Faculty. Members mustagree to have their name and profession being made available to the public, including being published on the ERC website.

3.4.3 Recruitment by advertisement - Applications for membership shall be called from members of the Faculty Board. The Dean and two senior academic staff members (one of whom should have experience in ERC activities) nominated by the Faculty Board shall review prospective applications, interview the candidates if necessary and make recommendations to the Faculty Board.

3.4.4 Recruitment by nomination - When the expertise of specific individuals is required the ERC willrequest the Dean to take steps to appoint such individuals to the ERC.

3.4.5 Members are appointed by the Dean with the approval of the Faculty Board and will receive a formal letter of appointment (Annex 4.3.1).

3.4.6 The letter of appointment shall include the date of appointment, length of tenure, roles and responsibility and 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.

3.4.7 Members shall accept the appointment by returning a signed copy of the appointment letter to the ERC secretariat.

3.4.8 Members will be required to sign a confidentiality (Annex 4.3.2) undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the ERC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the ERC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as an ERC member.

3.4.9 ERC secretariat shall maintain personal files for ERC members containing following documents updated CV, letter of appointment and acceptance, confidentiality agreement, records of GCP and other training.

3.4.10 New members to the ERC are expected to observe a meeting of the ERC before they are assigned as primary reviewers.

3.4.11 Upon appointment, members shall receive copies of the following documents.

1. Standard Operating Procedures of the ERC
2. List of members' names and contact information
3. Current FERCSL and relevant national and international guidelines on ethical conduct of human research
4. Any other relevant information about the ERC's processes, procedures and protocols

3.4.12 Members shall receive access to the Google drive folder containing documents listed in 3.4.11.

3.4.13 New members will be provided with training in research methodology, research ethics, Good Clinical Practice (GCP) and SOP based on their individual requirements.

3.4.14 Members are appointed for a period of three years, renewable at the discretion of the Dean with the approval of the Faculty Board for a period not exceeding three consecutive terms.

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

3.4.16 The Chairperson and Secretary shall be experienced persons in research methodology and ethics.The Chairperson will be appointed by the Dean with approval of the Faculty Board on recommendations made by the ERC.

3.4.17 Members may seek leave of absence from the ERC up to a period of three months.

3.4.18 The membership will lapse, if a member fails to

1. attend three consecutive meetings of the ERC in full without priorpermission or
2. attend at least half of all scheduled ERC meetings each year.
3. submit duly completed review forms for three consecutive months, despite repeated reminders.

The Chairperson will notify the member of such lapse of membership in writing.

3.4.19 A member may resign from the ERC at any time, upon giving notice in writing to the Dean through Chairperson.

3.4.20 The Dean may take steps to dissolve the ERC and appoint a new committee if the ERC fails to carry out its functions to the satisfaction of the Faculty Board. The Dean may take this action only if requested to do so by the majority of the members of the Faculty Board.

4.1 Purpose:

To describe the functions of the members of the ERC, FM/UoK.

4.2 Scope:

This SOP describes the Terms of Reference (TOR) which provide the framework for functions of members of the ERC.

4.3 Responsibility:

It is the responsibility of the ERC members to read and understand their functions as members of the ERC.

4.4 Detailed instructions:

4.4.1 All members of the ERC shall,

1. review applications assigned to them and send the duly completed assessment forms to the ERC secretariat one (1) working day prior to the scheduled ERC meeting.
2. attend the full board meeting and lead the discussion on the applications assigned to them.
3. actively participate in discussion of all applications taken at the full board meeting.
4. participate in special subcommittee meetings assigned by the Chairperson.
5. perform any other duties assigned by the Chairperson.
6. disclose conflict of interests and where a conflict does exist with respect to a study, abstain from reviewing the protocol and leave the room during discussion of and voting on the protocol.
7. undergo periodic training on research ethics according to the requirements of the ERC.

In addition to responsibilities listed above,

8. Scientific members are expected to evaluate a research project on its scientific merits, standards of practice and risks to benefit ratio to the study subjects.
9. Nonscientific members are expected to provide input on matters relevant to their individual knowledge, expertise and experience, professional and otherwise. They are expected to provide feedback on Participant Information Sheets and Informed Consent Forms representing the perception of the study participants.

4.4.2 Apart from functions of members the **Chairperson** shall,

1. conduct all meetings of the ERC according to the SOPs.
2. oversee the work and various activities of the ERC and of its secretariat.
3. elaborate the plans of ERC meetings and other activities.
4. represent the ERC before the appointing authority.
5. sign official ERC documents.
6. oversee and propose educational/training activities for ERC members.

7. provide, on behalf of the ERC, specific consultations with researchers, or appointing authority.
8. take decisions on behalf of ERC, where appropriate (eg: emergency situations or minor action).

4.4.3 Apart from functions of members the **Vice-Chairperson** shall,

1. conduct ERC meetings in the absence of the Chairperson.
2. assist the Chairperson in performing the duties assigned to the Chairperson.
3. oversee up-to-date maintenance of ERC database.

4.4.4 Apart from functions of members the **Secretary** shall,

1. convene ERC meetings.
2. prepare the agenda and maintain minutes of ERC meetings.
3. ensure timely response to applications.
4. convey ERC's opinion on ethical acceptability of the research proposals under its review.
5. communicate with the investigators of approved ongoing research projects.
6. classification of new submissions as initial, expedited or exemption from review.
7. prepare and submit the ERC budget.

4.4.5 Apart from functions of members the **Assistant Secretary** shall,

1. assist the Secretary in performing his/her duties.
2. fulfil the duties of the Secretary in his/her absence.
3. assist the Secretary in classification of new submissions as initial, expedited or exemption from review.
4. take necessary action with regard to submissions with minor modifications and report to the ERC.
5. review final reports submitted and report to the ERC.
6. maintain ERC website.
7. prepare and coordinate clinical trial site visits.

4.4.6 The **Scientific Assistant/Demonstrator** shall,

1. oversee initial submission process for completeness, competence of the investigators andconflicts of interest.
2. prepare documents for ERC meetings, including the agenda and the minutes with the guidance of the ERC Chairperson and Secretary.
3. oversee documentation and archiving processes adhering to SOP.
4. communicate with applicants in matters related to new submissions, continuous monitoring and study closure under the supervision of the Chairperson and Secretary.
5. communicate with ERC membership in relation to meeting notifications and document sharing
6. maintain ERC database.
7. provide administrative support.

4.4.7 The **Office Assistant** shall,

1. receive all paper-based ERC correspondence (new applications, clinical trial communications etc.
2. registration and coding of the protocols at submission for ethics review.
3. distribute proposals and clinical trial communications to relevant reviewers.
4. maintain logbooks for industry-sponsored clinical trials.
5. Provide administrative support.

4.4.8 ERC Subcommittee (ERC-SC)

1. ERC shall have a subcommittee formed with membership from the main committee to attend to the functions stated below.
    1. Expedited review of research protocols with minimal risk to participants.
    2. Review of re-submissions with minor modifications.
    3. Review of minor amendments to previously approved protocols.
    4. Review of progress reports and final reports.
    5. Review communications related to clinical trials including SAEs, SUSARs, protocol deviations/ violations and site visit reports.

2. The minimum composition of the ERC-SC would be the Chairperson, Vice-Chairperson, Secretary, Assistant Secretary and one ERC member nominated by the Chairperson. Primary reviewers of clinical trials will participate at ERC-SC meetings on invitation, if and when communications relating to a particular clinical trial is tabled at the ERC-SC meeting.

3. The ERC-SC shall meet between scheduled ERC meetings and attend to the assigned functions.

4. The ERC-SC shall recommend decisions and appropriate actions to the ERC. Final decision will be taken by the ERC, based on the recommendations made by the ERC-SC.

5. Minutes of the ERC-SC meeting will be included in the agenda for ratification at the next ERC meeting.

4.4.9 Ad hoc sub-committees

1. The ERC may form ad hoc sub-committee/s for the review of student research proposals submitted in bulk(> 10) and the decisions of the ad hoc committee/s will be tabled at the next ERC full board meeting.

2. The ERC may form ad hoc sub-committee/s for expedited review of research addressing pandemic situations or national emergencies.

5.1 Purpose:

To describe the procedures in orientation of new members and continuous training in research ethics for all members of ERC, FM/UoK.

5.2 Scope:

This standard operating procedure describe the procedures for providing adequate orientation of new members and providing continuous training in research ethics for all members of the ERC, FM/ UoK.

5.3 Responsibility:

It is the responsibility of the ERC to provide opportunities to its members to be trained in all aspects of ethical review. It is the responsibility of all members to have themselves educated and trained periodically.

5.4 Detailed instructions:

5.4.1 Orientation of new members may involve all or some of the following:

1. Introduction to other ERC members prior to the ERC meeting.
2. Informal meeting with Chairperson and/ or Secretary to explain their responsibilities as an ERC member,the ERC processes and procedures.
3. Participation at the first ERC meeting following appointment as an 'observer'.

5.4.2 New members will receive training in,

1. Standard Operating Procedures of the committee.
2. Research Ethics and Human Subject Protection.

5.4.3 Training of ERC members

Every member of the ERC should aim to attend at least one training session annually.

ERC, FM/UoK recognizes the importance of training and Continuing Professional Development (CPD) in ethical review. ERC shall,

1. conduct CPD activities at regular intervals.
2. provide financial assistance from ERC funds when required, for specific training and study visits for ERC members subject to approval by the Management Committee of the Faculty of Medicine, University of Kelaniya.

5.4.4 ERC secretariat shall maintain records of the training/workshop/conference activities of each ERC member in chronological order (Annex 4.5.1).

6.1 Purpose:

To describe the procedures for engaging the expertise of independent consultants to the ERC, FM/UoK.

6.2 Scope:

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

6.3 Responsibility:

Upon the advice or recommendation of the secretariat or any ERC member, it is the responsibility of the ERC to nominate name/s of the special consultant/s to be endorsed by the Chairperson.

6.4 Detailed instructions:

6.4.1 The ERC members will nominate suitable experts for external review based on expertise, availability and independence criteria subjected to that person(s) having no conflict of interest and providing an undertaking of confidentiality.

6.4.2 The Secretary / Secretariat will contact the consultant and send the relevant documents for review with the confidentially agreement/COI form (Annex 4.3.2) and the appropriate study assessment form (Annex 4.10.1).

6.4.3 The consultant must return the duly completed confidentiality/COI agreement form and the study assessment form to the Secretary ERC. This will be reviewed by the ERC at the time the study is reviewed.

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

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

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

7.1 Purpose:

Purpose of this SOP is to describe the procedures for declaring and handling COI.

7.2 Scope:

This SOP covers the procedures for declaring COI by the ERC members and handling of COI by the ERC, FM/ UoK.

7.3 Responsibility:

It is the responsibility of the ERC members to understand, accept and report any conflict of interest before the ERC meetings

7.4 Detailed instructions:

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

7.4.2 Examples of conflict of interest may include any of the following:

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

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

7.4.4 All declarations of conflict of interest and the resolutions of same will be recorded in the minutes.

8.1 Purpose:

To describe the procedures of management of protocol submissions

8.2 Scope:

Protocol submissions include: Submission for initial review, resubmission of protocols with corrections, protocol amendments, continuing review of approved protocols, and study closures

8.3 Responsibility:

It is the responsibility of the ERC secretariat to coordinate the process of receiving, recording and distribution of applications for review

8.4 Detailed instructions:

8.4.1 ERC shall receive applications for ethical review in the format given in the application template (Annex 4.8.1–Application Form) or other relevant forms as appropriate (Annex 4.8.2, 4.14.1, 4.14.2,4.14.3). These forms shall be readily available to applicants in the ERC website (http://medicine.kln.ac.lk/prog/erc/).

8.4.2 ERC website shall contain clear instructions to assist applicants in the preparation of theirapplications. Electronic version of the application and the complete set of document should be e-mailed to erc@gmail.com. One hard copy should be submitted to the ERC office before the deadline of submission.

8.4.3 ERC secretariat shall review and verify all documents submitted as per checklist.

8.4.4 ERC secretariat shall ensure that the appropriate fee has been paid at the time of application submission. The fee structure shall be readily available to applicants in the ERC website.

8.4.5 All applications must be submitted to the ERC office by close of business on the last working day of each month. Information on closing date for receipt of new applications for the next ERC meeting shall be readily available to prospective applicants in the ERC web site.

8.4.6 Incomplete applications will be returned to applicant. If the application is complete, ERC secretariat shall date stamp all documents and issue a receipt of acknowledgement to the applicant.

8.4.7 A new application will receive a unique protocol identification number in the format of: P or CT/running protocol number per calendar year/ two digit month of the next available meeting / Year (four digit). e.g.: **Research studies- P/01/03/2022, Clinical trials, CT/01/03/2022.**

8.4.8 The application will be classified as FM/UoK undergraduate research studies, clinical trials and non-interventional studies and will be added to the ERC database.

8.4.9 A protocol specific file will be created to file all documents relevant to the protocol. Soft copy of the protocol will be uploaded to the Google drive folder which can be accessed by all ERC members.

8.4.10 The Secretary and/or Assistant secretary shall screen and categorize applications as full board, expedited or exemption from review.

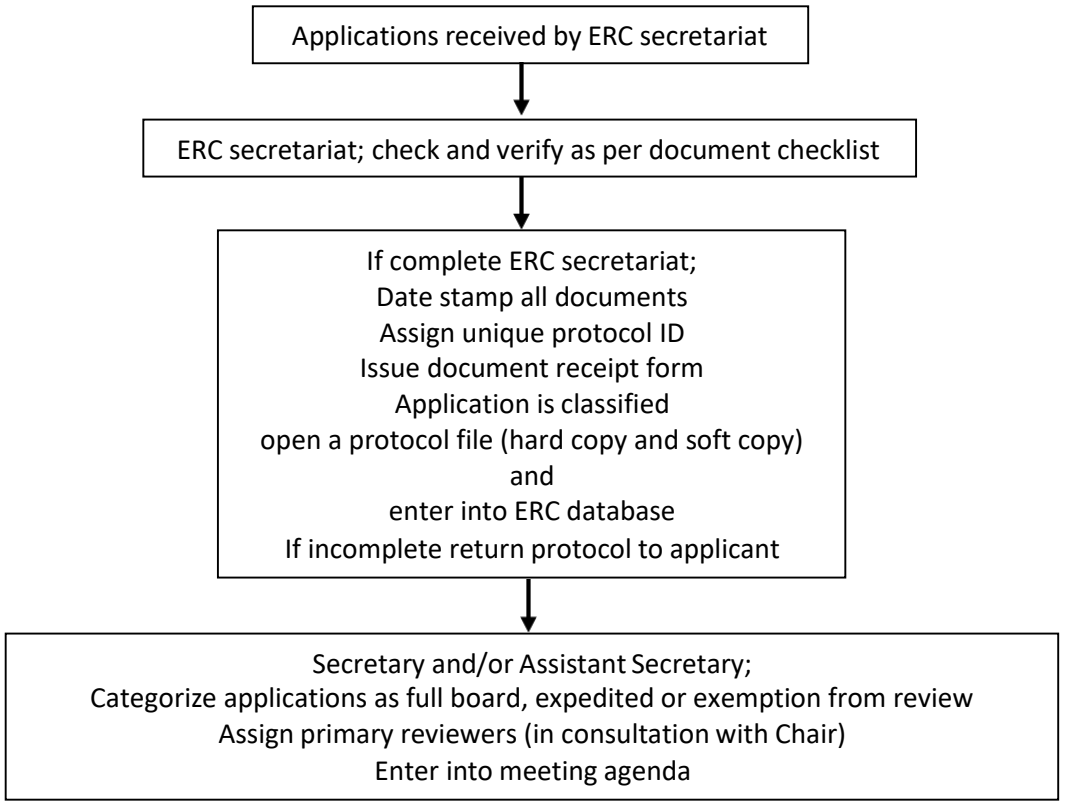
8.4.11 The new applications that require full board review shall be included in the agenda of the next ERC meeting.

Procedures for expedited or exemption from review are described in SOPs 12 and 13.

8.4.12 Student proposals when submitted in bulk (>10) will be evaluated by an ad hoc subcommittee/s and the decisions will be informed to the main committee at the next ERC meeting.

8.4.13 Secretary in consultation with the Chairperson shall appoint three (3) primary reviewers for each protocol including a subject expert wherever possible and a non-science/lay member. Only two primary reviewers will be assigned to student proposals submitted (Department of Disability Studies and Community health strand). Any applications received in relation to the existing protocols shall be directed to the original reviewers of the protocol.

Flowchart 4.8.1: Submission procedure for applications



9.1 Purpose

To identify the administrative process and provide instructions for the preparation, review, approval and distribution of agenda, minutes and action/invitation/notification letters of the ERC meetings.

9.2 Scope

This SOP applies to administrative processes concerning all regular ERC meetings.

9.3 Responsibility

It is the responsibility of the Secretariat to prepare the agenda for the ERC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson should review and approve the agendaand the minutes sent to him/her.

9.4 Detailed instructions

9.4.1 Before the ERC meeting

1. Preparation of the meeting agenda

1. The ERC shall meet on a regular basis, which will usually be at monthly intervals. The Secretary shall prepare an agenda for each meeting.
2. All completed applications and relevant documents received by the closing date will be included in the agenda
3. Agenda items will be numbered by meeting number preceding the item number.
4. Agenda will include the following items.
    1. Apologies
    2. Declaration of conflicts of interest
    3. Confirmation of minutes of the previous meeting
        1. Full board meeting
        2. Subcommittee meeting
    4. Matters arising from the previous minutes
    5. New applications
    6. Resubmissions with modifications
    7. Amendments to approved protocols
    8. Continuing review of protocols
        1. Extension
        2. Progress reports
        3. Protocol deviation/violation
        4. SAEs/SUSARs
        5. Final reports

9. Correspondence
10. Any other business
11. Continuous professional development activity
12. Date and venue for the next meeting

2. Circulation of the agenda and inviting the members to the meeting

1) The Secretary will circulate the agenda, protocols and assessment forms (Annex 4.10.1) and all meeting related documents among members of the ERC at least seven (7) calendardays prior to the respective meeting.

2) Administrative staff members would keep record on the documents circulated and ensure receipt by contacting ERC members.

3. Preparation for the meeting

The venue and facilities would be arranged by the ERC administrative staff.

9.4.2 During the ERC meeting

1. Members may attend ERC meetings in person or via teleconference or video link. Members who are unable to attend a meeting should contribute prior to the meeting through submission of written comments to the Secretary of the ERC. The minutes should record the submission of written comments.
2. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when half plus one of the existing members are present including at least one non-affiliated / lay member.
3. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur the ERC will convene another meeting within ten (10) working days of the cancelled meeting to ensure all agenda items are taken up for discussion.
4. In exceptional circumstances (E.g. meeting to provide information), the Chairperson shall decide to proceed with the meeting even in the absence of a quorum but no decision can be made without quorum.
5. Meetings will not be scheduled for an allocated time. Meetings will continue until all agenda items have been considered. All deliberations will be conducted in a manner that is non-offensive, unbiased, sensitive and inclusive.
6. The ERC meeting will be conducted in private to ensure confidentiality and open discussion. Members will be advised of the venue in the meeting agenda.
7. The ERC may agree to the presence of visitors or observers at a meeting. The visitors/observers should sign confidentiality agreement and declare any conflicts of interest prior to attending the meeting (Annex 4.3.2).

8. Any member of the ERC who has any interest, financial or otherwise in a proposal or other related matter(s) considered by the ERC, must declare such conflicts of interest beforehand (SOP 7).
9. The meeting proceeds in the order organized in the agenda; however, the Chairperson may switch between agenda items depending on the situation.
10. The Secretary records the discussions and the decisions made during the meeting.
11. The approval process starts when one of the primary reviewers gives a briefing about the study and presents his/her observations and comments.
12. In case none of the primary reviewers can be present during the meeting, a member of the Secretariat or an ERC member nominated by the reviewers may give the briefing about the study by reading the comments and evaluation of the reviewers.
13. The other members would give their comments following the primary reviewer's summary – the discussion of the study.
14. The proposals will be reviewed for their scientific merit, risk-benefit ratio, informed consent process, respect for potential and enrolled study participants, and fair participant selection (Annex 4.10.1).
15. The application will be reviewed by all members of the ERC present at the meeting. The ERC will take into consideration written comments received from members in lieu of attendance as well when arriving at a decision. In order to facilitate consideration of an application, the ERC may invite the applicant to attend the relevant meeting to discuss the application and answer questions. The applicant will be asked to leave the meeting prior to ERC deliberation concerning the application and decision-making.
16. The ERC will endeavour to reach a decision by consensus. Any significant dissenting view or concern shall be noted in the minutes. Where a unanimous decision is not reached, the decision will be considered to be carried by the method of plurality after an open vote among the members present as detailed in the section 5.3.
17. The ERC, after consideration of an application at a meeting, will make one of the following decisions.
    1. Approval
    2. Minor modification
    3. Major modification
    4. Disapproval
18. In the event the ERC is not in a position to make a final decision at the meeting, the proposal would be assigned to the next ERC meeting.
19. The ERC may communicate with the applicant either for clarifications or to suggest modifications to improve the quality of the application. This may include inviting the applicant to attend the ERC meeting.

9.4.3 Voting

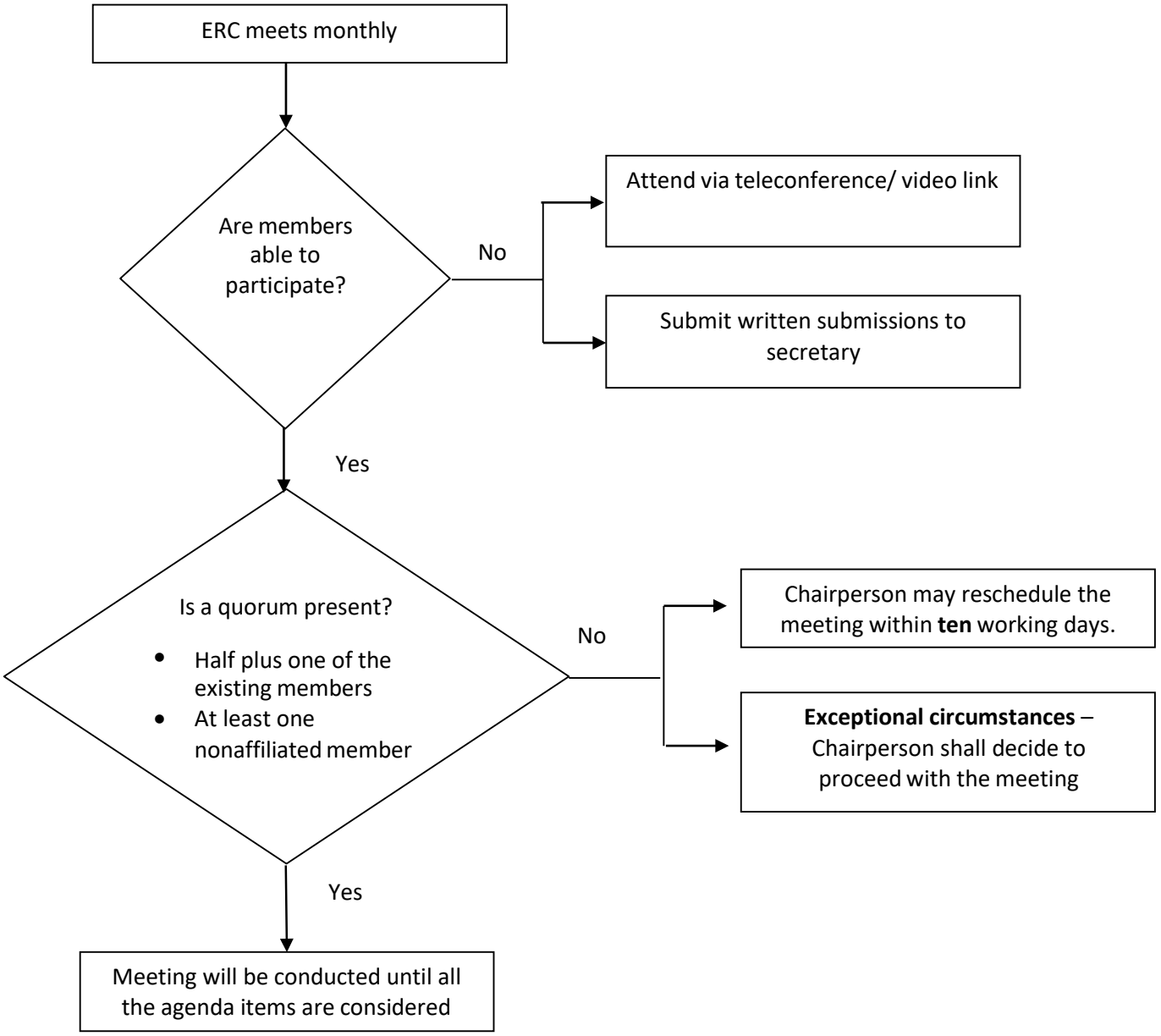
1. All voting will take place after the observers / presenters / ERC members with a conflict of interest leave the meeting room.
2. The Chairperson determines if the number of voting ERC members is sufficient to constitute a quorum and proceeds accordingly.
3. An ERC member makes a motion to recommend action on a protocol or issue being discussed.
4. The motion is seconded and voting takes place.
5. A motion is carried out once the majority of ERC members vote in favor of the motion.

9.4.4 Preparing the Minutes

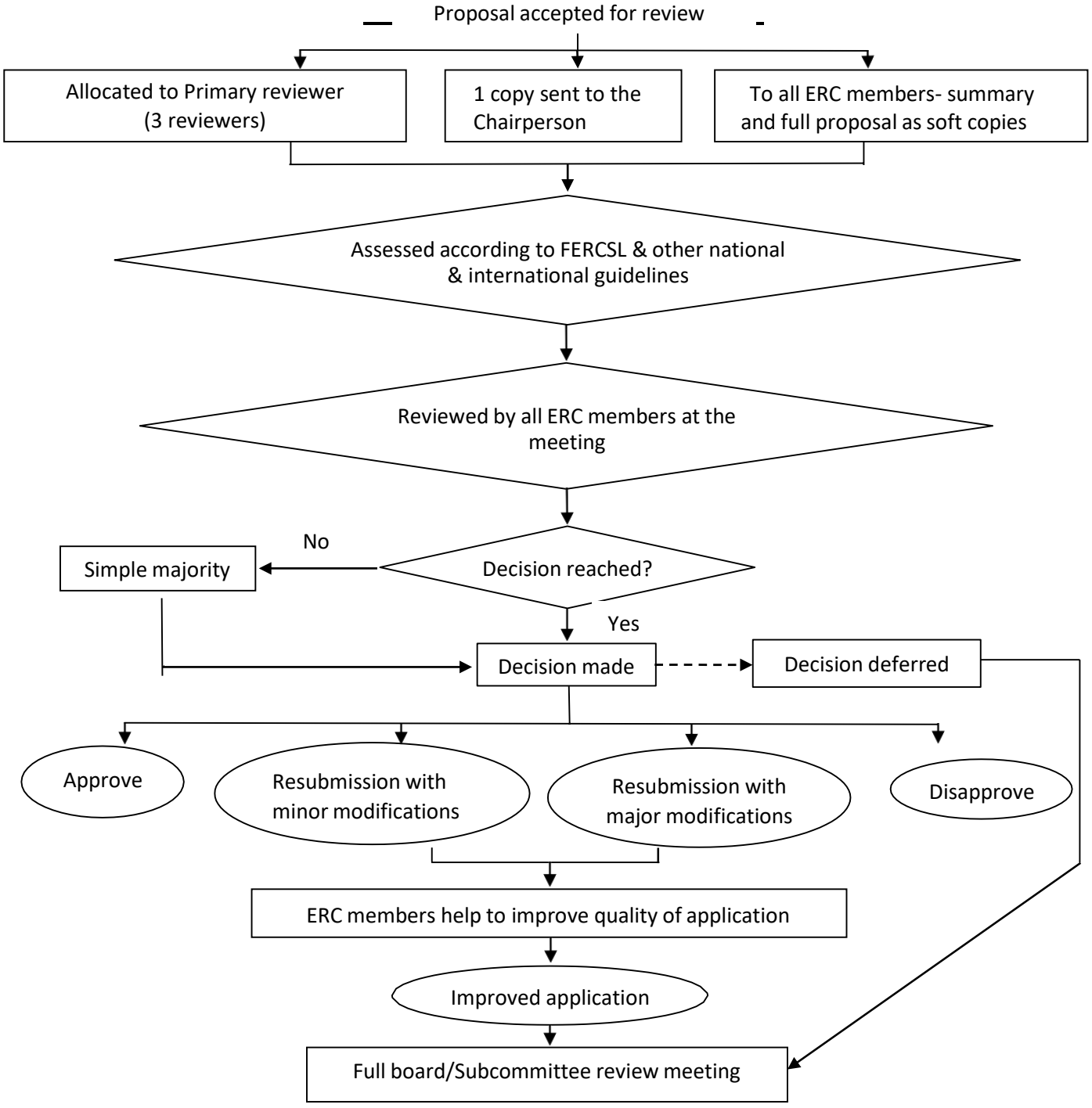
1. The Secretary of the ERC shall prepare and maintain minutes of all meetings of the ERC.
2. Minute items will be numbered by meeting number preceding the item number.
3. The format of the minutes will include the following items,
    1. Attendance.
    2. Conflicts of interest.
    3. Details of confirmation of minutes of the previous meeting.
        1. Full board meeting
        2. Subcommittee meeting
    4. Matters arising from the previous minutes.
    5. New applications.
    6. Resubmissions with modifications.
    7. Amendments to approved proposals.
    8. Continuing review of proposals.
        1. Extension
        2. Progress reports
        3. Protocol deviation/violation
        4. SAEs/SUSARs/Drug safety reports/updates
        5. Final report
    9. Correspondence.
    10. Any other matters.
    11. Continuous professional development activity.
    12. Close and next meeting.
4. The minutes should include the recording of decisions taken by the ERC as well as a summary of relevant discussions. This includes reference to views expressed in writing by absent members.

5. In relation to the review of new applications or amendments, the minutes shall record the ERC's decision and any requests for additional information, clarification or modification of the proposal.
6. In recording a decision made by the ERC, any significant dissenting view or concern will be noted in the minutes.
7. To encourage free and open discussion and to emphasize the collegiate character of ERC deliberations, particular views shall not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.
8. Declarations of conflicts of interest by any member of the ERC and the absence of the member concerned during the ERC consideration of the relevant application will be minuted (Refer to SOP 7 regarding a member's declaration of a conflict of interest).
9. The minutes will be produced within **seven (7)** working days following the relevant meeting and will be checked by the Chairperson for accuracy.
10. The minutes will be circulated among all members of the ERC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their ratification. The minutes will be formally ratified at the next ERC meeting.
11. The confirmed and amended minutes of each meeting (with the inclusion of revisions if any) will be retained in a 'Minutes file' and a copy will be sent to the Dean. Excerpts from the minute relevant to the protocol will be included in the protocol file.

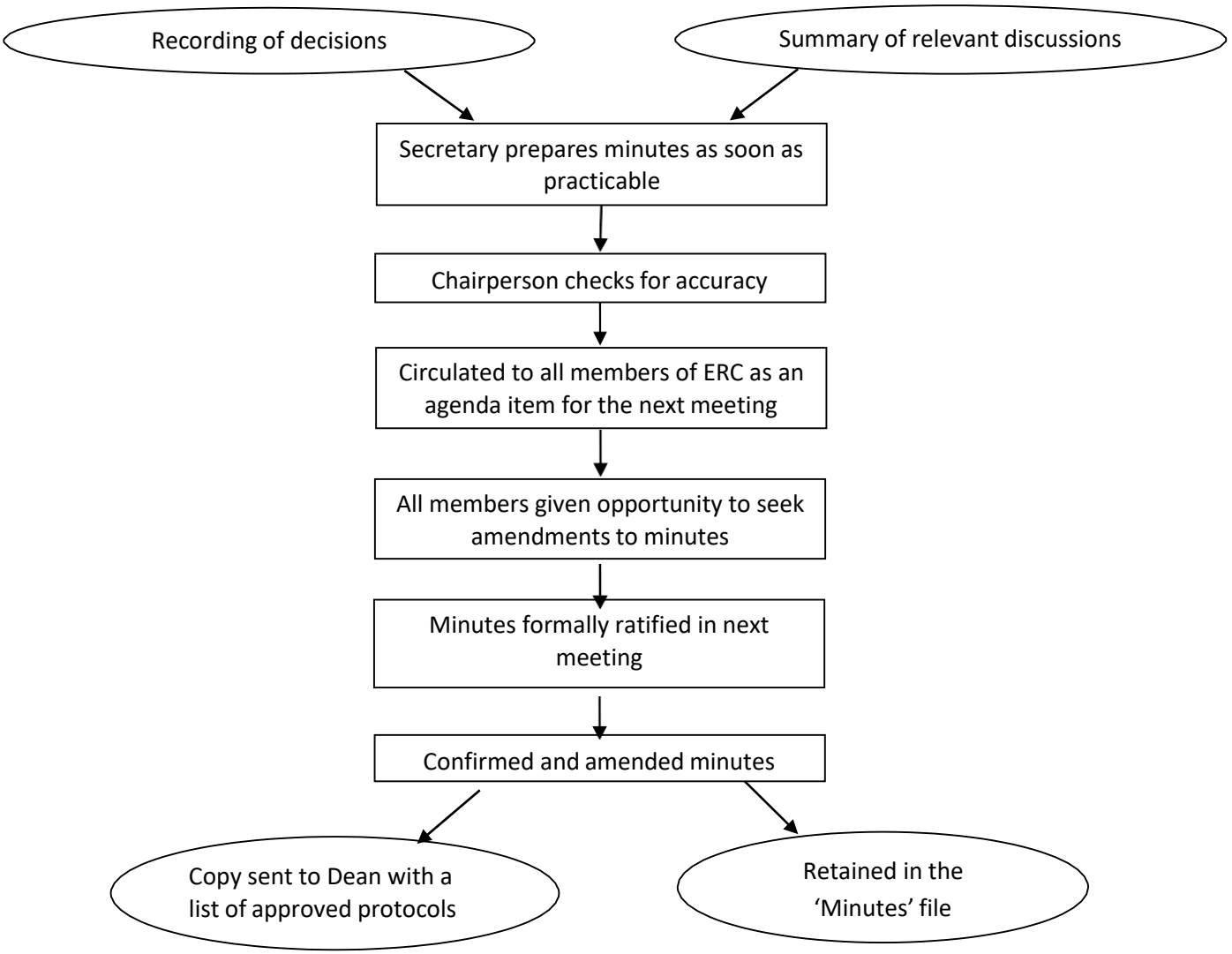
Flowchart 4.9.1: Conduct of meetings



Flowchart 4.9.2: Consideration and approval of applications submitted for ethical review



Flowchart 4.9.3: Preparation of Minutes



10.1 Purpose:

To describe the elements of initial review.

10.2 Scope:

This SOP describes the review process of a new protocol classified for full board review.

10.3 Responsibility:

10.3.1 The ERC office is responsible for the distribution of the protocols classified for full board review to the reviewers, get them reviewed and convey the results to the applicants.

10.3.2 Primary reviewer/s assigned is responsible for thoroughly reviewing the protocols assigned to them, complete and return duly completed assessment form (Annex 4.10.1- Assessment from (Normal/Database) to the ERC office by due date.

10.4 Detailed instructions:

10.4.1 The ERC secretariat shall share the protocols with primary reviewers. All ERC members shall receive access to Google drive folder with protocols in the agenda of that particular month at least seven (7) calendar days prior to the scheduled meeting date.

10.4.2 It is the responsibility of the primary reviewers to review the protocol in detail prior to the meeting and submit written comments to the ERC secretariat by completing the assessment form and to lead the discussion on the protocol at the ERC meeting.

10.4.3 Each application will be reviewed by all members of the ERC present at the meeting or by providing written comments in lieu of attendance.

10.4.4 The ERC will assess each protocol in accordance with relevant national and international guidelines. The ERC shall ensure that it is sufficiently informed on;

1. all aspects of a research protocol, including its scientific merit.
2. anticipated risks and benefits to the participants.
3. participants selection equitably.
4. protection of vulnerable populations.
5. informed consent process.
6. actions taken to ensure protection of privacy and data.
7. researchers plan for monitoring the data collected to ensure the safety of the participants to make fair assessment of ethical acceptability of the application.

10.4.5 The ERC may invite the applicant/an advocate for any participant or group of participants to the ERC meeting to ensure informed decision-making process. Invitees will be requested to sign a confidentiality agreement and will be asked to leave prior to the deliberation and decision making ofthe application.

10.4.6 Where research involves recruitment of persons whose working language is not English, the ERC shall ensure that the PIS and ICF are translated into the participant's language/s and/or that an interpreter is present during the discussion of the project.

10.4.7 ERC shall reach the decision concerning the ethical acceptability of a protocol by consensus. Any significant dissenting view or concern shall be noted in the minutes. Where a unanimous decision is not reached, the decision will be considered to be carried by a method of plurality after an open vote among the members present provided that the majority includes at least one non-medical (or non-science) person.

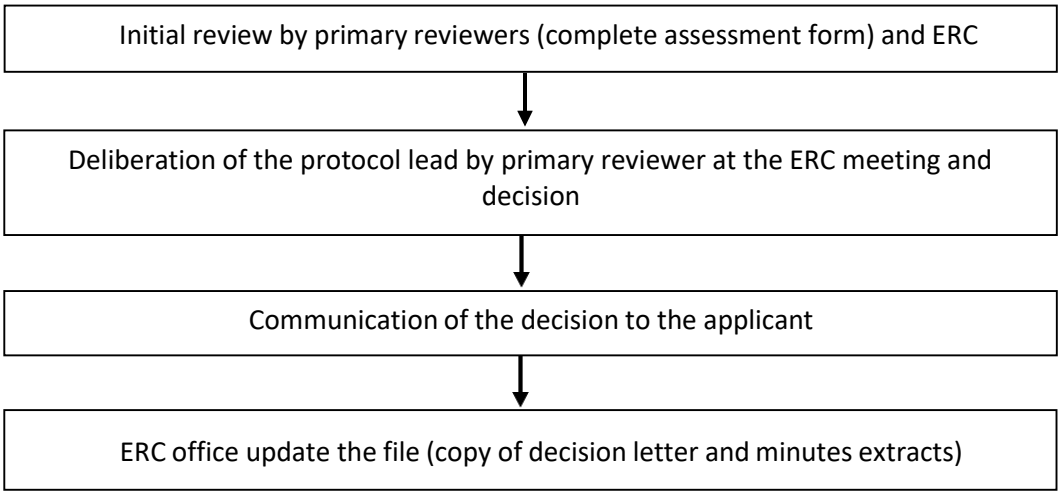
10.4.8 The ERC will deal with multi-center research applications in accordance with both SOPs 20 and 21

10.4.9 The ERC, after consideration of an application, shall reach one of the following decisions:

1. Approve the proposal (no changes required).
2. Minor modification (would be eligible for expedited review once the revisions are done).
3. Major modification (would require an assessment by the primary reviewers and a full board review once the revisions are done).
4. Disapproval.

10.4.10 In the event the ERC is not in a position to make a final decision at the meeting, the proposal would be assigned to the next ERC meeting.

Flow Chart 4.10.1: Initial Review Process



11.1 Purpose:

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

11.2 Scope:

This SOP applies to study protocols that have gone through the initial review process with recommendations from ERC for minor or major revisions.

11.3 Responsibility:

It is the responsibility of the ERC secretariat to direct resubmitted protocols for review through the appropriate channel. Review of a re-submitted protocol containing minor revisions as decided at the initial review, will be considered under expedited review (SOP 13) and review of a re-submitted protocol containing major revisions shall be considered under full board review.

11.4 Detailed instructions:

11.4.1 The ERC website shall contain clear instructions to assist applicants in the preparation of resubmissions.

11.4.2 In case of resubmission with minor modification the revised proposal should be submitted within 30 days of the formal ERC letter informing the decision. The resubmission should address the concerns raised by the ERC and should include a covering letter indicating the revisions. Review of the modified proposal will be delegated to ERC-SC for review and approval. If the modifications are satisfactory a formal letter of approval will be issued and the ERC shall be informed at the next meeting. If the modifications are not satisfactory the investigator will be informed to adequately address the ERC recommendations in a second and final resubmission.

11.4.3 In case of resubmission with major modification the revised proposal should be submitted within 90 days of the formal letter. The resubmission should include a covering letter indicating the revisions carried out and/or justification/s for not executing the revisions suggested bythe ERC. Review of the modified proposal will be delegated to the previously assigned primary reviewers of the protocol and will be reviewed at the next ERC full board meeting.

11.4.4 In the event the ERC is not in a position to make a final decision at the meeting, the proposal would be assigned to the next ERC meeting.

11.4.5 In case of protocols that are not re-submitted within the stipulated time period will be removed from the meeting agenda. This message is conveyed to the investigator with the initial comments. The period may be extended upon request by a PI if the ERC considers the reasons for extension valid.

12.1 Purpose:

To identify the protocols for exemption of ERC review.

12.2 Scope:

This SOP describes the procedure for exemption of a protocol from ethical review.

12.3 Responsibility:

The Secretary and/or Assistant Secretary will screen suitability of protocols to be exempted from review as per checklist (Annex 4.12.1)

12.4 Detailed instructions:

12.4.1 Exemptions are not applicable to studies which involve vulnerable populations.

12.4.2 Protocols that fulfill any of the following conditions can be exempted from ethical review.

1. Research that does not involve collection or use of individual level data or community level data that are on sensitive topics
2. All data to be used are in the public domain.
3. Audit projects carried out using existing data.
4. Research conducted in established or commonly accepted educational settings on education instructional strategies, effectiveness of instructional techniques, curricula, or classroom management methods.
5. Research designed to study, evaluate, or otherwise examine public benefit of service provided by institutions.
6. Research designed as surveys that do not access to sensitive information and identifiable.

12.4.3 Procedure for exempt from review

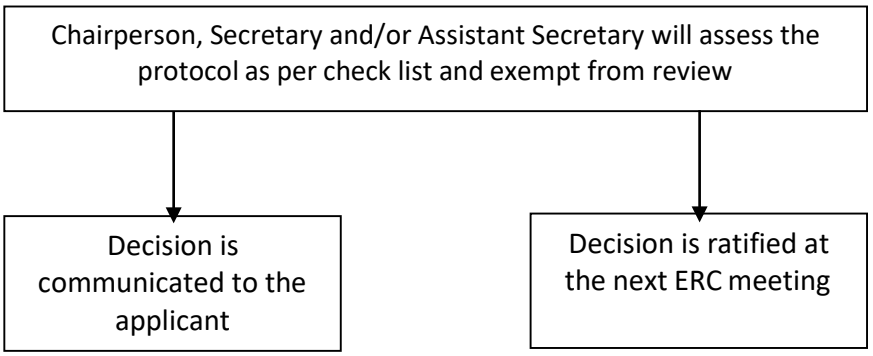
Chairperson, Secretary and/or Assistant Secretary will assess the protocol as per checklist in Annex4.12.1 and may exempt from review.

12.4.4 If required, views of suitably qualified subject experts would be sought before reaching a decision.

12.4.5 If exemption can be granted a formal letter of approval will be issued by the chairperson (Annex 4.12.2)and the decision will be notified to the ERC at the next meeting.

12.4.6 If it is found that the protocol requires full board review, it would be forwarded to the next ERC meetin

Flowchart 4.12.1: Exemption from Review



13.1 Purpose:

To describe the expedited review process.

13.2 Scope:

This SOP applies to

13.2.1 initial review of study proposals with minimum risk to participants.

13.2.2 minor protocol amendments and other study changes of already approved studies that does not require full board review.

13.2.3 resubmissions with minor modifications.

13.3 Responsibility:

It is the responsibility of ERC secretariat to direct the proposals identified for expedited review through the expedited channel.

13.4 Detailed instructions:

13.4.1 Expedited review of protocols may be undertaken between scheduled meetings, at the discretion of the ERC-SC.

13.4.2 New applications that fulfill all of the following conditions are eligible for expedited review.

1. The participants are not considered a vulnerable group.
2. There is minimal or no risk to participants.
3. The topic of research is not considered a sensitive topic.
4. Does not involve use of biological material.
5. Collection of data from voice, video, digital, or image recordings previously made for research purposes
6. Research involving materials (data, documents, records, or specimens) that have been /will be collected solely for non-research purposes (such as medical treatment or diagnosis).
7. Research addressing pandemic situations or national emergencies. Amendments and other study changes that fulfill following conditions are eligible for expedited review.
8. study site is permanently closed to the enrolment of new participants;
9. all participants have completed all research-related interventions; and the research remains active only for long-term follow-up of participants; or where no new participants have been enrolled and no additional risks have been identified; or where the remaining research activitiesare limited to data analysis.

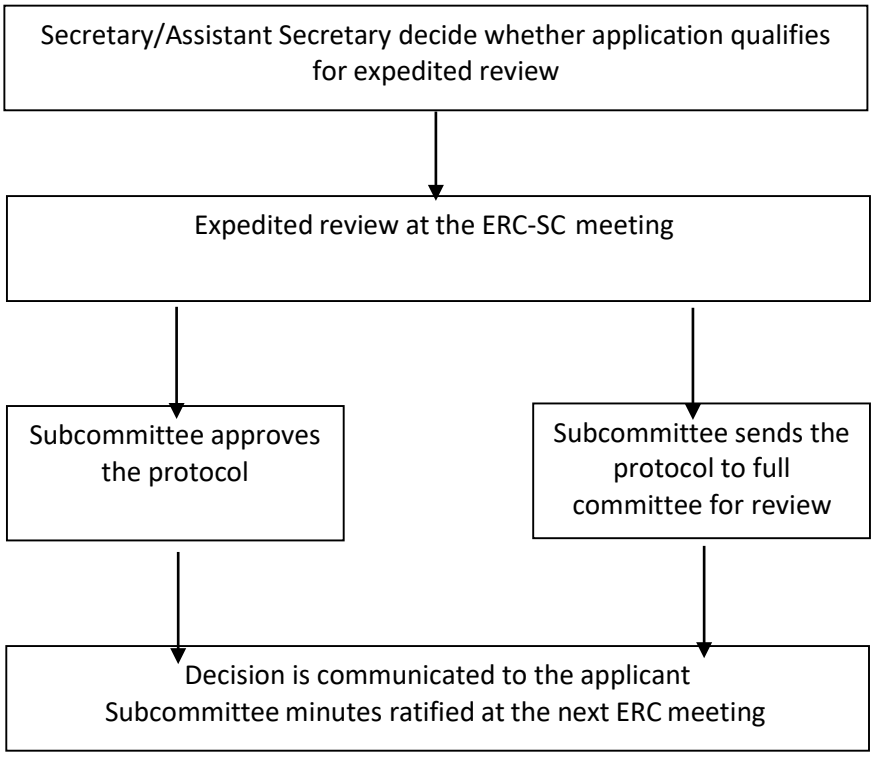
13.4.3 Continuing review of research, not conducted under an investigational new drug application which was determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified are eligible for expedited review.

13.4.4 ERC-SC shall review the protocol as per SOP 10 (review of new application) or SOP 14.4.2 (amendments). If required, views of suitably qualified subject experts would be sought before reaching a decision

13.4.5 If approval can be granted a formal letter of approval will be issued by the Chairperson and /or Secretary and the decision will be notified to the ERC at the next available meeting.

13.4.6 If it is found that the protocol requires full board review, it would be forwarded to the next ERC meeting

Flowchart 4.13.1: expedited review process



14.1 Purpose:

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

14.2 Scope:

This SOP applies to continuing review of study protocols under the approval of the ERC including;

a) Progress reports and extensions
b) Amendments to approved protocols
c) Protocol deviations and violations
d) Safety reports
e) Final reports

14.3 Responsibility:

It is the responsibility of the ERC to

a) monitor the progress of the approved studies
b) review and approve protocol amendments
c) review and take action to protocol deviations and violations
d) review final reports and closure of study files

14.4 Detailed instructions:

14.4.1 Progress reports and extensions

14.4.1.1 ERC shall ensure that periodic reminders are sent to the principal investigators regarding study protocols that are due for continuous review.

14.4.1.2 The ERC shall monitor approved projects to ensure compliance with the conditions for ethical approval. Periodic review of studies approved by the ERC is necessary to determine whether approvalshould be continued or withdrawn.

14.4.1.3 Continuing review of protocols shall be done at intervals appropriate to the degree of risk but not less than once a year.

14.4.1.4 ERC shall require the investigators to provide annual progress reports in the format specified below accompanied with a duly completed progress report submission form (Annex 4.14.1). For research projects lasting less than a year final report would suffice. In the case of clinical trials, the ERC shall require a progress report at 6 months following approval and annual reports thereafter until the completion of the trial, which shall be reviewed by the ERC. In addition, the ERC could call for a progress report at any time when it is deemed necessary.

14.4.1.5 The ERC shall require the following information in the progress reports

1. Progress of the protocol since the time of the last review
2. Any changes to the protocol including changes of investigators and sources of funding

3. Maintenance and security of records
4. Compliance with the approved protocol
5. Compliance with conditions of approval
6. In the case of clinical trials, the progress report should also include:
    a) Number randomized
    b) Number of drop outs
    c) Number of subjects being followed
    d) Summary of SAE, SUSAR with confirmation that they have already been reported to the ERC
    e) Details of protocol deviations and corrective measures taken
    f) Total number randomized in other centers if applicable

14.4.1.6 ERC secretariat shall assign the review of the progress report to the previously assigned primary reviewers of the protocol. The application will be included in the agenda for next ERC meeting.

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

14.4.1.8 The ERC shall require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of the ethical approval of the proposal, including, but not limited to:

1. any unforeseen events that might affect continued ethical acceptability of the project
2. new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the project, or which may indicate the need for amendments to the protocol.

14.4.1.9 The ERC may undertake random site visits as part of monitoring. These site visits will be based on SOP 17.

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

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

14.4.2 Amendments to approved protocols

14.4.2.1 ERC shall ensure that all requests for amendments are accompanied with a duly completed protocol amendment request form (Annex 4.14.2) and a progress report. A processing fee will be levied for review of amendments.

14.4.2.2 Requests for amendments shall include:

1. Details and nature of the proposed amendments
2. Assessment of the ethical implications, if any, that arise as a result of the amendment
3. Protocol and supporting documents incorporating the amendments with revised version numbers and dates. The amended sections should be highlighted.

14.4.2.3 The secretary and/or assistant secretary depending on the nature of the amendments will decide on the type of review.

1. Major amendments will be subjected to full board review and will be reviewed by the same primary reviewers who reviewed the initial protocol. Review of major amendments shall be included in the agenda of the next ERC meeting.
2. Minor amendments shall undergo expedited review by the ERC-SC as described in SOP 13. The decisions will be ratified at the next ERC meeting.

14.4.2.4 The ERC shall make a written communication of the ERC decision to the principal investigator.

14.4.2.5 All reviewed and approved requests for amendments shall be recorded in the relevant protocol file.

14.4.3 Protocol deviations and violations

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

14.4.3.2 The report should include (A template is available on ERC website),

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

14.4.3.3 ERC secretariat shall assign the review of the reported deviations and violations to the previously assigned primary reviewers of the protocol. The submission will be included in the agenda for next ERC-SC meeting.

Detection of Protocol deviation/ non-compliance/ violation/ waiver

a) Protocol deviation/ violation may be reported by holder of the ERC approval to the ERC.
b) The ERC members performing monitoring of the project at trial site may detect protocol deviation/violation if the project is not been conducted as per protocol/ national/ international regulations.
c) The Secretariat may detect protocol deviation/ violation from failure to comply with statutory requirements/ failure to respond to requests from ERC within reasonable time limit/ failure to respond to communication made by ERC.
d) The ERC members may detect protocol deviation/ violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the holder of the approval.
e) Communication/ complaint/ information from research participants who have been enrolled or any individual who has been approached for enrollment.
f) Any report / communication brought to the notice of the ERC

Noting the protocol deviation/ non-compliance/ violation/ waiver

a) The ERC members who have performed monitoring of a particular site and detect protocol deviations / non-compliance/ violation/ waiver will inform the Secretary in writing within 24 hours of first knowledge of the holder of approval on protocol deviations / non-compliance/ violation/ waiver
b) Whenever the protocol deviations / non-compliance/ violation/ waiver has been observed, the Secretary will ensure that the issues as well as the details of the non-compliance involving researchinvestigators are included in the agenda of the ERC meeting.

Board discussion, decision and actions

a) Protocol deviations / non-compliance/ violation/ waiver will be scrutinized for gravity and implications in the ERC meeting.
b) The ERC will review the information and available and take a decision depending on the seriousness of the violation.
c) If unable to come to a decision, ERC will call for additional information.
d) The decision will be taken by consensus and if no consensus is arrived at, a voting will be conducted.
e) The decision will be taken to ensure that the safety and rights of the research participants are safe guarded.
f) The actions taken by the ERC could include one of the following:
    i. Inform the PI that the ERC has noted the violation / deviation, and instruct the PI to ensure that deviations/ violations do not occur in future and to follow ERC recommendations.
    ii. Enlist measures that the PI would undertake to ensure that the deviations / non-compliance/ violation do not occur in future.
    iii. Reprimand the PI.
    iv. Suspend the study till additional information is made available and is scrutinized.
    v. Suspend the study till recommendations made by the ERC are implemented by the PI and found to be satisfactory by the ERC.

vi. Suspend the study for a fixed duration of time.
vii. Revoke the approval of the current study.
viii. Inform other relevant regulatory authorities.
ix. Review and/or inspect other studies undertaken by the PI/Co – PI.

Notify the PI

a) The Secretary records the ERC decision and drafts and types the notification letters.
b) The Chairperson and Secretary, and if needed a member/s signs and dates the letter.
c) The ERC makes copies of the notification letter.
d) The original letter is sent to the PI.
e) Copies of the notification letters are sent to - relevant regulatory authorities –Co-investigators, Sponsor, Director/ Vice Chancellor of the Institution of the PI

14.4.4 Final reports

14.4.4.1 ERC shall receive a final report of completed studies accompanied by a duly completed final report submission form (Annex 4.14.3) within three months of the completion of the study.

14.4.4.2 The final report should comprise of complete summary of the study including outcomes, deviations if any, conclusions and recommendations for future work.

14.4.4.3 ERC secretariat shall assign the review of the final report to the previously assigned primary reviewers of the protocol. The submission will be included in the agenda for next ERC meeting.

14.4.4.4 The submission will be discussed at the ERC. Based on the information provided ERC shall decide whether the study is considered as closed or any further information is needed. Decision will be informed to the PI in writing.

14.4.4.5 Closed study files will be marked as inactive and archived for the stipulated time period (Clinical trials - 15 years, student proposals - 3 years, other studies - 5 years).

15.1 Purpose

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

15.2 Scope

This SOP provides standards and procedures for communicating the decisions of the ERC regarding new applications, resubmissions, amendments and other communications related to studies under the approval ofthe ERC

15.3 Responsibility

It is the responsibility of the chairperson and the ERC secretariat to communicate the decisions of the ERC to applicants

15.4 Detailed instructions

15.4.1 Contents of an ERC decision letter

1. Notification of ethical approval will be given in writing, and will contain the following information:
    1. Title of the project
    2. Unique ERC project identification number
    3. Name of the principal investigator(s)
    4. Version number and date of all documentation reviewed and approved by the ERC including protocols, PIS, ICF, advertisements, questionnaires etc.
    5. Date of the ERC's approval
    6. Duration of the ERC's approval
    7. Conditions of the ERC's approval, if any.
2. If the ERC determines that a project is ethically unacceptable, the notification of the ERC's decision will include the grounds for rejecting (Annex 4.15.1.l) the proposal with reference to the FERCSL guidelines or other relevant guidelines/legal requirements.

15.4.2 Distribution of ERC decision letters

1. ERC decision letter (Annex 4.15.1) of submitted proposals can be collected from the ERC office, Faculty of Medicine, University of Kelaniya, fourteen working days after the monthly ERC meeting unlessnotified otherwise. A scanned copy of the approval letter will also be e-mailed to the PI within 14 days of approval. Approval will be communicated after the necessary payment has been made to the ERC.
2. The status of the project will be updated on the ERC's register of received and reviewed applications.

15.4.3 Other communications related to studies under approval

1. If the ERC determines that further information, clarification or modification is required for the consideration of a protocol, the correspondence to the PI should clearly articulate the reasons for this determination, and clearly set out the information that is required.

Where possible, requests for additional information /clarification /modification should refer to the FERCSL guidelines or other relevant documents.

2. The ERC shall endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of proposals relating to ethical issues. The ERC may nominate one of its members to communicate directly with the applicant or invite the applicant to attend the relevant ERC meeting.

16.1 Purpose:

To describe the actions of the ERC in handling of adverse events reported from approved clinical trials.

16.2 Scope:

This SOP describes the definition of adverse events in a clinical trial, the requirements in reporting them to the ERC and the action taken by the ERC in response to reported adverse events of an approved clinical trial.

16.3 Responsibility:

It is the responsibility of ERC-SC to review the reported adverse events and to communicate recommendations to the ERC and to decide on any further action required. The chairperson shall communicate such recommendation to the investigators.

16.4 Detailed instructions:

16.4.1 The ERC defines Serious Adverse Events (SAE) and serious and unexpected adverse reactions (SUSAR) as per the most updated version of ICH GCP guidelines.

16.4.2 The ERC shall require, as a condition of approval of each proposal that researchers report to the ERC of a SAE in relation to the research project. This should also include ones that have occurred at other institutions participating in the same study including all Sri Lankan sites and any other overseas institutes/sites. Reporting should be done as soon as possible and no later than 15 calendar days after its first knowledge of the holder of the ERC approval.

16.4.3 The ERC shall require, as a condition of approval of each proposal that researchers/sponsors report to the ERC of any fatal or life threatening SUSAR in relation to the study as soon as possible but no later than seven (7) calendar days of its first knowledge of the holder of the ERC approval. This should be a notice that a case qualifies for expedited reporting and it should be followed by a complete report within eight (8) additional calendar days. SUSARs that are not fatal or life threatening must be filed as soon as possible, but no later than 15 calendar days of its first knowledge of the holder of the ERC approval.

16.4.4 The ERC shall require a summary of all SUSARs related to the same investigational product reported from all sites involved with the same protocol driven clinical trial, with a causality statement by researchers/sponsors to the ERC in the form of quarterly line listed reports.

16.4.5 The ERC shall receive notifications of SAEs and SUSARs in the appropriate CIOMS format, and shall include all documentation as required by the ERC. This documentation shall include as a minimum:

1. Patient details – initials, other relevant identifier, gender, age and/or date of birth, weight, height
2. Suspected Medicinal Product(s)
3. Other treatments (concurrent medication)

4. Details of suspected and unexpected adverse reaction – full description of reaction(s) including body site and severity, start date and time of onset of reaction, duration of reaction, setting (e.g. hospital, home), and outcome. This should also include details such as;

    1. Management of events
    2. Causality assessment
    3. Details of reporter – Name, address, telephone number
    4. Other administrative information

16.4.6 The ERC will make the recommended CIOMS form (Annex 4.16.1) available for download in the ERC website.

16.4.7 Safety event reports will be reviewed by the ERC- SC consisting of the chairperson, secretary, assistant secretary and two clinicians of the ERC. ERC-SC will recommend an appropriate course of action depending on the degree of severity. Such action may include one of the following:

1. A notation on the project file of the occurrence
2. Increased monitoring of the project
3. Request for an amendment to Patient Information Sheet/Consent Form
4. Request for additional information (e.g. occurrence of similar events in other centers if the study is being conducted in multiple center)
5. Emergency ERC meeting
6. Immediate suspension of ethical approval
7. Termination of ethical approval

16.4.8 The recommendations of the ERC-SC will be informed to the ERC, at the next meeting.

16.4.9 The ERC shall agree or propose modifications to the recommendations and a final decision will be made for further action required to be taken. This decision will be conveyed to the investigators by the Chairperson.

16.4.10 In the event of suspension or termination of ERC approval the decision of the ERC will also be conveyed to the following authorities:

1. Clinical Trials Registry
2. National Medicines Regulatory Authority

17.1 Purpose:

To describe the method of monitoring approved studies by way of study site visits and to describe the action taken by the ERC based on observations of such site visits.

17.2 Scope:

This SOP describes the method of initiating a site visit to a study site of an approved study, the composition and formation of site monitoring team and the methods of carrying out a site visit and further action taken based on the observations of such a visit.

17.3 Responsibility:

The Chairperson will be responsible for appointment of a site visit team that will make the visit and make recommendation to the ERC and the chairperson shall convey the decisions arrived at the ERC meeting to the investigators and other relevant organizations.

17.4 Detailed instructions:

17.4.1 The ERC shall require as condition of approval the agreement of the PI for site visits for monitoring purposes for all studies approved by the ERC. Such visits may include all study sites and the laboratory facilities used in such studies.

17.4.2 The ERC may undertake such visits on its discretion or to resolve any complaints or concerns regarding the conduct of a study. The Indications for a site visit will include, but not exclusively:

1. reports of remarkable number of serious adverse events/SUSAR
2. reports suggesting non-compliance or suspicious conduct
3. failure to submit progress reports
4. a complaint from study participants, staff on study site or any other interested party

17.4.3 The Chairperson shall appoint monitoring team to carry out the site visit comprised of a minimum of three ERC members out of whom at least one has been trained in carrying out a site visit previously by participating as an observer in a previous site monitoring visit.

17.4.4 The PI shall be contacted and agreed on a mutually convenient date and time for the site visit.

17.4.5 The monitoring team shall complete a site monitoring visit record (Annex 4.17.1) during the visit.

17.4.6 As part of the site monitoring visit the monitoring team shall carryout the following procedures where necessary.

1. Interview
    1. PI and other investigators
    2. Study staff
    3. Study participants if available

2. Review documents
    1. Completed consent forms
    2. Approved versions of the protocol and related documents
    3. Correspondence with the
        1. Regulatory authority
        2. Study sponsor and monitors
        3. ERC
3. Observe
    1. Subject recruitment
    2. Follow-up visits
    3. Laboratory procedures

17.4.7 Based on the observations at the site visit the monitoring team shall complete the site visit report within 14 days of the visit and forward to the ERC secretariat. Secretary shall check the report for completeness and forward the report to ERC-SC or ERC for full board review.

17.4.8 The lead of the monitoring team shall present the findings of the site-visit at next immediate ERC meeting.

17.4.9 The ERC shall consider the observations of the site visit and decide on any further action required to be taken.

17.4.10 Such decisions may include one of the following:

1. continuation of the project with no modifications in its conduct
2. modification to the study conduct
3. temporary suspension or termination of project

17.4.11 The decision of the ERC shall be conveyed to the PI by the chairperson in writing within 14 days ofERC meeting.

18.1 Purpose:

To describe the procedures to follow in handling complaints received by the ERC regarding ERC decisions and the conduct of approved studies.

18.2 Scope:

This SOP applies to any complaint received by the ERC either of a decision of the ERC regarding a review of the ERC or regarding the conduct of an approved study.

18.3 Responsibility:

The Chairperson shall receive complaints regarding decisions of the ERC and of conduct of approved research projects and the ERC shall discuss and decide on any further action required that will be conveyed to the relevant parties by the Chairperson.

18.4 Detailed instructions:

Handling of complaints regarding decisions of the ERC

18.4.1 The Chairperson shall receive written complaints from an applicant or an investigator of an approved study, who is not satisfied with the ERC decision on review or monitoring after such decisions have been conveyed.

18.4.2 The complaint will be tabled at the next ERC meeting and the ERC will appoint a panel of three ERC members to review the decision.

18.4.3 The panel will make recommendations to the next ERC meeting and a decision will be taken on any further action required.

18.4.4 The Chairperson shall convey the decision of the ERC to the complainant within three months of the complaint.

18.4.5 A complainant who is not satisfied with the outcome of the ERC's review of the complaint may complain to the Dean in writing.

18.4.6 In response to such a complaint the ERC shall provide the Dean with all relevant information about the complaint/concern, including:

1. the complaint.
2. material reviewed.
3. The decision of the review panel.
4. any other relevant documentation.

18.4.7 Further action if necessary will be at the discretion of the Dean, and may include one or more of the following:

1. Agree with the ERC decision.

2. Appoint a three member panel comprising the Dean or his/her nominee and two senior academics to review and give recommendations.
3. Any action deemed suitable considering the recommendations of the panel.

Handling of complaints received regarding conduct of research projects approved by the ERC.

18.4.8 The ERC shall receive complaints from research participants, researchers, or other interested individuals regarding the conduct of approved research projects. The ERC shall require the contact details of ERC be included in the Patient / Participant Information Sheet for each project.

18.4.9 The Chairperson of the ERC shall receive any such concern or complaint and the ERC will be notified as soon as possible.

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

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

18.4.12 A panel consisting of a minimum of three (3) members of the ERC will be appointed by the ERC to conduct an investigation of the complaint. This panel upon completion of the investigation shall make recommendations to the ERC on the appropriate course of action. Such recommendations may include one or more of the following actions.

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

18.4.13 The decision of the ERC shall be taken as soon as required but within three months of receiving the written complaint.

18.4.14 The Chairperson shall inform the complainant the action taken in response to the complaint. The complainant will be further informed of their right to refer the complaint to the Dean in the event they are not satisfied with the decision and action taken by the ERC.

19.1 Purpose:

To describe the procedures of the ERC in premature termination of a study, suspension or discontinuation of an approved study.

19.2 Scope:

This SOP applies to any study approved by the ERC undergoing investigator initiated premature termination, or suspension of discontinuation of a study on recommendation by the ERC, sponsor or other authorized body prior to its scheduled completion.

19.3 Responsibility:

The Chairperson shall terminate any study on the recommendation of the ERC and communicate such decisions to the PI and other relevant authorities.

19.4 Detailed instructions:

19.4.1 The Chairperson shall receive recommendations from the PI, sponsor or any other authorized body for premature termination of an approved study. Such recommendations may also originate from the ERC following a complaint or from the monitoring process of a study.

19.4.2 The Chairperson may request the PI to submit all relevant documentation and information that are necessary for the ERC to make a decision.

19.4.3 Such recommendations will be discussed at the ERC meeting and a decision will be taken to either suspend or discontinue the study.

19.4.4 The chairperson shall inform the PI of the decision of the ERC. Such recommendations may also be conveyed to all concerned authorities.

19.4.5 In the event of temporary suspension, the PI shall be notified of any further action that is required prior to review of the decision.

19.4.6 The above notifications will be done within 14 days of the ERC meeting.

19.4.7 In the event the premature termination is not investigator-initiated, the PI will be informed of their right to appeal in writing to the Chairperson and such appeals will be reviewed as described in SOP concerning “handling of complaints”.

20.1 Purpose:

To describe the additional procedures in reviewing protocols of multi-center research.

20.2 Scope:

This SOP describes the additional procedures applies to the review of research conducted at multiple centers.

20.3 Responsibility:

It is the responsibility of the primary reviewer/s to review multi centre research assigned to them considering additional procedures described here.

20.4 Detailed instructions:

20.4.1 This SOP should be read in conjunction with SOP 10 and 21.

20.4.2 In addition to the standard procedure, to facilitate the review of multi-center research, the ERC may:

1. communicate with other ERC(s).
2. take in to consideration the decision of another ERC if it is an accredited Sri Lankan ERC.
3. share its scientific/technical and/or ethical assessment of the research with another ERC.

20.4.3 The ERC will give strong consideration to the equity aspects of benefits of the project to the participants and the community.

20.4.4 If a proposal deals with study subjects away from the local purview of the ERC, investigators may be requested to obtain approval from local ERCs.

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

21.1 Purpose:

To describe review procedures of research involving human biological material (HBM) and data that may require additional considerations by the ERC.

21.2 Scope:

This SOP applies to review of research involving HBM and data.

21.3 Responsibility:

It is the responsibility of the ERC to review research involving HBM taking additional criteria into consideration.

21.4 Detailed instructions:

21.4.1 When reviewing proposals which collect HBM for research, the ERC should ensure that:

1. the burden on the donor is justified by the potential benefits of the proposed research.
2. those involved in the collection of the bio-specimens are suitably qualified or experienced, and follow current best practices.
3. suitable provisions, including financial and governance arrangements have been made for the intended processing, storage, distribution and/or use and disposal of the bio-specimens.

21.4.2 The ERC should ensure that consent in research involving collection and use of HBM includes,

1. consent of the participant who will donate biological materials; or
2. consent of an authorized third party on behalf of a participant who lacks decision-making capacity, taking into account any research directive that applies to the participant; or
3. consent of a deceased participant through a donation decision made prior to death, or by an authorized third party.

21.4.3 Secondary use of HBMs

1. Secondary use of identifiable HBM

1. The ERC shall ensure that additional precautions are taken in the secondary use of identifiable HBMs for research. Secondary use refers to the use of HBMs originally collected for a purpose other than the current research. (Example: use of human biological materials left over from a diagnostic examination or surgical procedure, or materials that were collectedfor an earlier project).
2. When requesting ERC approval for secondary use of HBM, where prior donor consent for useof HBMs in research has been obtained, ERC shall ensure that evidence of such a consent process is provided with the application.
3. Where consent for secondary use of identifiable HBMs in research was not obtained from donors at the time of HBMs collection, a consent waiver may be considered for low or negligible risk.

4 The ERC shall assess the merits of each application for waiver of consent on a case-by-case basis taking the following into consideration.

That:

4.1. secondary use of HBM without consent is unlikely to adversely affect the welfare of individuals or the family from whom the materials were collected.

4.2. appropriate measures have been taken to protect the privacy of individuals.

4.3. the researcher complies with previously expressed concerns of individuals.

4.4. it is impossible or impractical to seek consent from individuals from whom thematerials were collected.

5. When secondary use of identifiable human biological materials without consent has been approved, ERC should make the researcher aware that if the requirement to contact individuals for additional biological materials or information arises that they should seek ERCapproval of the plan for making contact. ERC shall consider following prior to granting permission for such contacts.

That:

5.1. The potential benefits of follow-up contact outweigh the risks to individuals.

5.2. Proposed manner of follow-up contact carries minimal risks to individuals.

5.3. The person who will contact the individuals to invite their participation in the research, and the nature of their relationship with those individuals, are clearly defined.

5.4. Plan for follow-up contact complies with applicable privacy legislation; for example, some privacy laws prohibit researchers from contacting individuals unless the researchers have previously obtained individuals' consent to be re-contacted.

6. ERC should make sure that researchers seek consent from individual participants for any new collection of data or biological materials.

2. Secondary use of non-identifiable HBM

Secondary use of non-identifiable HBMs requires ERC approval but not participant consent.

21.4.4 Transfer of bio-specimens between institutions and countries is subject to a Materials Transfer Agreement (MTA) (Reference - FERCSL) that is in accordance with local policies.

22.1 Purpose:

To describe the procedures for the review and approval of applications for establishment and maintenance of a research database.

22.2 Scope:

This SOP applies for review of research involving establishment and maintenance of a research database.

22.3 Responsibility:

22.3.1 The ERC office is responsible for the classification of protocols that request establishment and maintenance of a research database and assign for full board review.

22.3.2 Primary reviewer/s assigned is responsible for thoroughly reviewing the protocols assigned to them, complete and return duly completed assessment form (Annex 4.10.1.b) to the ERC office by due date.

22.4 Detailed instructions:

22.4.1 In this context, a "research database" means a collection of personal data on human subjects for use in research.

22.4.2 ERC shall assess the application from researchers who wish to establish and maintain research databases taking the following into consideration.

1. A list of data collected
2. Method of data collection
3. Type of the research projects to be undertaken
4. Procedure to obtain consent from patients for use of data
5. Data management process and the methods employed to ensure data security
6. Procedure for amendment and termination
7. Permission from the Head of the Institution to establish and maintain research databases

22.4.3 The ERC shall grant initial approval for maintenance of a database for a period of three (3) years. This could be further extended by 5-year periods.

22.4.4 The ERC approval for establishment and maintenance of a research database is subject to following conditions:

a) Management of such databases is the responsibility of the database research team. Eg: ensure the continued security and confidentiality of data, minimize access of identifiable data within database research team.

b) Any research studies carried out using data available in the database should seek ERC approval separately for conduct of research.

c) Any data given to researchers outside the research database team specified in the application should be anonymized.
d) Any modifications to the database should be approved by the ERC prior to implementation of such modifications.
e) Submission of annual progress reports to the ERC including the number of subjects, the research output and any breaches in security.

23.1 Purpose:

To describe the type of research projects for which ERC may grant a waiver for the requirement of obtaining written informed consent.

23.2 Scope:

This SOP applies to all protocols requesting a consent waiver.

23.3 Responsibility:

It is the responsibility of the ERC to review and approve a request for written consent waiver.

23.4 Detailed instructions:

23.4.1 When a request for waiver of consent is received from the PI in the given format (Annex 4.23.1), the following steps are taken;

1. The Secretariat shall check if the concerned documents are filled completely and the required list of documents is enclosed.
2. The protocol will be assigned to a reviewer for review, taking into consideration the criteria on which waiver of consent may be granted. The submission will be included in the agenda.
3. The ERC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.
4. The final decision whether to grant the waiver is taken at the next meeting, unless the project is considered under expedited review, in which case the waiver is ratified at the next full board meeting.
5. The decision regarding approval/disapproval of waiver is informed to the PI in writing. If the waiver is not granted ERC will provide reasons for same

23.4.2 The ERC may approve a waiver/alteration of the requirements for informed consent for minimal risk research when all four of the following criteria are met:

1. The research involves no more than minimal risk to participants.
2. The waiver/alteration will not adversely affect the rights and welfare of participants (i.e., the research or specific components to which the waiver/alteration applies are designed to protect participant privacy, interests, and well-being).
3. The research could not practicably be carried out without the waiver/alteration (e.g., due to the number or the age of records, it may not be feasible for researchers to contact all persons whose records will be reviewed for a study or the research design requires information about the study be withheld or altered when disclosed to participants).
4. Whenever appropriate, participants will be provided with additional pertinent information

after completing the relevant research activity. Eg: An alteration of the requirements for informed consent for research involving incomplete disclosure/deception, it is appropriate to provide participants with information after participation on the purpose of the research and the purpose of incomplete disclosure/deception.

23.4.3 Type of research projects which may qualify a consent waiver includes, but not limited to,

1. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies
2. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA,samples or data from repositories or registries etc
3. In emergency situations when no surrogate consent can be taken. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the patients whenever he / she gains consciousness or to relative / legal guardian when available later

24.1 Purpose:

To provide instructions for preparation, circulation, maintenance and archiving of ERC documents.

24.2 Scope:

This SOP applies to all study files and their related documents that are maintained in the ERC office.

24.3 Responsibility:

It is the responsibility of ERC Secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

24.4 Detailed instructions:

24.4.1 The ERC Secretariat shall prepare and maintain written records of ERC activities, including agendas, minutes and all communications and relevant documents of all meetings of the ERC.

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

1. Unique project identification number
2. Name/s of principal investigator(s)
3. Name of the responsible institution or organization
4. Title of the project
5. Decision/s of the ERC - approval or non-approval - with date/s
6. Approval or non-approval of amendments and extensions
7. Terms and conditions, if any, of approval of the project
8. Action taken by the ERC to monitor the conduct of the research

24.4.3 The file for each study shall contain a copy of the application with signatures, and any relevant correspondence between the applicant and the ERC, all approved documents and other relevant materials. Excerpts from the minute relevant to the protocol will be included in the protocol file.

24.4.4 All records of the ERC including applications, minutes and correspondence will be kept asconfidential files.

24.4.5 To ensure confidentiality, all documents that are no longer required, will be disposed of in a secure manner such as shredding or via confidential disposal bins. Members are expected to leave their documents in the ERC Office for disposal.

24.4.6 Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum retention period for research excluding clinical trials is five (5) years from the date of publication or completion of the research or termination of the study. Data on clinical trial research shall be retained for a minimum of fifteen (15) years from the date of publication or completion of the research, termination of the study or termination of the ethics approval. 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).

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

25.1 Purpose:

To describe the procedure for review of SOPs and Terms of Reference of ERC, FM/UoK.

25.2 Scope:

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs.

25.3 Responsibility:

It is the responsibility of the ERC Secretariat to appoint a SOP team from ERC members with a thorough understanding of the ethical review process. The SOP team is responsible for the formulation of the SOPs by following the procedure, format, and coding system recommended by the ERC.

25.4 Detailed instructions:

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

25.4.2 The SOP may be amended before three years if the necessity arises. Proposals for such amendments can be proposed by;

1. Accrediting/ recognizing authority
2. Faculty board members
3. ERC members

25.4.3 When amendments are proposed by Faculty board or ERC members, the following steps should be taken,

1. Request for SOP amendment should accompany a SOP revision request form (Annex 4.25.1)
2. The proposed amendments must be circulated among all ERC members for their consideration.
3. The views of the members should be discussed at the next scheduled meeting of the ERC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his/her views in writing.
4. The proposed amendments shall be ratified if two thirds of the members agree to the amendments. ERC decision will be informed in writing to the person who requested the amendment.
5. The Chairperson shall send the amendments to the Dean for approval of the Faculty Board.

25.4.4 The Secretariat will archive the superseded SOPs in a separate file and maintain revision records.

References:

1. Declaration of Helsinki (DoH) of the World Medical Assembly (WMA), 2013.https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf - Accessed on 10.08.2018

2. Council for International Organizations of Medical Sciences (CIOMS), World Health Organization (WHO). International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002.https://cioms.ch/wp-content/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf - Accessed on 08.08.2018

3. International Ethical Guidelines for Epidemiological Studies - Prepared by the Council for International Organizations of Medical Sciences (CIOMS),2009.https://cioms.ch/wp-content/uploads/2017/01/International_Ethical_Guidelines_LR.pdf - Accessed on 21.08.2018

4. International Ethical Guidelines for Health-related Research Involving Humans - Prepared by CIOMS in collaboration with the WHO, Geneva 2016. https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf - Accessed on 21.08.2018

5. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organization, 2011.http://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf;jsessionid=98F2CB91990C29722D4ACD7156AC300A?sequence=1 - Accessed on 20.08.2018

6. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) E6 (R1), 1996.

7. Ethics review committee guidelines, Forum of Ethics Review Committees, Sri Lanka, 2018.

8. WHO Operational Guidelines for Ethical Review Committee that review biomedical research, Geneva 2000.http://www.who.int/tdr/publications/documents/ethics.pdf - Accessed on 21.08.2018

9. https://www.nhmrc.gov.au/book/chapter-3-4-human-biospecimens-laboratory-based-research - Accessed on 15.08.2018

Annex 4.3.1 - The Letter of Appointment

Date:
Name:
Address

Dear.....,

Appointment to the Ethics Review Committee, Faculty of Medicine, University of Kelaniya

I am pleased to inform that you have been appointed as a member to the Ethics Review Committee, Facultyof Medicine, University of Kelaniya (ERC, FM/UoK) for a period of three years effective from <date/month/year>.

As a member of the ERC you are expected to;

1. review proposals submitted for ethics approval as per the standard operating procedures (SOPs) of the ERC, FM/UoK and relevant national and international guidelines
2. regularly attend the ERC meetings
3. undergo periodic training on research ethics

The faculty of Medicine, University of Kelaniya will provide indemnity in respect of liabilities that may arise in the course of *bona fide* conduct of duties as an ERC member during your appointment. The SOP, ERC/FM, UoK is attached herewith.

Please sign the attached copy of the letter of appointment in acceptance of your appointment as an ERC member, and the confidentiality/ conflict of interest agreement and hand over to the ERC office.

Thanking you most sincerely for agreeing to serve as a member of ERC, FM/UoK.

…….
Dean
Faculty of Medicine
University of Kelaniya

LETTER OF ACCEPTANCE

Dean
Faculty of Medicine
University of Kelaniya

Dear Sir,
I accepted this appointment on the terms and conditions specified above.

Date: ……. Signature: ……..

Annex 4.3.2: Confidentiality/ Conflict of Interest Agreement (COI)

Ethics Review Committee

SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC

Faculty of Medicine,University of Kelaniya, Ragama, Sri Lanka

FWA00013225

CONFIDENTIALITY / CONFLICT OF INTEREST AGREEMENT FORM

In recognition of the fact, that I, ...,

herein referred to as the "Undersigned", have been appointed as a member of the Ethics Review Committee, Faculty of Medicine, University of Kelaniya (ERC, FM/UoK) and have been asked to review research studiesinvolving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national/local regulations, institutional policies and national and international guidelines.

Whereas, the appointment of the Undersigned as a member of the ERC, FM/UoK is based on individual merit and not as an advocate or representative of a province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an ERC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the ERC, FM/UoK must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The Undersigned, as a member of the ERC, FM/UoK, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with his/her duties as a member of the ERC, FM/UoK. Any written informationprovided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information")in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the ERC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her

performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

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

It is the policy of the Ethics Review Committee, Faculty of Medicine, University of Kelaniya that no member may participate in the review, recommendation or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the ERC. The Undersigned will immediately disclose to the Chairperson of Ethics Review Committee, Faculty of Medicine, University of Kelaniya any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and will abstain from any participation in discussions or recommendations in respect of such proposals, except to provide information that may be requested by the Committee.

If an applicant submitting a protocol believes that an ERC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict existswith the ERC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

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

A member is an investigator, or a supervisor of the investigator of the protocol

A member is involved in a potentially competing research program

A member is an employee of a drug company sponsoring the research

Any other perceived conflict of interest, including financial, personal and academic

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST

In the course of my activities as a member of the ERC, FM/UoK, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measuresto protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson and will abstain from any participation in discussions or recommendations in respect of such proposals, except to provide information that may be requested by the Committee.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

……..

Name

…… ……

Signature Date

…… ……

Signature of the Chairperson Date
ERC, FM/UoK

Annex 4.5.1: Training Record

Training Record of ERC, FM/UoK

Name of ERC member ……

Date	Name & Duration of Training Programme/ Workshop/ Conference	Conducted by	Certificate of Participation to personal file

Annex 4.8.1: Application Form

Ethics Review Committee

SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC

Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka

FWA00013225

For office use only									
Application No	**P**					**Date received**	**D D**	**M M**	**Y YYY**

Names of the Reviewers

Reviewer 1	
Reviewer 2	
Reviewer 3	

Application for:

Research ☐

Establishment of Database ☐

Study type:

Intervention ☐

Non intervention ☐

Undergraduate project: MBBS ☐ BSc ☐

Part I

Title of the Project

2. Investigators

2.1 Principal investigator

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

2.2 Co-investigator 01/ Supervisor

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

Co-investigator 02/ Supervisor

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

Co-investigator 03/ Supervisor

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

Co-investigator 04/ Supervisor

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

(If there are any more investigators please add their details in an additional sheet)

2.3 Is the principal investigator affiliated to the University of Kelaniya? ☐ Yes ☐ No

2.4 Are any of the co-investigators affiliated to the University of Kelaniya? ☐ Yes ☐ No

2.5 Is ERC, Faculty of Medicine, University of Kelaniya the closest Ethics Review Committee to the study site? ☐ Yes ☐ No

2.6 Is this an industry sponsored study? ☐ Yes ☐ No

*****If the answers to all above questions (2.3-2.6) are 'No', please note ERC, Faculty of Medicine, University of Kelaniya is unable to accept your application.**

3. Select all that applies to this study

a) Does this research involve collection or use of individual level data? ☐ Yes ☐ No

b) Does this research involve collection or use of community level data that are on sensitive topics? ☐ Yes ☐ No

c) Are all data to be used in the research in the public domain? ☐ Yes ☐ No

d) Is this an audit carried out using existing data? ☐ Yes ☐ No

e) Are participants in this study considered as a vulnerable group? ☐ Yes ☐ No

f) Is the risk involved to the participants minimal? ☐ Yes ☐ No

g) Does the research involve use of biological material? ☐ Yes ☐ No

4. Nature of the research project

4.1 Specify the type of study

4.1.1 Observational/non interventional study:

In ☐

In ☐

4.1.2 Clinical trial:

Investigator initiated ☐

Industry sponsored ☐

4.1.3 Other intervention studies ☐

4.1.4 Research database

4.1.5 Other

4.2 **Is this for an academic degree?** ☐ Yes ☐ No

4.2.1 If for an academic degree, specify:

4.2.2 Degree awarding University:				
4.2.3 Registration status	Registered	☐	Pending	☐
	Date of Registration			

5. Proposed dates of commencement and completion the study

[From initial recruitment of participants until completion of all data collection]

Date of commencement ***Click here to enter a date.***

Date of completion ***Click here to enter a date.***

6. Has ethical approval for this study been requested earlier from this Ethics Review Committee? ☐ Yes ☐ No

If yes,

Reference number	
Decision*	
Date	

* Attach documentary evidence

7. Has ethical approval for this study been requested from any other Ethics Review Committee? ☐ Yes ☐ No

If yes,

Name of ERC	
Reference number	
Decision *	
Date	

* Attach documentary evidence

8. Has this project been subjected to scientific review? ☐ Yes ☐ No

If yes,

Name and address of the committee	
Decision *	
Date	

* Attach documentary evidence

9. Estimated budget of your project*

Less than Rs.100,000 ☐
Rs.100,000 - Rs.300,000 ☐
Rs.300,000 - Rs. 1 Million ☐
Rs. 1 Million - Rs. 5 Million ☐
Over Rs. 5 Million ☐

*** Include budget in the proposal**

10. Funding status

10.1 Status ☐ Planning to apply ☐ Decision pending ☐ Funding secured ☐ Self funded
10.1.1 If funded:

Name and address of funding agency	
Amount	

10.2 Do the study subjects have to incur any expenses by being participants in the study? ☐ Yes (Specify) ☐ No

11. Collaborative research

11.1 List the collaborating institutes and its role

	Institution	Recruitment	Lab facility	Logistics	Intellectual	Any other
1.						
2.						
3.						

*** Attach documentary evidence**

11.2 Has this study been submitted to an ERC / similar body in the country/ countries of foreign collaborator/s? ☐ Yes ☐ No

If yes,

a)

Name and address of the committee	
Decision *	
Date	

b)

Name and address of the committee	
Decision *	
Date	

c)

Name and address of the committee	
Decision *	
Date	

*** Attach documentary evidence**

If no, give reason/s

11.3 What is the relevance of this study to Sri Lanka?

11.4 Are biological samples to be transferred abroad? ☐ Yes ☐ No

If yes,

a) Attach the material transfer agreement

b) Describe the fate of the biological sample at the conclusion of the study

12. Intervention study

12.1 What phase clinical trial/intervention study is being conducted?

Phase I ☐

Phase II ☐

Phase III ☐

Phase IV ☐

Others (Specify) ☐

12.2 If it is the clinical trial, is it registered with a clinical trial registry (CTR)? ☐ Yes ☐ No

12.2.1 In which CTR is this registered?

Name of the registry	

***Please provide evidence of registration if already registered/ once registration has been obtained**

12.3 Is it a multicenter trial? ☐ Yes ☐ No

If yes, list the other centers.

Country	Center	Effective date of joining the trial

12.4 Has ethical approval been obtained to conduct the study in centers given in 12.3 from relevant bodies? * ☐ Yes ☐ No

Center	Name of the ERC	Date of approval

***If yes, attach documentary evidence**

***If no, give justification**

12.5 What is the procedure for dealing with adverse events?

12.6 What is the procedure for reporting adverse events?

*** Attach documentary evidence**

12.7 What is / are the criteria for termination of the trial?

12.8 Are the participants paid? ☐ Yes ☐ No
If yes, amount of money per participant per visit?

12.9 Are the investigators paid? ☐ Yes ☐ No
If yes, by whom and the amount?

12.10 Details of insurance coverage for participants

***Attach documentary evidence**

12.11 If Patient recruitment is not taking place in foreign collaborating institution explain why?

13. Conflicts of Interest

13.1 Declare any conflicts of interest that you may have in conducting this project (commercial/ financial/ intellectual/ other)

13.2 Does any member of the research team have any affiliation with the providers of funding/ support or financial interest in the outcome of research? ☐ Yes ☐ No
If yes, explain

14. Declaration of Applicant

1. As the Principal Investigator of this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants.
2. I understand that if there is any deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation.
3. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study.
4. I declare that I am not seeking approval for a study that has already commenced or has already been completed.
5. I will submit progress reports/reports of adverse events and side effects/ final report as requested by the ERC.

…….. ……..

Signature of the Principal Investigator Date

15. Consent from all investigators

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

Name	**Institutional Affiliation**	**Signature**

Part II – Protocol Checklist
Title of the Project:

		Page
1	Title	
2	Summary of the project	
3	Introduction/ background	
4	Objectives of the study	
5	Justification	
6	Review of literature	
7	Budget	
Methodology		
8	Study design	
9	Place of study	
10	Duration of the study	
11	Study population	
12	Sample size and calculation of sample size	
13	Inclusion criteria	
14	Exclusion criteria	
15	Study instrument/s	
16	Pilot study	
17	Sampling/ recruitment procedure	
18	Description of procedure	
19	Data collection	
20	Data analysis	
21	Maintenance and fate of data	
22	Dissemination of results	
Ethical issues		
23	Assessment of risks/ benefits	
24	Procedure for obtaining consent	
25	Informed consent form	
26	Participants Information sheet	
27	Justification for including vulnerable population	
28	Fair participant selection	
29	Procedures to protect the rights of participants	
30	Confidentiality/Privacy	
31	Voluntary participation right to refuse or withdraw without penalty	
32	Safety monitoring	
33	Responsibilities of the researchers	
34	Provision of medical and psychological support to participants	

Biological Samples		
35	Justification for using biological sample/s	
36	Procedures for collection, storage and disposal of biological sample/s	
37	Consent for collecting biological sample/s	
38	Protection of the rights of local collaborator	
39	Justification for transfer of data and /or biological/ genetic materials to the country of foreign collaborator	
40	Fate of transferred data and biological/ genetic material	
Clinical trial		
41	Investigator brochure	
42	Clinical record forms	
43	In case of multi centre studies listing of overseas centre(s) and ERC/IRB approval status if relevant and copies of ERC/IB approval letters from other centers	
44	Principle investigators'/ coordinating PI's curriculum vitae and evidence of Good Clinical Practice training	
45	Product liability letter or insurance certificate	
46	Patient recruitment procedures	
47	Patient's diary cards (if required in non clinical trial proposals as well) Justification for use of placebo	
49	Criteria for termination of participants from the trial	
50	Criteria for termination of the trial	
51	Adverse event monitoring, management and reporting	
52	Justification for withholding/ withdrawing standard therapy	
53	Provision for making the trial drug available after completion of the trial	

I understand that the application for ethics clearance will not be accepted unless all necessary documents are submitted and are in correct format. I hereby state that I have declare all conflicts of interests related to project financial or otherwise and I am not seeking approval for a study that has already commenced or has already been completed.

		DD	MM	YYYY
	Date			

Signature of the Principal Investigator

Annex 4.8.2: Checklist for ERC application submission

Ref No: New/Major/Minor/Amendment

Please make sure to complete this check list before submission of your proposal

All documents (**PDF formats only**) mentioned in the checklist below should be submitted as **soft copies** at the initial submission to ERC office email (erc@kln.ac.lk). Required hard copies specified in the ERC checklist should be handed over to the ERC office once the proposal is accepted.

1.	Complete application form- **1 hard copy**					Yes	
2.	Single paged summary- **1 hard copy** (if the summary is not in the correct format the proposal will not be accepted)					Yes	
3.	Protocol (English)- **1 hard copy**			Yes	Version:	Date:	
4.	**Are the following included in the protocol**						
	Participant information sheet	English	Yes	NA	Version:	Date:	
		Sinhala	Yes	NA	Version:	Date:	
		Tamil	Yes	NA	Version:	Date:	
	Consent Form	English	Yes	NA	Version:	Date:	
		Sinhala	Yes	NA	Version:	Date:	
		Tamil	Yes	NA	Version:	Date:	
	Questionnaire/Data collection instrument	English	Yes	NA	Version:	Date:	
		Sinhala	Yes	NA	Version:	Date:	
		Tamil	Yes	NA	Version:	Date:	
5.	Short CV (maximum 2 pages) of the Principal investigator (Signed and dated) indicating previous research experience in conducting research- **1 hard copy**					Yes	
6.	Short CVs of all investigators (Maximum 2 pages from each) indicating their previous experience in conducting research (Soft copy only. Preferably PDF files. DO NOT SUBMIT HARD COPIES)					Yes	
7.	Is the title in the application, summary and proposal same?					Yes	
8.	Budget					Yes	
9.	ERC fee						
	▪ University of Kelaniya undergraduate project					Free	
	▪ Industry sponsored intervention/observational study					$ 1 000	
	▪ Other applications according to budget						
	- <Rs.100,000					Rs. 1 000	
	- Rs. 100,000 - 300,000					Rs. 2 000	
	- Rs. 300,000 - 1,000,000					Rs. 5 000	
	- Rs. 1,000,000 - 5,000,000					Rs.10,000	
	- >Rs. 5,000,000					Rs.20,000	
	▪ Application for establishment of database					Rs. 1 000	
	▪ Annual renewal of Industry sponsored studies					$ 500	
	▪ Significant amendments to Industry sponsored studies					$ 250	
	▪ Significant amendments to other projects					Rs. 2 500	
10.	Evidence of GCP Training (compulsory for clinical trial applications)					Yes	No
11.	Research for Postgraduate Degreerequirement	Supervisors Letter				Yes	No
		Approval Letter from Post Graduate Institute				Yes	No

Investigator's Name/ Designation:

Investigator's Signature: Date:

Recipient's Signature: Date:

Annex 4.10.1.a: Assessment form for research studies

Ethics Review Committee

SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC
Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka
FWA00013225

Protocol Assessment Form

Ref. number:	P/……..	……..	……..	Reviewer's Name:

If not acceptable, please give reasons. Suggestions for improvement can be given even when something is acceptable.

Assessment of Protocol								
1.	**Study type (Circle all applicable)**							
	Prospective	Retrospective	Survey	RCT	Non - RCT	Genetic	Behavioral	Epidemiological

		Yes	No	Remarks
2.	**Scientific validity**			
a.	Is the title reflective of study?			
b.	Are literature review and justification adequate?			
c.	Are general and specific objectives clearly stated?			
d.	Is the study design appropriate to achieve objectives stated?			
e.	Is the study population appropriate?			
f.	Are inclusion and exclusion criteria appropriate?			
g.	Is sample size adequate?			
h.	Is sampling procedure clearly described?			
i.	Is methodology clear?			
j.	Are outcomes achievable?			
k.	Is plan for data analysis and statistics use acceptable?			
l.	Are biological samples being collected?			

3.	**Ethical aspects of protocol**			
a.	Is the research team competent (check CVs)			
b.	Will the study increase knowledge or contribute towards improvement of human health?			
c.	Is the need for human participants justified?			
d.	Has the study population been selected based on the study aims?			

e.	Is the risk/benefit acceptable?			
f.	Are there any conflicts of interests including payments/ other rewards?			
g.	Is the initial contact and recruitment procedure acceptable?			
h.	Dose the selection of participants favour or stigmatized any groups?			
i.	Are the participants considered a vulnerable group?			
If the participants are considered vulnerable group assess (j) and (k)				
j.	Can the research be conducted in less vulnerable population with similar outcomes			
k.	Is the risk/benefit favourable?			
l.	Are the facilities at the study site adequate?			
m.	Is consenting procedure acceptable?			

A - Acceptable U - Not acceptable
If not acceptable, please give reasons. Suggestions for improvement can be given even when something is acceptable.

4.	**Participant information sheet (PIS)**	A	U	
a.	Purpose of the study			
b.	Description of procedure			
c.	Risks / benefits			
d.	Privacy/ Confidentiality			
e.	Voluntary participation and right to refuse			
f.	Right to withdraw without penalty			
g.	Contact information of investigators and ERC			
	Use of biological material			
h.	Collection procedure and quantity			
i.	Transfer overseas			
j.	Storage for future use			
k.	Consent to contact for future use			

5.	**Consent form**	A	U	
a.	Information sheet is provided to participant			
b.	Understanding of information sheet by the participant (purpose/ risks/ benefits explained)			
c.	Voluntary agreement to participate			
d.	Right to withdraw from the study			

e.	Agreement of participant for use of his biological samples and personal information			
f.	Agreement of participant for store HBM and consent to contact			

6.	**To be completed only for research using Human Biological Material (HBM)**			
a.	Is the collection of HBM justified?			
	Are the participants informed of:			
b.	the type(s) of HBM collected?			
c.	quantity of the HBM collected?			
d.	what tests are carried out?			
e.	Will samples be stored for future use?			
f.	If samples are stored for how long, location of storage and for what purpose?			
g.	Do the participants have to bear the cost of lab tests?			
h.	Are the materials being transferred overseas?			
i.	Is the MTA attached?			

7. Budget category				
< Rs. 100,000	Rs. 100,000 - RS. 300,000	Rs. 300,000 - RS. 1 M	Rs. 1 M - RS. 5 M	> Rs. 5M
Is budget realistic?			Yes	No

8. Decision	
Approved	
Resubmission with minor modifications	
Resubmission with major modifications	
Disapproval	

9. Other remarks if necessary

Date: Signature of Reviewer:

Annex 4.10.1.b: Assessment Form for establishment and maintenance of a research database

Ethics Review Committee

SIDCER (Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC

Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka

FWA00013225

Assessment Form for establishment and maintenance of a research database

Ref. number:	P/			Reviewer's Name:
Title:				

A - Available & Acceptable
U - Available & Unacceptable
NA- Not available
NR- Not relevant

	Item	A	U	NA	NR	Comments
1	Involvement of the research data base team in care of the patient population.					
2	Specifying a key person responsible for the database					
3	Specifying the list of data to be collected.					
4	Description of the method of the data collection					
5	Outline of type of research project to be undertaken					
6	Description of the method of data collection.					
7	Description of security of collected data.					
8	Specifying the access to database is specified					
9	Specify the procedure for amendments					
10	Specifying the procedure of termination					
11	The consent form					
12	The Data collection form					

Other comments:	

Based on the above comments,

proposal can be approved.	
request resubmission of the proposal with minor modifications.	
request resubmission of the proposal with major modifications.	
disapprove the proposal.	

Signature:……. Date:……

Annex 4.12.1: Checklist for Exemption

CHECK LIST FOR PROTOCOLS EXEMPTED FROM REVIEW

Ethics Review Committee, Faculty of Medicine University of Kelaniya

		Yes	No	Comments
1.	Audits of educational practices/programmes that are conducted			
2.	Research on regular or special education instructional			
3.	Research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods			
4.	Research on immortalized cell lines			
5.	Research on cadavers or death certificates			
6.	Research on microbes cultured in the laboratory provided such research reveals no identifying personal data			
7.	Analysis of data freely available in public domain			
8.	Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to			
If YES to any of the above, check:				
9.	Is the risk involved to the participants minimal?			
10.	Does the research involve vulnerable groups?			
11.	Does the research involve interviews?			
12.	Does the research involve observation of public behavior or minors and the researcher participates in the activities being			
13.	Does the survey deals with sensitive or highly personal aspects of the subject's behaviour, life experiences or attitudes? (sensitive surveys) e.g. substance abuse, criminal behaviour, sexual activity/attitude, sexual abuse etc.			
14.	Does the data provide identification of subjects?			

15.	Would the information if disclosed outside research reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?			
16.	Does the research involve use of biological material?			
If NO to ALL of the above → Exempt from review				

<Signature>

Chairperson/ Secretary/Assistant Secretary
ERC

Annex 4.12.2: Template of Standard letter for Exemption

< Date>

< ERC Ref. No: >

<Name and Address of the corresponding investigator >

Dear <Name of the corresponding investigator >

< Proposal title>

< Investigators>

I am pleased to inform you that, ERC after reviewing the following documents according to guidelines set by Standard Operating Procedure Version 4 - SOP 12, has exempted the above titled research from ethical review. Thisdecision is subject to confirmation at the next ERC meeting to be held on <next meeting date>.

	English		**Sinhala**		**Tamil**	
	Version	**Date**	**version**	**Date**	**version**	**Date**
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Yours sincerely,

< Signature >
Chairperson /ERC

Annex 4.14.1: Progress report submission form

Ethics Review Committee

SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC

Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka

FWA00013225

Progress report submission form

Ref. number:	**P**												**Research**	**Clinical trial**	**Database**

Details of the study

Title:											
Original date of approval:	**Date**			**Month**			**Year**				
Principal investigator:											
Name:											
Address:											
Phone			**E-mail:**								
Start date:			**Number recruited:**								

Please attach Progress report containing following information

For all studies

a. Progress to date
b. Maintenance and security of records
c. Compliance with the approved protocol
d. Compliance with conditions of approval

For clinical trials the progress report should also include:

a. number randomized and number of drop outs
b. number of subjects being followed up
c. summary of SAE, SUSAR and protocol deviations and corrective measures taken
d. total number randomized in other centers if applicable

For Databases the progress report should also include:

a. breaches of security if any
b. Summary of research output

Signature of the principal investigator:		**Date:**	DD	MM	YYYY

Annex 4.14.2: Protocol Amendment Request Form

Ethics Review Committee

SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC
Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka
FWA00013225

Protocol Amendment Request Form

ERC Reference No: P/ / /				
Protocol Title:				
Principal Investigator				
Name:				
Address:				
Phone No:	**E mail Address:**			
ERC Approval date: DD/MM/YYYY	**Amendment No:**			
Do these amendments increase the risk to the participants?		**Yes**	**No**	
***If yes provide details**				
Do these amendments raise any new ethical issues?		**Yes**	**No**	
***If yes provide details**				
Attach a Summary of amendments with reasons and page no				
Signature of PI:	**Date**	**DD**	**MM**	**YYYY**

Annex 4.14.3: Final Report Submission Form

Ethics Review Committee

SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC

Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka

FWA00013225

Final Report Submission Form

Ref. number:	**P**											**Research**	**Clinical trial**	**Database**

Details of the study											
Title:											
Original date of approval:	**Date**			**Month**			**Year**				
Principal investigator:											
Name:											
Address:											
Phone				**E-mail:**							
Date of submission				**Total number of participants recruited:**							

Study site(s):								
Number analysed:								
Start date of recruitment:			**End date of recruitment:**			**Project end date:**		
DD	**MM**	**YYYY**	**DD**	**MM**	**YYYY**	**DD**	**MM**	**YYYY**
Adverse events:								
Main findings:								

Details of conference presentations:					
Details of publications/ plans for publication:					
Is final report attached?					**yes**
Signature of the principal investigator:		**Date:**	**DD**	**MM**	**YYYY**

Annex 4.15.1: ERC Decision Letter Templates

Annex 4.15.1.a: Template of Standard Approval letter (without comments) for research proposal

< Date>

<ERC Ref. No:>

< Name and address of the corresponding investigator>

Dear<Name of the corresponding investigator>,

< Proposal title>

<Investigators>

Thank you for submitting the above referenced research proposal. I am pleased to inform you that the Ethics Review Committee, which met on < meeting date > has granted approval to the above study after reviewing the following documents.

	English		Sinhala		Tamil	
	Version	Date	version	Date	version	Date
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Please note that this approval will remain valid for a period of one year from the meeting date stated on this letter.
Please note that the ERC expects to be informed about the following.

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

An application for extension of approval should be submitted along with a progress report if the study is expected to continue beyond the approved period. Such application should be submitted at least two months prior to expiry of the period of approval.

The final report of the study should be submitted within three months of completion of the study.

Thank you.
Yours sincerely,

< Signature >
Chairman and / Secretary/ERC

Annex 4.15.1.b: Template of Approval letter (with comments) for a research proposal

< Date>

<ERC Ref. No >

< Name and address of the corresponding investigator>

Dear<Name of the corresponding investigator>,

< Proposal title>

<Investigators>

Thank you for submitting the above referenced research proposal. I am pleased to inform you that the Ethics Review Committee which met on < meeting date > has granted approval to the above study after reviewing the following documents.

	English		Sinhala		Tamil	
	Version	Date	version	Date	version	Date
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Conditions of approval

- <insert comments>

Please note that this approval will remain valid for a period of one year from the meeting date stated on this letter.
Please note that the ERC expects to be informed about the following.

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

An application for extension of approval should be submitted along with a progress report if the study is expected to continue beyond the approved period. Such application should be submitted at least two months prior to expiry of the period of approval.

The final report of the study should be submitted within three months of completion of the study.

Thank you.
Yours sincerely,

< Signature >
Chairman and / Secretary/ERC

Annex 4.15.1.c: Template of Extension of approval

< Date>

<ERC Ref. No >

< Name and address of the corresponding investigator>

Dear<Name of the corresponding investigator>

< Proposal title>

<Investigators>

I am pleased to inform you that Ethics Review Committee has extended the ethical approval for the above project for one (1) year period from <date of expiration of ERC approval >. Please note that document approved and conditions of approval remain as stated in the previous approval letter.

Thank you.

Yours sincerely,

< Signature >
Chairman and / Secretary/ERC

Annex 4.15.1.d: Template of Amendment approval

< Date>

<ERC Ref. No >

< Name and address of the corresponding investigator>

Dear<Name of the corresponding investigator>

< Proposal title>

<Investigators>

I am pleased to inform you that Ethics Review Committee which met on < meeting date > has approved amendments to the following documents.

	English		Sinhala		Tamil	
	Version	Date	Version	Date	Version	Date
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Please note that the ERC approval period and condition of approval remains as stated in the previous approval letter.

Thank you.

Yours sincerely,

< Signature >
Chairman and / Secretary/ERC

Annex 4.15.1.e: Template of Approval letter for clinical trial

<Date>
<Our Ref No>
< Name and Address of the corresponding investigator>
Dear < Name of the corresponding investigator >
<Title>
I am pleased to inform you that Ethics Review Committee of the Faculty of Medicine, University of Kelaniya (ERC) has approved above titled clinical trial.
Details of the approval are as follows:
Project ref. No:
Investigators: <Name>
Approval date:
First progress report due:
Documents approved: Annex A
ERC approval is valid for one (1) year from the approval date stated in this letter and is granted subject to following conditions.

Conditions of Approval

1. All Clinical Trials must comply with the requirement to register on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE) requirements.
2. Submit the clinical trials registry registration number to the ERC prior to the recruitment of the first subject.
3. Notify the ERC of the actual date of commencement of the trial.
4. Continuing compliance with the National guidelines on Ethical Conduct in Human Research.
5. Submission of a progress report at six months following approval and annual reports thereafter until the completion of the trial. Failure to submit reports will result in withdrawal of ethics approval for the project.
6. All serious adverse event (SAE) in relation to the research project, including those that have occurred at other institutions participating in the same study should be notified as soon as possible and no later than 15 calendar days after its first knowledge.
7. The ERC shall require, as a condition of approval of each proposal that researchers/sponsors report to the ERC of any fatal or life threatening serious and unexpected adverse event (SUSAR) in relation to the study assoon as possible but no later than 7 calendar days of its first knowledge. This should be a notice that a case qualifies for expedited reporting and it should be followed by a complete report within 8 additional calendardays. SUSARs that are not fatal or life threatening must be filed as soon as possible, but no later than 15 calendar days of its first knowledge.
8. All protocol deviations/violation should be notified to the ERC as soon as possible, but no later than 15 calendar days of its first knowledge.
9. Any developments that might affect continued ethical acceptability of the project should be reported to the ERC as soon as possible.
10. Any changes to the project including protocol changes and changes of research personnel must be notifiedto the ERC and approval obtained before such changes are implemented.

Principal Investigator's responsibilities:

1. You must retain copies of all signed Consent Forms (if applicable) and provide these to the ERC on request.
2. It is your responsibility to provide a copy of this letter to any internal/external agencies if requested.

Please do not hesitate to contact the ERC Office should you require further information or clarification.

Thank you.

Yours sincerely,
<Signature>
Chairman and /Secretary/REC

Annex A: Documents approved
Annex B: List of members present at ERC meeting held on < date of meeting >

Annex A: Documents Approved

List of Documents Approved

Project ref. No:
Approval Date:

	English		Sinhala		Tamil	
	Version	**Date**	**version**	**Date**	**version**	**Date**
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Annex B: List of members present at ERC meeting held on < date of meeting >

Following members were present at the ERC meeting:
<Insert names>

Annex 4.15.1.f: Template of Approval letter for clinical trial extension

<Date>

<Our Ref No>

< Name and address of the corresponding investigator >

Dear< Name of the corresponding investigator >

<Title>

I am pleased to inform you that Ethics Review Committee of the Faculty of Medicine, University of Kelaniya (ERC), which met on < date of meeting > has extend the ethics approval for the above study for one year period from the <previous approval expiring date>

Details of the approval are as follows:

Project ref. No:

Investigators: <Name>

Original approval date:

Next progress/annual report due:

Documents approved: Annex A

ERC approval is granted subject to following conditions**.**

Conditions of Approval

1. Continuing compliance with the National/international guidelines on Ethical Conduct in Human Research.
2. Provision of annual reports until the completion of the trial. Failure to submit reports will result inwithdrawal of ethics approval for the project.
3. All serious adverse event (SAE) in relation to the research project, including those that have occurred at other institutions participating in the same study should be notified as soon as possible and no later than 15 calendar days after its first knowledge.
4. The ERC shall require, as a condition of approval of each proposal that researchers/sponsors report to the ERC of any fatal or life threatening serious and unexpected adverse event (SUSAR) in relation to the study assoon as possible but no later than 7 calendar days of its first knowledge. This should be a notice that a case qualifies for expedited reporting and it should be followed by a complete report within 8 additional calendardays. SUSARs that are not fatal or life threatening must be filed as soon as possible, but no later than 15 calendar days of its first knowledge.
5. All protocol deviations/violation should be notified to the ERC as soon as possible, but no later than 15 calendar days of its first knowledge.
6. Any developments that might affect continued ethical acceptability of the project should be reported to the ERC as soon as possible.
7. Any changes to the project including protocol changes and changes of research personnel must be approved by the ERC before the research project can proceed.

Principal Investigator's responsibilities:

1. You must retain copies of all signed Consent Forms (if applicable) and provide these to the ERC on request.
2. It is your responsibility to provide a copy of this letter to any internal/external agencies if requested.

Please do not hesitate to contact the ERC Office should you require further information or clarification.

Thank you.

Yours sincerely,

<Signature>

Chairman and / Secretary/ERC

Annex A: Documents approved

Annex B: List of members present at ERC meeting held on < date of meeting >

Annex A: Documents Approved

List of Documents Approved

Project ref. No:
Approval Date:

	English		Sinhala		Tamil	
	Version	**Date**	**version**	**Date**	**version**	**Date**
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Annex B: List of members present at ERC meeting held on < date of meeting >

Following members were present at the ERC Meeting:
<Insert names>

Annex 4.15.1.g: Template of Approval letter for databases

<Date>
<Our Ref No>
< Name and address of the corresponding investigator >
Dear < Name of the corresponding investigator >
<Title>
I am pleased to inform you that Ethics Review Committee of the Faculty of Medicine, University of Kelaniya (ERC) has approved above titled research database.
Details of the approval are as follows:
Project ref. No:
Investigators: <Name>
Approval date:
First progress report due:
Documents approved: Annex A
ERC approval is valid for three (3) year from the approval date stated in this letter and is granted subject to following conditions.

Conditions of Approval

1. The approval will be granted for establishment and maintenance of the database only. Any research studies carried out using data available in the database should obtain ERC approval separately.
2. Submission of annual progress reports to the ERC. This should include the number of subjects, the research output and any breaches in security. Failure to submit reports will result in withdrawal of ethicsapproval for the project.
3. Any modifications to the database should be informed to the ERC prior to implementation of such modifications.
4. Any data given to researchers outside the research database team specified in the application should be anonymized.
5. Any developments that might affect continued ethical acceptability of the project should be reported to the ERC as soon as possible.

Principal Investigator's responsibilities:

1. You must retain copies of all signed Consent Forms (if applicable) and provide these to the ERC on request.
2. It is your responsibility to provide a copy of this letter to any internal/external agencies if requested.

Please do not hesitate to contact the ERC Office should you require further information or clarification.

Thank you.
Yours sincerely,

<Signature>
Chairman and / Secretary/ERC

Annex A: Documents approved
Annex B: List of members present at ERC meeting held on < date of meeting >

Annex A: Documents Approved

List of Documents Approved

Project ref. No:
Approval Date:

	English		Sinhala		Tamil	
	Version	**Date**	**version**	**Date**	**version**	**Date**
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Annex B: List of members present at ERC meeting held on < date of meeting >

Following members were present at the ERC meeting:
<Insert names>

Annex 4.15.1.h: Template of Approval extension letter for databases

<Date>
<Our Ref No>
< Name and address of the corresponding investigator >
Dear < Name of the corresponding investigator >
<Title>
I am pleased to inform you that Ethics Review Committee of the Faculty of Medicine, University of Kelaniya (ERC) has extended the ethical approval to maintain above titled research database for a period of five (5) years from the <original approval expiry date>.
Details of the approval are as follows:
Project ref. No:
Investigators: <Name>
Original approval date:
Next progress report due:
Documents approved: Annex A
ERC approval is extended granted subject to following conditions.

Conditions of Approval

1. The approval will be granted for maintains of the database only. Any research studies carried out using data available in the database should obtain ERC approval separately.
2. Continuing compliance with the National guidelines on Ethical Conduct in Human Research.
3. Submission of annual progress reports until the completion to the ERC including the number of subjects, the research output and any breaches in security. Failure to submit reports will result in withdrawal of ethics approval for the project.
4. Any modifications to the database should be informed to the ERC prior to implementation of such modifications.
5. Any data given to researchers outside the research database team (those named in the application) should be anonymised.
6. Any developments that might affect continued ethical acceptability of the project should be reported to the ERC as soon as possible.

Principal Investigator's responsibilities:

1. You must retain copies of all signed Consent Forms (if applicable) and provide these to the ERC on request.
2. It is your responsibility to provide a copy of this letter to any internal/external agencies if requested.

Please do not hesitate to contact the ERC Office should you require further information or clarification.

Thank you.
Yours sincerely,

<Signature>
Chairman and / Secretary/ERC

Annex A: Documents approved
Annex B: List of members present at ERC meeting held on < date of meeting >

Annex A: Documents Approved

List of Documents Approved

Project ref. No:
Approval Date:

	English		Sinhala		Tamil	
	Version	**Date**	**version**	**Date**	**version**	**Date**
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Annex B: List of members present at ERC meeting held on < date of meeting >

Following members were present at the ERC meeting:
<Insert names>

Annex 4.15.1.i: Template of Standard letter for resubmission with minor revisions

< Date>

<ERC Ref. No>

< Name and Address of the corresponding Investigator >

Dear < Name of the corresponding Investigator >

<Proposal title>

<Investigators>

Thank you for submitting the above referenced research proposal. Ethics Review Committee which met on <meeting date>reviewed the proposal and suggested following minor modifications prior to approval.

- < Modifications >

Please resubmit one hard copy and a soft copy of the proposal document (with changes highlighted) along with a covering letter indicating the changes. Please resubmit within 30 days of the date of this letter.

Yours sincerely,

< Signature>
Chairman and / Secretary/ERC

Annex 4.15.1.j: Template of Standard letter for resubmission with major revisions

< Date>

< ERC Ref. No :>

< Name and address of the corresponding investigator>

Dear <Name of the corresponding investigator>

<Proposal title>

<Investigators>

Thank you for submitting the above referenced research proposal. Ethics Review Committee which met on <meeting date>reviewed the proposal and suggested following modifications prior to consideration for approval.

- < Modifications >

Please resubmit four hard copies and a soft copy of the proposal document (with changes highlighted) along with a covering letter indicating the changes. Please resubmit within 90 days of the date of this letter.

Yours sincerely,

< Signature>
Chairman and / Secretary/ERC

Annex 4.15.1.k: Template of Standard letter for Expedited approval

< Date>

<ERC Ref. No :>

< Name and address of the corresponding investigator>

Dear<Name of the corresponding investigator>,

<Proposal title>

<Investigators>
Thank you for submitting the above referenced research proposal. I am pleased to inform you that above research was granted ethical approval after an expedited review. This is subjected to confirmation at the next meeting of the Ethics Review Committee to be held on <next meeting date>.

Documents reviewed.

	English		Sinhala		Tamil	
	Version	Date	version	Date	version	Date
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Approval Date:
Please note that this approval will remain valid for a period of one year from the date stated on this letter.
Please note that the ERC expects to be informed about the following,

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

An application for extension of approval should be submitted along with a progress report if the study is expected to continue beyond the approved period. Such application should be submitted at least two months prior to expiry of the period of approval.

The final report of the study should be submitted within three months of completion of the study.

Thank you.

Yours sincerely,

< Signature >
Chairman and / Secretary/ERC

Annex 4.16.1.I: Template of Standard letter of Rejection

< Date>

< ERC Ref. No: >

<Name and address of the corresponding investigator >

Dear <Name of the corresponding investigator >

< Proposal title>

< Investigators>

Thank you for submitting the above referenced research proposal. I regret to inform you that the Ethics Review Committee, which met on <Meeting Date>, did not approve the above proposal based on the submitted documents.

	English		Sinhala		Tamil	
	Version	Date	version	Date	version	Date
Protocol						
Instruments						
Participant Information sheet						
Consent form						

Reasons for this decision among many are,

- <comments>

You may make a new application after addressing all above concerns.

Yours sincerely,

< Signature >
Chairman and / Secretary/ERC

Annex 4.16.1.I: Template of Standard letter to be issued for pending grants

< Date>

< ERC Ref. No: >

<Name and address of the corresponding investigator >

<Dear <Name of the corresponding investigator >

< Proposal title>

< Investigators>

This is to inform you that the Ethic Review Committee has completed the review process of your proposal and the committee met on (*include the date*) decided to approve the proposal. However, the approval letter to commence the research work will be provided once you submit evidence for receiving your research grant and complete the payment procedure according to the fee structure in the ERC based on the amount of your research grant.

Yours sincerely,

< Signature >
Chairman and / Secretary/ERC

Annex 4.16.1: CIOMS Form

(https://cioms.ch/wp-content/uploads/2017/05/cioms-form1.pdf - Date accessed 20.08.2018)

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20 DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO-DUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOWUP	

Annex 4.17.1: Clinical Trial Site Monitoring Visit Record

Ethics Review Committee

SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC
Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka
FWA00013225

Clinical Trial Site Monitoring Visit Record

(Time- Start: End:)

Date of visit :
Review Team Members :

ERC Reference No :
Protocol :

Sponsor :
Site No :
Hospital :
Principle Investigator :

	Criteria	Checked	Comment
Ethics and Regulatory Documents			
1	ERC approval letter for study		
2	Regulatory approval letter for study		
3	Acknowledgements of Bi Annual Reports		
4	SLCRT registration of the trial		
5	Financial Disclosure Agreements		
6	ERC approval for latest version of study protocol		
7	ERC approval for latest version of ICF		
8	ERC approval for latest versions of posters/pamphlets		
9	ERC approval for latest versions of Investigator's Brochure		
10	Insurance Statement		
Investigator and Study Team Eligibility			
11	CV of clinical research coordinators *Standard Operating Procedures (Version 4), Octobe*	*2018 – ERC, Faculty of Medicine University of Kelaniya* 100	
12	GCP training evidence of study staff		

13	Training log for study staff		
Subject Eligibility			
14	Procedure for review of inclusion and exclusion criteria for patients		
Informed Consent			
15	Review evidence of conducting informed consent process (documented or observed)		
16	Consent withdrawals and reasons		
Subject Safety			
17	ERC acknowledgement of all SAEs		
18	ERC acknowledgement of all SUSARs within stipulated time lines		
19	Review of subject withdrawals and their reasons		
20	Follow up of subjects who have withdrawn consent / who have been withdrawn from the Study		
21	ERC acknowledgement of all protocol deviations		
22	Decoding procedures (For blinded studies)		
23	Subject Identification Code List		
Conducting the Clinical Trial			
24	Responsibility Delegation log		
25	Subject screening log		
26	Subject enrollment log		
27	Source documents		
28	Adequate monitoring by Sponsor and evidence		
Investigational Product Management			
29	Condition of Storage of IP		
30	IP labels		
31	Instruction to handle IP		
Laboratory			
32	Accreditation for the laboratories used for the Study		

33	Laboratory and Diagnostic samples (Labeling, storage, shipment, laboratory manual if applicable)		

Persons Interviewed		
Name		**Designation**
1.		
2.		
3.		
4.		
5.		

Comments (Add additional sheets if required):

Signature of reviewers	**1)**	**2)**	**3)**

Annex 4.23.1: Waiver of Informed Consent Request Form

Ethics Review Committee

SIDCER (Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC**Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka**

FWA00013225

Waiver of Informed Consent Request Form

Name of Principal Investigator	
Protocol Number	
Title of Study	

1 Does the research involve more than minimal risk to participants? ☐ Yes ☐ No

2 Will the waiver of informed consent adversely affect the welfare and rights of the participants? ☐ Yes ☐ No

3 Reasons for requesting a consent waiver –
Please tick the reason(s)

a) There is no direct contact between the researcher and participant ☐

b) Retrospective studies, where the participants are de-identified or cannot be contacted ☐

c) Certain types of public health studies/surveillance programmes/programme evaluation studies ☐

d) Research on anonymized biological samples/data ☐

e) Research on using data available in the public domain ☐

f) Any other (please specify)- ☐

4 Attach a statement including the following information-

a) justification for the waiver of consent
b) assurance that the rights of the participants are not violated
c) measures described in the protocol for protecting confidentiality of data and privacy of research participant

My signature below indicates my assurance that my answers to the above questions are complete, true and accurate.

Name & Signature of PI/ Designee : Date:

Ethics Review Committee

SIDCER (Strategic Initiative for Developing Capacity in Ethical Review) recognized ERC

Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka

FWA00013225

SOP revision request form

Name:				
Designation:				
Are you an ERC member?	Yes		No	
Details of the proposed amendment:				
a. SOP Version No:				
b. SOP Number and Title:				
c. Proposed amendment :				
d. Justification for the proposed amendment:				
Signature:	Date	DD	MM	YYYY