STANDARD OPERATING PROCEDURES

Faculty of Medicine University of Ruhuna

Ethics Review Committee

September 2018

[Version 2]

STANDARD OPERATING PROCEDURES

Ethics Review Committee
Faculty of Medicine University of Ruhuna

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	Title: History and Functions of ERC	

1. History of Ethics Review Committee, Faculty of Medicine, University of Ruhuna

Ethical review Committee (ERC), FM, UOR reviews all types of research proposals involving human and animal studies. It was established in 1985 with six members and 50% of them were clinicians. Membership of Forum for Ethics Review Committees of Sri Lanka was obtained in 2017. The objective is to maintain standards of practice in research, including protection of human participants, animals and other living organisms, while promoting high quality research which is ethically and scientifically sound. The ERC is involved in the capacity building in research ethics among the academics, students and the scientific community in Southern Province.

2. Purpose

It describes the overall function and responsibilities of the Ethics Review Committee. This SOP describes the Terms of Reference (TOR) which provide the framework for the constitution, responsibilities and activities of the Ethics Review Committee (ERC), Faculty of Medicine (FM), University of Ruhuna (UOR) and applies to all activities of the ERC, FM, UOR.

3. Scope

3.1. The primary objectives of the ERC,FM,UOR are to protect the rights, dignity and safety of human participants used in research, to facilitate ethical research through efficient and effective review and monitoring processes, to promote ethical standards of human research and to review research in accordance with the current *Ethics Review Committee Guidelines* of the Forum of Ethics Review Committees in Sri Lanka (FERCSL Guidelines) and the latest versions of relevant national and international guidelines (1-13).

3.2. The ERC shall entertain applications for ethics approval from researchers as specified below. Such applicants should show qualifications and experience in the relevant field or be under the supervision of a senior researcher in the same field. Principal Investigator/at least one of the investigators must belong to one of the following categories to accept the application for reviewing;

(a). A member of the academic staff (permanent/temporary) of the University of Ruhuna

(b). Staff members attached to the hospitals in the Southern Province

(c). Undergraduates of University of Ruhuna

(d). Trainers and trainees of the Faculty of Graduate Studies(FGS), University of Ruhuna

(e). A researcher who is conducting the research project in a study setting in Southern Province.

3.3. The Ethics Review Committee shall:

3.3.1. advise the FM, UOR, Faculty Board (FB) on all matters relating to the ethics of research involving human subjects;

3.3.2. review proposals for research involving human subjects taking care that the cardinal ethical principles of research i.e. autonomy, beneficence, non-maleficence and justice are adhered to in the research proposals; and

3.3.3. make an annual, or more frequent, report to the FM, UOR, FB which should be made available to the public on request.

3.4. The ERC shall ensure that research is never permitted to override the health, well-being, and care of research participants. This also takes into consideration the principle of justice. Justice requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture, and ethnic considerations.

3.5. The ERC is responsible for acting in the full interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of the Forum of Ethics Review Committees in Sri Lanka (FERCSL) and the ethical guidelines of the World Health Organization (WHO), and other international guidelines.

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

4. Responsibility

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

5. Detailed instructions

5.1. All applications will be subject to a handling charge as recommended by the ERC and approved by the FB, FM, UOR , Finance Committee and the Council of UOR.

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

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

5.4. The term "human research participant" includes human research or clinical research involving human participants, their biological materials and/or data, such as:
- 5.4.1. Surveys, interviews, focus groups or ethnographic observations.
- 5.4.2. Review of medical records where there is access to personal information.
- 5.4.3. Interventional studies including psychological, physiological or medical treatment / testing;
- 5.4.4. Collection of data from registries, repositories or databases where personal medical information are stored and/or
- 5.4.5. Use of biological specimens, including cadaveric specimens (tissues, biopsies, organs, blood, urine, saliva, faeces).

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

5.6. The ERC will do its best to review and approve projects, using the knowledge of its members, but will not hesitate to make use of external experts especially when the committee lacks the expertise among its members to review specific subject areas (**SOP 06**).

	Ethics Review Committee Faculty of Medicine University of Ruhuna	SOP-02-2018 Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Membership composition	

1. Purpose

To describe the membership composition of the ERC, FM, UOR, ERC.

2. Scope

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

3. Responsibility

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

4. Detailed functions

4.1. The composition of the ERC, FM,UOR shall be in accordance with the FERCSL Guidelines and other relevant national and international guidelines.

4.2. The committee will comprise at least ten (10) and not more than twenty Five (25) members.

4.3. Members shall be appointed to ensure that the ERC has the expertise required to assess the applications submitted to it for consideration. The composition of the ERC shall be diverse in language, culture and gender.

4.4. Membership of the FM, UOR Ethics Review Committee will be constituted as follows:
- 4.4.1. Medical members. Both clinicians and non-clinicians will be included.
- 4.4.2. Non-medical scientists.
- 4.4.3. Legal member.
- 4.4.4. Lay members.

4.5. The committee shall elect its chairperson from among its members and is appointed by the FB.

4.6. Ethics Review Committee members shall be appointed by the FB of FM, UOR. An established ERC may propose names where appropriate.

4.7. Where required, the ERC may seek advice and assistance from appropriate independent external reviewers to assist with the review of a proposal. However, the ERC must be satisfied that such reviewers have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, or any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter (**SOP 06**).

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 03 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Appointment of ERC members	

1. Purpose

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

2. Scope

It describes the Terms of Reference (TOR) which provide the framework for appointment of members of the ERC, FM,UOR .

3. Responsibility

It is the responsibility of the ERC members follow the responsibilities set by the ERC, FM, UOR.

4. Detailed instructions

4.1. Members will be appointed by the FB of the FM, UOR. The Dean FM, UOR will issue the letters of appointment with terms of reference. Dean functions as an ex-officio and not interfere with the proposal evaluation until the new ERC is reconstituted in April 2019. In the newly reconstituted ERC in April 2019 the Dean will not be an Ex-officio member. Only the 50% of the committee will be replaced with the new members when the committee is reappointed in view of providing the quality service with the expertise.

4.2. Members of the ERC, FM, UOR may be recruited by advertisement and calling applications among the affiliated members and appointed by the Dean, FM, UOR. In Certain situations appointments are made by the Dean, FM,UOR on the recommendation of the ERC, FM, UOR based on the requirement. Members are appointed as individuals for their knowledge and experience and not by positions held or as representatives of any organization, group or opinion. When the vacancies are advertised the affiliated members shall apply for the membership in the ERC. Priority will be given to the applicants who are willing to participate in training programmes.

4.3. Members shall be asked to provide a copy of their signed and updated Curriculum Vitae to the ERC, FM,UOR. Members must agree to their names and professions being made available to the public, including being published on the ERC website.

4.4. The letter of appointment **(UOR/01-002)** shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as an ERC member, the circumstances whereby membership may be terminated and the conditions of appointment.

4.5. Members will be required to sign a confidentiality agreement and a conflict of interest agreement **(UOR/02-002)** upon appointment, stating *inter alia,* 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

4.6. Upon appointment, members shall be provided with the following documentation:
- 4.6.1. Standard Operating Procedures of the ERC;
- 4.6.2. Up-to-date list of members' names and contact information.
- 4.6.3. Any other relevant information about the ERC's processes, procedures and proposals.

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

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

4.9. The committee shall elect its Chairperson, Vice Chairperson and Secretary from among its members already in the committee at the end of its term and inform the FB of the FM, UOR for approval.

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

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

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

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

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

5. Annexures

UOR/01-002
UOR/02-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 04 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Functions of members	

1. Purpose

To describe the functions of members of the FM, UOR, ERC.

2. Scope

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

3. Responsibility

It is the responsibility of the ERC members, FM, UOR to function as members of the ERC, FM, UOR as per SOP and TOR.

4. Detailed instructions

In additions to functions described in 4.3, the Chairperson and the Secretary of the ERC are expected to perform additional duties as detailed below:

4.1. Chairperson and Vice Chairperson:

4.1.1 Chairperson

(a). Conduct all meetings of the ERC according to the SOPs.
(b). Provide guidance to ERC members and office staff.
(c). Periodically review existing policies and formulate new ERC policies and guidelines in consultation with the members of ERC.
(d). Review applications.
(e). review of progress reports, and monitor studies whenever required.

4.1.2 Vice Chairperson

(a). If for reasons beyond control, the Chairperson is not available or if the Chairperson has a conflict of interest for a particular matter, the Vice Chairperson will conduct the meeting and will attend to those specific matters and the urgent matters that the Chairperson should attend.

4.2. Member Secretary/Alternate Member Secretary:

4.2.1 Member Secretary

(a). Organize the meetings, maintain records and arrange communications with all concerned.
(b). Prepare the minutes of the meetings, attend to general correspondence with applicants and get it approved by the Chairperson before communicating with the members /applicants.
(c). Ensure that membership files are current and up-to-date.

(d). Assign primary reviewers for applications in consultation with the Chairperson and co-ordinate the review process.
(e). Provide guidance and supervision to the ERC office staff.
(f). Perform any other duties of the ERC assigned by the Chairperson.
(g). Review applications.
(h). Classification of Protocols into various categories
(i). Summarize the discussion after each protocol during the board meeting
(j). review of progress reports, and monitor studies whenever required.

4.2.2 Alternate Member Secretary

(a). If for reasons beyond control, the Member Secretary is not available or if the Member Secretary has a conflict of interest for a particular matter, the Alternate Member Secretary will attend to those specific matters and the urgent matters that the Member Secretary attend.

4.3. All members of the ERC, FM, UOR:

4.3.1. All members

(a). Review applications assigned to them and lead the discussion on the application at full board meetings.
(b). Complete the assessment form for the protocols assigned as primary reviewers prior to the meeting and hand over the completed forms to Secretary at the meeting. If unable to attend, the forms should be sent to Secretary ERC two (02) working days before the scheduled ERC meeting.
(c). Perform any other duties assigned to members according to the SOPs.
(d). Present the protocol review findings and participate in the discussions on applications.
(e). Disclose conflicting interests and where a conflict does exist with respect to a study and abstain from reviewing the protocol and leave the room during discussion of and voting on the protocol.
(f). Respect each other's' views and the deliberative process.
(g). Decide independently if the design and conduct of proposed studies will protect participants' safety, rights and welfare.
(h). Remain impartial and objective when reviewing protocols.
(i). Keep up-to-date with national and international research ethics and regulatory guidance.
(j). Take part in research ethics-related continuing education.
(k). Perform any other duties assigned by the Chairperson/Secretary.

4.3.2 Lay person and legal person

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

4.4. ERC office staff (a designated Administrative Assistant will be appointed for the ERC)

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

(b). Maintain the electronic database of the ERC and to use database to track protocols and send reminders..

(c). Check all applications for completeness.

(d). Consult Chairperson and Secretary to schedule the ERC meeting date, agenda preparation, meeting procedure and minutes.

(e). Prepare the meeting agenda according to the standard format in consultation with Chair and Member secretary.

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

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

(h). Send the approved minutes (hard copies) to all ERC members and arrange all study related documents for subcommittee/full board meetings to be discussed.

(i). Follow strict procedures to maintain confidentiality of ERC documents.

(j). Perform any other duties assigned by the Chairperson and Secretary.

(k). Maintain training records for all ERC members

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 05 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 1
	Title: Orientation of new members and training	

1. Purpose

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

2. Scope

It describes the procedure of orientation of new members of the ERC, and training of all the members in the ERC.

3. Responsibility

It is the responsibility of new members of the ERC to understand their functions as members of the ERC, FM, UOR. It is the responsibility of all members to undergo continuing professional development. It is the responsibility of the ERC to orient and provide adequate opportunities/information to the new members to get themselves trained.

4. Detailed instructions

4.1. New ERC members must be provided with adequate orientation. New member orientation may include the following:

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

(b). Informal meeting with the Chairperson, Secretary and officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures.

(c). Encourage the new members to attend the training workshops conducted by FERCSL or any other local or international bodies

(d). Advise the members to follow the online training programmes

(e). Conducting regular training sessions along with the monthly ERC meeting on important topics in research ethics by the experienced members who are in the ERC or by past ERC members

(f). SOP training sessions along with the monthly ERC meeting by the allocated members in the ERC

4.2. New members will receive training in:

(a). Research Ethics and Human Subject Protection

(b). Standard Operating Procedures of the committee

(c). Good clinical practice

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	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 06 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Independent external reviewers	

1. Purpose

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

2. Scope

If the Chairperson/Secretary determines that a study will involve procedures or information that are not within the area of expertise of its members or the member who possess the expertise has a COI, the Chairperson/Secretary may invite individuals with competencies in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the ERC.

3. Responsibility

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

4. Detailed instructions

4.1. The ERC shall be free to consult any person(s) considered by the ERC to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subjected to that person(s) having no conflict of interest and providing an undertaking of confidentiality.

4.2. All ERC external experts must sign confidentiality/conflict of interest agreements regarding meeting deliberations, applications, information on research participants, and related matters.

4.3. Responsibilities of the independent external reviewers
The responsibilities of the external experts are to review applications assigned to them using the standard protocol assessment form and provide written comments to be discussed at the full board meetings.

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	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 07 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 3
	Title: Submission procedure for applications for ethics review	

1. Purpose

To describe the procedure for the submission of applications

2. Scope

Submission procedure for applications include in initial submission and corrections/amendments.

3. Responsibility

It is the responsibility of the ERC Secretary/Administrative Assistant to receive, register the protocols. Distribution of the application form, research protocol and other relevant documents and primary reviewer allocation are the responsibilities of the Secretary, If necessary in consultation with the Chairperson.

4. Flowchart

Research proposal (protocol & related documents) received by the Administrative Assistant/Secretary of the ERC

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Verification done as per document checklist by the Administrative Assistant/Secretary

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Date stamp all documents in the proposal

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Issue document receipt form and register in the ERC with a unique identification number

↓

Categorization of protocols as exempted, expedited or full board reviewing

↓

Appoint reviewers

5. Detailed instructions

5.1. Applications must be submitted in the format prescribed by the ERC, **(UOR/03-002, UOR/04-002)** which is available on the FM,UOR website and shall include all necessary documentation, including a declaration by the applicant that all required documents have been submitted by completing and signing the application checklist(**UOR/05-002**).

5.2. One copy of the correctly filled applications should be accompanied by six set of the following documents

5.2.1. Complete research protocol, curriculum vitae of the principle investigator/s, training certificates on Research Ethics, Good Clinical Practice and Research Methodology and conflict of interest statement.

5.2.2. Information sheets, consent forms and assent forms - in English, Sinhala and Tamil where appropriate.

5.2.3. Other relevant documents such as data collection tools and questionnaires in English, Sinhala and Tamil where appropriate.
*The number of copies of the above documents to be submitted is specified in the website (**http://www.medi.ruh.ac.lk/ethics/**).*

5.2.4. The proposal submitted by postgraduate students must be identical to that approved by the Board of Study or submitted to the Board of Study).

5.2.5. Soft copies of all above documents should also be submitted as **a single pdf file** on a CD or data traveler or emailed to the ERC email address (**ethics@med.ruh.ac.lk**).

5.3. A non-refundable fee will be charged per application from all the investigators (except from undergraduate of University of Ruhuna) for review by the ERC. This has to be paid to the FM, UOR account before the submission of the research proposal to the ERC. Receipt of payment should be produced on submission of the proposal to the ERC office. The charges will be revised from time to time and approved by the FB of the FM, UOR and the Finance Committee/Council of UOR.

5.4. The ERC accepts new applications from Monday to Friday during office hours. Acceptance of applications for ethical review submitted to the ERC office is closed (as indicated in the website) on the last working day of each month due to be taken up at the scheduled ERC meeting of the following month.

5.5. Applications will be checked by the Administrative Assistant of the ERC using a checklist and all documents will be date stamped.

5.6. For submission of any document (eg: complete new applications), the ERC office will Issue a receipt to the Principal Investigator or the person who hands over the application **(UOR/06-002).**

5.7. Once a completed application has been accepted for ethics review, the ERC shall assign a unique identification number to the application containing the calendar year and chronological order of applications [YYYY/ P/ unique identification number] The application shall be added to the ERC's register of received applications.

Eg: 2019/P/001

5.8. Store the hard copy and the soft copy of protocol and all relevant documents in protocol specific file.

5.9. The Secretary/Administrative Assistant of the ERC will scrutinize the applications and incomplete applications will be returned to the applicant.

5.10. Categorization of protocols

5.10.1 Chairperson/Vice Chairperon, Member Secretary/Alternate Member Secretary and another ERC memebr (methodology specialit as per required) meet in the first week of the month and screen all the new proposals received until the closing date of the previous month and assess the degree of risk involved and decides the type of review.

5.10.2 Degree of Risk

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

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

5.10.3.1. Exemption from review
No risk is associated and proposals are exempted from ethics review when there is no possibility of harm arising as a result of the conduct of the research project or when the information being collected is available from the public domain **(SOP 14).** Applications not requiring ERC review will be issued an exemption letter signed by the Chairperson of the ERC.

5.10.3.2. Expedited review
A proposal is considered for expedited review when the research procedures present no more than minimal harm to the research participants or communities. In this case, the proposal is reviewed by at the above meeting. If it needs further reviewing, one suitable primary should be allocated. Expedited approval (before the full board meeting) is granted based on the primary reviewer's comments **(SOP 15).**

5.10.3.3. Full committee review
All research protocols with more than minimal risk to human subjects are subjected to full board review (third week of every month except April and December). For applications requiring full board review, the Secretary shall, in consultation with the Chairperson, appoint 3 primary reviewers for each application. Primary reviewers shall include a subject expert, a methodological expert and another relevant reviewer **(SOP 12).**

6. Annexures

UOR/03-002
UOR/04-002
UOR/05-002
UOR/06-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 08 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Preparation of agenda	

1. Purpose

To provide procedures for preparation of the agenda by the Member Secretary (Alternate Member Secretary) for ERC meetings.

2. Scope

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

3. Responsibility

It is the responsibility of the Member Secretary (Alternate Member Secretary) of ERC to prepare the agenda.

4. Detailed instructions

4.1. The Member Secretary (Alternate Member Secretary) of ERC will prepare an agenda for each ERC meeting.

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

4.3. All complete applications with relevant documents, and all correspondence received by the Member Secretary (Alternate Member Secretary) of ERC will be included on the agenda for the consideration of the ERC at its next meeting.

4.4. The agenda and associated documents will be prepared by the Member Secretary (Alternate Member Secretary) ERC and circulated to all ERC members at least one week prior to the next meeting.

4.5. Documentation pertaining to clarifications of previously reviewed proposals will be included on the agenda and/or tabled at the meeting if they are submitted before the closing date, on or before the last working day of the preceding month (refer to website).

4.6. Agenda items will include at least the following items (**UOR/07-002):**

4.6.1. Confirmation of the minutes of previous meeting and
4.6.2. Matters arising from minutes
4.6.3. New items
(a). Unique identification number [YYYY/P/001]
(b). Date of submission
(c). Title of protocol
(d). Name(s) of Principal investigator, co-investigators and supervisors
(e). Names of primary reviewers
(f). Type of review
4.6.3. Conflict of interest for new items
4.6.4 Any other matters
(a). Amendments to approved protocols
(b). Extension of ERC approval
(c). Reports of Serious Adverse Effects
(d). Progress reports
(e). Final reports
(f). Protocol deviations, violations, non-compliance
(g). Any other correspondence
4.6.5. Announcements
4.6.6. Close and date for next meeting

5. Annexure

UOR/07-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 09 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Conduct of meetings	

1. Purpose

To describe the conduct of meetings of the ERC.

2. Scope

It describes the procedures for conduct of the ERC meetings.

3. Responsibility

It is the responsibility of the Chairperson and Secretary/Administrative Assistant to inform members and facilitate the conduct of regular and special meetings of ERC.

4. Detailed instructions:

4.1. The ERC shall generally meet on the 3rd week of each month (liable to change with the academic commitments) except in April and December. Dates of ERC meetings for the year shall be pre-decided and be publicly available.

4.2. It is important for the members to attend ERC meetings in person. Members who are unable to attend a meeting should send a written excuse (email) to the Secretary of the ERC. The minutes should record the submission of excuses.

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

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

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

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

4.7. Any member of the ERC who has any conflict of interest, financial or otherwise, in a proposal or other related matter(s) considered by the ERC must declare such interest beforehand. This will be dealt with in accordance with **SOP - 11/2018**.

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

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP –10 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Minutes of meetings	

1. Purpose

To describe the preparation and format of minutes of a meeting of the ERC, FM, UOR.

2. Scope

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

3. Responsibility

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

4. Detailed instructions

4.1. The Member Secretary (Alternate Member Secretary) of the ERC shall prepare and maintain minutes of all meetings.

4.2. The format of the minutes shall include at least the following items **(UOR/08-002):**

4.2.1 Attendance
4.2.2 Confirmation of the minutes of previous meeting and
4.2.3 Matters arising from minutes
4.2.4 New items
- 4.2.4.1 Unique identification number
- 4.2.4.2 Title of protocol
- 4.2.4.3 Name(s) of principal investigators, co-investigators and supervisors
- 4.2.4.4 Names of primary reviewers
- 4.2.4.5 Type of review (exemption from review /Full board/ expedited review
- 4.2.4.6 Conflict of interest
- 4.2.4.7 Observations (scientific, ethical, administrative) discussion and decision

4.2.5 Any other business
- (a). Amendments to approved protocols
- (b). Extension of ERC approval
- (c). Reports of Serious Adverse Effects
- (d). Progress reports
- (e). Final reports
- (f). Protocol deviations, violations, non-compliance
- (g). Any other correspondence

4.2.6 Announcements
4.2.7 Close and date for next meeting.

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

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

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

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

4.7. Declarations of conflicts of interest by any member of the ERC and the absence of the member concerned during the ERC consideration of the relevant application will be minuted **(SOP - 11/2018).**

4.8. Minutes shall be prepared as soon as practicable (within **7-10 days** from the meeting) and shall be checked by the Chairperson for accuracy.

4.9. The minutes shall be circulated to all ERC members at least one week before the date of meeting.

4.10. The original copy of each meeting's confirmed minutes shall be retained in the 'Minutes' File.

4.11 The extracts of minutes of each committee meeting shall be forwarded to the FB of the FM, UOR for information.

5 Annexure

UOR/08-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 11- 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 1
	Title: Conflict of interest	

1. Purpose

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

2. Scope

It covers the agreement on conflict of interest concerning information and procedures followed by the ERC, FM,UOR **(UOR/02-002).**

3. Responsibility

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

4. Detailed instructions

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

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

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

5. Annexure

UOR/02-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 12 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 3
	Title: Management of new submissions	

1. Purpose

To describe how the ERC reviews a new application submitted.

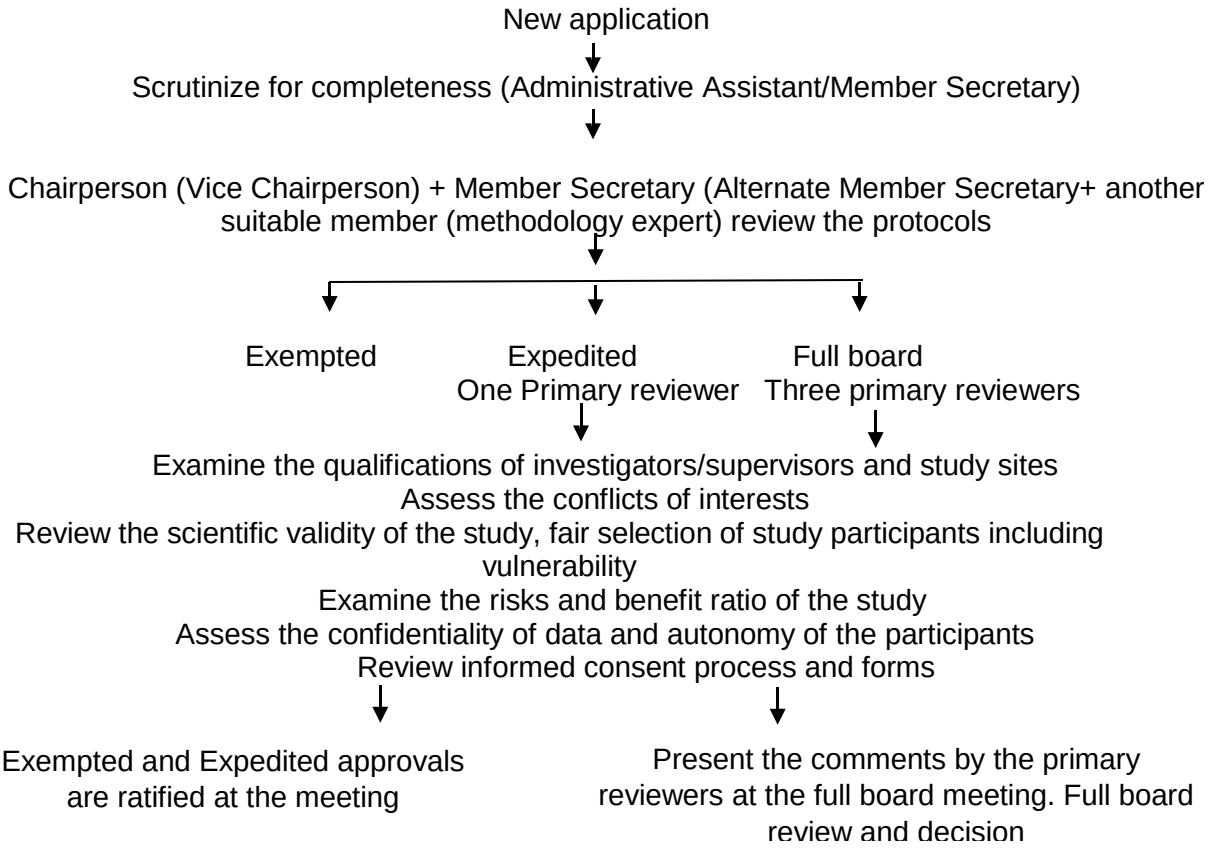
2. Scope

It describes the review process of new ERC applications submitted.

3. Responsibility

It is the responsibility of the assigned reviewers to thoroughly review the applications delivered to them, give their decision, observations and comments to the ERC in the protocol assessment form and return it to the ERC office on or before the due date. The Secretary/ Administrative Assistant are responsible for receiving, verifying and managing the submission forms. It is the responsibility of the Administrative Assistant to create a protocol specific file, distribute the proposals, other documents, and deliver the review results to the applicants under the supervision of the Secretary.

4. Flowchart



4. Detailed instructions

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

4.2. Each application will be scrutinized by the Administrative Assistant/Secretary for completeness. Once the application is accepted and registered in the ERC, the ERC may exempt it from review in accordance with **SOP - 14/2018.** Other applications will be reviewed either by expedited or full board review system.

4.3. The Secretary shall assign each application to three (03) primary reviewers one of whom has subject expertise appropriate, methodology expert and another relevant reviewer to the protocol.

4.4. Primary reviewers would:
(a). review the application in detail prior to the meeting.
(b). inform the ERC about the ethical issues using the Research Proposal Evaluation Form **(UOR/09-002)** and the ICF assessment form **(UOR/10-002)** and present the comments and participate in the discussion on the application at the ERC meeting.
(c). whenever necessary, request the applicant to submit additional documents or a revised version of the proposal through ERC.

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

4.6. The ERC shall assess proposals submitted to it for review in accordance with the FERCSL and other national and international guidelines and with national and international laws to determine their acceptability on matters of ethics. The ERC must ensure that it is sufficiently informed on all aspects of a research proposal, including its scientific validity, to make an assessment.

4.7. The ERC may consider whether an advocate for any participant or group of participants should be invited to the ERC meeting to ensure informed decision-making.

4.8. Where research involves the recruitment of persons unfamiliar with the English language, the ERC shall ensure that the participant information sheet and informed consent form are translated into the participant's language. All study related information/material to be given to research participants.

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

5. Elements of the Review Process

A protocol will be reviewed by the primary reviewers according to the FFERCSL guidelines 2018. The framework is proposed to ensure quality and consistency of the ethics review process:

5.1. Social or Scientific Value
5.2. Scientific Validity
5.3. Fair Participant Selection
5.4. Favourable Risk/Benefit Ratio
5.5. Informed Consent Process
5.6. Respect for Potential and Enrolled Participants and Communities

6. ERC decision

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

(a). **Approve the proposal** as being ethically acceptable, no changes requested
(b). **Minor revisions needed** and improved proposal will be reviewed by one of the primary reviewers and eligible for chairperson's approval later once these are done.
(c). **Major revisions needed** which would require review by three primary reviewers and full board review once the revisions are done.
(d). **Disapprove the proposal** and reasons will be conveyed to the applicant.

6.2 Decision making process:

In the presence of quorum, the ERC will endeavour to reach a decision concerning the ethical acceptability of a protocol by consensus. If consensus is not possible, voting is carried out. Only members who are physically present are allowed to participate in the voting. The decision will be considered to be carried by a majority of two-thirds of members, provided that the majority includes at least one non-medical member.

6. Annexures

UOR/09-002
UOR/10-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 13 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Management of resubmissions	

1. Purpose

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

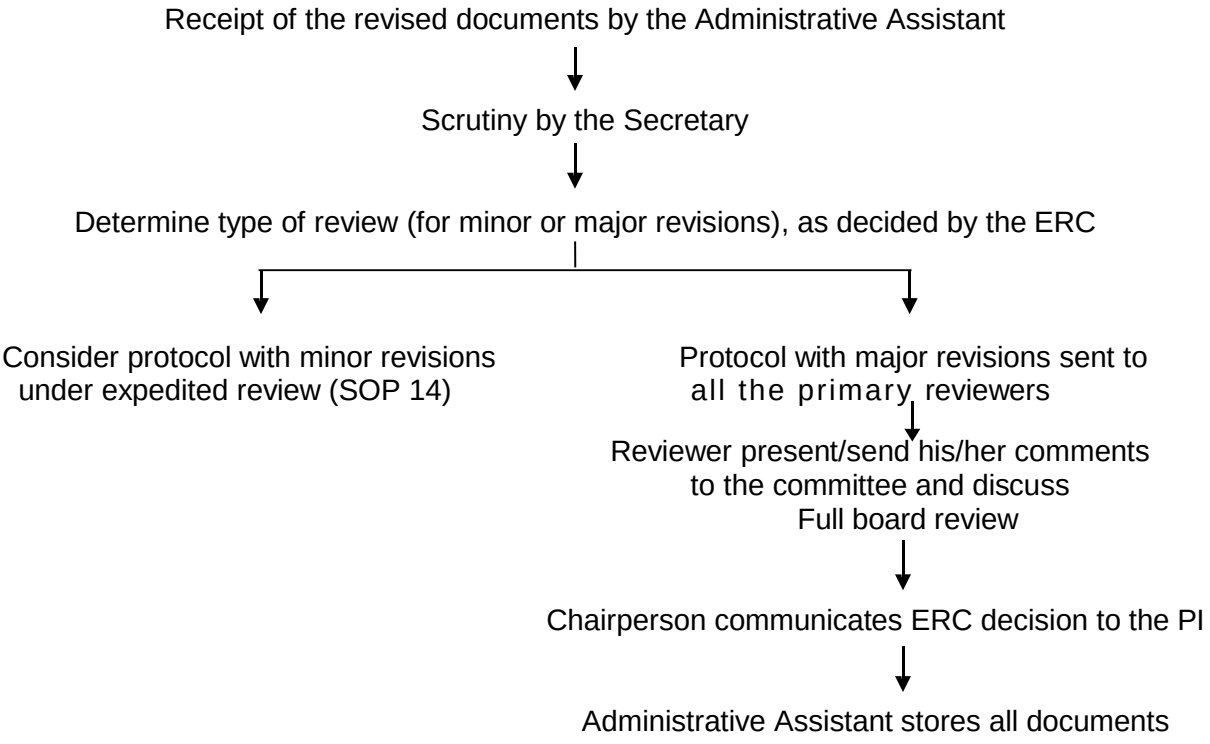
2. Scope

It describes the review of the study protocols that have been recommended for revisions, either minor or major during the initial review process.

3. Responsibility

It is the responsibility of the Secretary/Administrative Assistant, ERC to ensure the completeness of the resubmitted documents. Secretary should arrange the reviewing process and notify the Chairperson that a protocol has been resubmitted for reconsideration. The review of a resubmitted protocol containing minor revisions as decided at the initial review, may consider under expedited review (**SOP-15/2018).** The review of amended protocol containing major revisions shall be considered at a full board meeting after reviewed by three primary reviewers.

4. Flowchart



5. Detailed instructions

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

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

5.3. The Secretary or designated member peruses the revised protocol, refers to the meeting minutes as guidance for the review and assigns those that had required minor revisions to be considered under expedited review **(SOP 15).**

5.4. Those that require major revisions will be resent to all three primary reviewers for their observations and will undergo a full board review.

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5.5. If the ERC previously decided to see the new revision, the revisions will be sent to the original primary reviewers for comments. The revised protocol will be discussed at the next scheduled ERC meeting where the primary reviewer presents a brief oral or written summary and his/her comments to the ERC members and the Chairperson entertains discussion on the protocol revision. Further recommendations for modifications to the protocol, consent form, and any other document as requested by the Committee are noted in the meeting minutes and will be communicated to the principal investigator. Once the major revision is accepted by the ERC, the approval will be communicated to the PI as given in the flowchart.

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

5.7. Investigators who do not respond to comments within 3 months of their submission it will be removed from the meeting minutes. This message is delivered to the investigators within the initial comments. The period may be extended upon request by a PI if the ERC considers the reasons for extension valid.

5.8. The original completed documents along with revised documents, the completed re-review report, and assessment forms and all study related documents will be stored in the protocol specific file by the Administrative Assistant.

NOTE: Minor revisions include topographical errors, absence of contact details of the investigators in the information sheet and errors in the Gantt chart etc.

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 14 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Exemption from review	

1. Purpose

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

2. Scope

It describes how protocols may be exempted from review from full ERC meeting. Ethical review is not required for studies that amount to quality assurance or medical audit provided always that the results of the aggregation or analysis are not made available in a form which identifies the subjects of the information. The use of personal medical records without approaching or involving the patients concerned is, in principle, ethically acceptable provided confidentiality and anonymity are preserved. Research involving vulnerable groups is not exempted.

3. Responsibility

The Chairperson (or nominee) and the Secretary (or nominee) will assess the protocol as per checklist in Annex **UOR/11-002**. If they find that the protocol needs to be submitted for a full board evaluation, it will be reviewed as per **SOP-12/2018**

4. Detailed instructions

4.1. The Chairperson (or nominee) and the Secretary (or nominee) will assess the protocol as per checklist in Annex (**UOR/11-002**) and may exempt from review following research:

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

4.1.2. Educational research proposals are exempted provided all of the following conditions are met:

(a). The research involves normal educational practices (e.g. comparison of instructional techniques).

(b). The study procedures do not cause a significant deviation in time or effort from the usual educational practices at the study site.

(c). The study procedures involve no increase in the level of risk or discomfort associated with routine educational practices.

(d). The study procedures do not involve sensitive subjects (e.g. sex education).

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

4.2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior are exempted, unless:
  4.2.1. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  4.2.2. any disclosure of the human participants' responses outside the research that could place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

4.3. Taste and food quality evaluation and consumer acceptance studies are exempted:
  4.3.1. if wholesome foods without additives are consumed; or
  4.3.2. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the relevant Sri Lanka Governmental agency.

4.4. A standard exemption letter will be issued, in the format set out in annexure **UOR/11-002.**

5. Annexures

UOR/11-002
UOR/12-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 15 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 3
	Title: Expedited review	

1. Purpose

To describe the procedure for expedited review of research proposals.

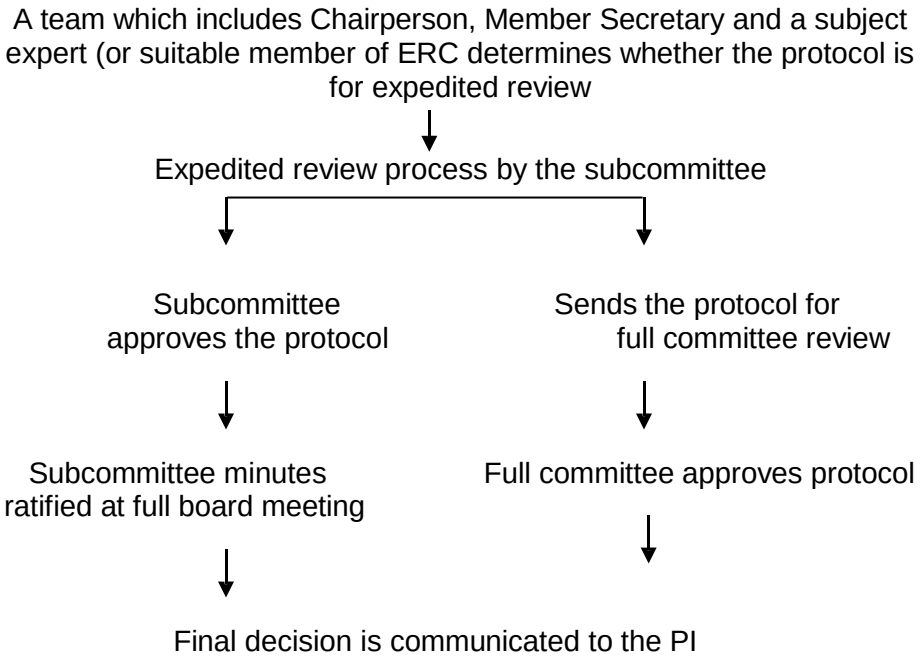
2. Scope

It describes the how a) the initial review and approval of study proposals with minimal risk to participants, b) minor protocol amendments or informed consent changes to a previously approved application and c) minor revisions to a protocol or informed consent form currently under review.
NOTE: Minor revisions include topographical errors, absence of contact details of the investigators in the information sheet and errors in the Gantt chart etc.

3. Responsibility

Expedited review shall be conducted by a subcommittee, consisting the Chairperson(Vice Chairperson), Member Secretary (Alternate Member Secretary) and two members (subject expert and one non-medical member if possible), appointed as detailed in 5.1.

4. Flowchart



5. Detailed instructions

5.1. Expedited review of research protocols may be undertaken between scheduled meetings, at the discretion of the Chairperson and the Member Secretary. A subcommittee will be appointed for this purpose and shall consist of the Chairperson and the Member Secretary and two other ERC members, one subject expert and one non-medical member.

5.2. Expedited review process

5.2.1. The Administrative Assistant sends the protocols to the selected members with the assessment forms.

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

5.2.3. Review should not take more than two (02) weeks.

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

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

5.3. The Sub Committee may undertake expedited review of research protocols which carry not more than minimal risk and research protocols on non-sensitive topics in the following circumstances:

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

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

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

5.3.4. Research previously approved by the full board ERC meeting that

5.3.4.1 requires extension of period that meets the following criteria:

(a).the research is permanently closed to the enrolment of new participants;

(b).all participants have completed all research-related interventions;

(c).the research remains active only for long-term follow-up of participants;

(d).no additional risks have been identified; or where the remaining research activities are limited to data analysis.

5.3.4.2 requires minor amendments shall be dealt with in accordance with expedited Review (**SOP - 15/2018**) provided that its decisions are ratified at the next Scheduled ERC meeting

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

5.3.6. The Sub Committee may consider other items of business that are considered to be of minimal risk to participants.

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

5.3.7.1. When the research design involves no more than minimal risk

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

5.3.7.3. Research on anonymous bio specimens and secondary data.

5.3.7.4. Use of personal medical records without approaching or involving the patients concerned is, in principle, ethically acceptable provided confidentiality and anonymity are preserved. Such studies are entitled for waiver of the requirement for obtaining informed consent, but ethics review is essential

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

5.5. Where the Chairperson, Member Secretary or the nominated ERC members consider that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the proposal must be considered by the full ERC and cannot be dealt by expedited review.

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

5.7. A standard approval letter will be issued in the format set out in **Annex UOR/13-002.**

5.8. In the event that the Subcommittee cannot be convened, the protocols will be reviewed at a full board meeting.

6. Annexure

UOR/13-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 16 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Management of amendments to approved protocols	

1. Purpose

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

2. Scope

It describes how amendments made to previously approved study protocols are being reviewed. Amendments made to protocols may not be implemented until reviewed and approved by the ERC, FM, UOR.

3. Responsibility

It is the responsibility of the Member Secretary, ERC to manage protocol amendments. The Member Secretary in consultation with the Chairperson and allocate reviewers as per SOP and decides the need for expedited review or full board review.

4. Detailed instructions to the investigators

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

4.1.1. details of the nature of the proposed amendments;
4.1.2. The submission should include the following
(a). a cover letter to the Chairperson
(b). a copy of previous ERC approval letter
(c). a table indicating the amendments and the page number/s
(d). If the amendment is major (defined in the glossary) four sets (04) of documents incorporating the amendments, identified by revised version numbers and dates. If the amendment is minor (defined in the glossary) two sets (02)of the above should be submitted. The amendments should be highlighted in the text.

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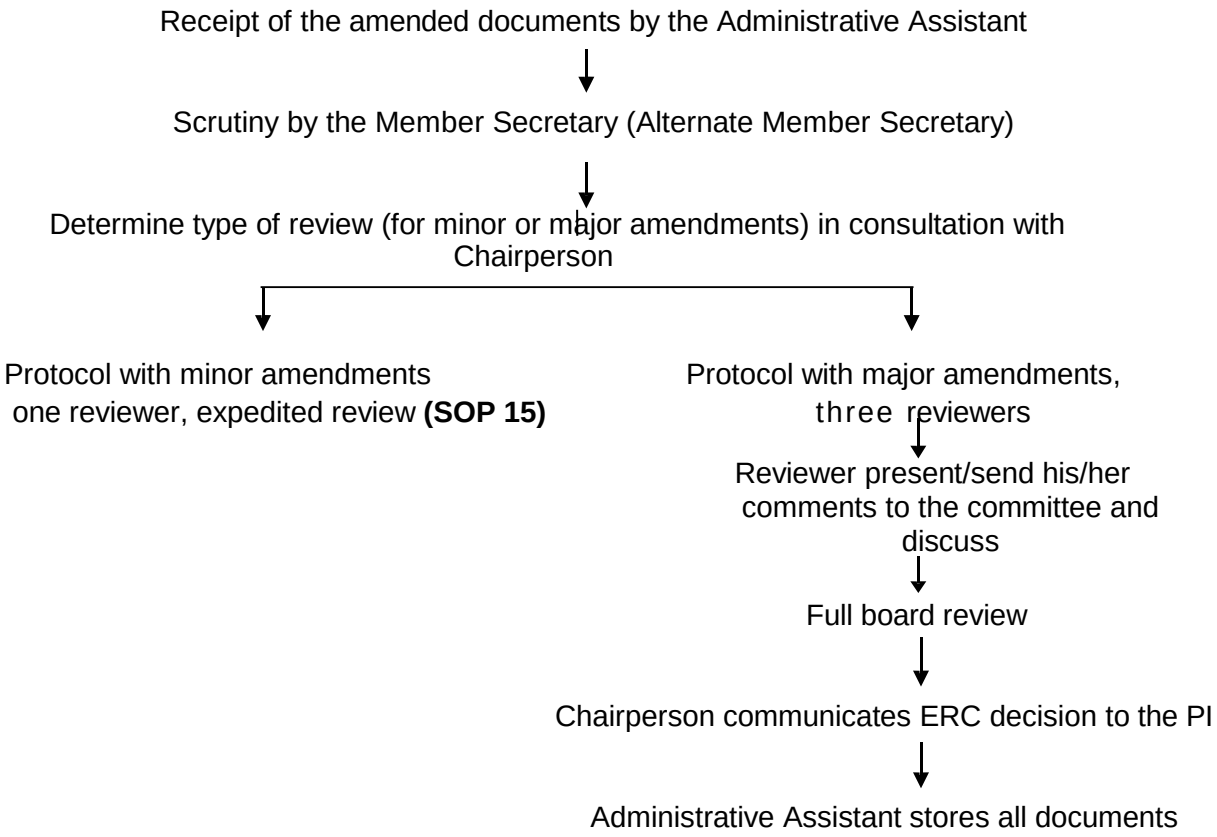
5. Process of review
Review process is indicated in the flowchart



6. The ERC shall
   6.1. assess the ethical implications and scientific effects on the original approved protocol, if any, that arises as a result of the amendment;
   6.2. write to the principal investigator within 14 working days of the meeting at which the request was considered (the scheduled ERC meeting).
   6.3. communicate the decision in the format set out in Annexure **UOR/14-002**.
   6.4 record all reviewed and approved requests for amendments in the relevant protocol file and where appropriate in the ERC's register of received and reviewed applications.

7. Annexure

UOR/14-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 17 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Communication of decisions of the ERC	

1. Purpose

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

2. Scope

This SOP applies to all communications related to the studies under review of the ERC, FM, UOR.

3. Responsibility

It is the responsibility of all ERC members, Secretary and the Chairperson conducting activities of the ERC to complete a written communication, record of telephone, or interpersonal discussions related to past, present and future studies and/or processes involving the ERC.

4. Detailed instructions

4.1. Decisions of the ERC with regard to all applications discussed will be conveyed in writing and/or via email to the principal investigator, within fourteen (14) working days from the monthly meeting unless notified otherwise.

4.2. If the ERC determines that further information, clarification or modification is required for the consideration of a proposal, the correspondence to the principal investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the FERCSL Guidelines or other relevant documents including legislation. A standard letter will be issued, in the format set out in **UOR/15-002.**

4.3. The ERC should promote active communication with applicants to speedily resolve outstanding requests for further information, clarification or modification of protocols. The ERC may nominate one of its members to communicate directly with the applicant/ principle investigator (PI)

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

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

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

(a). Name and address of PI
(b). Unique ERC identification number:[YYYY/P/001]
(c). Title of the proposal
(d). Name of the principal investigator(s), co-investigator/s, supervisors with affiliations
(e). Date of Meeting where the proposal first considered
(f). Date of ERC meeting at which the approval was granted
(g).Version number and date of all documents reviewed and approved by the ERC including clinical protocols, patient information sheets, consent forms, advertisements, questionnaires, and other relevant documents etc.
(h).Statement on conflict of interest
(i). The conditions, if any, to which the ERC approval is subjected
(j). The period of validity of the ERC's approval
(k). The frequency of progress reports
(l). Instructions for submission of the final report.
(m). Instructions for the application of extension.

4.7. A standard approval letter will be issued, in the format set out in **UOR/16-002.**

4.8. Research protocols may not commence until written/electronic (email) notification has been received by the applicant confirming approval.

4.9. If the ERC determines that a proposal is disapproved on ethical or other grounds, the communication of the ERC's decision will include the reason for disapproval of the proposal with reference to the FERCSL Guidelines or other relevant pieces of legislation. A standard letter will be issued, in the format set out in **UOR/17-002.**

4.10. The status of the proposal shall be updated on the ERC's register of received and reviewed applications. Database will also be updated.

5. Annexures

UOR/15-002
UOR/16-002
UOR/17-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 18 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Management of serious adverse events	

1. Purpose

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

2. Scope

It applies to all communications and actions related to all adverse events as defined in the glossary, occurring in studies under the approval of the ERC, FM, UOR.

3. Responsibility

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

4. Detailed instructions

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

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

4.3. **Reporting time frame**: The following time frames for reporting such events occurring at local trial sites should be adhered to, according to guidelines set out by the Subcommittee of Clinical Trials of National Medicines Regulatory Authority, Ministry of Health to:

(a). All adverse drug reactions that are both serious and unexpected (SUSAR) are subject to expedited reporting. The **principal investigator(s)** should report all serious and unexpected adverse drug reactions occurring during a clinical trial **to the sponsor as soon as possible, but no later than twenty four hours after he was first aware of the reaction.**

(b). The sponsor should report any serious unexpected adverse drug reaction (as defined in the Good Clinical Practices (GCP) Guidelines of the World Health Organization) in CIOMS-I format as soon as possible, **but no later than fifteen calendar days** after the sponsor was first aware of such reaction **to the SCOCT, the relevant Ethics Review Committee** and the investigator(s) participating in the clinical trial.

(c). Any fatal or life-threatening serious unexpected adverse drug reaction should be reported by the sponsor **to the SCOCT, the relevant Ethics Review Committee** and the investigators participating in the clinical trial as soon as possible, but **no later than seven calendar days after** the sponsor was first aware of such reaction.

(d). All serious and unexpected adverse drug reactions related to the same investigational product reported from all sites involved with the same trial protocol driven clinical trial, should be reported with a causality statement by sponsor to the SCOCT and the relevant Ethics Review Committee that accorded approval to the trial protocol in the form of quarterly line listed reports.

4.4. Notifications of Suspected Unexpected Serious Adverse Reactions (SUSAR) And Serious Adverse Events (SAE) must be submitted in the format as set out in **UOR/18-002** and shall include all the documentation required by the ERC. These documents shall include at least:

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

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

4.5. The procedure and format for notification of adverse events to the ERC shall be readily available to investigators (refer to ERC website).

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

4.7. The special committee shall consist of the following:

- Chairperson ERC (Vice Chairperson/Cover up if and when required)
- Member Secretary ERC (Alternate Member Secretary)
- A clinical pharmacologist
- A clinician with special training/interest in the clinical discipline.
- Non-medical member (if possible)

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

4.8.1. a notation on the proposal file of the occurrence;
4.8.2. increased monitoring of the research;
4.8.3. a request for an amendment to the protocol and/or patient information sheet / consent form;
4.8.4. suspension of ethics approval; or
4.8.5. withdrawal of ethics approval.

4.9. The Chairperson may take a course of action as he/she feels fit in the circumstances for those adverse events deemed serious and requiring immediate attention. This may include:
4.9.1. Referral to the Clinical Trials Sub-committee of the Ministry of Health
4.9.2. Immediate request for additional information;
4.9.3. Immediate suspension of ethics approval;
4.9.4. Immediate termination of ethics approval.

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

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

4.12. The Chairperson shall immediately notify the Dean, FM, UOR and the Head of the institution/s where the research is carried out, if a research study has been suspended or terminated because of a serious adverse event.

4.13 Decision of ERC for the monitoring of study for safety of participants with SAE/Death:
Site monitoring visit should be arranged for the studies that have reported fatal or life-threatening serious unexpected adverse drug reaction.

4.14 Follow up of SAEs:
Principal investigator should keep the ERC informed of the progress of SAE management until it is resolved or in case of death, whether and how the participant was compensated as per Clinical Trials Agreement (as indicated in Guidelines for the Conduct of Clinical Trials in Sri Lanka .

5. Annexures

UOR/18-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 19 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 3
	Title: Monitoring of approved research protocols	

1. Purpose

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

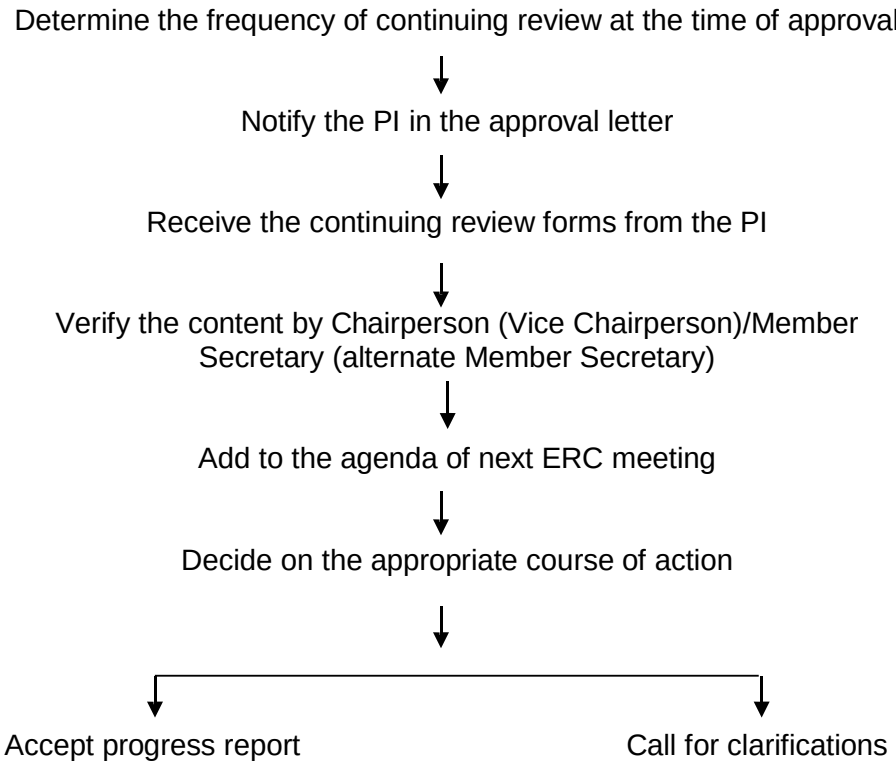
2. Scope

It applies to all studies under the approval of the ERC, FM, UOR.

3. Responsibility

The principal investigator (PI) should send periodic progress reports to FM, UOR. The frequency of reports will be decided by the ERC depending on the nature and duration of the study. The PI should send the final report to the ERC at the completion of study.

4. Flowchart



5. Detailed instructions

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

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

5.3. The ERC will require applicants (PI) to provide progress reports, at least annually (or as requested by the ERC), in high risk studies more frequently, and a final report at the conclusion of the study **(UOR/19-002, UOR/20-002).**

5.4. In the case of clinical trials the ERC shall require six monthly reports which shall be reviewed by the special subcommittee (or the Clinical Trials Sub-committee). The progress reports shall contain at least the following information:
5.4.1. progress to date or outcome in the case of completed research;
5.4.2. statements regarding maintenance and security of records;
5.4.3. statements supporting compliance with the approved protocol;
5.4.4. statements supporting compliance with any conditions of approval.
Extension of approval for a further period will be subject to the PI submitting progress reports as called for in the letter of approval.

5.5. In determining the frequency and type of monitoring required for approved studies, the ERC will give consideration to the degree of risk to participants in the research. The ERC may adopt those measures it considers appropriate for monitoring, such as:
5.5.1. written reports;
5.5.2. random inspections of research sites, data and signed consent forms etc.
5.5.3. interviews, with their prior consent, of research participants.

5.6. The ERC shall require, as a condition of approval of each proposal, that investigators immediately report anything which might warrant review of the ethical approval of the protocol, including:
5.6.1. proposed changes in the protocol;
5.6.2. any unforeseen events that might affect continued ethical acceptability of the study; and
5.6.3. new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.

6. Annexures

UOR/19-002
UOR/20-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 20 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 1
	Title: Management of protocol deviation, non-compliance and violation	

1. Purpose

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

2. Scope

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

3. Responsibility

It is the responsibility of the Member Secretary (Alternate Member Secretary) to receive any non-compliance/deviation/violation reports (**UOR/21 -002)** sent by the investigators and or any other party, and place them on the agenda of the meeting. It is the responsibility of the ERC to review and take action on these reports.

4. Detailed instructions

4.1. Ensure that the issues as well as the details of non-compliance/violation involving research, investigators are included in the agenda of the ERC meeting. Seek explanations and clarifications from the PI on the complaint.
4.2. Maintain a file that identifies investigators who are found to be non-compliant with national and international regulations or who fail to follow protocol approval stipulations or fail to respond to the ERC request for information or action.
4.3. The ERC may decide to suspend or withdraw approval of current studies or refuse to accept and review subsequent applications from the investigators cited.
4.4. The Chairperson notifies the decision of the ERC in writing to the investigator as follows:
  4.4.1. Temporary suspension
  4.4.2. Termination of the approval of the current study
  4.4.3. Refusal to accept and review subsequent applications from the investigator cited for major violations without informing the ERC
4.5. Make 4 copies of the notification letter signed by the Chairperson and Secretary; original copy to the investigator, a copy to the relevant national authorities and institutes, third copy to the sponsor of the study, the last copy in the 'non-compliance' file of the ERC.

5. Annexures

UOR/21 -002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 21 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Site monitoring visits	

1. Purpose

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

2. Scope

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

3. Responsibility

It is the responsibility of the ERC, FM, UOR to perform or designate some qualified agents to perform on its behalf, site inspection of the research projects it has approved. The Chairperson (Vice Chairperson)/Member Secretary (Alternate Member Secretary) or the members may initiate an on-site evaluation of a study site for cause or for a routine audit.

4. Detailed instructions

4.1. Selection of the study site is based on following criteria:
- 4.1.1. New study sites
- 4.1.2. Reports of remarkable events
- 4.1.3. Non-compliance or suspicious conduct
- 4.1.4. Frequently fail to submit progress reports/final reports

4.2. Before the visit
- 4.2.1. Contact the site and notify them about the visit
- 4.2.2. Make appropriate travel arrangements
- 4.2.3. Review the ERC files at the office and make appropriate notes

4.3. During the visit
- 4.3.1. Use the “Checklist for a site monitoring visit” form **(UOR/22-002)**
- 4.3.2. The ERC members will
  - review the informed consent forms
  - review randomly the subject files to ensure that the subjects are signing the correct informed consent forms
  - observe the laboratory and other facilities for the study
  - obtain immediate feedback

4.4. After the visit

4.4.1. write a report within 2 weeks.

4.4.2. forward a copy of the site visit report to the ‘site monitoring file’ for full board review.

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

5. Annexure

UOR/22-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 22 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Study termination	

1. Purpose

To describe how the ERC manages the termination of a research study. Protocols are usually terminated at the recommendation of the ERC based on serious adverse events, protocol deviation, non-compliance and violation of national and international regulations.

2. Scope

It applies to any study approved by the ERC, FM, UOR that is being terminated before its scheduled completion.

3. Responsibility

a) It is the responsibility of the ERC Chairperson to terminate any study that the ERC has previously approved when the benefit or safety of the study participants is doubtful or at risk. The Member Secretary and the Chairperson are responsible for management of the termination process. Should the ERC become aware, on good grounds, of circumstances that have arisen which prevent a research study from being conducted in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC shall inform the Principal Investigator and the institution of such withdrawal of approval in writing, and recommend to the institution that the research study be discontinued or suspended, or that other necessary steps be taken.
b) It is the responsibility of the principal investigator to inform the ERC of inability to proceed / premature termination of the approved study, giving reasons.

4. Detailed instructions

a). Premature termination by ERC

4.1. Receive recommendation for study termination.
- 4.1.1. Receive recommendations and comments from ERC members, sponsor or other authorized bodies for study protocol termination.
- 4.1.2. Request principal investigator to prepare ‘Study Termination Memorandum’ and the original continuing review application form.
- 4.1.3. Administrative Assistant to initial and date the documents upon receipt.

4.2. Review and discuss the termination process.
- 4.2.1. Chairperson reviews the results, reasons and accuracy of data.
- 4.2.2. Chairperson calls for an emergency meeting within 5 working days to discuss the recommendation.

4.2.3. Chairperson signs and dates the continuing review application form in acknowledgement and approval of the termination. Notify the principal investigator about the decision within 10 working days of the ERC receiving the recommendation to terminate.

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

b) Premature termination by principal investigator

4.7. Receive study termination notification from the principal investigator.

4.8. Request principal investigator to prepare 'Study Termination Memorandum' and the original continuing review application form.

4.9. Review and discuss the reasons for termination, and take appropriate action.

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 23 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 3
	Title: Complaints about the conduct of a research project	

1. Purpose

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

2. Scope

It applies to all studies under the approval of the ERC, FM, UOR.

3. Responsibilities

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

4. Detailed instructions

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

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

4.3. If the Chairperson considers the complaint to be of a sufficiently serious nature, he/she shall bring it to the attention of the Dean, FM, UOR as soon as possible.

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

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

4.6. The Chairperson will inquire into the complaint and confirm its validity, or cause an inquiry by suitably qualified persons, and recommend a suitable course of action to the ERC at its next meeting. The investigation will take no longer than four (04) weeks from the time of notification of the complaint, unless exceptional circumstances exist. Both the complainant and the PI will be given an opportunity to make submissions. Where the complaint concerns the conduct of any other person of ERC will also provide that person with an opportunity to make submissions.

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

4.7.1. increased monitoring by the ERC as to whether investigators are adhering strictly to the approved protocol;
4.7.2. suspension of the research till remedial action has been taken;
4.7.3. termination of the study; or
4.7.4. any other action to address issues raised by the complainant.

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

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

4.9.1. the nature of the complaint;
4.9.2. material reviewed in the Chairperson's investigation inquiry;
4.9.3. the results of the Chairperson's inquiry; and
4.9.4. any other relevant documentation and pertinent information.

4.10. The Dean, FM, UOR will determine whether there are sufficient grounds to review the decision of the Chairperson and if so, whether a further inquiry of the complaint is warranted. Where there is to be no further inquiry, the Dean will inform the complainant and the Chairperson of this.

4.11. If the Dean, FM, UOR determines that there are grounds for a review of the initial inquiry, and then he/she will establish a panel to consider the complaint in appeal.

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

4.12.1. Dean, FM, UOR or his/her nominee, as convenor of the panel;
4.12.2. two nominees of the FB, FM, UOR (who are not members of the ERC);
4.12.3. ERC Chairperson or his/her nominee.

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

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

4.15. The Dean, FM, UOR will notify the complainant, the Chairperson and the investigators (if an allegation has been made against them) of the outcome of the review in the following terms: either the appeal is dismissed and the decision of the Chairperson upheld; or the Dean directs suitable action to be taken to resolve outstanding issues that arose in the appeal.

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 24 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Complaints concerning the ERC's review process	

1. Purpose

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

2. Scope

It applies to the conduct and actions of the ERC, FM, UOR with regard to the review process of applications submitted.

3. Responsibility

Any concern or complaint about the ERC's review process should be directed to the attention of the Chairperson of the ERC and/or the Dean, FM, UOR. The preliminary investigation is the responsibility of the Chairperson and the Dean, FM, UOR. They will decide if a further inquiry is necessary.

4. Detailed instructions

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

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

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

4.4. If the complainant is not satisfied with the outcome of the ERC investigation, then he/she can appeal to the Dean, FM, UOR against the ERC determination of the complaint.

4.5. The Chairperson of the ERC will provide the Dean with all relevant information about the complaint/concern, including:
- 4.5.1. the complaint;
- 4.5.2. material reviewed in the Chairperson's or the nominee's investigation
- 4.5.3. the results of the Chairperson's or the nominee's investigation and
- 4.5.4. any other relevant documentation.

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

4.7. If the Dean determines there is to be a further investigation, then he/she will Establish an appeal panel to review the complaint and ERC decision.

4.8. The appeal panel shall include, at least, the following members:
4.8.1. the Dean, FM, UOR or his/her nominee, as convenor of the panel.
4.8.2. two nominees of the Dean, FM, UOR (not members of the ERC).

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

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

4.11. The Dean will notify the complainant and the ERC of the outcome of the investigation. The outcomes of this process may include:
4.11.1. the appeal is dismissed.
4.11.2. the appeal is referred back to the ERC for consideration, bearing in mind the findings of the panel.

4.12. The panel may also make recommendations about the operation of the ERC including such actions as:
4.12.1. a review of the Terms of Reference and Standard Operating Procedures;
4.12.2. a review of the ERC's membership
4.12.3. any other action, as appropriate.

	Ethics Review Committee Faculty of Medicine University of Ruhuna	SOP – 25- 2018 Version 2 Effective Date : 01 September 2018 Page 1 of 2
	Title: Recordkeeping	

1. Purpose

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

2. Scope

It describes the administrative processes concerning the maintenance of records of activities of the ERC, FM, UOR.

3. Responsibility

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

4. Detailed instructions

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

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

(a). date of receiving the original application and subsequent documents.
(b). the unique identification number
(c). the name and affiliations of principal investigator(s), co-investigators, supervisors
(d). Curriculum vitae of principle investigator
(e). Training certificates on research ethics and/or GCP of investigators
(f). conflict of interest statement
(g). the name of the responsible institution or organization
(h). the title of the project
(i). the date of review at a ERC meeting and the decision(s) taken at this meeting
(j). the decision of the ERC with date
(k). the approval or non-approval of any changes to the project
(l). the terms and conditions, if any, of approval of the project
(m). the type of approval given
(n). submission of progress report
(o). report of SAE/deviation/complaints of protocol etc.
(p). submission of final report

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

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

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

4.6. All records pertaining to research protocols shall be held for sufficient time to allow for future reference. The minimum period for retention will be ten (10) years after the receipt of final report. Files which are no longer required for retention shall be electronically archived, prior to shredding.

4.7. A register of all the applications received /dispatched and reviewed shall be maintained.

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 26 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 1
	Title: ERC reporting requirements	

1. Purpose

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

2. Scope

It applies to minutes of meetings, annual reports, Standard Operating Procedures and membership of the ERC, FM, UOR.

3. Responsibility

It is the responsibility of the Member Secretary of ERC to forward a summary/extract of the minutes and any other communication to the FB, FM, UOR on behalf of the ERC.

4. Detailed instructions

4.1. The extracts of minutes of every ERC meeting shall be forwarded to the FB.

4.2. The ERC shall provide an annual report to the FB, FM, UOR at the end of each calendar year on its progress, including;
- 4.2.1. Membership changes
- 4.2.2. Number of meetings
- 4.2.3. Number of proposals reviewed, approved, rejected
- 4.2.4. Monitoring procedures for ethical aspects of research in progress
- 4.2.5. Description of any complaints received and their outcome
- 4.2.6. Description of any research where ethical approval has been withdrawn and reasons for withdrawal of approval and general issues raised

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

	Ethics Review Committee **Faculty of Medicine University of Ruhuna**	**SOP – 27- 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 1
	Title: Review of SOPs and Terms of Reference	

1. Purpose

To describe the procedure for the amendment of the ERC Terms of Reference and Standard Operating Procedures within the ERC.

2. Scope

It covers the procedures of writing, reviewing, distributing and amending SOPs within the FM, UOR, ERC.

3. Responsibility

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

4. Detailed instructions

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

4.2. The Terms of Reference and Standard Operating Procedures may be amended consequent to the request for revision made by ERC members or the FB, FM,UOR .

4.3. Those request for revision made by an ERC member:

4.3.1. The request for revision must be in writing and circulated to all ERC members for their consideration.

4.3.2. The views of the members shall be discussed at a scheduled meeting of the ERC. Any member unable to attend such a meeting may send his/her views in writing (**UOR/23-002**).

4.3.3. The request for revision shall be ratified if two thirds of the members agree to the amendment.

4.3.4. The Chairperson shall send the amendment to the FB, FM, UOR for approval.

5. Annexures

UOR/23-002

	Ethics Review Committee **Faculty of Medicine University of Ruhuna** **Title: Research involving laboratory animals**	**SOP – 28 - 2018** Version 2 Effective Date : 01 September 2018 Page 1 of 1

1. Purpose

To describe the procedure to evaluate an application for ethical approval for a research involving laboratory animals.

2. Scope

It applies to the review process of an ERC application for a research involving laboratory animals.

3. Responsibility

It is the duty and the responsibility of the members of the ERC to ensure that research procedures carried out on animals are appropriate and humane prior to granting approval.

4. Detailed instructions

4.1. The ERC will provide ethical review for all research that involves sentient animals (i.e. animals that feel sensations and experience emotions).

4.2. The researcher is expected to submit the appropriate application form **(UOR/04-002)** to the ERC following the same procedures and standard operating procedures applicable for research on humans.

4.3 It is the duty of the committee to ensure that no research utilizing animals can be commenced prior to ethical approval being granted and that animals may only be utilized when a non-sentient alternative cannot be found.

4.4 The welfare of the animal must be accounted for, ensuring that minimal pain, fear and discomfort occur. This should extend beyond experimental research to ensure that humane conditions prevail for the animal in terms of procurement, transportation, nutrition, injury, infection and euthanasia.

4.5 The research design should use the smallest number of animal participants required to obtain the most valid results, using the best methods, ensuring that the animal is safeguarded.

4.6 The researcher must assure the ERC that the proposed research will contribute significantly to the knowledge that will be of benefit to either humans or animals.

4.7 The ERC, FOM, UOR aligns itself with the “Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka”, published by the Forum for Ethics Review Committees of Sri Lanka, 2009 (ISBN 978-995-1747-01-5) and any subsequent revision made thereafter. These guidelines apply to any research involving animals, including research on live animals, or animal products or parts (i.e tissues, cells, organs, embryonated eggs, secretions etc). Applicants are expected to adhere to the above guidelines involving study design, transportation of animals, experimental procedures, surgery and anaesthesia, euthanasia etc.

GLOSSARY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ERC, FM, UOR: Ethics Review Committee, Faculty of Medicine, University of Ruhuna

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

FERCSL: Forum for Ethical Review Committees in Sri Lanka

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

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

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

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

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

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

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

Major amendment: Modifications/amendments of protocols (which had been already approved) such as addition or deletion of procedural items, significant risk research activity and research activity with more than minor risk from previous approved protocols.

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

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

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

Minor amendment: Modifications/amendments of protocols (which had been already approved) such as administrative revisions, addition or deletion of non-procedural items, non-significant risk research activity and research activity with no more than minor risk from previous approved protocols.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SAEs: Serious Adverse Events: The SAE is serious and should be reported when patient outcome is:
Death - Report if the patient's death is suspected as being a direct outcome of the adverse event.
Life threatening - Report if the patient was at substantial risk of dying at time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death.
Hospitalization (initial or prolonged) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event.
Disability - Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activity or quality of life.
Congenital anomaly - Report if it is suspected that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.
Requires intervention to prevent permanent impairment or damage - Report if it is suspected that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.

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

SUSARs: Suspected, unexpected serious adverse reactions

TOR: Terms of Reference

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

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

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

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

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

REFERENCES

1. World Medical Assembly (WMA). Declaration of Helsinki (DoH), 2013.
2. World Health Organization. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.
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4. Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO). International Ethical Guidelines for Epidemiological Studies, 2008.
5. Forum of Ethics Review Committees Sri Lanka. Ethics Review Committee Guidelines, 2018.
6. Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO). International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002.
7. World Health Organization (TDR/WHO). Operational Guidelines for Ethics Committees That Review Biomedical Research, 2000.
8. ICH Harmonised Tripartite Guideline - Guideline for Good Clinical Practice E6 (R1). Geneva, ICH, 1996.
9. International council for harmonization of technical requirements for pharmaceuticals for human use (ICH). Integrated addendum to ICH E6 (R1): Guideline for good clinical practice E6 (R2). 2016.
10. WMA Declaration of Taipei on ethical considerations regarding Health Databases and Bio banks, 2016.
11. NHS. Governance Arrangements for Research Ethics Committees, 2018.
12. Forum for Ethics Review Committees of Sri Lanka. Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka 2009 (ISBN 978-995-174).
13. Sub Committee on Clinical Trials National Medicines Regulatory Authority Ministry of Health National Medicines Regulatory Authority, Ministry of Health Guidelines for the conduct of clinical trials in Sri Lanka Version 2.0 2016: 8.

Annexure: (UOR/01-002)
Letter of appointment

Date:

Name:
Address:

Dear Prof./Dr./Mr./Mrs./Ms……

APPOINTMENT TO THE ETHICS REVIEW COMMITTEE

I am pleased to inform you that you have been appointed as a member of the Ethics Review Committee of the Faculty of Medicine, University of Ruhuna for a period of three years (03) years effective from ……. ……

As a member of the committee you would be entrusted with the task of reviewing proposals submitted for ethics approval as per the standard operating procedures (SOPs) of the ERC and relevant national and international guidelines. The SOPs are attached herewith for your reference.

The Faculty of Medicine, University of Ruhuna will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. The following are the terms of reference (TOR).

(a). ……..
(b). ……..

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

Yours sincerely

……..
Dean
Faculty of Medicine, University of Ruhuna

Annexure: (UOR/02-002)
Confidentiality / Conflict of interest agreement forms

Faculty of Medicine University of Ruhuna, Ethics Review Committee
CONFIDENTIALITY AGREEMENT

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 Ruhuna (ERC, FM, UOR), and have been asked to assess research studies involving 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, UOR 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 Ethics Review Committee, Faculty of Medicine, University of Ruhuna, Sri Lanka 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 Ethics Review Committee, Faculty of Medicine, University of Ruhuna, is expected to meet the same high standards of ethical behaviour 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, UOR. Any written information provided 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 recognised that the potential for conflict of interest will always exist, but the Faculty of Medicine, University of Ruhuna 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 Ruhuna 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 Ruhuna 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 exists with 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 cases may be 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.

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST

In the course of my activities as a member of the ERC, FM,UOR I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to 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.

…….
Signature of Member
Date

Signature of Chairperson
ERC, Faculty of Medicine, University of Ruhuna

Date

Annexure: (UOR/03-002)
Ethics review application form for human research

ETHICS REVIEW COMMITTEE
Faculty of Medicine, University of Ruhuna,

P.O Box: 70, Galle, Sri Lanka

Email:

Office use only

Unique Identification No …….…….. **Date received** ____/____/_____

Version:

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

APPLICATION FORM – HUMAN RESEARCH

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

The spaces in this form are expandable as you type.

Please read the **instructions carefully when completing the application** and ensure all relevant documents as per the document checklist are submitted.

PART 1 (Administrative details)

1. Title of Research Project:

2. Details of Principal Investigator

Title(Prof./Dr./Mr/Ms):	Name:
Current designation and name and address of institution where the applicant is attached:	
Highest educational qualification of applicant:	
Mailing address:	
Phone no for contact:	e-mail:

3. Is this study a requirement for a postgraduate degree/requirement by PGIM for Board Certification, Faculty of Graduate studies (FGS)?

Yes ☐ No ☐

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

Type of degree (MSc/PhD/MD/MS/other):		
Awarding University:		
Date of registration :	Date of protocol approval by Board of Study :	Letter annexed ☐

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

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

4.1 Details of Supervisors:

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

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

Please append additional pages with Supervisors names if necessary

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

5.1 Details of co-investigators:

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

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

Please append additional pages with co-investigators names if necessary

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

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

6.2 Specify all study sites

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

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

Please append the letter drafted to seeking the permission from the relevant authorities.

7. Other Research Ethics Committee approval(s)

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

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

8. Funding of this project

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

9. For Clinical Trials only

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

Phase I ☐

Phase II ☐

Phase III ☐

Phase IV (post marketing) ☐

Other ☐

If OTHER specify:

9.2 Is it a multi-centre trial?

Yes ☐ No ☐

If yes, list the other trial sites

Please attach ethics approval from the sponsoring country or country of the overseas principal investigator (if any)

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

Yes ☐ No ☐ Pending ☐

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

If No, give reasons

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

Yes ☐ No ☐ Pending ☐

If yes, give details of Approval Number

If No, give reasons

9.5 Data Safety Monitoring Board (DSMB) (only if available)

Name and Designation of Members*	Role

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

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

PART 11 (Research Proposal)

10. Project start and end dates
Estimated start date that involves human participants or data:

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

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

11. 1 Collaborative partnership		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The collaborations you have established with institutions where the study is to be conducted	☐	☐	
2.	The collaborations you have established with the community where the study is to be conducted	☐	☐	
3.	The benefits to institutions, communities, and participants in your research	☐	☐	

11.2 Social Value		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The beneficiaries of your research and the benefit to them	☐	☐	
2.	The plan for dissemination of study findings	☐	☐	

11.3. Scientific Validity		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The scientific importance of your study in relation to improving healthcare and/or knowledge on the subject.	☐	☐	
2.	The justification for a replication study, if your study is a replication study.	☐	☐	
3.	How the sample size was calculated?	☐	☐	

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

11.5 Rights of the participants		Applicable		Section in Protocol & page
		Yes	No	
1.	Procedure for subjects to withdraw from the research at any time	☐	☐	
2.	Procedure for subjects to ask questions and register complaints	☐	☐	
3.	The contact person for research subjects	☐	☐	
4.	Provisions for participants to be informed of results	☐	☐	
5.	Provision to make the study product available to the study participants after research	☐	☐	

11.6 Fair participant selection		Applicable		Section in Protocol & page
		Yes	No	
1.	The justification for the selection of the study population	☐	☐	
2.	The inclusion and exclusion criteria	☐	☐	

11.7 Responsibilities of the researcher		Applicable		Section in Protocol & page
		Yes	No	
1.	The provision of medical services to research participants with special reference to research/trial related injuries	☐	☐	
2.	The provisions for continuation of care after the research is completed	☐	☐	
3.	Declaration of conflicts of interests and how the investigators plan to manage the conflicts	☐	☐	
4.	The ethical/legal/social and financial issues relevant to the study	☐	☐	

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

11.9 Research funded by foreign agencies/companies		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	Justification for conducting the study in Sri Lanka	☐	☐	
2.	Relevance of the study to Sri Lanka	☐	☐	
3.	Post research benefits to Sri Lanka	☐	☐	
4.	The steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka	☐	☐	
5.	The sharing of rights to intellectual property	☐	☐	
6.	The fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study	☐	☐	
7.	How the results of research will be conveyed to relevant authorities in Sri Lanka?	☐	☐	
8.	The agreement between the sponsor/funding agency and the investigator	☐	☐	Please Attach
9.	The materials transfer agreement, if biological material is to be transferred abroad	☐	☐	Please Attach

11.10 Community based research		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The impact and relevance of the research on the community in which it is to be carried out	☐	☐	
2.	The steps taken to consult with the concerned community during the design of the research	☐	☐	
3.	The procedure used to obtain community consent	☐	☐	
4.	The contribution to capacity building of the community	☐	☐	
5.	The procedure for making available results of research to the community	☐	☐	

11.11 Clinical trials		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	Justification for withdrawing any therapy from participants to prepare them for the trial	☐	☐	
2.	Justification for withholding standard therapy from trial participants (e.g. control group)	☐	☐	
3.	Justification for providing care which is not the standard of care	☐	☐	
4.	Procedure for dealing with adverse events	☐	☐	
5.	Procedure for reporting adverse events	☐	☐	
6.	Measures in place for management of trial related injuries	☐	☐	
7.	Provisions for safety monitoring	☐	☐	
8.	Provisions/criteria for termination of the trial	☐	☐	
9.	Provisions for making the trial drug available to participants after the trial if found to be effective	☐	☐	

11.12 Information Sheet (IFS)/Informed Consent Form (ICF) **Checklist** (List the sections in IFS/ICF where you have dealt with the following)		**Section IFS/ICF**
1.	Purpose of the study	
2.	Voluntary participation	
3.	Duration, procedures of the study and participant's responsibilities	
4.	Potential benefits	
5.	Risks, hazards and discomforts	
6.	Reimbursements	
7.	Confidentiality	
8.	Termination of study participation	

11.13 Consent		Applicable		Section in Protocol & page
		Yes	No	
1.	The procedure for initial contact of participants*	☐	☐	
2.	The procedure for obtaining informed consent			
	Verbal	☐	☐	
	Written	☐	☐	
3.	The information (written/oral) provided to participants	☐	☐	
4.	The procedure for ensuring that subjects have understood the information provided.	☐	☐	
3.	The procedure for obtaining proxy consent.	☐	☐	
4.	The procedure for withdrawing consent.	☐	☐	
5.	Incentives/rewards/compensation provided to participants.	☐	☐	
6.	The procedure for re-consenting if the research protocol changes during the course of research.	☐	☐	
7.	The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited.	☐	☐	
8	The procedure for consenting if children aged 12 - 18 years of age are being recruited (for children aged 12-18 years in addition to parental consent, children's assent must be sought)**	☐	☐	

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

**** Please attach an assent form for children aged 12-18 years**

12. Data Collection

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

Page Number/s	
Section/s	

13. Experience of Investigators with this type of research

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

PART III – (Description of the risks and benefits)

14. Possible Risks

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

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

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

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

(iv) Legal risks (e.g., apprehension or arrest, subpoena): Yes ☐ No ☐

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

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

15. Possible Benefits

- Describe any potential direct benefits to participants from their involvement in the project
- Describe any potential direct benefits to the community (e.g., capacity building)
- Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

16. Compensation

16.1 Will participants receive compensation for participation?

Financial Yes ☐ No ☐ In-kind Yes ☐ No ☐

Other Yes ☐ No ☐

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

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

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

17. Feedback/debriefing/referral/after care

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

18. Do you have any conflict of interests with regards to this project?

Yes ☐ No ☐

If yes, please state below.

18.1 Commercially

18.2 Financially

18.3 Intellectually

18.4 Other (Explain)

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

Yes ☐ No ☐

If yes, please explain:

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

21. Declaration of applicant

1. As the Principal Investigator 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 understand that at least two months are required for ethics review and granting of ethics clearance.
6. I will submit progress reports/reports of adverse events and side effects as requested by the ERC. FM, UR.

……..

Signature of Principal Investigator Date: ___ /____/_____

Full name of Principal Investigator:

22. Consent from all Investigators

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

Name	Qualifications	Institutional Affiliations	Signature

23. Acknowledgement (*Office use only)*

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

Unique identification No ……. **Date received** **____/____/_____**

Version:

Thank you for submitting the above research proposal. The proposal has been assigned the protocol number stated above. It will be considered by the Ethics Review Committee at its meeting in ……and will be assigned to three principal reviewers. The ERC may contact you in due course if any clarifications; additional documentation; or revisions are required.

…….

Administrative Officer/Convenor/Secretary

ERC,FM, UOR

Annexure: (UOR/04-002)
Ethics review application form for animal research

APPLICATION FORM – ANIMAL RESEARCH
ETHICS REVIEW COMMITTEE
Faculty of Medicine, University of Ruhuna

Application No: [ ][ ][ ]/[ ][ ] **Date received** ____/____/_____
Version: [ ]

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

Office use only

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

Please read the **instructions given carefully when completing the application** and ensure all relevant documents as per the document checklist are submitted.

This form can be filled in and the spaces provided are expandable as you type

PART 1 (Administrative details)

1. Title of Research Project:

2. Details of principal investigator

Title(Prof./Dr./Mr/Ms):	Name:
Current designation AND name and address of institution where the applicant is attached:	
Highest educational qualification of applicant:	
Mailing address:	
Phone:	e-mail:

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

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

Type of degree (MSc/PhD/MD/MS/other):		
Awarding University:		
Date of registration :	Date of protocol approval by board of study :	Letter annexed ☐

Please append letter of approval from Board of Study (if available)

3.2 Do you have any other active studies at present? Yes ☐ No ☐
3.3 If yes, how many studies are there?

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

Title:	Name:
Department (or organization if not affiliated with FM/UR):	
Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Title:	Name:
Department (or organization if not affiliated with FM/UR):	
Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Please append additional pages with supervisors' names if necessary.

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

Title:	Name:
Department (or organization if not affiliated with FM/UR):	
Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Title:	Name:
Department (or organization if not affiliated with FM/UR):	
Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Please append additional pages with Co-investigators names if necessary.

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

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

6.2 Specify all study sites including laboratories, animal houses and other:

Type of site (laboratory/animal house)	Details

6.3 Will samples/tissue/data collected during the study be removed from the above study site/transported to a different site for investigation etc. Yes ☐ No ☐
If so provide details of these sites

6.4 Will samples/tissues collected during the study be taken out of the country for investigation storage Yes ☐ No ☐
If so provide details of these sites

7. Investigator(s) training to handle animals in research
7.1 Have all the investigator's handling animals in this study been trained? Yes ☐ No ☐
7.2 Specify all training received:

Name of investigator	Training site, duration of course and type of training received

8. Other research ethics board approval(s)

8.1 Has any other ERC approved this project? Yes ☐ No ☐

If Yes, please provide details and a copy of the approval letter.

9. Funding of this project

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

PART 11 (Research Proposal)

10. Project start and end dates

Estimated start date:
Estimated completion date:

11. Objective of the project and justification
Describe the objectives and rationale for the proposed project. The rationale for doing the study must be clear. Please include references in this section.

11.1 General objective

11.2 Specific objectives:

11.3 Justification (A clear justification should be given for investigating in ANIMALS). Explain why the research cannot be carried out with non-animal alternatives.

12. Methodology

12.1 Description of the procedures : Describe in DETAIL all procedures and techniques to be used, **emphasizing those performed on animals**. Use flowcharts to illustrate procedures as appropriate. Append additional page(s) if necessary.

Description of the procedure involving animals (for which ethical clearance if being sought). DO NOT LEAVE BLANK, sections13 - 20 must be filled for ALL projects

13. Description of animal

13.1 What is the species of animals used and the reason for selecting the said animal model?

13.2 What is the source of animals and the arrangements that you have made to ensure constant supply of animals?

13.3 What is the total number of animals used in the study and how did you calculate the sample size?

13.4 How long will animals be used in the study?

13.5 How often will animals be monitored?

13.6 Who will handle the animals?

Name	Position in study team (PI, research assistant/ supervisor, etc,	Training received to handle animals
		Yes ☐ No ☐
		Yes ☐ No ☐

14. Procedures and Drugs

Is there any administration of drugs/herbs/chemicals to the animals : Yes ☐ No ☐
If yes, specify for each agent (append additional pages if necessary):

Amount of agent and dosage: Route of administration: Potential health risks to humans or animals: Special animal care requirement(s): Precautions to be taken by personnel (including animal care staff):

14.1 What is the procedure for dealing with adverse events?

14.2 Is there any procedure for reporting adverse events?

15. Animal welfare

Are the facilities available at the animal house/facility adequate to conduct this study?
Yes ☐ No ☐

15.1 Are the facilities adequate to provide optimum welfare to animals? Yes ☐ No ☐
15.2 What are the arrangements made for feeding and for providing water?

16. Endpoints

Please specify ENDPOINTS: Endpoints are clear criteria to define the point at which humane intervention must be implemented to prevent or relieve unnecessary pain and/or distress. Should the experimental animal acquire experimentally-induced disease, illness or life threatening condition?

16.1 Are any drugs used for anaesthesia /analgesia of animals: Yes ☐ No ☐
If Yes, specify the drug, dosage and route of administration

16.2 Please specify the method of euthanasia:

16.3 Give details of final disposal of animals:

17. Experience of Investigators with this type of research

17.1 Please provide a brief description of previous experience with this type of research by (i) the principal investigator, (ii) the research team and (iii) the people who will have direct contact with the animals. If there has not been previous experience, please describe how the principal investigator/research team will be trained.

PART III – (description of the risks and benefits)

18. Assessment of Risks/Benefits

18.1. Are there any risks (physical, psychological) to animals in the study? Yes ☐ No ☐

If YES, identify them and state how you plan to prevent or minimize these risks?

18.2. Are there any benefits to the animals used in the study? Yes ☐ No ☐

If YES, identify them

18.3. Are there any risks to research team by conducting this study? Yes ☐ No ☐

If yes identify them and state how you would overcome these risks

19. Data Security, Retention and Access

19.1 Describe the provisions that will be made to protect confidentiality of data:

19.2 If data will be shared with other researchers or users, please describe how and where the data will be stored and any restrictions that will be made regarding access.

20. Conflicts of Interest

20.1 Will the researcher(s), members of the research team, and/or their partners or immediate family members: receive any personal benefits (e.g., financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection with this study? Yes ☐ No ☐

20.2 If **Yes**, please describe the benefits below. (Do not include conference and travel expense coverage, or other benefits which are considered standard for the conduct of research.)

21. Declaration of applicant

As the Principal Investigator on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving animal participants. I understand that if there is any significant deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study. I declare that I am not seeking approval for a study that has already commenced or has already been completed. I understand that at least two months are required for ethics review and granting of ethics clearance. I will submit progress reports/reports of adverse events and side effects as requested by the ERC FM/UR.

……..
Signature of Principal Investigator Date: ___ /____/_____

Full name of Principal Investigator:

22. Consent from all Investigators

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

Name	Qualifications	Institutional affiliations	Signature

23. Acknowledgement (*Office use only)*

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

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

Version :……

Thank you for submitting the above research proposal. The proposal has been assigned the protocol number stated above. It will be considered by the Ethics Review Committee at its meeting in ……and will be assigned to three principal reviewers. The ERC may contact you in due course if any clarifications; additional documentation; or revisions are required.

……
Administrative Officer/Convenor/Secretary
ERC,FM, UOR

Annexure: (UOR/05-002)
Checklist for initial submission

CHECKLIST **(**Please mark all documents submitted)

One copy *each of the following*

1. Cover letter signed by the applicant. ☐
2. Completed application form ☐
3. Letter from supervisor/s (if relevant). ☐
4. Copy of approval letter from Board of Study (*for postgraduate students only*). ☐
5. Email the soft copy with a complete set of documents in a single pdf file. ☐ ethics@med.ruh.ac.lk
6. A letter indicating that the investigator(s) have undergone training to handle Animals in research settings (if relevant) ☐
7. Curriculum vitae of the investigators ☐
8. Certificates of training (Research Methodology, Basic Research Ethics, GCP training) ☐
9. Letter signed by all investigators confirming their participation. ☐

10. ***Six copies*** of the detailed proposal including study instruments *(postgraduate students must submit a copy identical to that approved by the board of study or* submitted to the Board of Study)

			Date	Version
11. Study instruments	☐ English ☐ Sinhala ☐ Tamil	-	Where relevant	

PLEASE NOTE:
The six(06) copies of the documents submitted must be **stapled together** to form six complete sets of documents.
All documents must carry the **date and version number as a header/footer.**

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

Date received ____/____/_____

Annexure: (UOR/06-002)
Receipt form for any document

DOCUMENT RECEIPT FORM

Ethics Review Committee, Faculty of Medicine, University of Ruhuna

Protocol No: Version:		Date of submission:
Type of submission:	1. Initial review 2. Resubmission 3. Continuing review of approved protocol	4. Protocol amendments 5. Final report
Protocol Title :		
Principal investigator:		
Telephone Number:		Email:
Institution:		
Document submitted: 1. Complete 2. Incomplete, will submit on …….....		
Documents to be submitted :		
Received by :		
Date of received:		
This proposal will be considered by the ERC at its meeting on ……/……../2018 Administrative Officer/Secretary, ERC Date:		

Annexure: (UOR/07-002)
Template for the agenda

List of Committee members

Dear ERC member,

Ethical Review Committee Meeting

A meeting of the Ethical Review Committee will be held on …….. at …… am in the Office of Ethical Review Committee, CIU Building, Faculty of Medicine, Galle.

Please be present.

Agenda

1. Confirmation of the minutes of previous meeting and
2. Matters arising from minutes
3. New items
    (a). Unique identification number [YYYY/P/001]
    (b). Date of submission
    (c). Title of protocol
    (d). Name(s) of Principal investigator, co-investigators and supervisors
    (e). Names of primary reviewers
    (f).Type of review
    (g).Conflict of interest for new items
4. Any other matters
    (a). Amendments to approved protocols
    (b). Extension of ERC approval
    (c). Reports of Serious Adverse Effects
    (d). Progress reports
    (e). Final reports
    (f). Protocol deviations, violations, non-compliance
    (g). Any other correspondence
5. Announcements
6. Close and date for next meeting

…….
Secretary
ERC, FM, UOR
Date:

Annexure: (UOR/08-002)
Template for the minutes

Minutes of the Ethical Review Committee Meeting held on ……..

Attendance

The format of the minutes shall include at least the following items:

1. Attendance
2. Confirmation of the minutes of previous meeting and
3. Matters arising from minutes
4. New items
   - 4.1 Unique identification number
   - 4.2 Title of protocol
   - 4.3 Name(s) of principal investigators, co-investigators and supervisors
   - .4.4 Names of primary reviewers
   - 4.5 Type of review (exemption from review /Full board/ expedited review
   - 4.6 Conflict of interest
   - 4.7 Observations (scientific, ethical, administrative) discussion and decision
5. Any other business
   - (a). Amendments to approved protocols
   - (b). Extension of ERC approval
   - (c). Reports of Serious Adverse Effects
   - (d). Progress reports
   - (e). Final reports
   - (f). Protocol deviations, violations, non-compliance
   - (g). Any other correspondence
6. Announcements
7. Close and date for next meeting.

……..
Secretary
ERC
FM,UOR Date

Annexure: (UOR/09-002)
Research proposal evaluation form

Research Proposal Evaluation Form

Faculty of Medicine, University of Ruhuna

Name of evaluator (reviewer):

Title of the Research Project:

……

……

……

Details of Assessment (Please circle/underline the appropriate response)**:**

1. **Title:**

a. Does the title make the general objective clear? Yes/ No

b. Does it refer to the study population? Yes/ No

c. Does it reflect the study setting? Yes/ No

d. Is it free of phrases such as „a study on" and abbreviations and acronyms? Yes/ No

e. Is the title too long? Yes/ No

Comments:

……

……

……

2. Introduction:

Background Information:

a. Does **it provide a** c**o**ncise description of the nature of the problem? Yes/ No

b. Does it refer to the existing situation of the research problem? Yes/ No

c. Is the literature supported by relevant references? Yes/ No

Comments:

……

……

……

Justification:

a. Does it address the need for the study? Yes/ No

b. Does it refer to the potential benefits of the research findings? Yes/ No

c. Is it focused? Yes/ No

Comments:

……

……..

……

Objectives:

a. Does the general objective clearly address the aims of the study? Yes/ No

b. Are the specific objectives derived from the general objective? Yes/ No

c. Are they arranged in a logical sequence? Yes/ No

d. Are they stated in measurable terms using action verbs? Yes/ No

e. Do they refer to the study population and the study area? Yes/ No

Comments:

……

……

……

3. Methods:

A. Study design –

a. Is it the appropriate design to achieve the stated objectives? Yes/ No

Comments:

……

……

……

B. Study population/s

a. Adequately described? Yes/ No

b. Inclusion criteria stated correctly as per relevance? Yes/ No/ Not applicable

c. Exclusion criteria stated correctly as per relevance? Yes/ No/ Not applicable

Comments:

……

……

……

C. Sample size calculations

a. Has it being worked out using an appropriate formula? Yes/No

b. All items in the formula are described in terms of the proposed study? Yes/No

c. Are all estimates used in calculations justified based on references? Yes/No

d. Does the researcher demonstrate a clear understanding of the calculations performed? Yes/No

Comments:

……

……

……

D. Sampling technique

a. Is it the appropriate technique for the study? Yes/No

b. Are all relevant steps described adequately? Yes/No

Comments:

……

……

……

E. Study instruments

a. Has the researcher included all the instruments required to achieve the objectives? Yes/No

b. Does the researcher refer to standardization of observational techniques? Yes/No/ Not applicable

Comments:

……

……

……

Intervention (Applicable only for intervention studies)

a. Intervention has been described briefly but clearly Yes/No

b. Outcomes clearly stated Yes/No

Comments:

……

……

……

F. Data analysis

a. Plan of analysis is described for each specific objective? Yes/ No

b. Are the proposed analyses appropriate? Yes/ No

Comments:

……

……

……

G. Ethical Clearance

a. Has the researcher described the general ethical aspects that need to be considered? Yes/ No

b. Has the researcher identified the ethical aspects specific to the study proposed as per relevance? Yes/ No/ Not applicable

c. Has the researcher briefly indicated measures to be taken to minimize ethical issues? Yes/ No/ Not applicable

Comments:

……

……

……

H. Definitions of Variables

a. The variables specific to the research problem have been defined Yes/ No

b. Have they been operationalized? Yes/ No

Comments:

……

……

……

4. Referencing

Has they followed a standard referencing system? Yes/No

Comments:

……

……

……

5. Gantt chart

a. All main activities are included and timeline is appropriately designed? Yes/No

Comments:

……

……

6. Budget

a. All main likely costs have been included? Yes/No

b. The proposed amounts are realistic? Yes/No

Comments:

……

……

General Comments on the proposal

……

……

……

……

Decision:	**Approved**	☐
	Minor modifications needed	☐
	Major modifications needed	☐
	Disapproved	☐

Any other comments (Append extra sheets as needed)

Signature:…….

Name of the reviewer:……..

Date:

Annexure: (UOR/10-002)
ICF assessment form

Ethics Review Committee
Faculty of Medicine, University of Ruhuna
ICF ASSESSMENT FORM

Application Number:	Date reviewed (D/M/Y):
Reviewer's Name:	Signature:

Informed Consent Forms		**Yes**	**No**	**NA**	**Comments**
1	Are the written and oral information to be given to the research participants appropriate, adequate and complete?				
2	Is the language used in information sheets clear and understandable? **N.B. Check the use of scientific words.**				
3	Is there a statement to the effect that the participation in the research is voluntary?				
4	Are translations of all forms consistent and accurate?				
5	Is there an opportunity for the participant to ask questions regarding the research?				
6	Are there provisions for the participant to withdraw unconditionally from the research without penalty or loss of care?				
7	If biological samples are being collected, are the participants informed about - What is being collected - What tests will be done with them - Whether they will be stored for future studies - If stored for how long and what is expected to be done with samples				

	Informed Consent Forms	**Yes**	**No**	**NA**	**Comments**
8	**Consent Form** – has the participant consented for all procedures planned? e.g. Immediate activities of study, storing of samples, recording of interviews etc.				
9	Is Assent Form provided adequate?				
10	Are contact details of PI and other appropriate investigators for site given in the information				
11	Are there provisions for study participants to make complaints if needed? e.g. ERC contact details				

General/ any other comments

……

……

……

Signature:…….

Name of the reviewer: ……..

Date:

Annexure: (UOR/11-002)
Checklist for exemption from review

CHECKLIST FOR PROTOCOLS EXEMPTED FROM REVIEW
Ethics Review Committee, Faculty of Medicine University of Ruhuna

		YES	NO	COMMENTS
1	Audits of educational practices/programmes that are conducted			
2	Research on regular or special education instructional strategies			
3	Research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods			
4	Research on immortalized cell lines			
5	Analysis of data freely available in public domain			
6	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:				
1	Does the research involve vulnerable groups?			
2	Does the research involve interviews?			
3	Does the research involve observation of public behavior or minors **and** the researcher participates in the activities being observed			
4	Does the survey deals with sensitive or highly personal aspects of the subject's behaviour, life experiences or attitudes? (sensitive surveys) e.g. substance abuse, criminal behaviour, sexual activity/attitude, sexual abuse etc.			
5	Does the data provide identification of subjects?			
6	Would the information if disclosed outside research reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?			
If NO to ALL of the above → Exempt from review				

…… ……
Chairperson, ERC, FM, UOR Date: Secretary, ERC, FM, UOR

Annexure: (UOR/12-002)
Standard letter for exemption from review

EXEMPTION FROM ETHICS REVIEW
Ethics Review Committee, Faculty of Medicine, University of Ruhuna

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

Dear Prof/ Dr/Mr/Ms

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, FM,UOR , at its meeting held on ……./……../…….. This proposal is exempt from ethics review.

Yours sincerely,

……..

Name Date:…….
Chairperson
Ethics Review Committee
Faculty of Medicine, University of Ruhuna

Annexure: (UOR/13-002)
Standard letter for expedited review

EXPEDITED REVIEW
Ethics Review Committee, Faculty of Medicine University of Ruhuna

REFERENCE: «Proposal_No»
«date»
«Name_and_Address»
«Salutation»

Re: Proposal No «Proposal No» - "Proposal Title"

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

Approval is granted to proceed. It is anticipated that this approval will be ratified by the Ethics Review Committee at its meeting on «Date_of_Meeting».

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

You are asked to note the following:
 This approval is valid for one year and the Committee requires that you furnish it with «period» reports on the study's progress beginning in «Report_Due».

 This approval relates to the ethical content of the study only, and you are responsible for the following:
1) To negotiating individual arrangements with the Heads of service departments in those situations where the use of their resources is involved,
2) If appropriate, informing the study sponsor that the membership and procedures of the Ethics Review Committee FM, UOR comply with the relevant guidelines of the Forum of Ethics Review Committees in Sri Lanka.

Yours sincerely,

…… Date:……..

«name»
Chairperson
Ethics Review Committee
Faculty of medicine University of Ruhuna

Annexure: (UOR/14-002)
Standard letter for approval of amendments to a proposal

APPROVAL OF AMENDMENTS TO A PROPOSAL
Ethics Review Committee, Faculty of Medicine University of Ruhuna

REFERENCE: «Proposal_No»
«Date»
«Name_and_Address»
«Salutation»,

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

The Ethics Review Committee, at its meeting of …….. Considered your letter of

……. and gave its approval for the amendment.

This approval is subject to the following (delete if not applicable)

 [insert details of conditions]

In order for your response to be presented at the next Ethics Review Committee meeting, your acceptance of these conditions should be forwarded to the ERC Office by «Date»

This approval relates to the following:
 [insert details of amendment]
 [Insert details of other approved documents]

Yours sincerely,

…….. Date:…….

«name»
Chairperson
Ethics Review Committee
Faculty of Medicine
University of
Ruhuna

Annexure: (UOR/15-002)

Standard letter requesting additional information

LETTER REQUESTING ADDITIONAL INFORMATION Ethics Review Committee, Faculty of Medicine, University of Ruhuna

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

Dear Prof/Dr/Mr/Ms,

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

Approved	
Minor modifications needed	
Major modifications needed	
Disapproved	

The following additional information is requested:

You are advised that you may not commence this study until final approval has been granted. Please highlight the changes made to documents by attaching a table giving the original and revised items side by side, to assist the Committee's checking of the amended documents. (delete if not applicable).

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

Please note that investigators who do not respond to comments within 6 months of their submission it will be removed from the meeting minutes.

Yours sincerely,

……. Date:

Name

Chairperson
Ethics Review Committee
Faculty of Medicine
University of Ruhuna

Annexure: (UOR/16-002)
Standard letter granting ethical approval

APPROVAL OF A PROPOSAL
Ethics Review Committee, Faculty of Medicine, University of Ruhuna

«Date»
«Name_and_Address»

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

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

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

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

Please note that ethical approval will be revoked if any alteration is made to the research protocol without obtaining prior written consent from the ERC.

As the Principal Investigator, you are expected to ensure that procedures performed under the project will be conducted in accordance with all relevant national and international regulations and guidelines that govern research involving human participants.

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

Yours sincerely,

…… Date:
«name»
Chairperson, Ethics Review Committee
Faculty of Medicine, University of Ruhuna

Annexure: (UOR/17-002)
Standard letter for disapproval of a proposal

STANDARD LETTER FOR DISAPPROVAL OF AN APPLICATION
Ethics Review Committee, Faculty of Medicine University of Ruhuna

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

Dear Prof/Dr/Mr/Ms

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

The following decision was taken.

Approved	
Minor modifications needed	
Major modifications needed	
Disapproved	

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

1.
2.
3.

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

Yours sincerely,

«name»
Chairperson
Ethics Review Committee
Faculty of Medicine
University of Ruhuna

Annexure: (UOR/18-002)
Template for notification of serious adverse event

Serious Adverse Effect (SAE) Reporting Form
Faculty of Medicine, University of Ruhuna

Principal Investigator : Study Title : Name of the studying medicine/herbal/device : Sponsor :	Application Number : Protocol Number : Report Date : Initial ☐ Follow up ☐ Onset Date : Date of first use :	
Subject's initial / number :	Age :	Gender: Male ☐ Female ☐
Subject's history :	Laboratory findings :	
State the SAE :	Treatment: Outcome : resolved ☐ on-going ☐	

Seriousness : **Relation to Drug/Device/Study**

☐ Death	Not related/Possibly related/Definitely related
☐ Life Threatening	Not related/Possibly related/Definitely related
☐ Hospitalization	Not related/Possibly related/Definitely related
☐ Disability/ Incapability	Not related/Possibly related/Definitely related
☐ Congenital Anomaly	Not related/Possibly related/Definitely related
☐ Unknown	Not related/Possibly related/Definitely related
☐ Other	Not related/Possibly related/Definitely related

Changes to the protocol recommended? ☐ No ☐ Yes, attach proposal

Changes to the informed consent form recommended? ☐ No ☐ Yes, attach proposal

Reviewed by :
Comment :
Action :
Date :

Annexure: (UOR/19-002)
Template for progress review form

PROGRESS REVIEW FORM (SIX MONTHLY / ANNUALLY)
Ethics Review Committee, Faculty of Medicine University of Ruhuna

Protocol Number:	
Principal Investigator:	
Telephone:	Email:
Protocol Title:	
Number of participants enrolled	
Number of participants who withdrew	
Number of participants lost to follow-up	
A summary of any complaints about the research since the last committee review	
A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last committee review.	
Signature of PI	Date

Annexure: (UOR/20-002)
Template for final report

FINAL REPORT
Ethics Review Committee, Faculty of Medicine, University of Ruhuna

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

Annexure:(UOR/21 -002)
Template for reporting Deviations/Violations/Non-compliance

DEVIATION / NON-COMPLIANCE / VIOLATION REPORT FORM

Ethics Review Committee, Faculty of Medicine University of Ruhuna

Identification No:		Date:
Study Title:		
Name of the Investigator/s:		
Address:		Contact No:
Institution:		Contact No:
Sponsor:		Contact No:
□ Deviation from protocol □ Major	□ Non Compliance □ Minor	□ Violation
Description:		
ERC decision:		
Action taken:	Outcome:	
Found by : Date:	Reported by: Date:	

Annexure: (UOR/22-002)
Checklist for a site monitoring visit

CHECKLIST FOR A SITE MONITORING VISIT
Ethics Review Committee, Faculty of Medicine University of Ruhuna

Protocol No.:	Date of visit:
Study Title:	
Name of the Principal Investigator:	
Telephone:	Name of the sponsor:
Address:	Address of the sponsor:
Total number of subjects expected: □ yes □ No	Total number of subjects enrolled:
Are site facilities appropriate? □ yes □ No	Comments:
Are informed consent up to date? □ yes □ No	Comments:
Any adverse event found? □ yes □ No	Comments:
Ant protocol non-compliance/violence? □ yes □ No	Comments:
Are all case records forms up to date? □ yes □ No	Comments:
Are storage of data and investigating products locked? □ yes □ No	Comments:
How well are participants protected? □ Good □ Fair □ Poor	Comments:
Any outstanding tasks or results of visits? □ yes □ No	Details:
Duration of visit: hours.	Starting from:
Names of the ERC members 1. 2. 3.	
Date:	

Annexure: (UOR/23-002)
Request form for revisions

REQUEST FORM FOR REVISIONS
Ethics Review Committee, Faculty of Medicine, University of Ruhuna

Name of ERC/FB member:	Date:
Number and the title of the SOP which needs revision:	
Section of the SOP (Point) that needs revisions:	
Suggestions in detail for the revision:	
Date of the meeting:	
Signature of the applicant:	