STANDARD OPERATING PROCEDURES

ETHICS REVIEW COMMITTEE
Faculty of Allied Health Sciences
University of Ruhuna

First Edition: 2020
ISBN:

Standard Operating Procedures
Ethics Review Committee
Faculty of Allied Health Sciences, University of Ruhuna

Authors

Name and position in ERC	Signature	Date
Dr. (Mrs.) HH Peiris, Secretary		

Reviewed by

Name and position in ERC	Signature	Date
Dr.(Mrs.)WVRTDG Bandara, Chairperson		
Prof. S Gunawardhana, member		
Prof. B Perera, member		
Mrs. EB Weeratunga, member		
Mrs. KAKD Wijesekara		
Dr. A Dissanayake, member		
Dr. (Mrs.) SK Hettihewa, member		
Ms. KKPMK de Silva, member		
Ms. MWK Gamage, member		

Approved by

Name and Position	Signature	Date
Prof. Imendra Kotpola Dean/Faculty of AHS, University of Ruhuna		
Prof. Sujeewa Amarasena Vice Chancellor University of Ruhuna		

Table of Contents

Standard Operating Procedures

Table of Annexures

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna **SOP No: 001** **Title: Function of the Ethics Review Committee** **Effective Date:**	

1. Purpose

The Ethics Review Committee (ERC), Faculty of Allied Health Sciences (FAHS), University of Ruhuna, (UOR) is established in order to provide independent guidance, advice, and decision (in the form of "approved/ major modifications/ minor modifications/ rejected") on health related research/projects involving human and/or animal subjects.

These standard operating procedures (SOPs) describe the Terms of Reference (TOR) which provide the framework for constitution, responsibilities and activities of the ERC.

2. Scope

This SOP applies to all activities under the ERC. The ERC shall have the authority to review protocol/s in which at least one of the investigators of the protocol is a permanent staff member of the Faculty of AHS.

OR

The protocol/s received from the extended faculty members of the FAHS, attached to institutions which do not have any official ERC.

3. Responsibility

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

4. Detailed instructions

Overall Function:

4.1. The primary objectives of the ERC is to protect the mental and physical welfare, rights, dignity and safety of human participants and animals used in research, to facilitate ethical research through efficient and effective review and monitoring processes, to promote ethical standards of human and animal research and to review research in accordance with the Guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL Guidelines) and relevant national and international guidelines (1-5).

Responsibilities

4.2. The ERC shall

a. advise the FAHS/UOR on all matters related to the ethics of human and animal research.

b. review proposals of research involving human subjects and animals taking care that all the cardinal principles of research viz. autonomy, beneficence, non-maleficence and justice are adhered to in research proposals.
c. conduct ERC meeting at once a month and make a report to the Board of the FAHS/UOR.

4.3. ERC, FAHS/UOR will not act as a research funding or grant giving committee.
4.4. The ERC, FAHS/UOR will review all types of research proposals involving human and animal studies conducted by the staff and students of the FAHS/UOR.
4.5. All applications will be subjected to a handling fee as decided by the Board of FAHS/UOR.
4.6. The ERC will assess protocols submitted for review in accordance with the FERCSL and other national and international guidelines and legal requirements in order to determine their ethical acceptability.
4.7. ERC, FAHS/UOR will seek advice of another ERC and/or send the application to an external reviewer when the committee lacks the expertise among its members to review specific subject/technical areas.
4.8. ERC, FAHS/UOR will not entertain any request by a clinician/s with an ethical problem of medical practice (not pertaining to research) as it falls outside the purview of the ERC.

References

1. Declaration of Helsinki (DoH) of the World Medical Assembly (WMA), 2013.
2. International Ethical Guidelines for Epidemiological Studies - Prepared by the Council for International Organizations of Medical Sciences (CIOMS) 2008.
3. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organization 2011.
4. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) E6 (R1) 1996.
5. Ethics Review Committee Guidelines, Forum of Ethics Review Committees, Sri Lanka, 2007.

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 002 **Title: Membership Composition** **Effective Date:**	

1. Purpose

To describe the membership composition of the ERC/FAHS

2. Scope

The ERC, FAHS/UOR is composed of both scientists and non-scientists. It is independent in its reflection, advice, and decision. These SOPs describe the Terms of Reference (TOR) which provide the framework for constitution of ERC, FAHS/UOR.

3. Responsibility

The SOP applies to all activities under the ERC, FAHS/UOR.

4. Detailed instructions

4.1. The composition of the ERC shall be in accordance with the FERCSL Guidelines and other relevant national and international guidelines (1,2).

4.2. The committee will comprise of fifteen (15) members.

4.3. The membership will comprise of the following categories:

1. Members from FAHS/UOR
2. Members representing the Faculty of Medicine, University of Ruhuna (two medical members)
3. A Statistician
4. An Ayurvedic medical practitioner
5. A Lawyer
6. Non-scientific member (Lay person)

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

4.5. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least eight (8) members including Chairperson, Secretary or their designated members, and/or at least one medical and one non-affiliated member are present.

References

1. Forum of Ethics Review Committees, Sri Lanka, 2007.
2. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organization 2011.

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 003 **Title: Appointment of ERC Members** **Effective Date:**	

1. Purpose

To describe the procedure for the appointment of members to the ERC

2. Scope

These standard operating procedures describe the TOR which provides the framework for appointment of members of ERC, FAHS/UOR.

3. Responsibility

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

4. Detailed instructions

4.1. Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organization, group or opinion.

4.2. Members of the ERC, FAHS/UOR will be recruited by advertisement and calling applications among the affiliated members and appointed by the Dean, FAHS/UOR. In Certain situations, appointments are made by the Dean, FAHS/UOR on the recommendation of the ERC, FAHS/ UOR based on the requirement.

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

4.4. The letters of appointment will be issued by the Dean FAHS, UOR. Prospective members may be invited to attend a meeting of the ERC as observers. Such persons will be expected to sign the confidentiality undertaking as per SOP 003/y - 4.6.

4.5. The letter of appointment (Annexure 1) 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.

4.6. Members will be required to sign a confidentiality undertaking upon appointment (Annexure 2), stating that all matters of which he/she becomes aware during the course of his/her work on the ERC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the ERC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a ERC member.

4.7. Upon appointment, members shall be provided with the following documentation:
   a. ERC Terms of Reference (TOR)
   b. ERC Standard Operating Procedures (SOPs)
   c. An up-to-date list of members (names and contact information including that of the Dean).

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

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

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

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

4.12. Membership will lapse if a member fails to attend three (03) consecutive meetings of the ERC without reasonable excuse/apology, unless exceptional circumstances exist.
   a. A valid excuse is defined as being involved in designated academic or clinical work. This should be informed to the ERC in writing prior to commencement of the ERC meeting for which the member is going to be absent.
   b. The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy.

4.13. 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.

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

4.15. A member may resign from the ERC at any time upon giving notice in writing to the Chairperson/ERC and the Dean/FAHS. The effective date of resignation will be the date in which the resignation is formally accepted by the Board of FAHS.

4.16. Vacancies in the ERC will be filled as per SOP 003/2020 - 4.2 and 4.3.

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 004 **Title: Function of ERC Members** **Effective Date:**	

1. Purpose

To describe the functions of members of the ERC

2. Scope

These standard operating procedures describe the TOR which provides the framework for functions of members of ERC, FAHS/UOR.

3. Responsibility

It is the responsibility of the ERC, FAHS/UOR members to read and understand their functions as members of the ERC, FAHS/UOR.

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

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:

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

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. Secretary / Alternate Secretary

4.2.1. Secretary

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

4.2.2. Alternate Secretary

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

4.3. All members of the ERC, FAHS/UOR

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

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

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

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 005 **Title: Orientation of new members and training** **Effective Date:**	

1. Purpose

To describe the procedure for the orientation of new members 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

The FAHS/UOR recognizes the importance of training and continuing professional development, therefore the institution will provide funds when required for specific training and study visits for ERC members.

2. Scope

These standard operating procedures describe the Terms of Reference (TOR) which describe the procedure of orientation of new members of ERC, FAHS/UOR and training of all the members in the ERC.

3. Responsibility

It is the responsibility of new members of the ERC, FAHS/UOR to read and understand their functions as members of the ERC of the, FAHS/UOR. It is the responsibility of all members to have themselves educated and trained periodically.

4. Detailed instructions

4.1. New ERC members must be provided with adequate orientation

4.2. New member orientation will include the following:

a. Introduction to other ERC members prior to the ERC meeting.
b. Informal meeting with the Chairperson, Secretary and Officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures.
c. An opportunity to sit in on ERC meetings before their appointment takes effect.
d. “Partnering” with another ERC member in the same category.
e. Priority given to participate in training sessions.

4.3. New members will receive training in:

a. Research ethics, human and animal subject protection.
b. Standard Operating Procedures of the committee.

4.4. Obtaining training

a. Members should get information about training courses, workshops, conferences, etc. which is periodically announced on websites, bulletin boards and various media channels.
b. Members should select the relevant training they need and inform the secretary/secretariat.
c. Keeping the training records - Fill in the form (Annexure 3) to record the training/workshop/conference activities in chronological order. A copy must be retained in the ERC office.

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 006 **Title: Selection of independent consultants** **Effective Date:**	

1. Purpose

To provide procedures for engaging the expertise of a professional as a consultant to the ERC, FAHS/UOR

2. Scope

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

3. Responsibility

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

4. Detailed instruction

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

4.2. The Secretary / Secretariat will contact the consultant and send the relevant documents for review with the confidentially agreement form (Annexure 2) and the appropriate study assessment form (Annexure 6a/6b).

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

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

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

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

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 007 **Title: Submission procedure for applications** **Effective Date:**	

1. Purpose

To describe how the Secretariat of the ERC manages protocol submissions

2. Scope

Protocol submissions include: submission of new protocols, resubmission of protocols with corrections/amendments and continuing review of approved protocols.

3. Responsibility

It is the responsibility of the ERC Secretary/secretariat to receive, record, and distribute for review packages received by the ERC FAHS/UOR.

4. Detailed instructions

4.1. Applications must be submitted in the appropriate format as determined by the ERC, and shall include all documentation as required by the ERC including a declaration by the applicant that all required documents have been submitted by completing and signing the application checklist. Information about the procedures for application to the ERC and the application format shall be readily available to applicants in the web site of ERC, FAHS/UOR (Annexure 4a /4b).

4.2. Applications must be submitted in the application form given by the ERC and should be accompanied by the following documents:

a. The complete research proposal
b. All relevant documents – in English as well as in Sinhala and Tamil where appropriate
c. Information sheets and consent forms – in English as well as in Sinhala and Tamil where appropriate
d. For postgraduate study proposals - Letter from the relevant postgraduate board stating that the project has been evaluated and has been found to be satisfactory for the purpose of postgraduate research

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

4.4. All applicants will incur a handling fee as decided by the Board of FAHS/UOR. Handling fee for FAHS undergraduate student protocols conducted as a direct requirement of course work will be waived at the discretion of the ERC.

4.5. All applications for ethical review must be submitted to the office of the ERC on/before the last working day of each month.

4.6. Information about the closing date for receipt of new applications onto the next ERC agenda shall be readily available to prospective applicants on the ERC web site.

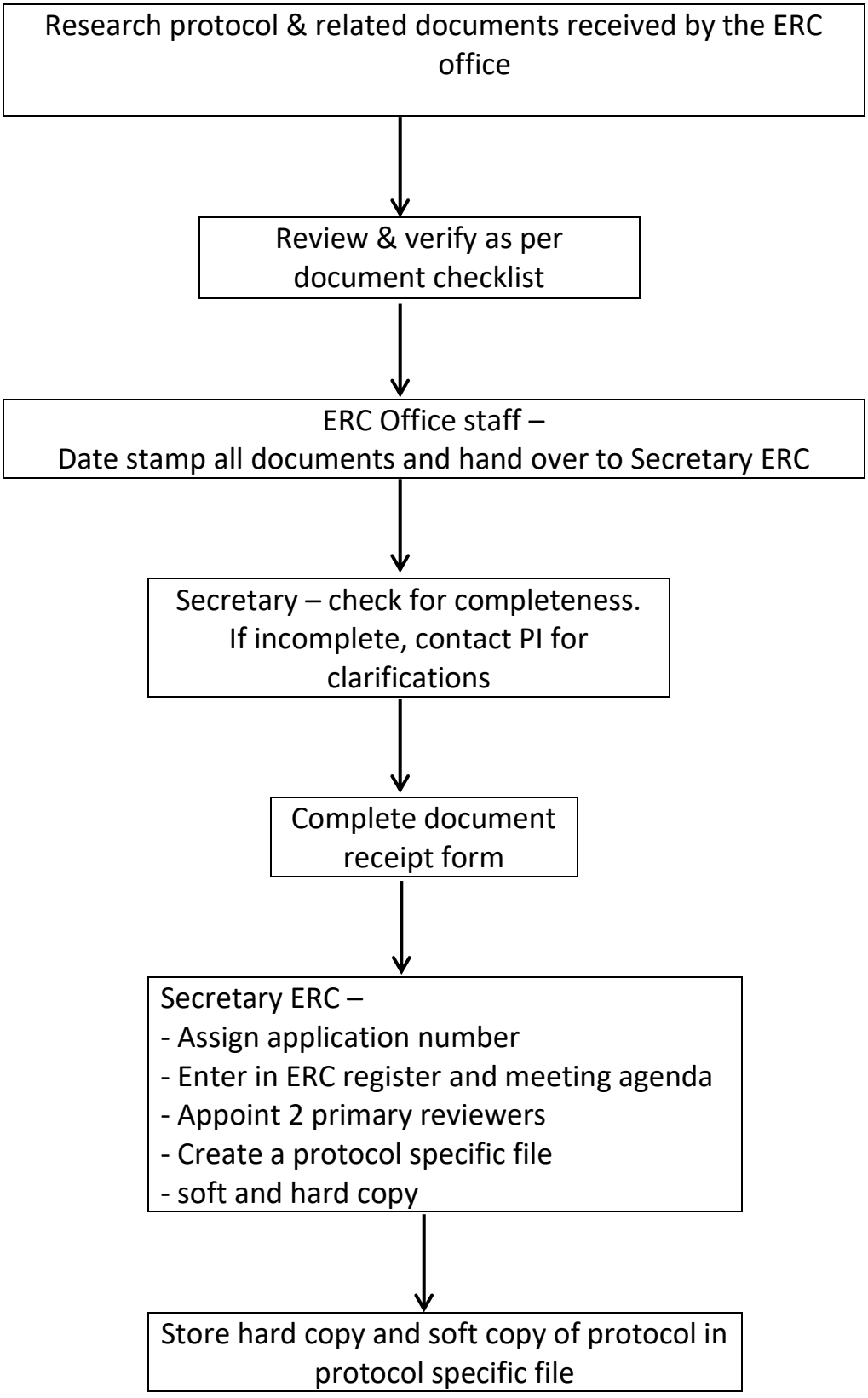
4.7. ERC office / Secretary will review and verify documents as per check list. Incomplete applications will be returned to applicant. Once the application is complete, ERC office will date stamp for all documents.

4.8. The ERC office will issue a receipt of acknowledgement to the Principal Investigator.

4.9. Once a completed application has been accepted for ethics review, the ERC shall assign a unique protocol identification number to the project containing the calendar year, month and chronological order of applications [YEAR/Month/ERC.no]. The protocol will be added to the ERC's register of received applications. A protocol specific file will be created to file all documents relevant to the protocol.

4.10. Three primary reviewers for each project will be appointed at a full board meeting. Primary reviewers shall include a subject expert.

Submission procedure for applications



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 008 **Title: Preparation of Agenda** **Effective Date:**	

1. Purpose

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

2. Scope

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

3. Responsibility

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

4. Detailed instructions

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

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

4.3. All complete applications and relevant documents received by the Secretary ERC will be included on the agenda for ERC consideration at its next meeting.

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

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 21st of the month.

4.6. Agenda items will include at least the following items (Annexure 5):

a. Excuses/apologies
b. Conflict of interest declaration
c. Minutes of the previous meeting
d. Matters arising from the previous minutes
e. New applications
f. Applications awaiting clarification
g. Amendments to approved protocols
h. Progress reports
i. Correspondence
j. Any other matters
k. Close and next meeting

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 009 **Title: Conduct of Meetings** **Effective Date:**	

1. Purpose

To describe the conduct of ERC meetings

2. Scope

These standard operating procedures describe the procedure for conduct of the ERC meeting.

3. Responsibility

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

4. Detailed instructions

4.1. The ERC shall meet on a regular basis, which will normally be at monthly intervals. Information about meeting dates and agenda closing dates shall be publicly available.

4.2. Members who are unable to attend a meeting should send written submissions to the Secretary of the ERC. The minutes should record the submission of written comments.

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 eight (8) members including Chairperson, Secretary or their designated members, and / or at least one medical and one non-affiliated member are present.

4.4. In circumstances where members cannot be present, they may provide written comments in lieu of attendance.

4.5. If the meeting does not achieve quorum, the Chairperson shall decide it can proceed only in exceptional circumstances. In such circumstances, decisions made by the ERC must be ratified by at least one lay representative.

4.6. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the ERC will convene within ten (10) working days of the cancelled meeting to ensure all agenda items are considered.

4.7. Meetings will not be scheduled for an allocated time. Meetings will continue until all agenda items have been considered.

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

4.9. Notwithstanding item 4.8, 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 ERC prior to attending ERC meeting.

4.10. Any member of the ERC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the ERC must declare such interest beforehand. This will be dealt with in accordance with SOP 010/2020.

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

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 010 **Title: Conflict of Interest** **Effective Date:**	

1. Purpose

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

2. Scope

This SOP covers the agreement on conflict of interest concerning information and procedures followed by the ERC, FAHS/UOR.

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 instruction

4.1. An ERC member shall, 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 prior to the commencement of the meeting.

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 research.

4.3. All declarations of conflict of interest and the resolutions of same will be minuted.

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 011 **Title: Initial Review of Submitted Protocol** **Effective Date:**	

1. Purpose

To describes how the ERC reviews an initially submitted protocol

2. Scope

This SOP applies to the review process of the study protocol package submitted for the first time.

3. Responsibility

It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments to the ERC in the Study Assessment Form (Annexure 6a/6b) and return to the Secretariat Office on the date due.

4. Detailed instructions

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

4.2. Each application will be assigned to three (03) primary reviewers, one of whom with expertise appropriate and relevant to the protocol.

4.3. Primary reviewers would:

a. review the application in detail prior to the meeting.
b. submit written comments on the application (by filling and forwarding the reviewers comment form to the Secretary at the monthly ERC meeting – Study assessment form (Annexure 6a/6b)
c. lead the discussion on the application at the committee meeting.

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

4.5. The ERC will assess each application in accordance with relevant national and international guidelines (1-3). The ERC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, to make an ethical assessment.

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

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

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

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

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

4.10. Chairperson's approval

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

- Chairperson alone or - Chairperson in oral or written consultation with one or more named members who were present at the meeting or who submitted written comments on the application. In such circumstances, the ERC shall be informed at the next meeting of the final decision taken on its behalf and this will be ratified by the full ERC at its next meeting.

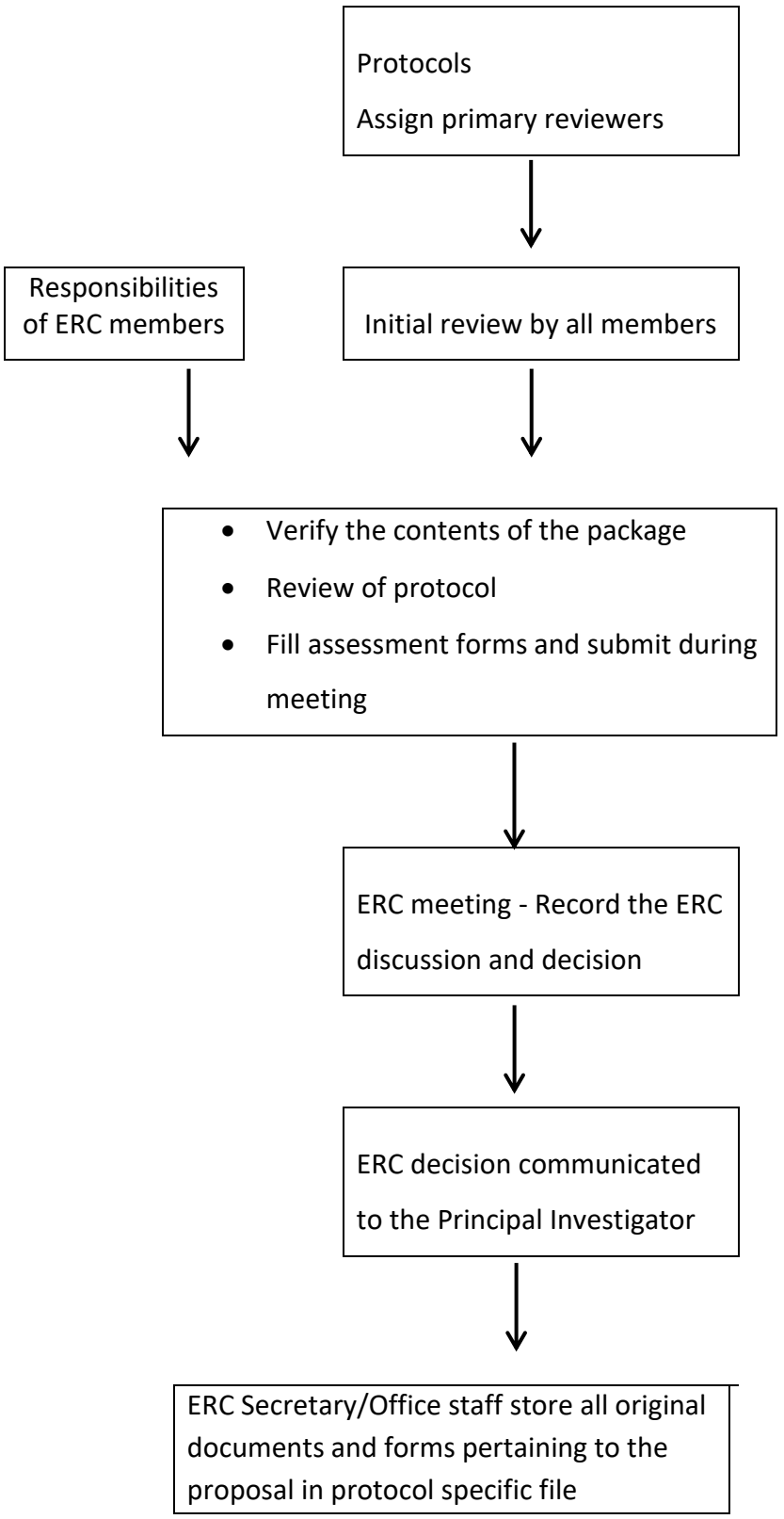
4.11. In order to facilitate consideration of an application, the ERC may invite the applicant to attend the relevant meeting to discuss the application and answer questions only. The applicant will be asked to leave the meeting prior to ERC deliberation and decision-making concerning the application.

4.12. The ERC may exempt protocols from review (SOP/013/2020) or conduct expedited review of protocols in accordance with SOP/ 014/2020

References

1. Declaration of Helsinki (DoH) of the World Medical Assembly (WMA), 2013.
2. International Ethical Guidelines for Epidemiological Studies - Prepared by the Council for International Organizations of Medical Sciences (CIOMS) 2008.
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) E6 (R1) 1996.

Initial Review of Submitted Protocol



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 012 **Title: Review of resubmitted protocol** **Effective Date:**	

1. Purpose

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

2. Scope

This SOP applies to study protocols that have been reviewed earlier with recommendations from ERC for some corrections in the initial review process.

3. Responsibility

It is the responsibility of the ERC Secretary/Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the ERC for reconsideration. A re-submitted protocol may be reviewed and approved by either the Chairperson (Chairperson's approval) or some ERC members/reviewers, or full committee. How the protocol will be reviewed should have been determined by the ERC at the time of the initial review.

4. Detailed instructions

4.1. The received protocol resubmitted package should contain:

- a memorandum addressing the corrections
- revised version of protocol
- related documents such as the informed consent document, data collection or case report forms.

4.2. The Secretary /Secretariat should date stamp upon receiving the packages.

4.3. The Secretary reviews the revised protocol, refers to the meeting minutes as guidance for the review and considers whether Chairperson's approval or a full review at the ERC committee meeting is required. Those that have required major revisions will be resent to primary reviewers for observations and will undergo a full board review.

4.4. For protocols which the ERC considers ethically acceptable with conditions / minor amendments, the ERC may choose to delegate the authority to review the applicant's response and give final approval for the project to proceed to the Chairperson in oral or written consultation with the Secretary and one primary reviewer who was present at the meeting or who submitted written comments on the application.

4.5. If Chairperson's approval has been decided (at the initial review), the Secretary in consultation with the Chairperson will review the application to verify if the recommendation of the ERC has been followed.

4.6. If recommendations have been met satisfactorily, Chairperson's approval will be given and this will be communicated to the Principal Investigator. Chairperson's approval thus given will be ratified by the ERC at its next scheduled meeting.

4.7. If the recommended changes have not been addressed sufficiently this will be communicated to the Principal Investigator in writing.

4.8. For protocols which the ERC has deferred making a decision until an issue is clarified or further information is provided or the protocols is modified, the protocols and the researchers' response will be considered at a subsequent meeting of the ERC.

4.9. All clarifications should reach the Secretary, ERC on or before 21st day of each month to be considered at the monthly meeting for that month.

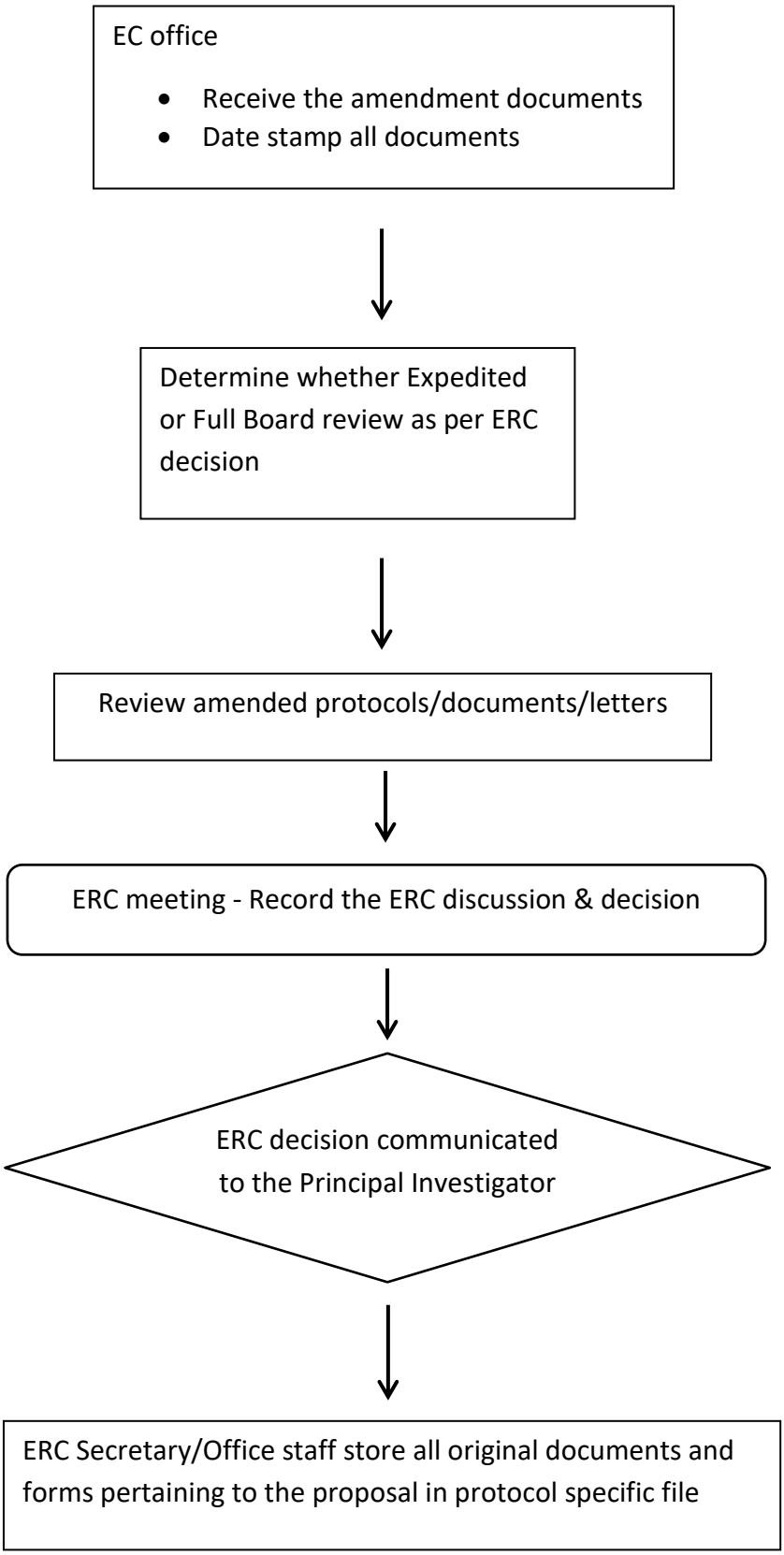
4.10. A protocol that does not receive corrections will be sent two reminders and those failing to reply within 3 months of the initial review will be removed from the meeting agenda. The period may be extended upon request by a principal investigator if the ERC considers the reasons for extension valid.

4.11. 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/or advertisements as requested by the Committee are noted in the meeting minutes will be communicated to the Principal Investigator (PI). Once the major revision is accepted by the ERC, then the approval will be communicated to the PI as given in the flow chart.

4.12. The original completed documents along with revised documents, the completed re-review report, the Assessment Form will be stored in the protocol specific file.

Review of Resubmitted Protocols



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 013 **Title: Exempt from review** **Effective Date:**	

1. Purpose

To identify the administrative process for exempting a protocol from ERC review.

2. Scope

This SOP applies to protocols that may be exempt from review at a full ERC meeting and to be considered at an Executive Committee.

3. Responsibility

The ERC secretariat will assess suitability of protocols to be exempted from review as per check list in Annexure 7 and inform Secretary ERC.

4. Detailed instructions

4.1. Chairperson (or nominee) and the Secretary (or nominee) will assess the protocol as per check list in Annexure 7 and **may** exempt from review research in the following circumstances:

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 exempt providing all of the following conditions are met:

a. All of the research is conducted in a commonly accepted educational setting (e.g. public school).
b. The research involves normal educational practices (e.g. comparison of instructional techniques).
c. The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existent at the study site.
d. The study procedures involve no increase in the level of risk or discomfort associated with normal, routine educational practices.
e. The study procedures do not involve sensitive subjects (e.g. sex education).
f. Provisions have been made to ensure the existence of a non-coercive environment for those students who choose not to participate.

g. The school or other institution grants written approval for the research to be conducted.

Note: This exemption is applicable to individuals with mental handicaps only if the research involves no change in the content, location, or procedures of instruction from those normally experienced by the subject.

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

NOTE: Sensitive survey research is **not** exempt. A sensitive survey is one that deals with sensitive or highly personal aspects of the subject's behaviour, life experiences or attitudes. Examples include chemical substance abuse, sexual activity or attitudes, sexual abuse, criminal behaviour, sensitive demographic data, detailed health history, etc. The principal determination of sensitivity is whether or not the survey research presents a potential risk to the subject in terms of possible precipitation of a negative emotional reaction. An additional risk consideration is, of course, whether or not there is risk associated with a breach of confidentiality should one occur. With respect to potential psychological risk associated with a survey, the presence or absence of subject identifiers is not necessarily a consideration since the risk may be primarily associated with the sensitive nature of the survey as opposed to being dependent upon confidentiality. Subject identifiers do, however, become a factor when confidentiality is an issue.

NOTE: This exemption applies to research with children or individuals with mental handicaps as follows:

a. research involving the use of educational tests is exempt;
b. research involving survey or interview procedures is **not** exempt;
c. research involving observations of public behaviour **is exempt only** when the investigator does not participate in the observed activities.

4.1.4. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviour that is not exempt under paragraph 2 of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information is maintained throughout the research and thereafter.

4.1.5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

4.1.6. Research and demonstration protocols which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

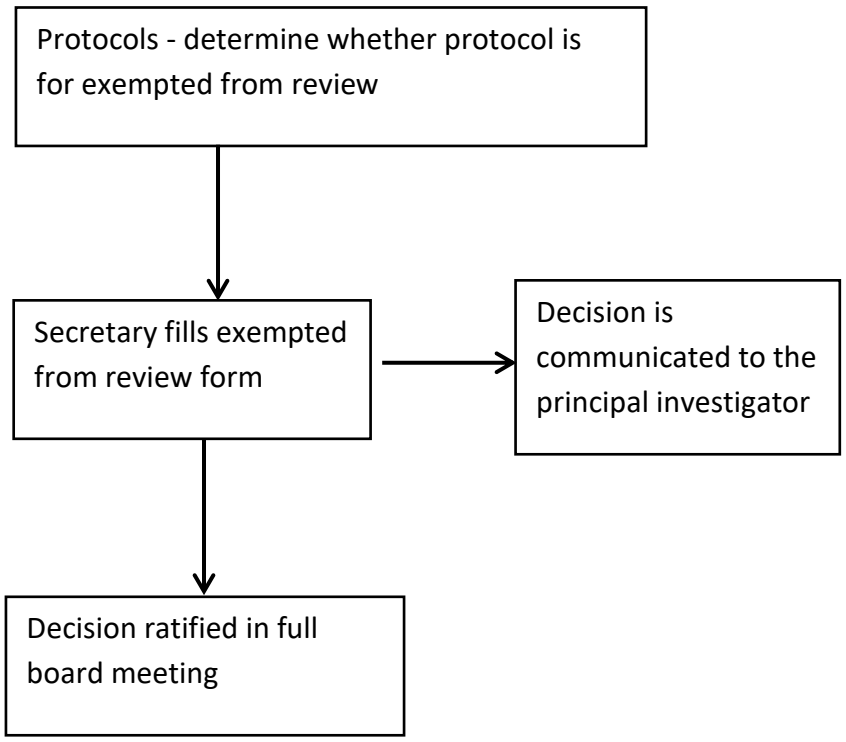
a. public benefit or service programs;
b. procedures for obtaining benefits or services under those programs;
c. possible changes in or alternatives to those programs or procedures; and/or
d. possible changes in methods or levels of payment for benefits or services under those programs.

4.1.7. Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

4.2. If the executive committee finds that the protocol needs to be submitted for a full board evaluation, it would be forwarded to the next available meeting and the decision will be conveyed to PI. The protocol will be reviewed as per SOP 011/2020.

4.3. A letter will be issued stating the reasons for exemptions, in the format set out in Annex 8 for exempted from review.

Exempted from Review



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 014 **Title: Expedited review** **Effective Date:**	

1. Purpose

To identify the administrative process of preparing for an Expedited Review Procedure

2. Scope

This SOP applies for the following instances.

2.1. To review protocols identified for expedited reviews, such as those with minimal risk and undergraduate protocols.

2.2. To review life threatening issues, additional investigators, continuing review, protocol amendments and other study activities of previously approved protocols that do not require Full Board Review.

3. Responsibility

The ERC Chairperson will appoint a subcommittee to evaluate such proposals

4. Detailed instructions

4.1. Expedited review of research protocols may be undertaken between scheduled meetings, at the discretion of the Chairperson and the Secretary. A subcommittee will be appointed for this purpose and shall consist of either the Chairperson or the Secretary and two other ERC members. The committee may seek views of suitably qualified experts if needed (as per SOP /06/2020) before reaching a decision.

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

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

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

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

4.2.4. Continuing review of research previously approved by the convened ERC as follows: where

a. the research is permanently closed to the enrolment of new participants;
b. all participants have completed all research-related interventions; and
c. the research remains active only for long-term follow-up of participants; or where no new participants have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.
d. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, which was determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

4.2.5. Expedited review of research protocols may be undertaken between scheduled meetings, at the discretion of the Chairperson, by the Chairperson and the Secretary. They may seek advice from other ERC members or suitably qualified experts, as appropriate, before reaching a decision.

4.2.6. The decision of this review must be tabled for ratification at the next ERC meeting.

4.2.7. The Sub Committee may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, project reports, minor amendments and the like.

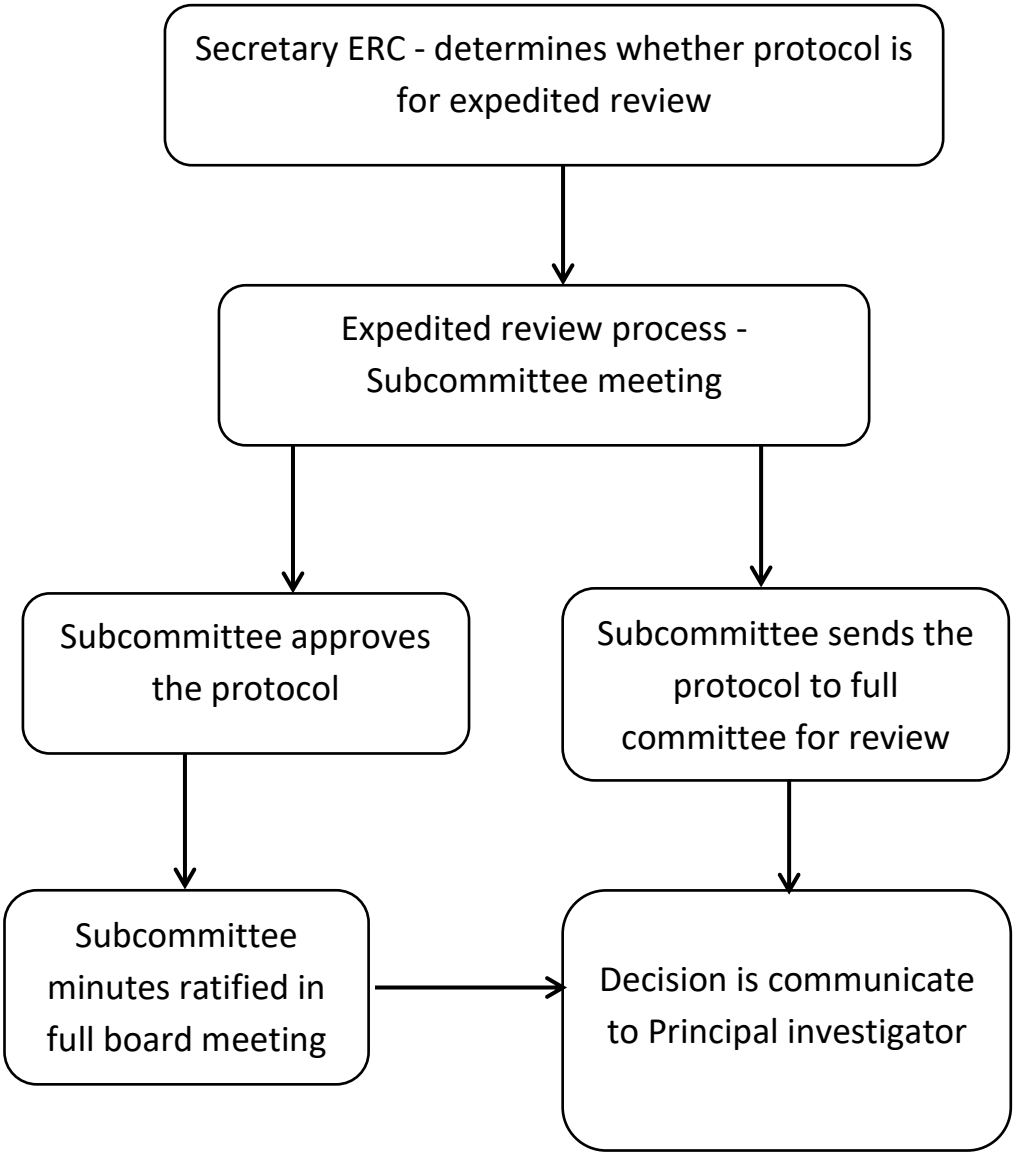
4.2.8. A summary of the matters dealt with at Sub Committee meetings will be included in the agenda for the next ERC meeting.

4.2.9. 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.

4.2.10. Where the Sub Committee considers that the protocol is outside the scope of expedited review procedure, the protocol must be considered by the full ERC.

4.2.11. A standard approval letter will be issued, in the format set out in Annexure 9.

Expedited Review



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 015 **Title: Submission of amendments/ extension to approved protocols** **Effective Date:**	

1. Purpose

To describe the procedure for the submission and ERC review of requests for amendments and extensions to approved protocols

2. Scope

This SOP applies to proposals submitted to the ERC FAHS/UOR undergoing amendments or subsequent extensions after initial approval.

3. Responsibility

It is the responsibility of the Secretary to forward such requests to the ERC considering the need for expedited/Chairpersons review or full committee review in consultation with the Chairperson.

4. Detailed instructions

4.1. Approval for proposed changes to approved research protocols or to the conduct of the research, including extensions to the length of ERC approval, must be sought by the PI in writing.

4.2. Requests shall outline the nature of the proposed changes and/or request for extension, reason/s for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must have the changes highlighted. The request for extension must be accompanied by a current progress report of the study.

4.3. Expedited review of requests for minor amendments and extensions may be undertaken by the ERC Executive Committee between scheduled meetings at the discretion of the Chairperson or the Secretary and in accordance with SOP/012/2020, on the condition that it is ratified at the next ERC meeting. Where an urgent protocol amendment is required for safety reasons, the Chairperson may review and approve the request. In such circumstances, the ERC will review the decision at its next meeting.

4.4. All other requests for amendments shall be reviewed by the ERC at its next meeting, provided the request has been received by the ERC office by the agenda closing date.

4.5. The ERC will report in writing to the principal investigator, advising of the ethical approval of the proposed amendment (A standard approval letter will be issued, in the format set out in Annexure 9b) and/or request for extension and that the

amended research may commence, within seven (7) working days of the meeting at which the request was considered (this may be the full ERC meeting or the Executive Committee meeting).

4.6. If the ERC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/ clarification/ modification should refer to the relevant pieces of legislation. A letter will be issued, in the format set out in Annexure 10.

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

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 016 **Title: Notification of decision of the ERC** **Effective Date:**	

1. Purpose

To ensure proper completion, distribution and filing of communications with investigators

2. Scope

This SOP applies to all communicating activities related to the studies under the approval of the ERC, FAHS/UOR.

3. Responsibility

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

4. Detailed instructions

4.1. The ERC will report in writing to the principal investigator, advising whether the application has received ethical approval (including any conditions of approval), within 7 working days of the monthly meeting, unless otherwise notified (Annexure 9a).

4.2. If the ERC determines that further information, clarification or modification is required for the consideration of a project, 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 Annexure 10.

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

4.4. The ERC will notify the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be in writing, and will contain the following information (Annexure 9a):

a. title of the project
b. name of the principal investigator(s)
b. unique ERC project identification number
c. version number and date of all documentation reviewed and approved by the ERC including clinical protocols, patient information sheets, consent forms, advertisements, questionnaires etc
d. date of the ERC meeting at which the project was first considered
e. date of the ERC's approval
f. conditions of the ERC's approval, if any
g. duration of the ERC's approval
h. frequency of progress reports and
i. date of submission of the final report.

For research protocols that the ERC has delegated authority to approve on behalf of the University of Ruhuna, the ERC may inform the applicant in writing that the research may commence. A standard approval letter will be issued, in the format set out in Annexure 9a. Research protocols may not commence until written notification which confirms this has been received.

4.5. If the ERC determines that a project is ethically unacceptable, the notification of the ERC's decision will include the grounds for rejecting the project with reference to the FERCSL Guidelines or other relevant pieces of legislation. A standard rejection letter will be issued, in the format set out in Annexure 11.

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

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 017 **Title: Handling of serious adverse events** **Effective Date:**	

1. Purpose

To describe the procedure for the reporting and handling of Serious Adverse Events (SAEs)

2. Scope

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

3. Responsibility

Principal Investigator should immediately report all serious adverse events in clinical trials to the Ethics Committee/s of the institution/s responsible for the conduct of the research in accordance with the reporting conditions required by ERC. Principal Investigator should report all adverse events and the response to those events in the periodic and final reports for the project. 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 project that researchers immediately report Suspected Unexpected Serious Adverse Events (SUSAR) or Serious Adverse Events (SAE) to the ERC, including those that have occurred at other institutions participating in the study.

4.2. As per the current guidelines of the Sri Lankan Drug Regulatory Authority the following timelines apply for reporting of such events occurring at local trial site to FAHS/ERC:

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

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

4.3. Notifications of Serious Adverse Events (SAEs) must be submitted in the appropriate format (Annexure 12), and shall include all documentation as required by the ERC. This documentation shall include as a minimum:

a. Advice from the Principal Investigator as to whether, in his/her opinion, the adverse event was related to the protocol or in the case of a drug/device trial, whether the adverse event was related to the study drug/device.
b. Advice from the Principal Investigator as to whether, in his/her opinion, the adverse event necessitates an amendment to the project and/or the patient information sheet/consent form.

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

4.5. Adverse events may be reviewed by a sub-committee of the ERC. The sub-committee will consist of the following:

- Chairperson ERC
- Secretary ERC
- A Clinical Pharmacologist from the Department of Pharmacology, FOM
- A Clinical Pharmacist from the Department of Pharmacy, FAHS
- A Clinician with special training/interest in the clinical discipline/field

4.6. The review shall take place within (one) 1 week of notification of the event. The sub-committee shall determine the appropriate course of action and inform ERC, FAHS/UOR of its recommendations. This may include:

a. a notation on the project file of the occurrence
b. increased monitoring of the project
c. a request for an amendment to the protocol and/or patient information sheet/consent form
d. suspension of ethical approval or
e. termination of ethical approval.

4.7. Any such adverse events and the recommendations of the committee/sub-committee shall be reported to the ERC at the next available meeting.

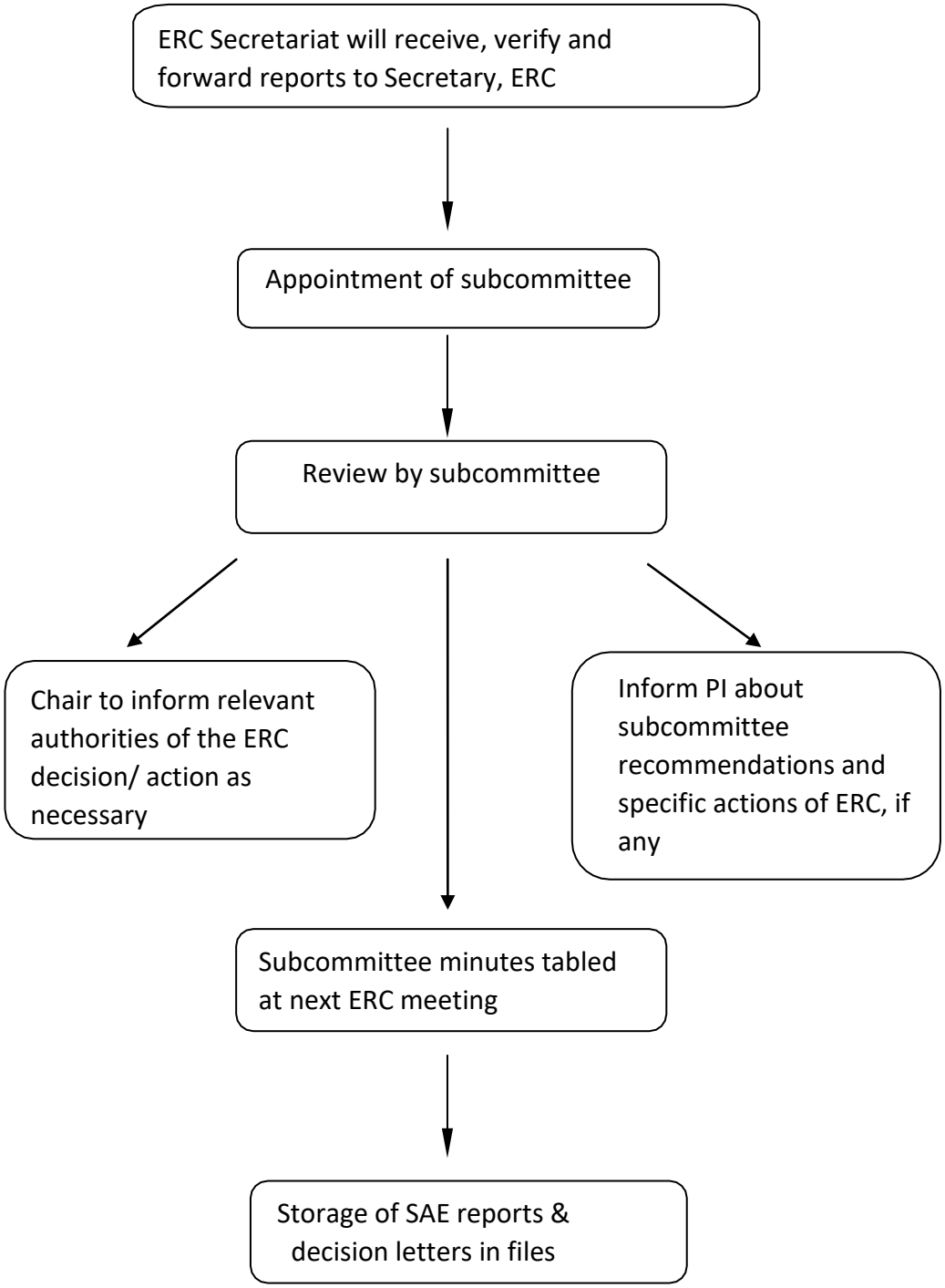
4.8. The Chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:

a. Referral to the Clinical Trials Sub-committee of the Ministry of Health.
b. Immediate request for additional information.
c. Immediate suspension of ethical approval.
d. Immediate termination of ethical approval.

4.9. The ERC shall provide notice to the investigator that it has received notification of the serious or unexpected adverse event, and the course of action it has deemed necessary to take.

4.10. The Chairperson shall immediately notify the Dean (or delegate) if a project is suspended or terminated because of a serious adverse event.

Handling of serious adverse events reports



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 018 **Title: Monitoring of approved research protocol** **Effective Date:**	

1. Purpose

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

2. Scope

This SOP applies to all studies under the approval of the ERC, FAHS/UOR.

3. Responsibility

Principal Investigator should send periodic progress reports (Annexure 13) to ERC, FAHS/UOR. The frequency of reports will be decided by the ERC depending on the nature and duration of the study. The Principal Investigator should send the final report to ERC, FAHS/UOR at the completion of study.

Principal Investigator should immediately report all serious adverse events in clinical trials to the Ethics Committee/s of the institution/s responsible for the conduct of the research in accordance with the reporting conditions required by ERC.

Principal Investigator should report all adverse events and the response to those events in the periodic (Annexure 13) and final reports (Annexure 14) for the project.

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 will monitor approved protocols to ensure compliance with its ethical approval. In this process, ERC may request and discuss information on any relevant aspects of the project with the investigators at any time.

4.2. The ERC will require Principal Investigator to provide progress reports (Annexure 13) periodically as determined by the ERC, and at the completion of the study. Continuing approval of the research will be subject to the PI submitting the reports as required.

4.3. The ERC shall require the following information in the progress report:

a. progress to date or outcome in the case of completed research;
b. maintenance and security of records;
c. compliance with the approved protocol; and
d. compliance with any conditions of approval.

4.4. The ERC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:
   a. periodic written reports;
   b. random inspections of research sites, data and signed consent forms;
   c. interview, with their prior consent, of research participants.

4.5. The ERC shall require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of the ethical approval of the protocol, including:
   a. proposed changes in the protocol;
   b. any unforeseen events that might affect continued ethical acceptability of the project; and
   c. new information from other published or unpublished studies
   d. 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.

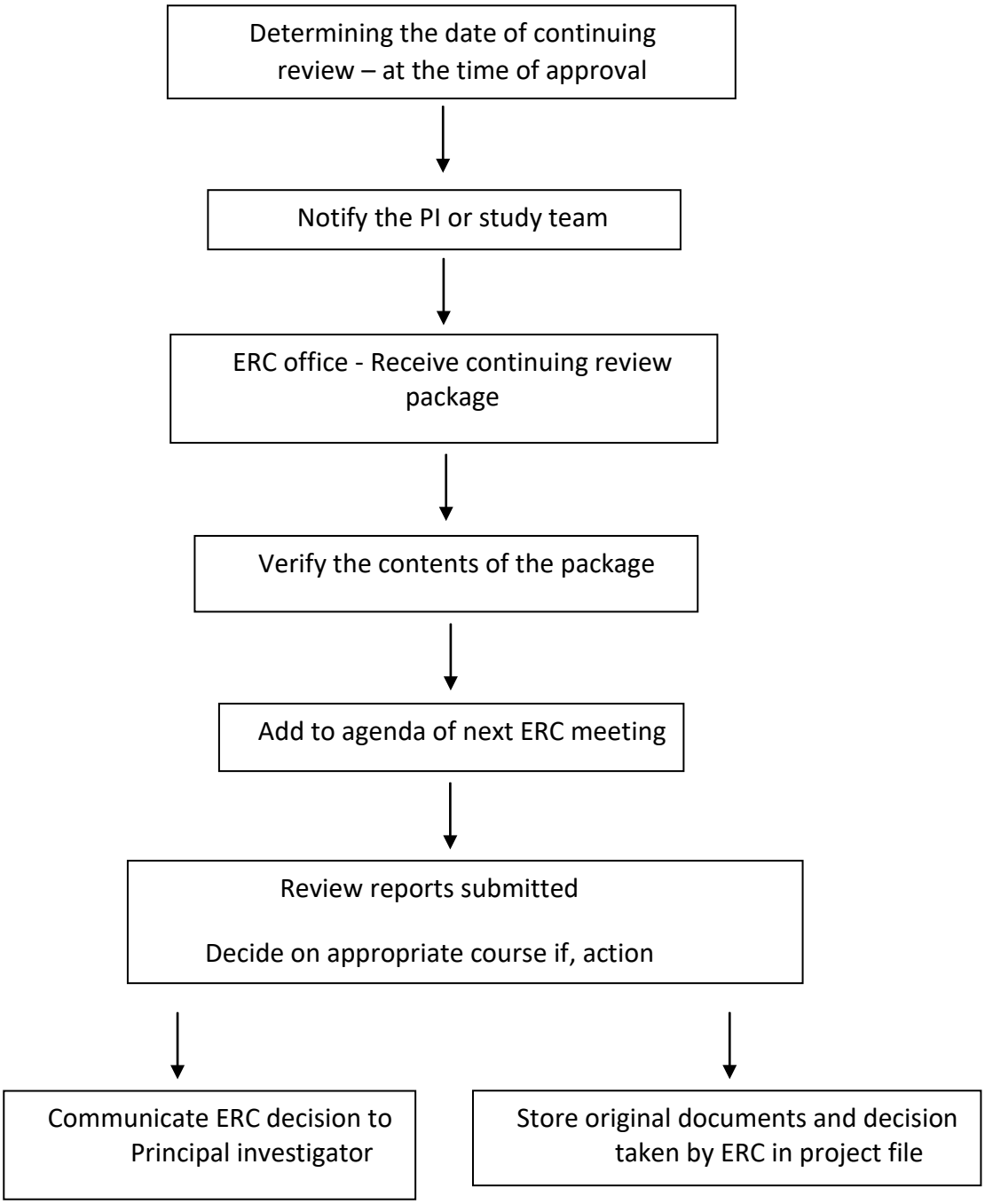
4.6. The ERC shall require, as a condition of approval of each project, that investigators inform the ERC, giving reasons, if the research project is discontinued before the expected date of completion.

4.7. Where the ERC is satisfied that circumstances have arisen which prevent a research project from being conducted in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC shall inform the Principal Investigator and the institution of such withdrawal of approval in writing, and recommend to the institution that the research project be discontinued, suspended, or that other necessary steps be taken.

4.8. In determining the frequency and type of monitoring required for approved protocols, the ERC will give consideration to the degree of risk to participants in the research project.

4.9. In the case of clinical trials the ERC shall require quarterly reports which shall be reviewed by the Clinical Trials Sub-committee in the first instance. The sub-committee will consist of the following:
   - Chairperson ERC
   - Secretary ERC
   - A Clinical Pharmacologist from the Department of Pharmacology, FOM
   - A Clinical Pharmacist from the Department of Pharmacy, FAHS
   - A Clinician with special training/interest in the clinical discipline/field

Monitoring of approved research protocols



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 019 **Title: Management of Premature Termination/ Suspension/ Discontinuation of the study** **Effective Date:**	

1. Purpose

The purpose of this SOP is to describe how the ERC, FAHS/UOR proceeds and manages the premature termination/suspension/discontinuation of a research study.

Research studies are usually terminated as per the recommendation of the ERC, Date and Safety Monitoring Committee (DSMSC), Principal Investigator (PI), sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled completion of the study

2. Scope

This SOP applies to any study approved by ERC, FAHS/UOR that is being recommended for termination/suspension/discontinuation before its scheduled completion.

3. Responsibility

It is the responsibility of the Chairperson, to terminate any study that the ERC, FAHS/UOR has previously approved when the safety or benefit of the study participants is doubtful or at risk, also to review the termination suggested by DSMSC, PI, Sponsor or other authorized bodies. The secretariat is responsible for management of the premature termination/ suspension/ discontinuation process.

4. Detailed instructions

4.1. **Receive recommendation for study termination/suspension/discontinuation**

4.1.1. The secretariat will receive recommendation and comments from DSMSC, PI, Sponsor or other authorized bodies for premature termination of study.

4.1.2. **Suspension/Termination/ Discontinuation by ERC**

The ERC can terminate or suspend previously approved study in following circumstances:

a. If protocol non-compliance/violation is detected
b. Increased frequency of SAEs occurring at trial site may require the study to be prematurely terminated for the safety of the patients
c. Violations of ERC approval conditions

4.1.3. **Suspension/Termination/ Discontinuation by Investigator/Sponsor:**

An investigator may also put on hold a previously approved research when in the judgment of the investigator this is appropriate to protect the rights or welfare of participants or when new safety information appeared in the literature, or evolved from this or similar research

4.1.4. The Secretary will inform the PI to prepare and submit a protocol termination package along with Premature Termination Report (Annexure 15)

4.1.5. The secretariat will receive the study protocol termination prepared and submitted by the PI and verify the contents of the report for inclusion of:

- Premature Termination Report/ suspension/ discontinuation signed and dated by the PI and/or other material (letter from PI/sponsor etc.)
- The Secretariat will check the completeness of the information
- The Secretariat will receive and acknowledge the reports

4.2. **Review and discuss the termination / suspension/discontinuation report**

4.2.1. ERC, FAHS/UOR will review the termination report/ suspension/ discontinuation at regular full board meetings.

4.2.2. The Secretary in the meeting will inform of the premature termination. suspension/discontinuation of the project and the ERC members will review the Premature Termination Report along with relevant SAE report/DSMSC reports.

4.2.3. A suspension of ERC approval is a decision taken at the convened ERC meeting either to stop temporarily some or all previously approved research activities for a particular study, or to stop permanently some previously approved research activities. Suspended protocols remain open and require continuing review.

4.2.4. A termination of ERC approval is a decision taken at the convened ERC meeting to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review**.**

4.2.5. The ERC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the ERC policies, is not in compliance with the local regulations or that has been associated with unexpected serious harm to participants. Suspensions and terminations will be reported to concerned authorities and appropriate institutional officials when applicable.

4.2.6. The reasons for the suspension or termination and if applicable, any actions ordered to be taken will be recorded in minutes by Secretary ERC.

4.3. **When ERC suspends/terminates any study the following will be checked:**

4.3.1. Whether PI has notified about the suspension/termination of the trial to the currently enrolled participants.

4.3.2. Whether procedures for withdrawal of enrolled participants take into account their rights and welfare (eg. making arrangements for medical care of study participants).

4.3.3. Have any adverse events or outcomes reported to the ERC, FAHS/UOR.

4.4. **Notifying the PI**

4.4.1. The Secretariat will prepare a notification letter acknowledging the acceptance of termination /suspension/discontinuation or query letter to request information regarding the premature termination/suspension/discontinuation.

4.4.2. The Secretariat will send the notification letter to the PI for their records within 14 working days of the meeting.

4.4.3. If a query is sent to PI, on receipt of the reply letter, it is reviewed in the forthcoming full board meeting and steps in 4.2 will be performed by the secretariat.

The letter will include:

- the activities to be stopped.
- actions to be taken by the PI to notify about the suspension/termination of the trial to the currently enrolled participants, whether arrangements for medical care of enrolled participants who are of a research study are made.
- an explanation of the reasons for the decision.
- a request to immediately notify the ERC with a list of names of participants who might be harmed by stopping research procedures and a rationale as to why they might be harmed.

4.4.4. The investigator may appeal or respond to the convened ERC in writing.

4.5. **Withdrawal of the suspension**

4.5.1. If a query is sent to PI, he/she should report to ERC on the actions taken as per RC recommendations. This will be reviewed at the next full board meeting.

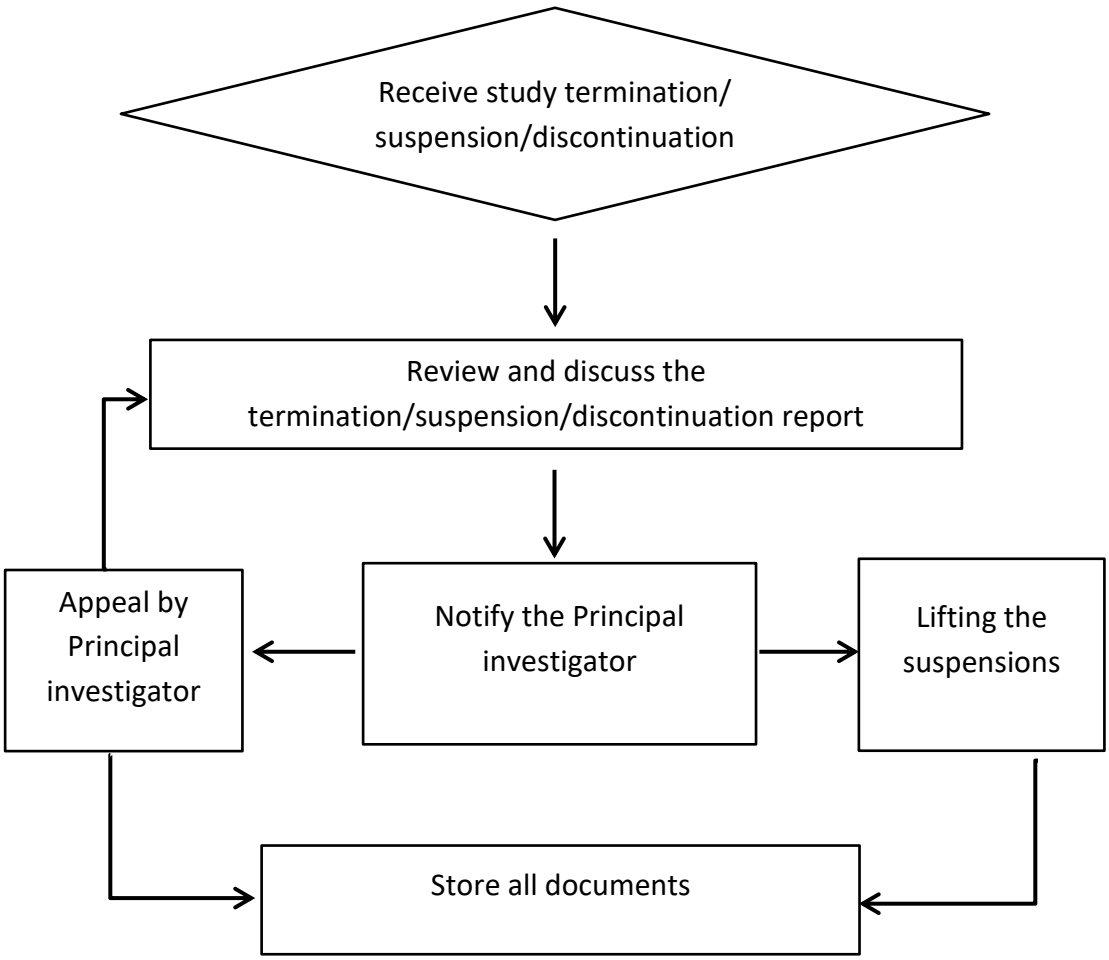
4.5.2. The convened ERC will decide to lift the suspension, continue or modify the suspension, or terminate the study.

4.6. **Storing the Report**

4.6.1. The Secretariat will keep the original version of the Premature Termination suspension/discontinuation report in the study file and send the file to archive.

4.6.2. The study documents will be stored for a period of 3 years from the date of project termination.

Premature Study Termination/ Suspension/ Discontinuation



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 020 **Title: Review of Protocol Deviation/ Violation/ Waiver/ Non-compliance** **Effective Date:**	

1. Purpose

To describe how the ERC, FAHS/UOR provides instructions for taking action and maintaining records, when investigators/ trial sites, fail to;

- follow the procedures written in the approved protocol
- comply with national / international guidelines for the conduct of human research, including those who fail to respond to the ERC, FAHS/UOR requests

2. Scope

This SOP applies to any study approved by ERC, FAHS/UOR.

3. Responsibility

It is the responsibility of the

- Secretary to receive any deviations /violations/waiver reports, and placing it on agenda of the meeting. Reporting of deviation/ non- compliance/ violation/ waiver in any other reporting format than on Annexure 16 will not be accepted.
- ERC will review and take action on these reports.

4. Detailed instructions

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

4.1.1. The ERC members performing monitoring of the project at trial site can detect protocol deviation/non-compliance /violation,

- if the project is not conducted as per protocol / national / international regulations
- when scrutinizing annual / periodic reports / SAE reports
- on any other communication received from the Investigator / trial site / sponsor / study monitor / CRO

4.1.2. The office of ERC can detect protocol deviation / non-compliance / violation from failure to

- comply with statutory requirements
- respond to requests from ERC, FAHS/UOR within reasonable time limit
- respond to communication made by ERC office of the FAHS/UOR

4.1.3. The PI himself / herself may forward protocol deviation / non- compliance/ violation / waiver reports to inform the ERC. Protocol Waiver is analogous to a Protocol Deviation, except that prior ERC approval must be obtained before

implementing the necessary departures from the protocol. Therefore, Protocol Waivers are anticipatory, while Protocol Deviations are not. e.g. Protocol Waiver means a prospective decision by a sponsor or investigator to permit accrual of a subject who does not satisfy the approved inclusion /exclusion criteria for enrollment.

4.1.4. Communication/ complaint/ information from research participants who have been enrolled or any individual who has been approached for enrollment.

4.1.5. Any report / communication brought to the notice of the ERC.

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

4.2.1. The ERC members who have performed monitoring of a particular site and detect protocol deviations / non-compliance/ violation/ waiver will inform the Secretary in writing within 24 hours of a working day.

4.2.2. Whenever the protocol deviations / non-compliance/ violation/ waiver has been observed, the Secretary will ensure that the issues as well as the details of the non-compliance involving research investigators are included in the agenda of the ERC meeting.

4.3 Board discussion, decision and actions

4.3.1 Protocol deviations / non-compliance/ violation/ waiver will be scrutinized for gravity and implications in the ERC meeting.

4.3.2 The ERC will review the information and available and take a decision depending on the seriousness of the violation.

4.3.3 If unable to come to a decision, ERC will call for additional information.

4.3.4 The decision will be taken by consensus and if no consensus is arrived at, a voting will be conducted.

4.3.5 The decision will be taken to ensure that the safety and rights of the research participants are safe guarded.

4.3.6 The actions taken by the ERC, FAHS/UOR could include one of the following:

- Inform the PI that the ERC has noted the deviations / non- compliance/ violation/ waiver and inform the PI that the deviations / non-compliance/ violation/ waiver do not occur in the future and follow the ERC recommendations.
- Enlist measures that the PI would undertake to ensure that the deviations / non-compliance/ violation do not occur in future.
- Reprimand the PI.
- Suspend the study till additional information is made available and is scrutinized.

- Suspend the study till recommendations made by the ERC are implemented by the PI and found to be satisfactory by the ERC.
- Suspend the study for a fixed duration of time.
- Revoke the approval of the current study.
- Inform other relevant regulatory authorities.
- Review and/or inspect other studies undertaken by the PI/Co – PI.

4.4 Notify the PI

4.4.1 The Secretary records the ERC decision and drafts and types the notification letters.

4.4.2 The Chairperson and Secretary, and if needed a member/s signs and dates the letter.

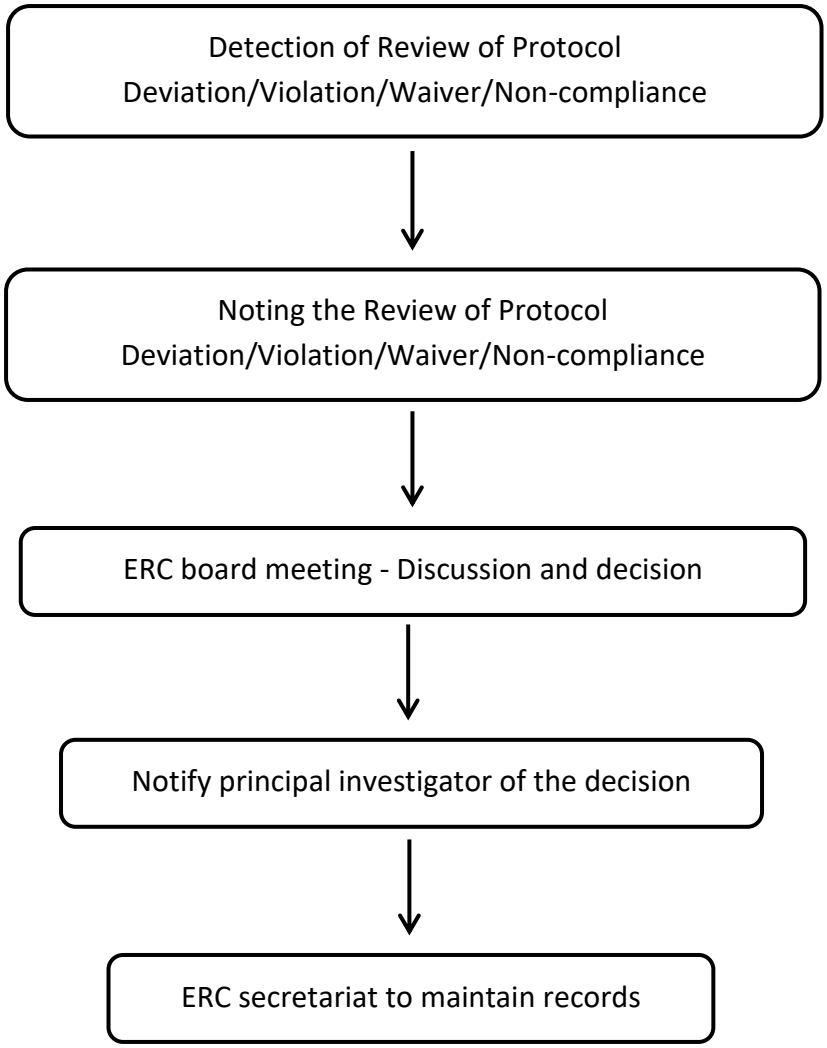
4.4.3 The ERC makes copies of the notification letter.

4.4.4 The original letter is sent to the PI.

4.4.5 Copies of the notification letters are sent to

- relevant regulatory authorities
- Co – PIs
- Director of the Institution of the PI
- Vice – Chancellor and Dean of the FAHS/UOR
- File of the relevant application
- Sponsor

Review of Protocol Deviation/Violation/ Waiver/ Non-compliance



	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 021 **Title: Preparation of meeting minutes** **Effective Date:**	

1. Purpose

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

2. Scope

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

3. Responsibility

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

4. Detailed instructions

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

4.2. The format of the minutes will include at least the following items (Annexure 17):

- attendance
- conflicts of interest
- minutes of the previous meeting
- matters arising from the previous minutes
- new applications
- applications awaiting clarification
- amendments to approved protocols
- continuing review items, progress reports
- protocol violations, complaints
- general correspondence
- any other matters
- closing time
- date and time of next meeting.

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

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

4.5. In recording a decision made by the ERC, 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 by name.

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 recorded in the minutes.

4.8. The minutes will be produced as soon as practicable following the relevant meeting and, when appropriate, should be checked by the Chairperson for accuracy.

4.9. The minutes will be circulated to all members of the ERC along with the agenda for the next monthly meeting. All members will be given the opportunity to seek amendments to the minutes prior to their ratification. The minutes will be formally ratified at the next ERC meeting.

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

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

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 022 **Title: Complaints about the conduct of a research project** **Effective Date:**	

1. Purpose

To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a project approved by the ERC

2. Scope

This SOP applies to all studies under the approval of the ERC FAHS/UOR

3. Responsibility

The ERC will require, as a condition of approval of each project, that the researchers indicates the details of the ERC nominee appointed to receive complaints about the conducts of the research.

4. Detailed instructions

4.1. The ERC shall nominate a person to receive complaints from research participants, researchers or other interested persons about the conduct of approved research. The name and/or position and contact details of the person so nominated must be included in the participant information sheet and consent forms.

4.2. Any complaints received by the ERC office about the conduct of research approved by the ERC should be referred to the person nominated to receive complaints. 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 will bring it to the attention of the Dean as soon as possible.

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

4.5. The Secretary will send a letter of acknowledgement to the complainant and a letter of notification to the principal investigator, outlining the complaint and the mechanism for investigating the complaint, as set out below.

4.6. The Chairperson of ERC will report the concern or complaint to any other institutional ERC that have approved the project.

4.7. The Chairperson will appoint an Incident Review Committee (IRC) to conduct an investigation of the complaint and its validity, and make a recommendation to the ERC on the appropriate course of action at its next meeting. The investigation will take no longer than 4 weeks from the time of notification for the concern or

complaint, unless exceptional circumstances exist. Both the complainant and the PI will be given an opportunity to make submissions. Where the complaint concerns the conduct of any other person the IRC will also provide that person with an opportunity to make submissions.

4.8. The IRC may seek any other information it requires and may access any documents relating to the project, interview other people, and seek internal and external expert advice, as it sees fit.

4.9. If the IRC is satisfied that the concern or complaint is justified it will determine the consequences by considering the following matters:

a. The severity of the matter
b. The sensitivity of any information concerned including the amount and type of information and the level of identifiability and
c. Whether any breach of the approved protocol, which may be established, was inadvertent, negligent or intentional.

4.10. The possible consequences include the following:

a. Notation on the file of the occurrence of the matter;
b. Requirement for amendments to the project, including increased monitoring by the ERC;
c. Suspension of the project;
d. Termination of the project; or
e. Other action to resolve the complaint.

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

4.12. The Chairperson of the ERC will provide the Dean or his/her nominee with all relevant information about the complaint/concern, including:

a. the complaint;
b. material reviewed in the Chairperson's investigation;
c. the results of the Chairperson's investigation; and
d. any other relevant documentation.

4.13. The Dean will determine whether there is to be a further investigation of the complaint. Where there is to be no further investigation, the Dean will inform the complainant and the Chairperson of this.

4.14. If the Dean determines there is to be a further investigation, then he/she will establish a panel to consider the complaint.

4.15. The panel will include, at least, the following members:
   a. the Dean or his/her nominee, as convener of the panel;
   b. two nominees of the Dean (not members of the ERC); and
   c. the ERC Chairperson or his/her nominee.

4.16. 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.

4.17. The panel may access any documents relating to the project. The panel may interview other parties, and seek internal and external expert advice, as it sees fit.

4.18. The Dean will notify in writing, the complainant, the Chairperson and the investigator (if an allegation has been made against them) of the outcome of the investigation. The outcomes may include:
   a. The complaint/concern is dismissed;
   b. The Dean directs appropriate action to be taken to resolve the complaint.

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 023 **Title: Appeals concerning the ERC's review process** **Effective Date:**	

1. Purpose

To describe the mechanism for receiving, handling and responding to concerns or appeals about the review or rejection of an application by the ERC

2. Scope

This SOP applies to the conduct and actions of the ERC, FAHS/UOR with regards to the review process of applications made.

3. Responsibility

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

4. Detailed instructions

4.1. Any concern or appeals about the ERC's review process should be directed to the attention of the Dean, FAHS/UOR detailing in writing the grounds of the concern or appeal.

4.2. The Dean will inform the Chairperson as soon as possible of any concern or appeals received by him/her.

4.3. The Dean will send a letter of acknowledgement to the appellant, outlining the following mechanism.

4.4. The Dean, FAHS/UOR will instigate an investigation of the concern or appeals and its validity, and make a recommendation to the ERC on the appropriate course of action. This investigation should take no longer than three (3) weeks from the time of notification of the concern or appeals, unless exceptional circumstances exist.

4.5. If the appellant is not satisfied with the outcome of the Dean, FAHS/UOR investigation, then he/she can refer the concern or appeals to the Vice Chancellor.

4.6. The Chairperson of the ERC will provide the Dean with all relevant information about the concern/appeal.

4.7. The Dean will determine whether there is to be a further investigation of the concern/ appeal.

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

4.9. The panel will include, at least, the following members:
   a. The Dean or his/her nominee, as convener of the panel.
   b. Two nominees of the Dean (not members of the ERC) one of whom should be a person experienced in the ethical review of research protocols
   c. Where the complaint concerns the rejection of an application, an expert in the discipline of research of the project under consideration

4.10. The panel will afford the ERC and the appellant the opportunity to make submissions.

4.11. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external expert advice. In conducting its review, the panel will ascertain whether the ERC acted in accordance with its TOR, SOP, the FERCSL guidelines and otherwise acted in a fair and unbiased manner.

4.12. The Dean will notify the appellant and the ERC of the outcome of the investigation. The outcomes of this process may include:
   a. The concern/appeal is dismissed.
   b. The concern/appeal is referred back to the ERC for consideration, bearing in mind the findings of the panel.
   c. The application may be referred for external review by an independent ERC if the Dean concludes that due process has not been followed by the ERC in reaching its decision.

4.13. If the ERC is requested to review its decision, then the outcome of this review by the ERC will be final. The panel or the Dean, FAHS cannot substitute its approval for the approval of the ERC.

4.14. The panel may also make recommendations about the operation of the ERC including such actions as:
   a. a review of the Terms of Reference and Standard Operating Procedures
   b. a review of the ERC's membership
   c. other such action, as appropriate.

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 024 **Title: Site Monitoring** **Effective Date:**	

1. Purpose

To provide the procedures for site monitoring by ERC, FAHS/UOR

2. Scope

This SOP applies to any visit and/or monitoring of any study sites of ERC approved study protocols.

Clinical trials sponsored by external funding sources and industry are continually audited for compliance and monitored for progress. Institutional clinical studies without outside sponsorship are the focus of the monitoring system of this committee. Industry sponsored clinical trials may also undergo for a cause monitoring should the need arise.

3. Responsibility

The Secretary, ERC appoints a subcommittee – Site Monitoring Committee (SMC) - to monitor the investigator initiated trials. The subcommittee shall consist of Chairperson/Secretary ERC or a nominee, one of the primary reviewers of the study and one other ERC member. The SMC will appoint a chief monitor among its members.

The SMC is charged with the mission of monitoring the overall progress of investigator initiated and other clinical trials and ensuring adherence to clinical trial and procedural requirements.

This includes review of the overall progress of each study to insure the safety of participants, validity of data, that the projected accrual goals are met on a timely basis, that excess accrual is avoided, that eligibility and evaluability rates do not fall below minimum acceptable standards, that risks are not excessive, that adverse events are appropriately monitored and reported to the appropriate agencies. Inherent in this process is the goal of enhancing the quality of the research by providing the investigator with constructive criticism.

4. Detailed instructions

4.1. Selection of study sites

4.1.1. Investigator initiated studies will be routinely monitored (at least annually). Sites will be identified for routine monitoring by the degree of intervention, sample size and complexity of the study and risk involved.

4.1.2. Industry sponsored studies are not routinely monitored but for-cause monitoring may be conducted.

4.1.3. For cause monitoring will be performed at sites for reasons identified by any member of ERC, approved by Chairperson. For cause monitoring could be initiated, in any of the following conditions

- Increased number of protocol violations
- Too many studies carried out by Principal Investigator
- Increased number of SAE reports
- High recruitment rate
- Non-compliance or suspicious conduct
- Any other cause as decided by ERC

4.2. Before the visit

4.2.1. For cause/routine monitoring of the project, the ERC Chairperson will inform SMC to perform the task of monitoring during discussion of the study, on receipt of annual status reports or review of SAEs.

4.2.2. The Secretariat will intimate the PI regarding the scheduled monitoring visit and will coordinate the monitoring visit.

4.2.3. A request regarding the monitoring visit will be sent to the SMC along with a copy of the monitoring visit form.

4.2.4. The chief monitor of SMC

- will notify the site about the scheduled visit.
- will review the study project files and make appropriate notes.
- may carry copy of documents from the ERC approved project files for verification and Site Monitoring Visit Report Form (Annexure 18).

4.3. During the visit,

The SMC will

4.3.1. review the informed consent document to make sure that the site is using the current, approved version.

4.3.2. review randomly the subject's source files for proper informed consent documentation. (usually about 10% of enrolled subjects, or maybe higher)

4.3.3. observe the informed consent process, if possible.

4.3.4. check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study). Storage times, conditions and expiry dates must also be acceptable and sufficient supplies available wherever applicable.

4.3.5. observe laboratory and other facilities necessary for the study at the site, if possible.

4.3.6. review the study files to ensure appropriate documentation

4.3.7. verify that the investigator follows the approved protocol and all approved amendment(s), if any.

4.3.8. ensure that the investigator and the investigator's trial staff are adequately informed about the trial.

4.3.9. verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.

4.3.10. verify that the investigator is enrolling only eligible subjects.

4.3.11. verify that source documents and other study records are accurate, complete, kept up-to-date and maintained.

4.3.12. check the accuracy and completeness of the Case Report Form (CRF) entries, source documents and other study related records against each other.

4.3.13. determine whether all Serious Adverse Events (SAEs) are appropriately reported within the time periods required by GCP/ Regulatory agencies, the protocol, the ERC, the sponsor, and the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e Adverse Events (AEs) and Serious Adverse Events (SAEs) for the volume or severity of adverse events.

4.3.14. collect views of the study participants, if possible.

4.3.15. fill the Site Monitoring Visit Report Form (Annex 18) and write the comments.

4.4. After the visit

4.4.1. The SMC will complete the report (Annex 18) within 14 days describing the findings of the monitoring visit and submit the same to the ERC secretariat. After the form is received at ERC office, it is checked for completeness.

4.4.2. Form is reviewed by ERC secretary, queries if any are sent to PI and the form is forwarded to ERC for action.

4.4.3. The chief monitor, SMC will lead discussant for the project at the ERC meeting and will present the monitoring visit findings in the full board meeting.

4.4.4. Full board recommendations to change the study/ premature termination/ continuation of the project will be informed to the Principal Investigator in writing within 14 days of the meeting.

4.4.5. The Secretariat will place the report in the appropriate protocol specific file.

4.5. Grounds for recommending suspension or termination of a clinical trial to the ERC include, but are not limited to:

- Three (3) major violations in the conduct of the study (including serious ERC violations) that result in an unacceptable audit rating.

- The decision to recommend suspension or termination of a clinical trial is carefully. considered and takes into account whether corrective actions had been requested at previous reviews and were not implemented.

If the decision is made to recommend suspension or termination of a clinical trial, the recommendation will be sent to ERC. ERC has the ultimate authority to effect termination or suspension of a clinical trial.

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 025 **Title: Record Keeping** **Effective Date:**	

1. Purpose

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

2. Scope

This SOP applies to administrative processes concerning the preparation of the agenda for all regular ERC FAHS/UOR meetings

3. Responsibility

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

4. Detailed instructions

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

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

a. the unique project identification number
b. the principal investigator(s)
c. the name of the responsible institution or organization
d. the title of the project
e. the date of review at an ERC meeting and the decision(s) taken at this meeting
f. the ethical approval or non-approval with date
g. the approval or non-approval of any changes to the project
h. the terms and conditions, if any, of approval of the project and
i. the type of approval, whether approval was by expedited review.

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 five (5) years. Files which are no longer required for retention shall be electronically archived.

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

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 026 **Title: ERC Reporting Requirement** **Effective Date:**	

1. Purpose

To describe the reporting requirements of the ERC to the Board of the FAHS

2. Scope

This SOP applies to minutes of meetings, annual report and Terms of Reference, Standard Operating Procedures and membership of the ERC, FAHS/UOR.

3. Responsibility

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

4. Detailed instructions

4.1. The minutes of each ERC meeting will be forwarded to the Board of the FAHS via the Dean.

4.2. The ERC shall provide an annual report to the Faculty Board at the end of each calendar year on its progress, including:

a. membership/membership changes
b. number of meetings
c. number of protocols reviewed, approved and rejected
d. monitoring procedures for ethical aspects of research in progress and any problems encountered by the ERC in undertaking its monitoring role
e. description of any complaints received and their outcome
f. description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval and
g. general issues raised.

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

	Ethics Review Committee Faculty of Allied Health Sciences, University of Ruhuna	
	SOP No: 027 **Title: Review of Standard Operating Procedures and Terms of Reference** **Effective Date:**	

1. Purpose

To describe the procedure for the process for writing, reviewing, distributing and amending SOPs within the ERC, FAHS/UOR

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the committees of ERC, FAHS/UOR.

3. Responsibility

It is the responsibility of the Secretary /Secretariat of ethics committee to appoint the SOP Team to formulate the SOPs by following the same procedures, 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 three years and amended as necessary.

4.2. The Terms of Reference and Standard Operating Procedures may be amended by following the procedure below:

a. For those proposals made by an ERC member:
   - The proposal/request (Annexure 19) must be in writing and circulated to all ERC members for their consideration.
   - The views of the members should be discussed at the next scheduled meeting of the ERC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his/her views in writing.
   - The proposal shall be ratified if at least two thirds of the members agree to the amendment.
   - The Chairperson shall send the amendment to the Dean for review and approval, if appropriate.

b. For those proposals made by the Dean and Faculty Board:
   - The Dean will send the proposal to the ERC and seek the views of any relevant person. The proposal shall be ratified if at least two thirds of the Faculty Board members agree to the amendment.

Glossary

Active Study File: Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study

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.

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

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.

ERC, FAHS/UOR: Ethics Review Committee, Faculty Allied Health Sciences, University of Ruhuna

FERCSL: Forum of Ethics Review Committees, Sri Lanka

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

Minutes: An official record of proceedings at a meeting

PI: Principal investigator of the protocol

SAEs: Serious Adverse Events
SUSARs: Suspected Unexpected Serious Adverse Events

SOP: Standard Operating Procedures

TOR: Terms of Reference

Quorum: Number of ERC members required to act on any proposal presented to the committee for action.

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

References

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

2) Council for International Organizations of Medical Sciences (CIOMS), World Health Organization (WHO). International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002.

3) International Ethical Guidelines for Epidemiological Studies - Prepared by the Council for International Organizations of Medical Sciences (CIOMS) 2008

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

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

6) Ethics review committee guidelines, Forum of Ethics Review Committees, Sri Lanka, 2007

7) Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka, Forum of Ethics Review Committees of Sri Lanka, 2009

Annexure 1: The 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 Allied Health Sciences, University of Ruhuna for the period of three (3) years effective from …….

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

Faculty of Allied Health Sciences, 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 TOR and the SOPs are attached herewith.

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

Yours Sincerely

……..

Dean
Faculty of Allied Health Sciences

Annexure 2: Confidentiality agreement form

Faculty of Allied Health Sciences, 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 Allied Health Sciences, University of Ruhuna (ERC, FAHS, 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, FAHS, 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, FAHS, UOR, 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, FAHS, UOR, 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, FAHS, 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 recognized that the potential for conflict of interest will always exist, but the Faculty of Allied Health Sciences, 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 Allied Health Sciences, 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 Allied Health Sciences, 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, FAHS/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 **Date**

ERC, Faculty of Allied Health Sciences, University of Ruhuna

Annexure 3: Training Record

Training Record of …….. (Name) ERC FAHS, UOR

Name of Training Session	Date	Conducted by

Annexure 4a: Application Form

Application Form

Instructions for Applicants

Postgraduate / Undergraduate Candidates

All candidates are expected to complete an Ethics Review Application Form prior to the commencement of the research or collecting any data after the enrolment as a Research Candidate.

Faculty Staff members / Others

The Application form must be completed in full consultation with any supervisors/co-investigators/ research students/ prior to the commencement of the research or collecting any data.

This application form consists of two sections with two subsections:

Section I: General information – Details of the candidate

Section II: The research project

Section II A – Ethical issues on the research proposal

Section II B – Risks and benefits

Candidate must complete all three sections and attach the necessary documents at relevance.

For office use only			
Application No:		Date Received:	
ERC Submission for	Date	Decision	
1.			
2.			
3.			
Name of Reviewers		Date Forwarded	
1.			
2.			
3.			

SECTION I: GENERAL INFORMATION

1. Title of the Research Project

Location of Research	
Date of Commencement of Research	
Expected Date of Completion of Research	

2. Information of the Investigator

2.1. Principal Investigator / researcher (Should be the applicant of ethics approval)

Title (Rev./Prof./Dr./Mr./Ms.)	Name:
Institution/Department:	
Designation (Prof. Senior Lecturer, Research officer, Student etc.)	
Mailing address	
Phone	
E-mail	

2.2. Co-investigator/ Co-researchers

Are co-investigators/ co-researcher's involved? Yes / No

If yes,

Co-investigator I	
Title (Rev./Prof./Dr./Mr./Ms.)	Name:
Institution/Department:	
Designation (Prof. Senior Lecturer, Research officer, Student etc.)	
Mailing address	
Phone	
E-mail	

Co-investigator II	
Title (Rev./Prof./Dr./Mr./Ms.)	Name:
Institution/Department:	
Designation (Prof. Senior Lecturer, Research officer, Student etc.)	
Mailing address	
Phone	
E-mail	

Please attach additional columns with the details of the co-investigators if necessary.

3. Nature of the research project
   3.1. Is the project for an academic degree? Yes / No
   3.2. Is for an academic degree specify: ……..
   3.3. Have you already registered for this degree? Yes / No

   3.4. If yes

Type of degree	
Awarding university	
Date of registration	

   3.5. Nature of the study

a.	Laboratory based study with Human samples	
b.	Laboratory based study with Animals	
c.	Clinical trial	
d.	Observational study	
e.	Literature review	
f.		
g.		
h.		

4. Are there supervisors for this project? Yes / No
   4.1. Details of supervisors:

   Principal supervisor

Title (Rev./Prof./Dr./Mr./Ms.)	Name:		
Institution/Department:			
Highest educational qualification			
Mailing address			
Phone		E-mail	

   Co-supervisor

Title (Rev./Prof./Dr./Mr./Ms.)	Name:		
Institution/Department:			
Highest educational qualification			
Mailing address			
Phone		E-mail	

   Please append additional pages with supervisor's names if necessary

5. Location(s) where the research will be conducted:
   5.1. Is this a multi-site study? Yes / No
   5.2. Specify all study sites

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

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

6. Other research ethics committee approval(s)

6.1. Has any other ERC approved this project? Yes / No

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

7. 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.	

8. For clinical trials only.

8.1. 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:	

8.2. Is it a multicentre trial? Yes / No

If yes, list the other trial sites.

……..

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

8.3. Is the clinical trial registered with a clinical trials registry? Yes / No / Pending

If yes, give details

Name of register	
Registration number	

If no, give reasons

8.4. 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

8.5. Data safety monitoring board (only if available)

8.6. Details of indemnity and insurance coverage for participations, investigators and ethics committee.

SECTION II A: ETHICAL ISSUES ON THE RESEARCH PROPOSAL

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

9.1. Collaborative partnership

	Applicable Yes / No	Section in Protocol Page
The collaborations you have established with institutions where the study is to be conducted		
The collaborations you have established with the community where the study is to be conducted		
The benefits to institutions, communities, and participants in your research		

9.2. Social Value

	Applicable Yes / No	Section in Protocol & page
The beneficiaries of your research and the benefit to them		
The plan for dissemination of study findings		

9.3. Scientific Validity

	Applicable Yes / No	Section in Protocol Page
The scientific importance of your study in relation to improving health care and/or knowledge on the subject.		
The justification for a replication study, if your study is a replication study.		
How the sample size was calculated		

9.4. Confidentiality

	Applicable Yes / No	Section in Protocol Page
How the data and samples will be obtained		
How long data and samples will be kept		
Justification for collection of personal identification data		
Who will have access to the personal data of the research participants		
How the confidentiality of participants will be ensured		
The procedure for data and sample storage		
The procedure for data and sample disposal		

9.5. Rights of the participants

	Applicable Yes / No	Section in Protocol Page
Procedure for subjects to withdraw from the research at any time		
Procedure for subjects to ask questions and register complaints		
The contact person for research subjects		
Provisions for participants to be informed of results		
Provision to make the study product available to the study participants after research		

9.6. Fair participant selection

	Applicable Yes / No	Section in Protocol &Page
The justification for the selection of the study population		
The inclusion and exclusion criteria		

9.7. Responsibilities of the researcher

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

9.8. Vulnerable population

	Applicable Yes / No	Section in Protocol & Page
Justification for conducting the study in this population		

9.9. Research funded by foreign agencies/companies

	Applicable Yes / No	Section in Protocol & Page
Justification for conducting the study in Sri Lanka		
Relevance of the study to Sri Lanka		
Post research benefits to Sri Lanka		
The steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka		
The sharing of rights to intellectual property		
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		Please attach
The materials transfer agreement, if biological material is to be transferred abroad		Please attach

9.10. Community based research

	Applicable Yes / No	Section in Protocol & Page
The impact and relevance of the research on the community in which it is to be carried out		
The steps taken to consult with the concerned community during the design of the research		
The procedure used to obtain community consent		
The contribution to capacity building of the community		
The procedure for making available results of research to the community		

9.11. Clinical trials

	Applicable Yes / No	Section in Protocol & Page
Justification for withdrawing any therapy from participants to prepare them for the trial		
Justification for withholding standard therapy from trial participants (e.g. control group)		
Justification for providing care which is not the standard of care		
Procedure for dealing with adverse events		
Procedure for reporting adverse events		
Measures in place for management of trial related injuries		
Provisions for safety monitoring		
Provisions/criteria for termination of the trial		
Provisions for making the trial drug available to participants after the trial if found to be effective		

9.12. Information Sheet (IFS) / Informed Consent Form (ICF) Check list

List the sections in IFS/ICF where you have dealt with the following	Section IFS/ICF
Purpose of the study	
Voluntary participation	
Duration, procedures of the study and participant's responsibilities	
Potential benefits	
Risks, hazards and discomforts	
Reimbursements	
Confidentiality	
Termination of study participation	

9.13. Consent

	Applicable Yes / No	Section in Protocol & Page
The procedure for initial contact of participants*		
The procedure for obtaining informed consent Verbal Written		
The information (written/oral) provided to participants		
The procedure for ensuring that subjects have understood the information provided.		
The procedure for obtaining proxy consent.		
The procedure for withdrawing consent.		
Incentives/rewards/compensation provided to participants.		
The procedure for re-consenting if the research protocol changes during the course of research.		
The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited.		
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**

10. Data collection

10.1. 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	

11. Experience of investigators with this type of research.

11.1. 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.

SECTION II B: RISKS AND BENEFITS

12. Possible risks

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

Physical risks (e.g., any bodily contact or administration of any substance):	Yes	No
Psychological/emotional risks (feeling uncomfortable, embarrassed, upset):		
Social risks (e.g., loss of status, privacy and/or reputation):		
Legal risks (e.g., apprehension or arrest, subpoena):		

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

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

13. 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

14. Compensation

14.1. Will participants receive compensation for participation?

	Yes	No
Financial		
In-kind		
Other		

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

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

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

15. 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.)

16. Do you have any conflict of interests with regards to this project? Yes / No
    If yes, please state below.

Commercially	
Financially	
Intellectually	
Other (Explain)	

17. 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:

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

Declaration of applicant

- As the Principal Investigator on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants.
- I understand that if there is any deviation from the project as 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 of the Faculty of Allied Health Sciences.

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

Full name of Principal Investigator: …….

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

Acknowledgment (*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 on …… and will be assigned to two principal reviewers. The ERC may contact you in due course if any clarifications; additional documentation; or revisions are required.

Secretary /ERC, FAHS

Annexure 4b: Check list

Check list for the submission of research proposals

		To be marked by the applicant	To be marked by ERC office
One copy each of the following (**1-6**)			
1.	Covering letter signed by the applicant *(if the applicant is a student of FAHS, letter should be send through the Head of the relevant department)*		
2.	Letter from supervisor (if relevant)		
3.	Curriculum Vitae of Principal Investigator		
4.	Letter signed by all investigators confirming their participation		
5.	CD including the Application form, Research Proposal, Research Project Information Sheet, and the Informed Consent Sheet, all in one PDF file.		
6.	Letter indicating that the investigator(s) have undergone training to handle animals *(It is compulsory for animal research only)*		
The following documents (where relevant) must be submitted. They must be stapled/temporary bound together to form **(03) complete sets** of documents from **6-12**. **All documents must carry the date and version number as a header/footer and page numbers**.			
6.	Proposal		
7.	Study instruments		
8.	Information Sheet **English**		
	Sinhala		
	Tamil *(If relevant)*		
9.	Consent forms **English**		
	Sinhala		
	Tamil *(If relevant)*		
12.	Application form		

Annexure 5: Template for the Agenda

Ethical Review Committee Meeting, Faculty of Allied Health Sciences

A meeting of the Ethical Review Committee will be held on …….. at …… am in the Office of Ethical Review Committee, Faculty of AHS, 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

Annexure 6: Study assessment form

Research Project Proposal Evaluation

1. Reference No: …….

2. Name of the candidate: ……..

3. *If candidate is an undergraduate of the Faculty of Allied Health Sciences;* Student No:

   ……

4. Study Department: …….

5. Title of the project: ……

   ……..

   ……..

6. Comments: *Please provide comments in the following table. If the given space is not enough, use separate sheets for each section and attached herewith.*

Title of the project	
Introduction	
Literature review	
Justification	
Objective/s (Scope)	

Methodology - Sampling - Design - Data analysis		
Ethical issues - Informed consent forms - Permission letters		
Plagiarism (Percentage)		
Ethical approval	- grant as it is	
	- consider after re-submit with corrections	
	- reject	

Name of the reviewer: ……..

Signature: …….

Date: ……

Annexure 7: Exempted from Review

Check whether research involves any of the following:

Audits of educational practices

Research on regular or special education instructional strategies

Research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods

Research on microbes cultured in the laboratory Research on immortalized cell lines

Research on cadavers or death certificates provided such research reveals no identifying personal data

Analysis of data freely available in public domain

Research is **not** exempt if any of the following are involved:

1. Prisoners, fetuses, pregnant women
2. Survey or interview techniques with minors
3. Research involving the observation of public behavior or minors if the researcher participates in the activities being observed
2. The review of health care records or other archival data records if information is recorded in such a way that individuals can be identified, and, if a breach of confidentiality should occur, the information could be potentially damaging to the individual's well-being
3. Deception of participants
4. Procedures which expose participants to more than minimal risk (greater than ordinarily encountered in daily life)

Check whether following documents are submitted and acceptable:

- Participant Letter/ Parental Participant Letter and Assent Letter
  Note: Research w/ minors is rarely exempt.
- Permission letter for access to data or recruitment of participants
- Survey instruments, interview questions or data collection forms
    - Rationale for selection of standardized instruments provided
- For researcher-developed instruments or questions, evidence of piloting, pre-testing or review by **2 professionals** in field of study
- Recruitment materials: advertisements, brochures, flyers, e-mail solicitation messages or other recruitment materials

Check List for protocols Exempted from Review

Check	Y	N	Comments
Audits of educational practices/programmes that are conducted with the approval of the head of the institution/department	☐	☐	
Research on regular or special education instructional strategies	☐	☐	
Research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods	☐	☐	
Research on immortalized cell lines	☐	☐	
Research on cadavers or death certificates	☐	☐	
Research on microbes cultured in the laboratory provided such research reveals no identifying personal data	☐	☐	
Analysis of data freely available in public domain	☐	☐	
Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe	☐	☐	
If yes to any of the above, check:			
Does the research involve vulnerable groups?	☐	☐	
Does the research involve interviews?	☐	☐	
Does the research involve observation of public behavior or minors **and** the researcher participates in the activities being observed	☐	☐	
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	☐	☐	

Does the data provide identification of subjects?	☐	☐	
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 FAHS/UOR
(or nominee)

……
Secretary, ERC FAHS/UOR
(or nominee)

N.B. Either the Chairperson or the Secretary must be one of the reviewers.

Annexure 8: Standard letter for exemption from review

EXEMPTION FROM ETHICS REVIEW
Ethics Review Committee, Faculty of Allied Health Sciences, 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, FAHS,UOR , at its meeting held on ……./……../……..
This proposal is exempt from ethics review for the following reasons.
1.
2.

The following documents have been reviewed by the committee.

Document	Version No	Date of Submission
Project proposal		
Study instruments		

Please not that this exception is pertaining to the submitted protocol and any alteration/deviation should be notified to the ERC.

Yours sincerely,
……..
Name Date: …….
Chairperson
Ethics Review Committee
Faculty of Allied Health Sciences, University of Ruhuna

Annexure 9: Expedited Review

EXPEDITED REVIEW
Ethics Review Committee, Faculty of Allied Health Sciences, 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:

1.1. To negotiating individual arrangements with the Heads of service departments in those situations where the use of their resources is involved,
1.2. If appropriate, informing the study sponsor that the membership and procedures of the Ethics Review Committee FAHS, 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 Allied Health Sciences, University of Ruhuna

Annexure 9a: Standard letter for granting ethical approval

APPROVAL OF A PROPOSAL
Ethics Review Committee, Faculty of Allied Health Sciences, University of Ruhuna

«Date»
«Name_and_Address»
«Salutation»,

Re: «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 Allied Health Sciences, 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:

Document	Version No	Date of Submission
Project proposal		
Study instrument - Sinhala		
Study instrument - English		
Study instrument - Tamil		
Participant information sheet - Sinhala		
Participant consent form - Sinhala		
Participant information sheet - English		
Participant consent form - English		
Participant information sheet - Tamil		
Participant consent form - Tamil		

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, FAHS, 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 Allied Health Sciences, University of Ruhuna

Annexure 9b: Standard letter of granting ethical approval for amendments

APPROVAL OF AMENDMENTS TO A PROPOSAL
Ethics Review Committee, Faculty of Allied Health Sciences, 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 Allied Health Sciences, University of Ruhuna

Annexure 10: Standard letter for requesting additional information/clarification

REFERENCE: «Proposal_No»

«date»

«Name_and_Address»

«Salutation»

Re: «Proposal_No» - " Proposal_Title "

Name(s) of Principal Investigator(s), Co-investigators, Supervisors

Thank you for submitting the above proposal to the ERC, FAHS/UOR. We are pleased to inform you that the Ethics Review Committee, Faculty of Allied Health Sciences, University of Ruhuna has reviewed your proposal and made the following observations and recommendations.

1. clarification/ correction)
2. clarification/ correction)

Requests for additional documents if any;

Please clarify and resubmit the proposal and the information sheet within three weeks for early processing. The corrections done should be in a separate document as a table indicating the change in the new document and the old one (Annexure 1).

Yours sincerely,

…… Date: .....

«name»

Chairperson, Ethics Review Committee

Faculty of Allied Health Sciences, University of Ruhuna

Annexure 10a: Answers to the Reviewer's Comments

Answers to the reviewer's comments

Reference No: ……

Comment	Before the revision	After the revision	Page No

……. …….

PI/Student's signature

Principal Supervisor's signature
(for undergraduate research only)

Date: ……

Date: ……

Annexure11: Standard letter for disapproval

STANDARD LETTER FOR DISAPPROVAL OF AN APPLICATION

Ethics Review Committee, Faculty of Allied Health Sciences, 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 ……/……../…….. and has not granted ethical approval 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.

If you have any further queries, please write to Chairperson ERC, FAHS/UOR citing the protocol number above.

Yours sincerely,

«name» Chairperson
Ethics Review Committee
Faculty of Allied Health Sciences, University of Ruhuna

Annexure 12: Template for notification of serious adverse event

Serious Adverse Effect (SAE) Reporting Form
Faculty of Allied Health Sciences, University of Ruhuna

Principal Investigator :	Application Number :
Study Title :	Protocol Number :
Name of the studying medicine/herbal/device :	Report Date :
Sponsor :	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 13: Template for progress review form

PROGRESS REVIEW FORM (SIX MONTHLY / ANNUALLY)
Ethics Review Committee, Faculty of Allied Health Sciences, 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 14: Template for final report

FINAL REPORT

Ethics Review Committee, Faculty of Allied Health Sciences, 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 15: Standard Premature study termination report

Premature Study Termination Report
Ethics Review Committee, Faculty of Allied Health Sciences, University of Ruhuna

Protocol No:
Protocol Title:

Principal Investigator :

Phone No: E mail Address:
Sponsor's Name:
Address:

Phone No: E mail address:
Study site(s):

ERC approval date Last progress report submission date

Study start date Original study termination date
Study participants (Provide numbers):

- Target accrual of study/trial
- Total patients to be recruited
- Screened
- Screen failure
- Enrolled
- Consent withdrawn and reason
- Withdrawn by PI and reason
- Active on treatment
- Completed treatment
- Patients on follow up
- Patients lost to follow up
- Any other

Any impaired participants (provide numbers)

- None
- Physically
- Mentally/Cognitively
- Both

SAE Total number
SAE events
PI Signature Date

Annexure16: Template for reporting Violation/Deviation/Waiver/Non-compliance

Violation/Deviation/Waiver/Non-compliance REPORT FORM

Ethics Review Committee, Faculty of Allied Health Sciences, University of Ruhuna

Identification No: Date:
Study Title:
Name of the Investigator/s:

Address: Contact No:

Institution: Contact No:

Sponsor: Contact No:

Specify if it is a
Violation / Deviation / Waiver / Non-compliance

Description:

ERC decision:

Action taken: Outcome:

Found by : Reported by:

Date: Date:

Annexure 17: 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
    5.1. Amendments to approved protocols
    5.2. Extension of ERC approval
    5.3. Reports of Serious Adverse Effects
    5.4. Progress reports
    5.5. Final reports
    5.6. Protocol deviations, violations, non-compliance
    5.7. Any other correspondence
6. Announcements
7. Close and date for next meeting.

…….. ……

Secretary Date

ERC

FAHS,UOR

Annexure 18: Check list for a site monitoring visit

CHECKLIST FOR A SITE MONITORING VISIT
Ethics Review Committee, Faculty of Allied Health Sciences, 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:	Total number of subjects enrolled:
□ yes □ No	
Are site facilities appropriate?	Comments:
□ yes □ No	
Are informed consent up to date?	Comments:
□ yes □ No	
Any adverse event found?	Comments:
□ yes □ No	
Ant protocol non-compliance/violence?	Comments:
□ yes □ No	
Are all case records forms up to date?	Comments:
□ yes □ No	
Are storage of data and investigating products	Comments:
locked? □ yes □ No	
How well are participants protected?	Comments:
□ Good □ Fair □ Poor	
Any outstanding tasks or results of visits?	Details:
□ yes □ No	
Duration of visit: hours.	Starting from:
Names of the ERC members	
1.	
2.	
3.	
Date:	

Annexure 19: Request form for revisions

REQUEST FORM FOR REVISIONS
Ethics Review Committee, Faculty of Allied Health Sciences, 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: