Ethics Review Committee
Faculty of Medicine and Allied Sciences
Rajarata University of Sri Lanka

STANDARD OPERATING PROCEDURES

4th Edition – January 2018

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Editors of the 1st Edition

1. Prof SH Siribaddana
2. Dr Anjana Silva
3. Dr Kosala Weerakoon
4. Ms Ranga Siriwardhana

Editors of the 2nd Edition

1. Prof SH Siribaddana
2. Ms Ranga Siriwardhana
3. Dr SMA Jayawardana
4. Dr D Rathish
5. Prof SB Agampodi
6. Dr SD Pilapitiya
7. Dr MACS Jayasumana

Editors of the 3rd Edition

1. Prof SH Siribaddana
2. Prof SB Agampodi
3. Ms Ranga Siriwardhana
4. Dr SMA Jayawardana
5. Dr D Rathish
6. Dr SP Wickramage
7. Dr S Senadheera

Editors of the 4th Edition

1. Prof SB Agampodi
2. Dr PHG Janaka Pushpakumara
3. Dr D Rathish
4. Dr MGRSS Gunathilaka
5. Dr SP Wickramage
6. Dr S Senadheera

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Approved at the

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Preface

Research and Innovation are considered a corner stone in the process of development in a country. Sri Lanka, having a robust history of medical innovation in traditional medicine and being the first country to establish a medical association in Asia Pacific Region, in which research is an integral component, has deep roots in medical research. Within the academic community as well as among practitioners, a growing interest on research has been observed during the last decade. Medical research always ended up in human subject involvement in the process of application and this process requires consideration of protection, safety, and rights of research subjects. In addition, researchers require guidance and monitoring on carefulness, openness, respect for intellectual property, confidentiality, responsible publication, non-discrimination in research process.

Major Ethics Review Committees (ERCs) in Sri Lanka that serve the research community are located in Colombo, Kandy, Galle and Jaffna, which are far away from researchers from North Central province and surrounding districts.The Ethics Review Committee (ERC) of the Faculty of Medicine and Allied Sciences (FMAS), Rajarata University of Sri Lanka (RUSL) was established with full documentation in November 2011. The primary objectives of the ERC/FMAS/RUSL is to protect the physical, psychological, social welfare, rights, dignity and safety of human participants used in research, while taking into account the interests and needs of researchers and the integrity of FMAS/RUSL. The ERC facilitates ethical research through efficient and effective review and monitoring processes, to promote ethical standards of human research and to review research in accordance with the Guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL Guidelines) and relevant national and international guidelines.The general management guidelines/ standard operating procedures of the ERC/FMAS/RUSL, assenting with these guidelines are outlined in this document. Moreover, these standard operating procedures (SOPs) that evolved through three revisions provide the framework for constitution, responsibilities and activities of ERC/FMAS/RUSL.

Third revision of the SOP was initiated in August 2017, based on SIDCER-FERCAP recommendations that were made after the site visit. Fourth edition of the SOP was developed as a self-sufficient document to cover all the functions of the ERC, combining with the important points in TOR. The current set of SOPs is effective from the 1st of January 2018.

Prof SB Agampodi
Chairperson/ERC/FMAS/RUSL

Contents

List of Annexures

Introduction

Rajarata University of Sri Lanka (RUSL) was established on the 7th of November 1995 under Section 21 of the Sri Lanka universities Act No. 16 of 1978 by amalgamating the resources of the Affiliated University Colleges in the Central, North Western and North Central Provinces. The main University is located in Mihintale, a world heritage site, 17 km from the city of Anuradhapura, once a well known center of learning, several centuries before the beginning of the Christian era.Currently, the University has five faculties – Faculty of Applied Sciences, Faculty of Management Studies and the Faculty of Social Sciences and Humanities located in the main campus in Mihintale, Faculty of Agriculture in Puliyankulama, and the Faculty of Medicine and Allied Sciences in Saliyapura.

The Faculty of Medicine and Allied Sciences was established in July 2006 as the eighth public medical faculty of Sri Lanka. The first batch of 171 medical undergraduates from 22 districts of the island was enrolled in 2006 and graduated in 2012. At present, Faculty of Medicine and Allied Sciences is the third largest medical faculty in Sri Lanka in terms of number of medical graduates trained per year.

First research publication with FMAS name on it was in 2008 and since then, researchers from FMAS have widely engaged in research activities. To facilitate the research activities among researchers from FMAS, as well as from North Central Province, Ethics Review Committee (ERC), Faculty of Medicine & Allied Sciences (FMAS), RUSL, was first established in 2009. It was initially established as Research and Publication Committee (RPC). Inaugural meeting of RPC was held on the 20th of May 2009 and Prof. D.J. Weilgama was the first Chairperson. At the beginning, it consisted of seven academic staff members of the faculty. Name of the committee was changed to Research Publication and Ethics Review Committee (RPERC), at the second meeting of RPC in October 2009. In addition to research ethics review, reviewing applications of awardees of RUSL and organizing CME programmes were done by the RPERC. Name of the committee was changed to Research, Ethical Review and Higher Degrees Committee (RERHDC) as a part of major reform of the RPERC that was done in October 2011. Higher degree related activities were added to the scope of the committee with these reforms. Moreover, membership was widened to 16 and full documentation practices were established as a part of these reforms. Prof. Sisira Siribaddana was the first Chairperson of the reformed committee. In October 2013, RERHDC was separated into two committees based on their functions as Ethics Review Committee (ERC) and Higher Degrees Research and Publication Committee (HDRPC). Since then, ERC has been functioning as an independent body devoted for ethics review. It has been a recognized ethics review committee by the Ministry of Health, Sri lanka, since 2013. In May 2017, ERC was accredited by the Subcommittee on Clinical Trials (SCOCT) of

the National Medicines Regulatory Authority (NMRA), Sri lanka as the seventh ERC in Sri Lanka which can review and approve clinical trials. Further, it has been accredited by SIDCER-FERCAP.

The first edition of the Standard Operating Procedures (SOP) and Terms of Reference (TOR) were developed in 2013. Second edition was effective in 2016 February onwards. Third edition of SOP and TOR were approved in August 2016. Third revision of the SOP was started in August 2017, based on SIDCER-FERCAP recommendations that were made after the site visit, as a part of SIDCER-FERCAP recognition to the ERC. Fourth edition of the SOP was developed as a self-sufficient document to cover all the functions of the ERC, combining with the important points in TOR.

The primary objectives of the ERC/FMAS/RUSL is to protect the physical, psychological, social welfare, rights, dignity and safety of human participants used in research, while taking into account the interests and needs of researchers and the integrity of FMAS/RUSL. The ERC facilitates ethical research through efficient and effective review and monitoring processes, to promote ethical standards of human research and to review research in accordance with the Guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL Guidelines) and relevant national and international guidelines.

1.1. Purpose

To describe the role of the Ethics Review Committee, Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka (ERC) which was established in May 2009. It provides independent guidance, advice and decision on health research or other specific research protocols involving human subjects conducted by researchers of or conducted in North Central, or neighbouring provinces (Northern, North Western, Eastern or Central) of Sri Lanka. The proposals of principal investigators attached outside RUSL will also be considered for review provided that they are submitted through the recommendation of the respective heads of their institutions.

Any proposed research should be scientifically sound if it is to be ethically acceptable. The ethics review committee shall consider scientific validity (justification, methodology, proposed analytical methods, etc.) and ethical issues.

1.2. Scope

The SOP applies to all activities in general under the ERC/FMAS/RUSL.

1.3. Responsibility

It is the responsibility of the ERC members to read, understand and respect the rules set by ERC of the Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka.

1.4. Detailed instructions

1.4.1. Overall Function:

The primary objectives of the ERC/FMAS/RUSL is to protect the physical, mental, social welfare, rights, dignity and safety of human participants used in research, while taking into account the interests and needs of researchers and the integrity of FMAS/RUSL. The ERC facilitates ethical research through efficient and effective review and monitoring processes, to promote ethical standards of human research and to review research in accordance with the Guidelines of the Forum

of Ethics Review Committees in Sri Lanka (FERCSL Guidelines) and relevant national and international guidelines. It also has the following additional objectives:

a. To contribute to the highest attainable quality of human subject research.
b. To provide reassurance to the public that proper ethics standards are maintained in research with the aim of safeguarding their rights.
c. Propose policies to enhance and facilitate the ethical conduct of research.

1.4.2. Responsibilities:

1.4.2. ERC will,

a. advise the Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka on all matters relating to the ethics of human research.
b. review proposals for research involving human subjects taking care that all the cardinal principles of research viz. autonomy, beneficence, non-maleficence and justice are adhered to in research proposals.
c. send an annual report and monthly extracts of the minutes to the Faculty Board of the ERC/FMAS/RUSL, which should be made available to the public on request.

1.4.3. The ERC/FMAS/RUSL will review all types of research proposals involving human studies. Applications of investigators will be subjected to a processing fee as decided by the Faculty Board of FMAS, RUSL. Undergraduate students of Rajarata University of Sri Lanka will be exempted from paying the processing fee.

1.4.4. Human research projects may include, but are not limited to, research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, medical records, as well as epidemiological, social and psychological investigations.

1.4.5. The ERC will assess projects submitted for review, in accordance with the FERCSL and other national and international guidelines and legal requirements, in order to determine their ethical acceptability.

1.4.6. ERC/FMAS/RUSL 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.

1.4.7. The ERC will develop standard operating procedures (SOP) for ethics review and ethical conduct of research in the medical and other related fields, within the limits of national/international guidelines.

1.4.8. The ERC will Conduct and promote education and training in research ethics for clinicians, researchers and others, both within and outside the institution, including medical and non-medical undergraduate and postgraduate students.

1.4.9. The ERC will Educate and train ethics review committee members to ensure the quality and consistency of ethics review.

1.4.10. The ERC will Liaise with other ethics review committees in matters of common interest.

1.4.11. The ERC will Advise, support and facilitate the work of other ethics review committees on ethical issues.

1.4.12. The ERC will Inform relevant government agencies of matters that may have policy implications that come to their notice during ethics reviews.

1.4.13. The ERC will Promote community awareness and consult with individuals, communities and government on ethical issues relating to research on human subjects.

1.4.14. The ERC will Keep abreast with international developments in relation to ethical issues and liaise with relevant international organisations and individuals.

2.1. Purpose

To describe the membership composition of the ERC.

2.2. Scope

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

2.3. Responsibility

The SOP applies to all activities under the ERC/FMAS/RUSL.

2.4. Detailed instructions

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

2.4.2. The committee will comprise of at least fifteen (15) and not more than eighteen (18) members.

2.4.3. The membership will comprise of the following categories:

- Atleast two (02) experts in basic medical sciences
- Atleast two (02) clinicians
- At least one (01) expert in the following fields:
    - Public Health / Biostatistics
    - Ethics of Medical Research
    - Law
    - Philosophy / Social Science
- At least one (01) lay person conversant with social values
- At least one (01) member who is not affiliated to the institution

2.4.4. The committee will strive to ensure that there is a gender balance in its composition.

2.4.5. The committee has the power to co-opt member/s when a specific expertise is needed to assess an application sent to the ERC/FMAS/RUSL.

2.4.6. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least 50%+1 of the membership is present along with the presence of at least one (01) lay person.

3.1. Purpose

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

3.2. Scope

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

3.3. Responsibility

It is the responsibility of the ERC/FMAS/RUSL members and the Faculty to read, understand and respect the rules set by ERC of the Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka.

3.4. Detailed instructions

3.4.1. Members are appointed as individuals for their expertise in relevant fields and qualifications.

3.4.2. Prospective members of the ERC/FMAS/RUSL will be asked to provide a copy of their Curriculum Vitae to the ERC. Members must agree to their full names and professions being made available to the public, including being published at the ERC website.

3.4.3. Curriculum vitae of the prospective applicant will be discussed in a forum among ERC members and a recommendation will be made to the Vice Chancellor through the Dean and the Faculty Board. The letters of appointment will be issued by the Vice Chancellor. Prospective members will be invited to attend a meeting of the ERC as observers. Such persons will be expected to sign the confidentiality agreement undertaking as per 3.4.7.

3.4.4. The committee shall elect its chairperson and secretary from among its members and inform the Dean and Faculty Board for approval. Eligibility to be elected to the posts of Chairperson/Secretary of ERC/FMAS/RUSL:

a. Chairperson/Vice Chairperson:

A member should have at least three years experience as a member of the ERC/FMAS/RUSL to be eligible for the post of chairperson.

A member can serve as the chairperson for a maximum of six years or two terms, whichever is longest.

b. Co-secretary:

A member should have at least one year experience as a member of the ERC/FMAS/RUSL to be eligible for the post of secretary. The secretary should be affiliated to the FMAS/RUSL. A member can serve as the Co-secretary for a maximum of six years or two terms, whichever is longest.

3.4.5. Upon recommendations of the ERC, the Dean and the Faculty Board will appoint the Chair and the Secretary. They will receive formal notices of appointment.

3.4.6. The letter of appointment (Annexure 01) 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.

3.4.7. Members and other ERC staff will be required to sign a confidentiality agreement (Annexure 02) when undertaking the appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the ERC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the ERC will be declared.

3.4.8. Upon appointment, members shall be provided with a copy of the latest Standard Operating Procedures (SOPs).

3.4.9. Duration of membership will be for a period of three years. At the end of three (03) years the committee will be reconstituted and at least 1/3rd of its membership will be retained during the re-constitution. All members of the reconstituted ERC will be issued a new appointment letter for a period of three (03) years as described in 3.4.3. Members are eligible for re-appointment for any number of terms. However, a member who has served the ERC for six consecutive years shall be given a break for the next three years.

3.4.10. In case of a chair failing to complete the full term, a new chair shall be appointed from the members of ERC till the full term of the ERC is over.

3.4.11. New members are expected to attend training sessions as soon as practicable after their appointment. All members are encouraged to attend education and training sessions.

3.4.12. 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 12 months.

3.4.13. 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 valid excuse is defined as being involved in designated academic or clinical work or medical reasons acceptable to ERC and informing the secretary of ERC in writing (letter or email) prior to commencement of the ERC meeting for which the member is going to be absent.

3.4.14. Membership will lapse if a member fails to attend in full at least one fifths (20%) of all scheduled ERC meetings in each year, barring exceptional circumstances. The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy accoding to 3.4.3.

3.4.15. Members will be expected to participate in relevant specialized working groups as required. The Chairperson will be expected to be available between meetings to participate in subcommittee meetings where required.

3.4.16. A member may resign from the ERC at any time upon giving notice in writing to the Secretary of the ERC, FMAS, RUSL. The effective date of resignation will be the date in which the resignation is formally accepted by the Faculty Board of FMAS.

3.4.17. Vacancies at the ERC will be filled as per 3.4.2 and 3.4.3.

4.1. Purpose

To describe the functions of members of the ERC.

4.2. Scope

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

4.3. Responsibility

It is the responsibility of the ERC members to read understands their functions as members of the ERC of the FMAS/RUSL.

4.4. Detailed instructions

In additions to functions described in 4.4.3, the Chairperson and the Secretary of the ERC are expected to perform additional duties as detailed below:

4.4.1. Chairperson and Vice Chairperson

a. Conduct all meetings of the ERC according to the SOPs. If, for reasons beyond control, the Chairperson is not available, the vice chairperson nominated by the members 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.

4.4.2. Co - Secretaries

a. Organize the meetings, maintain records and communicate with all concerned.
b. Take up the agenda items at the monthly ERC meeting
c. 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.
d. Ensure that the membership file is current and up to date.
e. Assign reviewers for applications in consultation with the chairperson and co-ordinate the review process.
f. Provide guidance and supervision to the ERC office staff.

g. Perform any other duties of the ERC assigned by the chairperson.

4.4.3. Members

a. The technical members will review applications assigned to them and lead the discussion at the ERC monthly meetings.
b. The technical members will also complete the proposal evaluation form (annexure 6) and hand over to the secretary at least a day before the next monthly ERC meeting.
c. The non-technical members will review the participant information sheet and the consent form (in English / Sinhala / Tamil) approved by the primary reviewer, for clarity and suitability. The review (annexure 18) should be submitted within 3 days of receiving.
d. All members will contribute towards the discussion at the ERC monthly meetings.
e. Perform any other duties assigned to them by the Chairperson.

4.4.4. ERC office staff

a. Receive all applications, coordinate and process them according to the instructions given by the secretary.
b. Issue receipts and receive the money and deposit them according to the instructions of the assistant bursar of the faculty.
c. Perform any other duties assigned to them by the Chairperson and the Secretary.

5.1. 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 occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

5.2. Scope

These standard operating procedures describe the terms of reference which are related to the procedure of orientation of new members of ERC/FMAS/RUSL and training of all the members in the ERC.

5.3. Responsibility

It is the responsibility of new ERC members of the ERC/FMAS/RUSL to read and understand their function. It is the responsibility of all members to have them educated and trained periodically.

5.4. Detailed instructions

5.4.1 New ERC members must be provided with adequate orientation

5.4.2 New members orientation will include the following:

5.4.2.1 Introduction to other ERC members prior to the ERC meeting.

5.4.2.2 Informal meeting with the officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures

5.4.2.3 An opportunity to participate in an ERC meeting as an observer before their appointment takes effect

5.4.3 New members will receive training within three (03) months of the initial appointment in:

5.4.3.1 Research ethics and human subjects' protection

5.4.3.2 Standard Operating Procedures of the committee

5.4.4 Obtaining training

5.4.4.1 Members should get information about training courses, workshops, conferences, etc. which are periodically announced by e-mails sent to the members.

5.4.4.3 Records of the workshops and training obtained (a copy of the certificate) must be kept in the ERC office

5.4.2.5 Priority will be given to participate in training sessions

5.4.2.4 ”Partnering‟ with another senior ERC member in reviewing

6.1. Purpose

To describe how the Secretariat of the ERC manages application submissions.

6.2. Scope

Protocol submissions include: New submission, submissions after major corrections.

6.3. Responsibility

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

6.4. Detailed instructions

6.4.1 Applications must be submitted in the appropriate up-to-date 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 (Annexure 3) shall be readily available to applicants in the ERC website (http://www.rjt.ac.lk/med/index.php/ethic-review-committee). Application must be submitted in the application form given by the ERC and should include the following documents:

6.4.1.1. A covering letter

6.4.1.2. A receipt obtained certifying the payment for review

6.4.1.3. Twenty one (21) copies of project summaries which include title, PI's name and affiliation, unstructured summary of their proposed work with the word count.

6.4.1.4. Three hard copies and a soft copy of the application enclosing the following documents

a. The complete research proposal
b. Diagrammatic representative (flow chart) of the research procedures
c. Information sheets (Annexure 5) and consent forms (Annexure 6) and other relevant documents – in English as well as in Sinhala and Tamil where appropriate (Information sheet and consent form should be available in both Sinhala and Tamil languages unless the research is confined to a particular ethnic group). Applicants are expected to read Annexture 4 before the preparation of information sheets and consent forms.

d. An adequate summary of the study product if applicable
e. Curriculum vitae of the principal investigator & other investigators if necessary (to assess the competency of the investigators).
f. Any document from prior scientific / ethics review

6.4.1.5 Two additional copies of information sheets, consent forms and study tools, in all three languages, should be available (if applicable).

6.4.2 All the documents in 6.4.1.4 should be printed on both sides of the paper.

6.4.3 Documents should be arranged into three files: a master file and two copy files. Master file should contain cover letter and receipt of the payment. Eighteen copies of project summaries and additional copies of information sheets, consent forms and study tools, should be submitted separately.

6.4.3 All the pages, including blank pages, of all three files should be numbered separately (numbering done manually is acceptable).

6.4.4 Guidelines shall be issued by the ERC to assist applicants in the preparation of their applications.

6.4.5 Applicants other than the undergraduate students of the RUSL will incur a handling charge as decided by the Faculty Board of the FMAS/RUSL.

6.4.6 All applications for ethical review must be submitted to the office of the ERC by the 15th of each month to be considered for the next monthly ERC meeting.

6.4.7 Applications will be checked for their completeness by the Secretary, ERC or a designated member at the time of submission. Incomplete applications will be returned to the applicant.

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

6.4.9 A date stamped receipt of acknowledgement (Annexure 7) shall be issued to the applicant once a completed application has been accepted by the secretariat, indicating following information:

a. Name of the PI
b. Title of the study/Protocol
c. Application number given by the ERC
d. The date of submission
e. The date of the meeting that the proposal is to be discussed

6.4.10 The Chairperson and the Secretary will do the risk assessment and decide whether the application could be exempted from ethics review or needs an expedited review or a full committee review.

6.4.11 Secretary shall, in consultation with Chairperson, appoint 2 primary reviewers for each application needing a full committee review. Primary reviewers shall include a subject expert whenever possible.

6.4.12 Index page (Annexure 8) will be pasted inside of the front cover of the master file. Index page shold include following information:

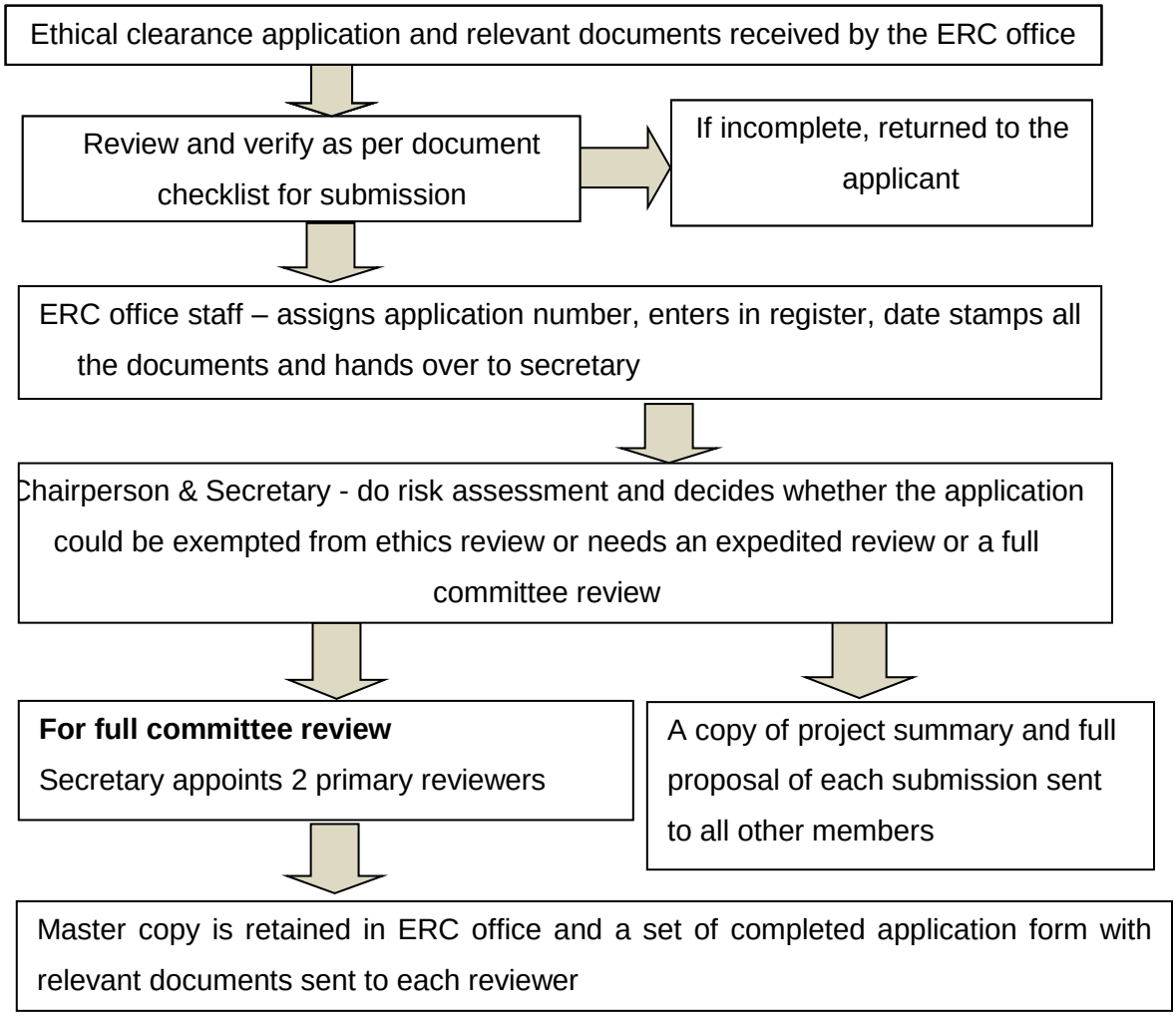
a. Name of the PI
b. Title of the study/Protocol
c. application number given by the ERC
d. The date of submission
e. The date of approval
f. Date of commencement and completing
g. Risk category and ERC recommendations
h. ERC decisions and dates
i. Conditions on approval
j. Availability and details documents that submitted with the application/ corrections/ amendments
k. Details of amendments and progress reports
l. Date of the final report

6.4.13 Two copy files will be sent to the primary reviewers. Following documents will be included in the primary reviewer's document set:

a. Review request letter
b. Copy File
c. Proposal evaluation form
d. Payment voucher

6.4.14 A hard copy of abstract/summary of the proposal and the soft copy of the complete research proposal will be sent to all the members of the ERC at least one week prior to the meeting date.

Processing of new submission



7.1. Purpose

This standard operating procedure describes how the ERC reviews an initially submitted applications.

7.2. Scope

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

7.3. 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 Proposal Evaluation Form (Annexure 6) and return to the Secretariat Office prior to the relevant meeting. The Secretary/ Secretariat are responsible for receiving, verifying and managing the contents of the received packages. In addition, the secretariat should create a protocol specific file, distribute the packages and get them reviewed by the ERC and deliver the review results to the applicants.

7.4. Detailed instructions

7.4.1 The ERC will consider a new application at its next monthly meeting provided the completed application is received on or before 15th day of each month.

7.4.2 Each application will be assigned to two (2) primary reviewers, who would:

7.4.2.1 Review the application in detail prior to the meeting

7.4.2.2 Submit written comments on the application [by filling and forwarding the Proposal Evaluation Form (Annexure 9) to the secretary at least a day before the next monthly ERC meeting]

7.4.2.3 Lead the discussion on the application at the committee meeting.

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

7.4.4 The ERC will assess each application in accordance with the FERCSL and other relevant national and international guidelines. 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.

7.4.5 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.

7.4.6 Where research involves the recruitment of persons unfamiliar with the English language, the ERC will ensure that the participant information sheet (annexure 5) and informed consent form

(annexure 6) are translated into the participants' language and/or that an interpreter is present during the discussion of the project. The non-technical members will review the participant information sheet and the consent form (in English / Sinhala / Tamil) approved by the primary reviewer, for clarity and suitability. The review (annexure 18) should be submitted within 3 days of receiving.

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

7.4.7.1 Approved – no changes required

7.4.7.2 Minor corrections – would be eligible for Chairperson's or Secretary's approval once ERC receives the primary reviewers' comments on corrections.

7.4.7.3 Major corrections – would require full board review once the resubmission is done with the major corrections addressed

7.4.7.4 Rejected – reasons will be conveyed to the applicant

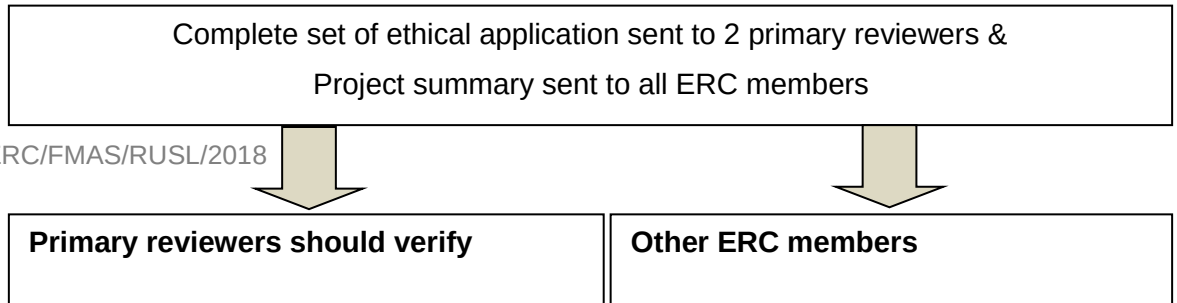
7.4.8 The ERC will reach a decision concerning the acceptability of an application by consensus. Any significant dissenting view or concern shall be noted in the minutes. Where an unanimous decision is not reached, decision-making shall be by anonymous voting. The decision carried by 50%+1 of members including at least one non-technical member shall be the committee decision.

7.4.9 In order to facilitate processing of an application,

a) Primary reviewer may directly contact the PI for clarifications or for additional information.
b) ERC may invite the applicant to attend the relevant meeting to discuss the application and answer questions only.
c) The applicant will be asked to leave the meeting prior to ERC deliberation and decision-making concerning the application.

7.4.10 The review reports of the primary reviewers will be attached to the master file.

Procedure in primary review



8.1. Purpose

To provide procedures for engaging the expertise of a professional as a external reviewer to the ERC/FMAS/RUSL

8.2. 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, the Secretary may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the ERC.

8.3. Responsibility

Upon the advice or recommendation of the Secretary in consultation with the Chairperson, it is the responsibility of the ERC to approve the names of the external reviewers to be endorsed.

8.4. Detailed instruction

8.4.1 The Secretary in consultation with the Chairperson 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.

8.4.2 The composition of external reviewers is as follows:

- Any institutional member with specific expertise
- Cosultants from subspecialities that are not represented in the ERC
- Experts from complementary and alternative medicine
- Basic non-medical scientists
- Methodology experts
- Any other expert as decided by the committee

8.4.3. The Secretary / Secretariat will contact the external reviewer and send the relevant documents for review with the confidentially agreement form.

8.4.4 The external reviewer should complete the proposal evaluation form (Annexure 9) and submit to the secretariat at least one day prior to the ERC meeting.

8.4.5 The consultant may be invited to attend the ERC meeting, present the report and participate in the discussion, if required. The consultation services are sought and applied in relation to a specific protocol and is not a continuous ongoing appointment/service.

	Communication with Principal Investigator/s	Effective Date:	01/01/2018
		Page (s):	22 - 23

9.1**. Purpose**

The purpose of this SOP is to ensure proper completion, distribution and filing of communications with investigators.

9.2. **Scope**

This SOP applies to all communicating activities related to the studies under the approval of the ERC/ FMAS/ RUSL

9.3**. Responsibility**

It is the responsibility of secretariat to complete a written communication record for electronic mails, telephone or interpersonal discussions related to past, present and/or future studies and/or processes involving the ERC.

9.4. Detailed instructions

9.4.1 The ERC will report in writing to the principal investigator, whether the application has received ethical approval (including any conditions of approval) or not, in the form of approved/ minor corrections/ major corrections/ rejected, within seven working days after ERC monthly meeting, unless otherwise notified (Annexure 10).

9.4.2 If the ERC determines that further information, clarification or modification is required for the consideration of an application, the correspondence to the principal investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required as described in SOP/009/17.

9.4.3 The ERC shall endeavor to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects 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.

9.4.4 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 in the forms of ethical approval letter (Annexure 11). And the ethical approval letter will contain the following information:

a. Title of the project;
b. Name/s of the principal investigator(s);
c. Name/s of the co-investigator(s);
d. Application number;
e. Version of all the documents;
f. Study period

g. Date of the ERC approval;

h. Duration of the ERC approval;

i. Frequency of progress reports;

j. Date of submission of the final report; and

k. Conditions of the ERC approval, if any;

9.4.5 If the ERC determines that a research study is ethically unacceptable, the notification of the ERC's decision will include the grounds for rejecting the application. The rejection will be informed in the letter of notification of ERC decision (Annexure 10)

9.4.6 The status of the application shall be updated on the ERC register.

	Re-submission and Review of Applications with Minor Corrections	**Effective Date:**	01/01/2018
		Page (s):	24 - 25

10.1. Purpose

This standard operating procedure how the Secretariat of the ERC manages application submissions and reviews of a re-submitted application with minor corrections.

10.2. Scope

This SOP applies to the protocols for which the ERC considers ethically acceptable with conditions.

10.3. Responsibility

It is the responsibility of the ERC Secretary/secretariat to inform the principle investigator, within seven working days after the respective ERC meeting, that the committee requested corrections. Also the ERC Secretary/secretariat should deliver the applicant's response to the primary reviewers upon its arrival.

10.4. Detailed instructions

10.4.1 The documents submitted in response to requested corrections should include,

a) A covering letter addressing the corrections/ alterations/ clarifications raised by the primary reviewers.

b) The corrected/ altered sections of the application/protocol/ other relevant documents in three copies.

10.4.2 The secretary /secretariat should date stamp forms upon receiving the packages.

10.4.3. The secretary/ERC will direct the received documents to the primary reviewers and issue the decision letter subsequent to their recommendations.

10.4.4 All documents related to minor corrections should reach the Secretary, ERC on or before 20th day of each month to table the decision at the very next monthly meeting.

10.4.5 If corrections are not received on time, two in-writing reminders will be sent to the PI (copy of reminders will be attached to the application files), before third and fourth meetings from the initial decision. Those failing to reply within 3 months of the initial notification will be removed from the meeting agenda. Further three months will be given for submission of documents related to minor corrections. However, if the documents related to corrections are not received within 6 months of the initial notification, the application file will be closed. Submissions later than 6 months of the initial notification should proceed as a new submission.

10.4.6 Original documents and documents related to corrections should be filed in the same application file.

	Ethics Review Committee Faculty of Medicine and Allied Sciences Rajarata University of Sri Lanka	**SOP Code:**	SOP/011/18
		Version:	4
	Re-submission and Review of Applications with Major Corrections	**Effective Date:**	01/01/2018
		Page (s):	26 - 27

11.1. Purpose

This standard operating procedure how the Secretariat of the ERC manages application submissions and reviews of a re-submitted application with major corrections.

11.2. Scope

This SOP applies to study protocols that have been reviewed earlier by the ERC at the initial review process as requiring major corrections.

11.3. Responsibility

It is the responsibility of the ERC Secretary/secretariat to inform the principle investigator, within seven working days after the respective ERC meeting, that the committee requested major corrections. Also the ERC Secretary/secretariat should deliver the applicant's response to the primary reviewers upon its arrival.

11.4. Detailed instructions

11.4.1 The documents submitted in response to requested corrections should include,

a) A covering letter addressing the corrections/ alterations/ clarifications raised by the primary reviewers.

b) The corrected/ altered sections of the application/protocol/ other relevant documents in three copies.

c) Twenty one (21) copies of the project summary

d) A copy of the receipt of payment for the review of major corrections

11.4.2 The Secretary /secretariat should date stamp forms upon receiving the packages.

11.4.3. The Secretary/ERC will direct the received documents to the primary reviewers and issue the decision letter subsequent to their recommendations.

11.4.4 All documents related to major corrections should reach the Secretary, ERC on or before 15th day of each month to be considered at the very next monthly meeting.

11.4.5 If corrections are not received on time, two in-writing reminders will be sent to the PI (copy of reminders will be attached to the application files), before third and fourth meetings from the initial decision. Those failing to reply within 3 months of the initial notification will be removed from the meeting agenda. Further three months will be given for submission of documents related to major corrections. However, if the documents related to corrections are not received within 6 months of the initial notification, the application file will be closed. Submissions later than 6 months of the initial notification should proceed as a new submission.

11.4.6 Original documents and documents related to corrections should be filed in the same application file. Same application number will be assigned to the set of documents submitted after corrections with the version number ([ERC/ YEAR/ SEQUENTIAL NO/VERSION NO].

12.1. Purpose

The purpose of this SOP is to identify the administrative process related to exempting an application from the review procedure.

12.2. Scope

This SOP applies to applications exempted from review.

12.3. Responsibility

The ERC Chairperson may call for sub-committee or an expedited review meeting as appropriate.

12.4. Detailed instructions

The ERC will establish a sub-committee consisting of at least the Chairperson (or nominee), the Secretary (or nominee) and a committee member of the ERC. The subcommittee may exempt a research from review in studies such as limited to quality control or medical audit, provided that the results of the aggregation or analysis are not made available in a form, which identifies the subjects of information.

	Ethics Review Committee Faculty of Medicine and Allied Sciences Rajarata University of Sri Lanka	**SOP Code:**	SOP/013/18
		Version:	4
	Applications eligible for expedited review	**Effective Date:**	01/01/2018
		Page (s):	29- 30

1. Purpose

The purpose of this SOP is to identify the administrative process for an expedited review procedure.

2. Scope

This SOP applies to expedited reviews, which may be scheduled to review/approve applications with minimal risk (as decided in the initial risk assessment), addition of new investigators, minor amendments/ extensions and other study activities that do not require full board review.

3. Responsibility

The ERC Chairperson may call for sub-committee or an expedited review meeting as appropriate.

4. Detailed instructions

13.4.1 The ERC will establish a sub-committee consisting of at least the Chairperson (or nominee), the Secretary (or nominee) and a committee member of the ERC. The sub-committee may decide to expedite the review process in the following circumstances:

a) Research undertaken in a public health emergency that would have strict time restrictions for completion in order to avoid potential loss of data or data quality, and in order to avoid delays in necessary public health interventions or implementation of public health policies.

b) Research with minimal risk (as decided in the initial risk assessment).

c) If previously unforeseen time restrictions have been imposed on research.

13.4.2 Expedited review of research projects may be undertaken between scheduled meetings.

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

13.4.6 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

13.4.7 A summary of the matters dealt with at sub-committee meetings will be included in the agenda for the next ERC meeting.

13.4.8 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.

13.4.9 Where the Chairperson considers that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered by the full ERC and cannot be dealt with by expedited review.

13.4.10 Ethical approval letter (Annexure 11) will be issued for the approved expedited reviews.

14.1. Purpose

The purpose of this SOP is to describe the procedure for the submission of requests for amendments and extensions to approved protocols

14.2. Scope

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

14.3. Responsibility

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

14.4. Detailed instructions

14.4.1 Approval for proposed changes to approved research projects or to the conduct of the research, including extensions to the length of ERC approval, must be sought by the principal investigator in writing.

14.4.2 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 it on the conduct of the research in a separate letter. All amended documents (questionnaires, information leaflets etc) must have the changes highlighted.

14.4.3 The ERC will report in writing to the principal investigator, advising of the ethical approval of the proposed amendment (An approval letter for amendments/ extension will be issued, in the format set out in Annex 12)

14.4.4 If the ERC determines that further information, clarification or modification is required, the correspondence to the investigator should clearly articulate the reasons for this determination. Where possible, requests for additional information/ clarification/ modification should refer to the relevant pieces of legislation.

14.4.5 All reviewed and approved requests for amendments and extensions shall be recorded in the relevant project file and, where appropriate, in the ERC register.

15.1. Purpose

The purpose of this SOP is to describe the procedure for the reporting and handling of Suspected Unexpected Serious Adverse Reactions (SUSAR) and Serious Adverse Events (SAEs).

15.2. Scope

This SOP applies to all communications and actions related to a serious adverse event (experience) or reaction [The FDA defines a Serious Adverse Event (SAE) as “any untoward medical occurrence that: results in death, or Is life-threatening (places the patient at risk of death), or requires hospitalization or prolongs an existing hospitalization, or causes persistent or significant disability or incapacity, or Is a birth defect, or requires medical intervention to prevent one of the above outcomes (e.g., an asthma attack that requires intensive treatment in an emergency room, a seizure that does not result in hospitalization but requires medical treatment)”] to an intervention, including a treatment or diagnostic procedure of studies under the approval of the ERC/FMAS/RUSL.

The SOP also applies to Suspected Unexpected Serious Adverse Reaction (SUSAR). For clinical studies that involve the use of marketed drugs (as opposed to investigational new drugs) FDA defines an unexpected AE as: “an AE that is not listed in the drug’s current labeling, or an AE that is more severe or more specific than indicated in the labeling”. For clinical studies in which investigational new drugs are used, the FDA defines an unexpected AE as: “an AE that is not consistent with the information about the drug’s risks that appears in the relevant source document(s) (e.g., protocol, investigator's brochure, and consent documents), or an AE that is not consistent with the risk information, or an AE that has occurred within the class of drugs, but not specifically with the investigational product”.

15.3. 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.

15.4. Detailed instructions

15.4.1 The ERC shall require, as a condition of approval of each project that researchers immediately report SUSAR or SAE to the ERC, including those that have occurred at other institutions participating in the study.

15.4.2 The following timelines apply for reporting of such events occurring at local trial site to ERC/FMAS/RUSL:

a. Death, life threatening event or injury in a patient on a trial or within 30 days off trial: report within 24 hours.

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.

15.4.3. Notifications of Serious Adverse Events (SAEs) must be submitted in the appropriate format (Annexure 13), 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.

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

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

a. Chairperson ERC

b. Secretary ERC

c. A Clinical Pharmacologist will be co-opted if necessary

d. A clinician with special training/interest in the clinical discipline/field will be co-opted if necessary

15.4.6. The review shall take place within one (01) week of notification of the event. The sub-committee shall determine the appropriate course of action and inform ERC/FMAS 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.

15.4.7. Any such adverse events and the recommendations of the committee/sub- committee (as mentioned in 14.4.5) shall be reported to the ERC at the next available meeting.

15.4.8. 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

15.4.9. The ERC shall provide notice to the investigator that it has received notification of the suspected unexpected serious adverse reactions and serious adverse events, and the course of action it has deemed necessary to take.

15.4.10. The Chairperson shall immediately notify the appropriate authority if a project is suspended or terminated because of a serious adverse event.

16. 1. Purpose

The purpose of this SOP is to describe the procedure for monitoring research projects approved by the ERC to ensure compliance with ethics approval

16.2. Scope

This SOP applies to all studies under the approval of the ERC/FMAS/RUSL

16.3. Responsibility

Principal investigator should send annual progress reports (Annexure 14) to ERC/FMAS/RUSL. For the proposals with a time period less than one year, submission of progress reports is not required but the final report should be submitted within three months of completion of the study.

Principal Investigator should report all adverse events and the response to those events in the periodic and final reports for the project.

In case of a SAE such as death or injury, principal investigator should inform the ERC within 24 hrs. The Chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention

16.4. Detailed instructions

16.4.1 The ERC will monitor approved projects 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.

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

16.4.3 The ERC shall require the information listed in Annexure 14 for the progress reports.

16.4.4 The ERC shall require the information listed in Annexure 15 for the final report.

16.4.4 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.

16.4.5 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 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.

16.4.6 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.

16.4.7 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 PI 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.

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

16.4.9 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:

a. Chairperson ERC

b. Secretary ERC

c. A Clinical Pharmacologist – will be co-opted if necessary

d. A clinician with special training/interest in the clinical discipline/field – will be co-opted if necessary

17.1. Purpose

The purpose of this SOP is to describe how the ERC 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), PI, sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled completion of the study.

17.2. Scope

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

17.3. Responsibility

It is the responsibility of the Chairperson, to terminate any study that the ERC 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.

17.4. Detailed instructions

17.4.1 Receiveing recommendation for study termination/suspension/discontinuation

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

17.4.1.2 Suspension/Termination/ Discontinuation by ERC

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

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

17.4.1.3 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

17.4.1.4 The Secretary will inform the PI to prepare and submit a protocol termination package along with Premature Termination Report (Annexure 16)

17.4.1.5 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 Principal Investigator/sponsor etc)
- The Secretariat will check the completeness of the information
- The Secretariat will receive and acknowledge the reports

17.**4.2 Review and discuss the Termination / suspension/discontinuation report**

17.4.2.1 ERC will review the termination report/ suspension/ discontinuation at regular full board meetings.

17.4.2.2 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.

17.4.2.3 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.

17.4.2.4 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**.**

17.4.2.5 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.

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

17.**4.3 When ERC suspends/terminates any study the following will be checked:**

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

17.4.3.2 Whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care off study participants).

17.4.3.3 Have any adverse events or outcomes reported to the IEC

17.4.4 Notifying the PI

17.4.4.1 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.

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

17.4.4.3 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 off 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.

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

17.4.5 Withdrawal of the suspension

17.4.5.1 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.

17.4.5.2 The convened ERC then decides to lift the suspension, continue or modify the suspension, or terminate the study.

17.4.6 Storing the Report

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

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

18.1. Purpose

The purpose of this SOP is to describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a project approved by the ERC

18.2. Scope

This SOP applies to all studies under the approval of the ERC/FMAS/RUSL

18.3. Responsibility

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

18.4. Detailed instructions

18.4.1 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 (annexure 5) and consent forms (annexure 6).

18.4.2 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

18.4.3 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.

18.4.4 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.

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

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

18.4.6 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.

18.4.7 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.

18.4.8 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 identification and

c. Whether any breach of the approved protocol, which may be established, was inadvertent, negligent or intentional.

18.4.9 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.

18.4.10 The complainant shall be informed in writing, of the outcome of the Chairperson's investigation.

18.4.11 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.

18.4.12 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.

18.4.13 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.

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

18.4.15 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.

18.4.16 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.

18.4.17 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.

18.4.18 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 Medicine and Allied Sciences Rajarata University of Sri Lanka	**SOP Code:**	SOP/019/18
		Version:	4
	Appeals concerning the ERC's review process	**Effective Date:**	01/01/2018
		Page (s):	43 - 44

19.1. Purpose

The purpose of this SOP is to describe the mechanism for receiving, handling and responding to concerns or appeals about the review or rejection of an application by the ERC.

19.2. Scope

This SOP applies to the conduct and actions of the ERC /FMAS/ RUSL with regard to the review process of applications made.

19.3. Responsibility

Any concern or complaint about the ERC's review process should be directed to the attention of the Dean, FMAS, RUSL. The preliminary investigation is the responsibility of the Dean, FMAS and will decide if a further inquiry is necessary. The Dean will investigate and submit the findings to the VC who will be the appellate authority.

19.4. Detailed instructions

19.4.1 Any concern or complaint about the ERC's review process should be directed to the attention of the Dean, FMAS, RUSL, detailing in writing the grounds of the concern or appeal.

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

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

19.4.4 The Dean 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 at its next meeting. This investigation should take no longer than three (03) weeks from the time of notification of the concern or appeals, unless exceptional circumstances exist.

19.4.5 If the appellant is not satisfied with the outcome of the investigation, then he/she can re-appeal to the Dean.

19.4.6 The ERC should provide the Dean with all relevant information related to the concern/appeal.

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

19.4.8 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 appellant and the Chairperson of this.

19.4.9 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 projects

c. Where the complaint concerns the rejection of an application, an expert (not a member of the ERC) in the discipline of research of the project under consideration

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

19.4.11 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, and the FERCSL guidelines and otherwise acted in a fair and unbiased manner.

19.4.12 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.

19.4.13 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, FMAS cannot substitute its approval for the approval of the ERC.

19.4.14 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.

20.1. Purpose

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

20.2. 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.

20.3. Responsibility

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

20.4. Detailed instructions

20.4.1 The Secretary of the ERC will prepare an agenda for each ERC meeting and obtain the prior approval of the Chairperson.

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

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

20.4.4 The meeting agenda and associated documents will be prepared by the Secretary of the ERC and circulated to all ERC members at least seven (07) calendar days prior to the next meeting.

20.4.5 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 15th of the month.

20.4.6 Agenda items will include at least the following items:

a. Attendance and apologies;

b. Conflicts of interest;

c. Ratification of the minutes of the previous meeting;

d. Matters arising from the previous minutes;

e. New applications;

- Full board reviews (with the names of primary reviewers);
- Expedited reviews;
- Exempted reviews;

i. Applications awaiting clarification;

j. Amendments to approved projects;

k. Continuing review items, progress reports, final reports, reports on SAE;

l. Protocol violations, complaints;

m. General correspondence;

n. Other business;

o. Close and date and time of next meeting.

21.1. Purpose

To describe the conduct of ERC meetings.

21.2. Scope

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

21.3. 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.

21.4. Detailed instructions

21.4.1 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 informed.

21.4.2 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. Agenda of the next meeting and the minutes of the previous meeting shall be made available for the members at least 07 days prior to the next meeting.

21.4.3 A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least 50%+1 of members including at least one non-technical member of the membership are present.

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

21.4.5 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.

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

21.4.7 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.

21.4.8 Notwithstanding item 21.4.7, the ERC may agree to the presence of visitors or observers at a meeting. However, they will be allowed only after signing the Confidentiality and COI agreement.

21.4.9 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.

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

21.4.11 Secratery should take up the agenda items at the monthly ERC meeting.

22.1. Purpose

The purpose of this SOP is to describe the procedure for reporting and handling of conflict of interest of the ERC members

22.2. Scope

This SOP covers the agreement on Conflict of Interest concerning information and procedures followed by the ERC/FMAS/RUSL

22.3. 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.

22.4. Detailed instruction

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

22.4.2 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.

22.4.3 All declarations of conflict of interest and the absence of the member concerned will be in the minutes.

	Ethics Review Committee Faculty of Medicine and Allied Sciences Rajarata University of Sri Lanka	**SOP Code:**	SOP/023/18
		Version:	4
	Preparation of meeting minutes	**Effective Date:**	01/01/2018
		Page (s):	50 - 51

23.1. Purpose

The purpose of this SOP is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting minutes of ERC/FMAS/RUSL meetings.

23.2. Scope

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

23.3. 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.

23.4. Detailed instructions

23.4.1 The Secretary of ERC/FMAS will prepare and maintain minutes of all meetings of the ERC.

23.4.2 The format of the minutes will include at least the following items:

a. Attendance and apologies;

b. Conflicts of interest;

c. Ratification of the minutes of the previous meeting;

d. Matters arising from the previous minutes;

e. New applications;

- Full board reviews;
- Expedited reviews;
- Exempted reviews;

i. Applications awaiting clarification;

j. Amendments to approved projects;

k. Continuing review items, progress reports, final reports, reports on SAE;

l. Protocol violations, complaints;

m. General correspondence;

n. Other business;

o. Close and date and time of next meeting.

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

23.4.4 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.

23.4.5 In recording a decision made by the ERC, any significant dissenting view or concern will be noted in the minutes.

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

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

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

23.4.9 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.

23.4.10 A copy of each meeting's conformed minutes will be retained in a 'minutes' file. Extract of the minutes will be included in the concerned protocol file.

23.4.11 The extracts of minutes of each Committee meeting shall be forwarded to the Dean and the Faculty Board of FMAS.

24.1. Purpose

The purpose of this SOP is 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/FMAS/RUSL meetings.

24.2. Scope

This SOP applies to administrative processes concerning the documentations related to all meetings and all correspondence of ERC .

24.3. 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, and to keep records of all other necessary documents. The Chairperson should review and approve the agenda and the minutes sent to him/her and verify the accuracy of all other documents whenever needed.

24.4. Detailed instructions

24.4.1 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.

24.4.2 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 decision with the date;
g. The decision on 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.

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

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

24.4.5 All records pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention will be 03 years or as long as the FERCSL Guidelines/sponsors require.

24.4.6 A register of all the applications received and reviewed shall be maintained in accordance with the FERCSL Guidelines.

25.1. Purpose

The purpose of this SOP is to describe the reporting requirements of the ERC to the Faculty Board.

25.2. Scope

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

25.3. Responsibility

It is the responsibility of the Secretary to forward the extract of the minutes and any other communications to the Faculty Board on behalf of the ERC.

25.4. Detailed instructions

25.4.1 The extract of the minutes of each ERC meeting will be forwarded to the Faculty Board via the Dean.

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

a. Membership/membership changes;
b. Number of meetings;
c. Number of projects 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.

25.4.3 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.

26.1. Purpose

The purpose of this SOP is to describe the procedure for the process for writing, reviewing, distributing and amending SOPs within the ERC/FMAS/RUSL.

26.2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ethics committees of ERC/FMAS/RUSL.

26.3. Responsibility

It is the responsibility of the Chair person 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.

26.4. Detailed instructions

26.4.1 The Standard Operating Procedures shall be reviewed periodically or as per any other necessity.

26.4.2 The Standard Operating Procedures may be amended by following the procedure below:

a. For those proposals made by an ERC member:

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

ii. The views of the members should be discussed at the next scheduled meeting of the ERC, and consent of ERC members will be taken at that meeting. Any member unable to attend such a meeting may register his/her views in writing.

iii. The proposal shall be ratified if at least 50%+1 of the quorum including at least one non-technical member agree to the amendment.

iv. 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. The proposal shall be ratified if at least two thirds of the Faculty Board members agree to the amendment.

26.4.3 The revised SOP will be submitted to the Faculty Board and Senate for approval.

27.1. **Purpose**

The purpose of this SOP is to describe the procedure on evaluating members and staff of the ERC in following the ERC policies, rules and SOPs .

27.2. **Scope**

This SOP applies to all members of the ERC/FMAS/RUSL

27.3. **Responsibility**

It is the responsibility of the sub-committee appointed by the faculty board, FMAS, RUSL and the members appointed from other ERCs (recognized by SCOCT, NMRA).

27.4. **Detailed instructions**

27.4.1. The faculty board, FMAS, RUSL headed by the Dean will be responsible in appointing a three member sub-committee every year to conduct the above evaluation. The three members of the sub-committee will be appointed as following:

a. Two senior lecturers (non-member of the ERC) of FMAS, RUSL expert in ethics review process

b. An administrative officer of RUSL

27.4.2. The sub-committee has to evaluate the ERC annualy using the pre-defined format (Annexure - 17). It has to evaluate whether the ERC members routinely follow the ERC policies, rules and SOPs with special attention to whether the ethical considerations articulated in the Helsinki declaration and FERCSL are being considered and applied consistently and coherently. The sub-committee is supposed to randomly select and evaluate 10% of the applications (minimum of 5), which were received and reviewed by the ERC during the said year.

27.4.3. Recognized external agencies will be invited periodically for independent, external evaluation.

27.4.4. Both the above mentioned groups will have to provide a detail report of their evaluation which will be tabled at the immediate next faculty board.

27.4.5. Appropriate changes and actions based on the above reports will be requested to be incorporated by the ERC and its members.

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Malik, F., V. H. W. Dissanayake, et al., Eds. (2007). Ethics Review Committee Guidelines: A Guide for Developing Standard Operating Procedures for Committees that Review Biomedical Research Proposals. Colombo, Sri Lanka, Forum of Ethics Review Committees - Sri Lanka (FERCSL).

National Drug Abuse Treatment Clinical Trials Network (2014). "Good Clinical Practice." from https://gcp.nidatraining.org/resources.

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World Medical Association (2013). "World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects." JAMA **310**(20): 2191-2194.

Date:

……

……

Dear ……...,

APPOINTMENT AS A MEMBER OF THE ETHICS REVIEW COMMITTEE

I am pleased to inform that you have been appointed as a member / Chairperson / Vice Chairperson / Co-Secretary of the Ethics Review Committee, Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka by me as the Vice Chancellor of the said institution with effect from ..... for a period of three years.

You are requested to extend your fullest cooperation, with the understanding of the terms of your membership as described under the standard operating procedures of ERC/FMAS/RUSL, during the course of conduction of duties as a member/ Chairperson / Vice Chairperson / Co-Secretary. You are required to sign a confidentiality agreement when undertaking the appointment. All the documents and information involved in the committee are confidential materials and you should use the information only for the purpose of review and evaluation process of the protocols/proposal, and should not distribute these documents to any person(s) without permission from the ERC, FMAS, RUSL. Upon acceptance of the appointment, you should agree to take full responsibility for keeping all the information confidential and to declare any conflict of interest, which exist or may arise during your tenure in the ERC.

You are expected to complete the recommended basic training in research ethics within 3 months of your appointment. You may seek a leave of absence from the ERC for extended periods. Steps shall be taken to fill the vacancy if this period exceeds 12 months. Membership will lapse if you fail to attend three (03) consecutive meetings of the ERC without reasonable excuse/apology, unless exceptional circumstances exist. Also, membership will lapse if you fail to attend in full at least one fifths (20%) of all scheduled ERC meetings of a calendar year, barring exceptional circumstances. You may resign from the ERC at any time upon giving notice in writing to the Secretary of the ERC, FMAS, RUSL.

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka will provide the indemnity in respect of all the liabilities that may arise in the course of bona fide conduct of your duties.

Yours sincerely,

Vice Chancellor,

Rajarata University of Sri Lanka, Mihintale

Confidentiality Agreement & Conflict Of Interest Declaration

I, Prof./Dr./Mr./Ms./……, member / staff / external reviewer of the Ethics Review Committee, Faculty of Medicine & Allied Sciences, Rajarata University of Sri Lanka, understand that all the documents and information involved in the committee are confidential materials and I shall use the information only for the purpose of review and evaluation process of the protocols/proposal, and shall not distribute these documents to any person(s) without permission from the ERC, FMAS, RUSL. I understand that upon agreement of this form, I agree to take full responsibility for keeping all the information confidential and to declare any conflict of interest, which exist or may arise during my tenure in the ERC.

……

Signature

Name: ……

Date: ……

Signed in the presence of

…….. ……..

Chairperson/ERC Secretary/ERC

Faculty of Medicine & Allied Sciences**,** Rajarata University of Sri Lanka

ETHICS REVIEW COMMITTEE

APPLICATION FOR ETHICS REVIEW

Checklist for Applicants

1 copy of the following (attached to the master file of the research proposal)

☐ Cover letter

☐ Receipt of payment

3 hard copies and a soft copy of the following

☐ *Part 1 & Part 11* of the application

☐ Research Proposal

☐ Diagrammatic representative (flow chart) of the research procedures

☐ Academic supervisors' letters (if relevant)

☐ Ethics approval from other institutions

☐ Instruments (questionnaires/interview guides/ checklists/ data extraction forms) to be used in the research in English with appropriate translated version (Sinhala, Tamil or both)

☐ Participant information leaflet in English and with appropriate translated version (Sinhala, Tamil or both)

☐ Informed consent form (for adult participants/guardians of children) in English and with appropriate translated version (Sinhala, Tamil or both) with the principal investigator's contact information and contact number for any complaints

☐ CV of Principal investigator and the other relevant co-investigators (if the PI is not the subject specialist)

21 copies of the,

☐ Project summary **(refer section 1.10 of this application)** with principal investigators name and the project title

Instructions to fill the ERC Application

Instructions for Part I & II

General Instructions

General instructions on submissions and completion of the application form are under alphabetical listing below. The specific instructions on each item in the application are given under the same corresponding number. Sample participation information leaflet and consent form are available in the web site and use them as a guide when preparing your participant/patient information leaflet and consent form

A. Ethical approval is required for all research involving human participants, biological samples or personal data. Personal data comprise information about living people who can be identified from the data or from combinations of the data and other information which the person in control of the data has, or is likely to have in future.
B. Application form should be filled in English. (Handwritten application forms will not be accepted). Applications can be obtained from the website and handed over to, ethics review committee, FMAS/RUSL.
C. Application forms should be submitted as Microsoft word documents with the font size 12, font type "Cambria" for text, font style "Calibri" for headings and line spacing at one point five. **Bold** should be used for headings rather than underlining. If and where there is a word limit please indicate the number of words. Instructions to the applicant are written in italics. Application forms with track changes will not be accepted.
D. The deadline for the submission is 15th of each month for it to be considered in the next Ethics Review Committee meeting. Proposals submitted after the deadline will be considered at the meeting of the following month.
E. Three full copies, each copy consisted of the application form with CVs of the principal and other relevant co-investigators (if the PI is not the subject specialist), research proposal, participant information leaflets, consent forms, questionnaires in English and the relevant languages and all supplementary documents should be submitted to the ERC. All three copies should be separately filed with no loose sheets hanging out. Filing and binding with a cord is sufficient. On top of each file cover print principal investigator's (PI) name and the title of the project. One of the copies (Master file) should contain cover letter and receipt of the payment. **All the documents should be printed on both sides of the paper. In the initial submission, all the pages, including blank pages, should be numbered.**
F. Twenty-one copies of the project summary with PI's name and title of the research project also should be submitted.
G. If the proposal has undergone a scientific review, the review report should be attached to the application.

H. Applicants will receive notification letter on the status of their proposal within seven working days of the relevant monthly ERC meeting.

I. The fee structure for reviewing and processing an application will be

   a. For undergraduate students of Rajarata University of Sri Lanka – No charges
   b. If the principle investigator is a member or from the teaching faculty of the FMAS, RUSL – Rs. 2,000/=
   c. For all other principle investigators – Rs. 3,000/=.
   d. International applicants – US$ 100
   e. Applicants from South Asian countries- US$ 50
   f. For industry – Rs. 10,000/= (non-pharmaceutical)
   g. Pharmaceutical industry sponsored Rs. 100,000/=
   h. For major corrections 50% of the above mentioned amount has to be paid

(However fee waiver can be considered on request for those who have financial restrictions). Payment should be made to the Shroff counter, FMAS, RUSL between 0900- 1600 hours of working days. Please note that all payments are non-refundable.

J. Any and all changes or additions to the proposal should be submitted in clear and concise English using the font styles and sizes mentioned above and triplicate copies should be handed over to the ERC secretariat.

K. The entire evaluation procedure could extend from a minimal of one to maximum of three months.

L. Submission of the copies of ethical approval from other ethics review committees and evidence of scientific review (grant approval, degree awarding institutions approval) with your application will expedite the review process..

Specific instructions for filling the application

1.1. In addition to a descriptive title a short running title should be provided

1.2. Please submit full CVs of the principal investigator/s

1.3. Please submit full CVs of the co-investigators (if the PI is not the subject specialist).

1.10. SUMMARY OF THE PROJECT

Project summary of no more than 500 words (in nontechnical language) should be submitted to the ERC. This initial summary would detail:

I. Introduction justification and existing knowledge in the relevant field
II. The objectives of the research or hypothesis
III. Expected outcomes of the research
IV. The methodology used for the research
V. The sample size used for the research
VI. The time frame of which the research will be conducted.

The summary should be written in clear, concise English and should be self-explanatory. This summary will be available to all the members of the ERC including lay members.

4.2. Use the given standard format (available in the web site, Annexure 5) for the participation information leaflet (English). Take it as a guide and include only relevant sections. If you are using Sinhalese and Tamil speaking participants, submission of participation information leaflet in the relevant language/s along with the English participation information leaflet is mandatory (read Annexure 4 prior to the preparation).

4.3. Format for consent form (Annexure 6) in English is available in the web site. Take it as a guide and include only relevant sections. If you are using Sinhalese and Tamil speaking participants, submission of consent form/s in the relevant language/s along with the English consent form is mandatory (read Annexure 4 prior to the preparation).

4.9. In case of research involving children below the age of 12 years, informed consent should be obtained from the parents. If participants are between 12 to 18 years, assent (consent from children) and consent from their parents should be obtained.

Instructions for Appendices

Appendix C: RESERCH INVOLVING Human Biological material including DNA / RNA

General instructions

Genotyping results should not be given to individual participants unless there is a high risk of a disease occurring because of the genetic variant carried.

When obtaining consent to take a sample of biological material for research it is important that donors have sufficient understanding not only of the process involved in taking the samples and any associated physical risks, but also of what the sample is to be used for and how the results of the research might impact on their interests.

The use of anonymised, unlinked samples is recommended wherever possible. Anonymised means that individual samples are not identifiable while 'unlinked' means that it is not possible to trace samples back to the individual, for example through the use of a key-code.

Where there is the potential for the sample being used for further research outside the remit of the study for which consent is being sought, a two part consent process should be used. The first should request consent for the planned research and the second should ask for consent for the storage and future use of the sample for further research. Only where a sample is irreversibly anonymised is it acceptable to seek blanket consent for the future use of tissue samples in all biomedical research (as opposed to seeking consent for use in specific projects or types of research e.g. projects looking at genetic variants associated with depression).

There are certain types of genetic research which give rise to particular concern, for instance, that relating to personality, behavioral characteristics, sexual orientation or intelligence. It is particularly

important that specific consent is obtained to use samples in these or other areas of research that are likely to cause special concern to the donors, even if the samples are to be irreversibly anonymised. When samples are not anonymised or may be linked to individuals, possible future research should be explained in terms of the types of studies that may be done, the types of disease that could be investigated, and the possible impact of the research on them personally.

Participants must be assured that all secondary uses will require approval by an ethics committee. Participants should be informed of when and how any surplus material will be disposed of.

"The human body and its parts shall not, as such, give rise to financial gain'. Therefore, while reasonable travel expenses may be reimbursed, research participants should never be offered any financial or material inducement to donate biological samples for research. There should be no inducements to donate but participants may be reasonably compensated for time, inconvenience and discomfort.

If samples are to be used by the commercial sector this should be detailed and the researcher must ensure that participants are made aware of this in the study information and that they know they will not be entitled to a share in the profits.

High risk genetic research

Tests done on samples of human material in the course of research may reveal information that has implications for the donors' future health or healthcare, or otherwise impacts on their interests. It is important to decide before the start of a research project what will be done if this arises. Researchers should be cautious about assuming that they, rather than the individuals concerned, are best placed to judge what information is of interest to donors on a case-by-case basis. For instance, some researchers may take the view that information should only be fed back if there is a treatment or preventive intervention available. However, research participants might wish to know predictive information about their future health, even if there is no treatment available, for example to take it into account when making important life decisions, such as whether to have children. Researchers should assume that participants have a right to know information that may affect their interests, but that they might choose not to exercise that right. When participants are asked to make a decision on whether or not they want results to be fed back to them they must be given sufficient information to allow them to decide what their interests are and to make any refusal meaningful.

Researchers must decide at the outset what their strategy is with regard to feeding back information on individual results to participants - noting that this should only be done when it is essential. If feedback is to be provided then the most appropriate method of keeping data is for researchers to retain a linking code between anonymised data and participant identities (meaning the anonymisation is reversible). In all other cases data should separated from identifiable information and rendered truly, irreversibly anonymous.

This must be set out in their submission to the ethics committee, and the policy adopted must be explained clearly to research participants before they consent to take part in the research. If you

decide that individual results will not be provided then the rest of the section will not be relevant to you – however, you should ensure that a clear justification for this decision is given within the application form.

Where a result that can be linked to an individual has immediate clinical relevance (for example, if it reveals a serious condition for which treatment is required), the researcher involved has a clear duty of care to inform the research participant, either directly or via the clinician responsible for his or her care (in which case the participant must give permission for the researcher to share this information). A research result should not be relied on as the sole basis for diagnosis, since quality control standards in research laboratories generally differ from those used for clinical testing. Research participants or their clinicians should be advised to seek a repeat or confirmatory test by a clinical diagnostic laboratory where possible. Where a confirmatory test is not available the diagnosis might need to be verified by the research laboratory using a new sample.

Genetic tests of known clinical or predictive value should not be done on samples that can be linked to an individual without their specific consent, and appropriate counseling should be available if consent for such a test is sought. Participants should be advised of the possible implications of genetic information for other family members and the potential impact on family relationships, and also of the implications of genetic risk information for employment or their ability to obtain insurance, before they decide whether to give consent to the test or whether they want to know the result. The feeding back of other genetic information, the significance of which is currently unknown could also have a similar implication in the future which is why this is not recommended.

Changes that may need to be incorporated into the consent form

- I give my consent for my blood to be genotyped for this study.
- I understand that I will not receive any results about my own genotype.
- I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data and samples up to the point of publication or up until the point stated on the Information Sheet.
- I understand that I will only have the option of receiving information about my particular genotype if I am found to carry a variant associated with the disease.
- I would/would not like to be informed if it is suspected that I am a carrier of a gene variant associated with the disease.

Changes that may need to be incorporated into the information leaflet

- Inherited risk and implications for wider family including brothers, sisters, and children e.g. future reproductive decisions.
- Insurance status, for example, at some point in the future, this result, if known to the individual, may result in rejection for a policy or loading of a premium.

- Knowing this result may mean that individual ought to receive treatment to reduce possible consequences.
- That knowing this result may now or in the future need to be declared during the course of a medical examination for employment, or applications for life assurance or sickness insurance, and that failure to declare this may be contrary to the terms of the policy of employment or contract.
- What counseling support would be available?
- It may be necessary to refer the participant for re-testing by genetic services outside the study.

APENDIX D : COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM)

This ethics review committee will accept to review research proposals in fields of complementary and alternative medicine. When reviewing such research it will look for the presence of accepted standards of research norms, ethical considerations, and research methodologies in the proposals. But it will also accept some important concepts and realities unique to CAM.

The committee will accept the following issues in CAM research when reviewing the proposals and will approve such proposals while making sure the basic ethical and methodological standards are met.

Some of the Issues that are recognized by the ERC, FMAS, RUSL would be as follows:

1. Need to allow research with CAM drugs without undergoing the same rigorous procedures as when researching with a new drug when the drug/s under study;
   A. had been mentioned in the original classical texts of their relevant fields,
      and/or
   B. Had been in use over a long period of time without reports of concern
      and
   C. Are already in wide use in CAM sector,
2. Need to accept the “Patient individualized treatment model” of some CAM systems like Ayurveda in clinical research.
3. Accepting the properties of single herbs will not be manifested when they are in combination with many others in complex drugs which are used in CAM systems and that these drugs may possess entirely different properties than if each ingredient is studied in isolation.
4. Please address these concerns and issues in your protocol
   - Disclosure of the formula of traditional drugs involved in the research.
   - Potential toxic effects in the traditional medicine
   - Importance of having western medical personnel in the research team.

PART 1 - BASIC INFORMATION

for official use	No; ERC		Checked by	
ERC Discussion		No Risk / Minimal Risk / Greater than Minimal Risk		
ERC Recommendation		Exempt from Ethics Review / Expedited Review / Full Committee Review		
Reviewer 1			Reviewer 2	
Instrument, PIL and ICF reviewer	Sinhala		Tamil	
Received date			Meeting Date	
Decision	Approved/ Approved with corrections/Resubmission/Rejection		Date Informed	

1.1 Title of Research Project: descriptive and short *(please read Page 3 of the application before completing this)*

Descriptive title:
Short title:

1.2 Principal investigator/ applicant (*please attach CVs*)-if you have more than one PI please duplicate this form

Title	Mr/Ms/Rev/Dr/Prof
Name	
Current designation	
Institute where the applicant is attached	
Highest educational qualification of the applicant	
Telephone (office)	
Telephone (home)	
Telephone (mobile)	
e mail (main method of communication)	
Address for correspondence	

1.3 Names, qualifications and affiliations of the co-investigators.

Name	**affiliation**	**Qualifications**

1.4 If this is a student project (undergraduate or post graduate) please give details of your academic supervisory arrangements.

Course/degree	
Faculty/ Institution	
Academic supervisor/s (*name, affiliation and qualifications*)	

1.5 Where will the study take place?

a. Is this a collaborative and multi-center trial?

☐ No

☐ Yes

If yes please describe the other centers and collaborating institutes or universities.

b. Please indicate what other research ethics committees have been approached and what the outcome of the proposal.

1.6 Has this research proposal undergone scientific review

☐ No

☐ Yes

If yes please give details

1.7 Please name the source of funding and the amount.

1.8 Data collection period (*from the initial recruitment of participants to completion of data collection*)

	D	D		M	M		Y	E	A	R
Starting date										
Finishing date										

1.9 Is this research in your opinion warrants expedited review?

☐ No

☐ Yes

If yes please justify in a separate letter addressed to Chairperson ERC

1.10 Project summary (*of no more than 500 words in non-technical language*) with PIs name, title of the research project on top and a word count in this form. Also submit thirty one copies of the project summary with PIs name, title of the project and word count in a separate file.

A structured project summary should include the rationale/ background (2-3 sentences), objectives of the proposed study and the methods. Study design, sample and sampling procedure, measurements and data collection, and data analysis with outcome measures should be included in the methods section of the summary.

Title of the research

PI name

Word count			

Project summary

PART 2 - DETAILED STUDY DESCRIPTION

SECTION A

RESEARCH PROJECT-*please attach a complete protocol of your research*

All proposals that has not undergone prior scientific review will undergo scientific review (Standards and operational guidance for ethics review of health-related research with human participants World Health Organization 2011)

2.1 **Please indicate study type**– *you may tick more than one box.*

	Laboratory study not using animals
	Laboratory study using animals
	Laboratory study using stored human biological material
	Participant observation
	Interviews, focus group
	Other type of qualitative study
	Social science research
	Research on medical records or other personnel information
	Health system research
	Implementation research
	Cross-sectional study
	Case-control study
	Cohort study
	Randomized Controlled Trial not using experimental drug or devi
	Randomized Controlled Trial using experimental drug or device
	Phase 1 or 2 of trial using a experimental drug or device
	Other type of study (please describe)

2.2 What are the Hypotheses or objectives of the research project?

2.3 How will the participants in the study be selected? What inclusion and exclusion criteria will be used?

2.4 Will any drugs or devices (in a clinical trial phases 1-4) used as part of the research that are additional to those which would be administered to these subjects as part of their routine clinical care?

☐ No

☐ Yes

If yes, please complete Appendix A

2.5 Will any ionizing radioactive substances or X-rays be administrated which are additional to those which would normally be administered to these subjects as part of their routine clinical care?

☐ No

☐ Yes

If yes please complete Appendix B

2.6 Does your study involve DNA analysis, storage, genetic modification, stem cell research?

☐ No

☐ Yes

If yes, please complete Appendix C

2.7 Does your study involves complementary and alternative medicine (CAM)

☐ No

☐ Yes

if yes please complete appendix D

2.8 Does your study involve animal research?

☐ No

☐ Yes

If yes please complete appendix E

SECTION B

PARTICPANT RISK

3.1 *Please fill the table below*

Investigation	*Routine Procedures*		*Additional Procedure*	
	Yes	*No*	*Yes*	*No*
Self completed questionnaires				
Structured interviews/researcher completed questionnaires				
Venepuncture				
Arterial puncture				
Biopsy				
Other tissue/ body sample				
Ionizing radioactive substances/X-rays				
Non-radioactive imaging investigations				
Non-invasive tests (eg. ECG)				
Anesthesia, sedation				
Other medicinal products				
Medical devices/ equipment				
Hospitalization				
Longer inpatient days				
Additional outpatient attendances				
Other investigations not part of routine care				

3.2 Description of the procedure to be carried out on these participants (administration of a questionnaire/drug/collection of blood/ samples/ investigation/surgery)

3.3 Safety measures employed during the procedure

3.4 Are there any potential hazards/ risks/discomfort / distress/ inconvenience to the participants, their relatives or the investigators? *Please describe*

3.5 How this will be minimized? *Please describe*

3.6 Potential benefits to the participants and the community and any steps taken to enhance these benefits. *Please describe*

3.7 Justification of potential benefits over the risks. *please discuss*

SECTION C

RECRUITMENT AND CONSENT

4.1 Who will approach the participants initially? *Please submit any letters / advertisements to employers/ schools etc. or newspaper advertisement that will be used. Please explain the training and educational qualification of the people who will obtain consent.*

4.2 Will there be a participant information sheet?

☐ Yes

☐ No

If no please justify. If yes, please attach copies in English and in the language of the participant

4.3 Will informed consent be sought?

☐ Yes

☐ No

If Not please justify

4.4 Will consent be written or oral? *Oral consent should be justified below. Please attach written consent form in English and in the language of the participant.*

4.5 Incentive or compensation if any offered to the participants

☐ No

☐ Yes

Please justify if yes, or no and if yes describe the incentive

4.6 Describe any steps to ensure whether participants have understood the information procedure

4.7 Please describe the procedure of obtaining consent (*describe the time interval between providing information to the participants and obtaining consent, the space given to discuss with their significant others about participating, any special considerations to vulnerable groups etc*)

4.8 Please describe the procedure if the participant wishes to withdraw from the study

4.9 Will there be proxy consent (in acutely ill patients, patients with cognitive impairment, and in children) please describe and justify

4.10 What data will be collected from the participants who refuse consent?

4.11Describe procedure for participants to ask questions and register complaints

SECTION D

CONFLICTS OF INTREST, INTELLECTUAL PROPERTY AND CONFIDENTIALITY

5.1 Are there any financial or other incentives for the participants or recruiting physicians, mid wives or any other official?

☐ No

☐ Yes

If yes, please give details

5.2 Are there any interests for the investigators over and above those detailed in this form?

☐ No

☐ Yes

If yes, please give details

5.3 Are there any conflicts of interest or duality of interests such as that between providers of funding and the investigators?

5.4 Who besides the named investigators will have access to the participants' medical/ personal records? Please describe the procedure to ensure confidentiality of data

5.5 Is there any indemnity, Insurance or liability cover for the project? (This may not be necessary in majority of research projects) If No who would take responsibilities in the event of a claim?

5.6 Will the proposed research use technology, materials or other invention that, as far as you are aware, are subject to any patents or other form of intellectual property protection? Please give details (no more than 200 words)

5.7 Is the proposed research, (in whole or in part) subject to any agreements with commercial, academic or any other organizations? If yes Please give details (no more than 200 words)

5.8 Is the proposed research likely to lead to any results that could be patented or commercially exploited? Please give details (no more than 200 words)

5.9 Will any potentially commercially exploitable results be based upon tissues or samples derived from human participants? Please confirm that there has been appropriate informed consent for such use.

SECTION E

DISSEMINATION OF THE FINDING, PUBLIC ENGAGEMENT & COMMUNITY CONSIDERATIONS

6. 1 Please describe if relevant the steps taken to consult with concerned community when designing the research and during the course of research (no more than 200 words)

6.2 Please describe briefly how you address or engage the community and the collaborations you have built with the community. (No more than 200 words)

6.3 Please outline your plans, for engaging non-academic public audiences. Particularly the way you intend to make the results of your research available to the participants and to the concerned community (no more than 200 words)

6.4 Please describe briefly the plan for dissemination of findings (no more than 200 words)

7. Declaration

I certify that the information given above is true and correct to the best of my knowledge. If there is change in the protocol or the research project is terminated before completion I will inform the ethics review committee. I will also inform if there are any serious adverse events to the human participants during the research project *(please see the notes below).*

Date: **Applicants signature: …….**

APPENDICES: A, B, C & D

(COMPLETE ONLY IF APPROPRIATE TO YOUR STUDY)

APPENDIX A

CLINICAL TRIALS

A.1 Is the clinical trial registered with a clinical trial registry and if yes please provide details.

A.2.Please tells us if it is a phase 1,2,3 or 4 study.

A.3 Please tell us the centers that are participating in the study or it is a single center study

A.4 Do you have trial steering committee, management group and data and safety monitoring board? If yes please provide brief description about it and the personnel

(*please attach CVs of all committee members*)

A.5 Is this product is registered in NMRA if yes please provide evidence and if not please justify

A.6 Is this clinical trial is related to new pharmaceutical product or device or a new indication of already registered pharmaceutical product or a device; if it is please provide details of it (approved name, purity, stability, dosage, frequency of administration, storage, dispensing, accountability, placebos, etc).

A.7 Details of animal studies, human toxicological data, adverse events, serious adverse events.

A.8 Details of indemnity and insurance coverage for participants, investigators and ethics committees.

APPENDIX B

RADIATION EXPOSURE

B.1 If you are intending to use non-ionising radiation, i.e. lasers, microwave, ultra-violet or other type of electro-magnetic energy, please provide details of exposure:

B.2 Details of radioactive substances (isotopes) to be administered or radiographic procedures.

B.3 Who will administer the radio-pharmaceuticals? Please provide name and list their qualifications.

B.4 Quantity of radioactivity to be given (MBq). Give source of reference or submit calculation.

B.5 What is the dose constraint expressed as the effective dose (mSv) for the research-related exposure for the participant? Give source of reference or submit calculation.

B.6 Have pregnant patients/volunteers (except in specified exceptional circumstances) been excluded?

B.7 Have breast-feeding volunteers (for radionuclide studies only) been excluded? If not justify why not.

B.8 For patients, are there any radiation exposures specific for the project over and above those required for normal clinical management.

B.9 Does the information to patients/volunteers make clear that some additional exposure to ionizing radiation is involved and the consequent risk.

B.10 Could the clinical information be obtained by an alternative method involving a smaller dose? If YES, attach details describing the reasons for choosing the proposed examination.

I have delegated authority to administer the radioactive substance(s) in this project to Prof/Dr/ Mr./Ms ……and I approve the arrangements that have been made.

……

……

Signature of Consultant/ Head Radiology or Nuclear Medicine Date

---

APPENDIX C

RESERCH INVOLVING Human Biological material including DNA / RNA

This section will be developed further

C.1 Are you using any part of the human body for research into DNA or RNA (biopsy, tissue, buccal smears, tumour, blood, hair, nail cadaveric tissues are human biological material). If yes please describe

C.2. Will the biological material stored after research. If yes please describe the storage and whether the human biological material is anonymised or unlinked.

APENDIX D

COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM)

(Please read the instructions, page 67)

General Guide on Consent Form and Participant Information Sheet

Knowledge of involvement

4.1 Subjects should know that they are involved in research, although it can sometimes be difficult or even impossible, e.g. in community projects, medical emergencies and in mentally handicapped subjects.

Meaning of consent

4.2 Potential research subjects are entitled to choose whether or not they will participate in research. Obtaining valid consent (i.e. informed, understood, and voluntary) is central to the ethical conduct of clinical investigations. The terms ‘valid’, ‘informed’, and ‘voluntary’ imply that subjects have enough information, in a form that they understand, to enable them to make an autonomous, deliberated (proper) judgment whether or not to participate. The word ‘consent’ encompasses these requirements, for if they are not met there is no consent. It is unnecessary to use qualifying adjectives and this may even be confusing.

4.3 There is no single preferred method of obtaining and recording consent that is appropriate for all research, but the committee should decide whether sufficient information has been provided, especially about potential risks and discomforts as well as any hoped for benefits, for an adequately informed choice to be possible.

4.4 Where it is proposed to withhold from subjects information that would be of use in making a decision to participate, this should always be fully disclosed to the ERC.

Modes of consent: written or oral consent

4.5 Healthy volunteers and patient volunteers engaged in non-therapeutic research should give written consent to all but the most trivial procedures, such as measurement of height, weight, and single venipuncture. These minor procedures may be done with a simple explanation (set out in the application form) and an oral response. In therapeutic research, consent procedures should be adapted to suit the circumstances.

Written consent

4.6 Written consent has two protective functions, for both the subjects (who are in no doubt that they are involved in research), and the investigators (which makes them less vulnerable to litigation).

4.7 Written consent in no way reduces the responsibilities of the investigator/s and in itself does not remove the ordinary rights of the subject.

Information to subjects

4.8 Information about the research project should be presented in the form of an information sheet, written in simple language that is easily understood by the potential research subject. It should set out:

- The purpose of the research and the study involves research
- The procedures especially invasive ones and including expected duration of the subjects participation
- The risks, discomforts (including psychological distress) and benefits, or absence of them, to the individual or to other or future individuals or to society
- A statement that the subjects may decline to participate (without incurring displeasure or any sort of penalty in the case of a dependent relationship, i.e. patient, student, employee) and also will be free to withdraw at any time without giving a reason and without in any way impairing their care
- Disclosure of alternative procedures and therapies available to the subjects
- Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records
- An invitation to ask questions.

Investigators should be made to understand that approval by an ethics committee should not be referred to in any way that may cause potential volunteers to think that the project is especially recommended or is especially safe.

In clinical trials following additional information should be provided to the subjects.

- Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
- Statement describing the financial compensation and medical management as under
    a. In the event of an injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.
    b. In the event of a trial related injury or death, the Sponsor or his representative, whosoever has obtained permission from the licensing Authority for conduct of the clinical trial, shall provide financial compensation for the injury or death.
- An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury
- The anticipated payment, if any, to the subject for participating in the trial
- Subject's responsibilities on participation in the trial

Additional elements that may be required

- Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.
- Additional costs to the subject that may result from participation in the study.
- The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by subject.
- Statement that the subject or subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue participation will be provided.
- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
- Approximate number of subjects enrolled in the study.

Consent form

4.9 The subjects must be given adequate time to study the information sheet and to consult their families and their family doctors where appropriate. They may then sign a form that states that the information sheet has been studied and discussed with the investigator and that the subject agrees to participate. A separate information sheet and a consent form are preferable to a single form incorporating all the information. A standard hospital ‘consent to treatment’ form is not appropriate for obtaining consent to a research project.

4.10 The information sheet for patients and healthy volunteers is an important process of getting consent. It should form a part of the application to the ERC. The committee should exercise discretion as to the mode of consent that is appropriate to the nature of the proposed research.

Witnessed consent

4.11 Witnessed consent is especially useful in the elderly and in those who have intellectual or cultural difficulties in speech or understanding, or who are distressed, but who are nevertheless capable of giving consent.

An independent person, e.g. a senior nurse, present when the investigator explained the project to the potential subject. He/she signs the document stating that he/she witnessed the procedure of informed consent and consent was given freely and with understanding.

Impaired capacity

4.12 Where capacity to consent is impaired, for example in children, mentally handicapped people, intoxicated patients and psychiatric patients, special consideration is required

"Capacity" means the ability to use and understand information to make a decision.

Any evidence that a person does not have this capacity has to show both of the following:

- A person's mind or brain is impaired or disturbed.
- The impairment or disturbance means the person is unable to make a decision at the current time.

Refusal to participate

4.13 Any fears that the patients might have about adverse consequences of refusal to participate must be allayed. They must be assured that refusal to participate will be accepted without question and routine care will not be affected.

Minimal risk

4.14 The term ‘minimal risk’ has been defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”.

Questionnaires

4.15 A copy of all questionnaires to be used in research must be given to the ERC.

4.16 Questionnaires may range from the innocuous to intrusive. Some of them may cause distress or resentment if presented to the subject without preparation. For these, it is appropriate to seek the subject’s consent prior to offering the questionnaire.

4.17 The ERC should be flexible about consent procedures regarding questionnaires.

Retention of documents & confidentiality

4.18 Copies of consent forms should be kept separate from the case records and research records.

Personal medical records

4.19 Using personal records without involving or approaching the patients concerned is, in principle, ethically acceptable provided confidentiality and anonymity are preserved.

4.20 Normally, access to personal medical records for formal protocol based studies should be reviewed by the ERC. However, it need not be concerned with work that involves what amounts to quality control, medical audit or preliminary clinical appraisal. Normal practice regarding access to medical records should be followed. This involves seeking approval of clinicians responsible for the patients or in the case of information abstracted from personal records, the agreement of the custodian of that information.

Where patients having a particular condition are identified by scanning registers and it is planned to approach them with a view to research, this should be done via the patients’ personal/attending doctor.

Research without consent

4.21 Waivers and alterations of the informed-consent processes may be applicable for some of research studies. ERC will take the final dicision considering the criteria given in 4.22 and timely important and specific coniderations.

4.22 Waivers and alterations of the informed-consent processes can be considered for the rearch that meets all of the following conditions: (1) subjects are exposed to no more than minimal risk; (2) the waiver or alteration does not adversely affect subject rights and welfare; (3) the research would not be feasible without the waiver or alteration; and (4) subjects will be provided with additional pertinent information after participation, when appropriate.

Grave illness

4.23 In certain situations attempts to obtain consent can be impossible or devastating, for example in unconscious patients, acute grave illness or in those unable to comprehend. In such instances that the subject has incapacity to consent, researchers are expected to obtain proxy consent for most appropriate person.

Other circumstances

4.24 In circumstances of urgency, e.g. where the patient is seen with some rare and ill understood condition, the Chairperson of the ERC may act, always referring to the full committee as soon as practicable.

4.25 Where incapacity to consent is transient, explanation to the subject when he is able to receive it is desirable.

4.26 Blanket approval to withhold information from all subjects in a study can be justified only in the most exceptional circumstances.

Institute/university (*Use only if applicable*)

Name of the project

Sample Participant information sheet

We would like to invite you to participate in a research project. Please read this leaflet carefully, and if you have any questions about the survey do not hesitate to ask from the researcher. Feel free to discuss the project with your family or friends before you make a decision on participating.

Introduction

This is a study about _____.

This research project is collaboration between _____.

This research project is funded by the _____.

This project has been approved by the Ethics Review Committee of Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka.

Why have I been invited?

You have been selected for this study because _____.

Must I take part?

No. Participation is entirely voluntary. There is no obligation for you to take part, and if you do not want to take part, this will have no effect on your medical care, or affect you in any other way. It is also possible for you to withdraw from the interview or withdraw data at any point without giving any reasons and without any penalty. As we are conducting this research to improve knowledge about the _____ in Sri Lanka, we would greatly appreciate your participation.

What will the research involve? *(the procedure needs to be explained)*

We will ask you to take part in _____.

Are there any risks?

(Indicate any potential risks and psychological stresses)

Are there any benefits?

You will be paid/will not be benefited by participating in this study. However, information gathered from this study would help to develop new interventions. Therefore, similar patients or society may benefit in future. Compensation will be paied for research related injuries/ additional expenses to the participants will be covered, i.e. Rs._____ for teveling.

Will the information I give stay confidential?

Yes, all information you give is strictly confidential. The information you give may be used for a research report or publications, but it will not be possible to identify you in any way from this.
If we find that you may be having a significant health related issue, we will suggest and direct you to the necessary health care providers, but only with your permission (use only if applicable)

If you have any further questions please ask:
Investigators: _____
Telephone : _____

If you have any complaints about this research or its conduct please contact:
Secretary, Ethics Review Committee, Faculty of Medicine and Allied Sciences,
Rajarata University of Sri Lanka
Phone number: +94(0)25 2053633 (please contact during working hrs 8 am – 4 pm)
E-mail: ethicsreviewcommittee@gmail.com

Institute/university (*Use only if applicable*)

Name of the study

Participant Consent Form

Investigators	Telephone number	Address

Please circle your answer

Have you read the information sheet? Yes/No

Did you have an opportunity to ask questions and discuss about the study? Yes/No

Have you received satisfactory answers to the questions you asked about the project? Yes/No

Who explained the study to you? ……

Do you understand that you are free to leave the study without giving any reason? Yes/No

Did you agree to take part on your own wish? Yes/No

I understand that the information I give is confidential. Yes/No

I give my consent to take part in the study and this will include *(list the procedures)* Yes/No

Name ……

Signature ……..

Date ……

Name of the witness ……..

Signature ……

Date ……

If you have any complaints about this research or its conduct, please contact:

If you have any complaints about this research or its conduct please contact:

Secretary, Ethics Review Committee, Faculty of Medicine and Allied Sciences,

Rajarata University of Sri Lanka

Phone number: +94(0) 25 2053633 (please contact during working hrs 8 am – 4 pm)

E-mail: ethicsreviewcommittee@gmail.com

Ethics Review Committee

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Receipt of Acknowledgement of Application/ Corrections

PI Name:	Submission Date
Title of the Study:	
Application Number[1]: ERC / 20 /	Next Meeting Date[2]: 20 / / .....

[1] Please use above mentioned ERC Reference Number in all the future communications relate to this application.

[2] Next meeting date will be the tentative decision date and you will be informed within seven days after the meeting about the decision.

ERC Office

2nd Floor, Para-clinical Building

Faculty of Medicine and Allied Sciences

Rajarata University of Sri Lanka

Saliyapura.

Tel:+94 252053633

e-mail: ethicsreviewcommittee@gmail.com

	Ethics Review Committee Faculty of Medicine and Allied Sciences Rajarata University of Sri Lanka	**Annexure**	8
		Version:	4
	Annexure 8 **Index page of the "Master File"**	**Effective Date:**	01/01/2018
		Page (s):	89 - 90

No	**ERC/**	**Date Submitted**		**Date Approved**	
Principle Investigator					
Title					
Starting date	D D / M M / Y Y Y Y	**Finishing date**	D D / M M / Y Y Y Y		

Reviewers	**Technical (All documents)**	**Non-technical (ICF/PIS/Tools)**
	01. 02. 03.	01. 02. 03.

Risk Category	No Risk		Minimal Risk		Greater than Minimal Risk	
ERC Recommendation	Exempted from the Review		Expedited Review		Full Committee Review	

Date of the ERC Meeting			
Decision			

Approved (A) /Minor corrections (MIC) / Major corrections (MAC)/ Rejected (R)

Conditions	

Document	**Availability**			**Date of Submission**			
	Yes	**No**	**NA**	**Version 1**	**Version 2**	**Version 3**	**Version 4**
Application							
Research Proposal							
Instruments							

Information Leaflet							
Consent Form							

Date of Progress Rep.	1:	2:	3:	4:	5:
Date of Amendment	1:	2:	3:	4:	5:

Document Checklist	
Cover Letter	
Receipt of Payment	
Academic Supervisors' Letter	
Ethics approval form other Institution	
CV	
Reviewer 1's Comments	
Reviewer 2's Comments	
Extract of ERC Meeting Minutes	
Soft Copy	

Extensions (duration)	1:	2:
Date of Final Report		
Additional Remarks:		

Ethics Review Committee

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Proposal Evaluation Form

For official use	*ERC No:*	*PI name;*	*Date received;_ _ /_ _ /_ _ _ _*

		Yes	No	NA	Comment
Background and social value (Refer background and justification sections of the protocol)					
1	Background and justification – sufficient?				
2	Literature review – adequate?				
3	Need for human participation justified?				
4	Has the protocol been approved by a competent body?				
5	Should the study be referred to a technical or statistical expert?				
Scientific value (Refer methodology section of the protocol)					
6	Objectives – clear?				
7	Methodology – clear?				
8	Study design – appropriate?				
9	Sample size – adequate?				
10	Statistics used – appropriate?				
Subject selection (Refer methodology section of the protocol)					
11	Inclusion criteria – appropriate?				
12	Exclusion criteria – appropriate?				
13	Voluntary, non-coercive recruitment of participants				
14	Inducement for participation				
15	Vulnerable populations involved?				

	If yes, is it justifiable?				
Assessment of risk/benefits					
16	Researcher qualifications, competence and experience suitable for safe conduct of research?				
17	Risks: benefits assessment acceptable?				
18	Medical and psychological support for participants – adequate?				
19	Provision for treatment in study related injuries?				
20	Provision for compensation (where applicable)?				
Informed consent					
21	Procedures for obtaining informed (written/verbal) consent – appropriate?				
22	Information sheet and consent form contain clear and adequate details?				
23	Translations of all sheets/forms consistent?				
24	Contact details of PI available for participants on the information sheet?				
25	Arrangements for proxy consent – appropriate? (where applicable)				
26	Incentives offered – approved?				
Respect for participants and confidentiality					
27	Privacy and confidentiality of the participants – safeguarded?				
28	Participants' right to dissent, unconditional withdrawal safeguarded?				
29	Data/ sample storage and disposal procedures appropriate?				
Independent review					
30	Disclosure or declaration of potential conflicts of interest				
Is all the documentation provided?					
Paticipant Information Sheet		**Need Further Modifications/ Adequate**			
Informed Consent Form		**Need Further Modifications/ Adequate**			

Recommendation	**Approved /Minor corrections / Major corrections/ Rejected**

Additional comments:

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Name of the reviewer: ……

Signature:…….

Date:……..

Date:

……..

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……..

Dear …….

Letter of ERC Decision on Application No. ERC/ / .

Ethics review committee reviewed your application and arrived at following decision at the meeting held on ……...,:

1. approved
2. minor corrections required
3. major corrections required
4. rejected

The summary of reviewer comments/suggestions are attached. Therefore, you may:

1. obtain the ethical clearance certificate from the ERC office
2. submit corrections with all relevant documents and a cover letter with point by point clarifications to all reviewers' comments (in three copies)

Thanking you.

Yours sincerely,

Secretary/ ERC

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Ethics Review Committee

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Ethical Approval Letter

Project Title:		
Principal investigator(s):		**ERC application number:**
		Approval Date:
Co-investigator(s):		**Approval Expiry Date:** ERC approval is for one year from the date of approval. Renewal could be obtained (if required) after submitting a request letter along with the annual progress report.

Documents approved and version:

Documents	**Version**					
Research Proposal						
Participant information sheet	**English**		**Sinhala**		**Tamil**	
Consent form	**English**		**Sinhala**		**Tamil**	
Advertisement	**English**		**Sinhala**		**Tamil**	
Questionnaire	**English**		**Sinhala**		**Tamil**	

Study period: From :	**To:**
Coditions of Approval:	

This letter of approval is valid for the above term provided there is no change in the research proposal, participant information sheet, consent form, advertisement or Questionnaire(s). Any protocol deviation should be informed to the ERC promptly.

ADVERSE EFFECTS OR UNFORESEEN EVENTS: The researchers should notify ERC immediately of any serious or unexpected adverse effect on participants or unforeseen events affecting the ethical acceptability of the project.

COMPLAINTS: The researchers are required to inform ERC promptly of any complaints made or expressions of concern are raised, in relation to the project.

AMENDMENTS & EXTENSIONS: The researchers are required to submit a request for amendment/extension to ERC. Substantial variations may require a new application.

FINAL REPORT: Final report should be submitted to the ERC within 3 months of completion of the study

MONITORING: Projects may be subject to an audit or any other form of monitoring by ERC at any time.

_____ Date:

Chairperson
Ethics Review Committee
Faculty of Medicine and Allied Sciences
Rajarata University of Sri Lanka

Ethics Review Committee

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Ethical Approval Letter for Amendments / Extensions

Project Title:	
Principal investigator(s):	**ERC application number:** **Approval Date:**
Co-investigator(s):	**Approval Expiry Date:** ERC approval is for one year from the date of approval. Renewal could be obtained (if required) after submitting a request letter along with the annual progress report.

Documents approved and versions:

Documents	**Version**					
Research Proposal						
Participant information sheet	**English**		**Sinhala**		**Tamil**	
Consent form	**English**		**Sinhala**		**Tamil**	
Advertisement	**English**		**Sinhala**		**Tamil**	
Questionnaire	**English**		**Sinhala**		**Tamil**	

Study period: From : **To:**
Coditions of Approval: All conditions mentioed in the 'Ethical Approval Letter' are applicable.
_____ Date: Chairperson Ethics Review Committee, Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Form to report Suspected Unexpected Serious Adverse Reaction (SUSAR) / Serious Adverse Event (SAE)

1. ERC protocol number:

2. Subject's details

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

3. Suspected investigational medicinal product(s)

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

4. Causality assessment

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

5. Other treatment(s):

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

6. Details of suspected Adverse Drug Reaction(s)

- Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious should be given. In addition to a description of the reported signs and symptoms, whenever possible attempts should be made to establish a specific diagnosis for the reaction:
- Setting (e.g. hospital, out-patient clinic, home, nursing home):
- Outcome: information on recovery and any sequelae; what specific tests and/or treatment may have been required and their results; for a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction should be provided. Any autopsy or other post-mortem findings (including a coroner's report) should also be provided when available:
- Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse, family history, findings from special investigations:

7. Details on reporter of event/suspected adverse reactions

- Name:
- Address:
- Telephone number:
- Email address:
- Profession (specialty):

8. Administrative and Sponsor details:

- Date of this report:
- Source of report: from a clinical trial / from the literature (provide copy) / spontaneous / other
- Date event report was first received by sponsor:
- Country in which reaction occurred:
- Type of report filed to authorities: initial or follow-up (first, second, etc)
- Name and address of sponsor / manufacturer / company:
- Name, address, telephone number and fax number of contact person in reporting sponsor:
- Case reference number (sponsor's/manufacturer's identification number for the case) (this number must be the same for the initial and follow-up reports on the same:

Ethics Review Committee

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Format for progress report

A. Title of the project:
B. ERC number:
C. Principle investigator:
D. Duration for which the report is submitted:
E. Date of commencement of the study:
F. Number of previous progress reports submitted for the same study:
G. Research work conducted (briefly explain the following)
    i. Objectives
    ii. Methodology in brief
    iii. Progress to date / outcome:
    iv. Maintenance & security of records:
    v. Steps taken to maintain confidentiality:
    vi. Informed consent procedure:
    vii. Compliance with the approved protocols:
    viii. Compliance with conditions of approval:
    ix. Any deviations/violation from the approved protocol:
    x. Reasons for deviations/violation:
H. Work planned for next one year:

Ethics Review Committee

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Format for Final report

A. Title of the project:
B. ERC number:
C. Principle investigator:
D. Duration of the study:
E. Date of commencement:
F. Number of previous progress reports submitted for the same study:
G. Date of completion:
H. Any extensions done:
I. Reasons for extension:
J. Research work conducted (briefly explain the following)
    i. Objectives
    ii. Methodology in brief
    iii. Progress to date / outcome:
    iv. Maintenance & security of records:
    v. Steps taken to maintain confidentiality:
    vi. Informed consent procedure:
    vii. Compliance with the approved protocols:
    viii. Compliance with conditions of approval:
    ix. Any deviations/violation from the approved protocol:
    x. Reasons for deviations/violation:

K. Details of dissemination of results (Full paper publications, abstracts, etc)

Premature Termination Report

Application number:	
Title:	
Name of PI:	
Contact Number and email address:	
Study site:	
Sponsor:	
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 failures: • Enrolled: • Consents withdrawn and reasons: • Withdrawn by PI and reasons: • 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 numbers:	
SAE events:	
PI signature:	Date:

Ethics Review Committee

Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Evaluation Form for Ethics Review Process

ERC No:	Reviewer: First/Second/Third		Date assessed:		
		Yes	**No**	**NA**	**Remarks on reviewers comments**
Background and social value (Refer background and justification sections of the protocol)					
1	Background and justification – sufficient?				
2	Literature review – adequate?				
3	Need for human participation justified?				
4	Has the protocol been approved by a competent body?				
5	Should the study be referred to a technical or statistical expert?				
Scientific value (Refer methodology section of the protocol)					
6	Objectives – clear?				
7	Methodology – clear?				
8	Study design – appropriate?				
9	Sample size – adequate?				
10	Statistics used – appropriate?				
Subject selection (Refer methodology section of the protocol)					
11	Inclusion criteria – appropriate?				
12	Exclusion criteria – appropriate?				
13	Voluntary, non-coercive recruitment of participants				
14	Inducement for participation				
15	Vulnerable populations involved? If yes, is it justifiable?				
Assessment of risk/benefits					
16	Researcher qualifications, competence and experience suitable for safe conduct of research?				

17	Risks: benefits assessment acceptable?				
18	Medical and psychological support for participants – adequate?				
19	Provision for treatment in study related injuries?				
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Respect for participants and confidentiality					
27	Privacy and confidentiality of the participants – safeguarded?				
28	Participants' right to dissent, unconditional withdrawal safeguarded?				
29	Data/ sample storage and disposal procedures appropriate?				
Independent review					
30	Disclosure or declaration of potential conflicts of interest				
Is all the documentation provided?					
Final recommendations					

Additional comments:

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Name of the Evaluator :

Sub-committee : Internal evaluation / External evaluation

Signature :

Date

Ethics Review Committe
Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

Translation Evaluation Form

Please consider that you are the person being invited to participate in this research.

Are explanations given on following information clear to you		Yes	No
1.	What kind of study is this		
2.	Why you have been invited		
3.	Why should you consider to participate in this research study		
4.	Data collection procedure involving you		
5.	Risks you are exposed		
6.	Benefits you will receive from the study		
7.	Confidentiality of the information you provide		
8.	Whom to contact if there are any concerns		
9.	Participant information leaflet		
10.	The advertisement (if available)		
11.	Are the questions in the study tool clear to you		

Additional comments:

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Language of the translation: ☐ **Sinhala** ☐ **Tamil**

Name of the reviewer :
Signature :
Date :

Ethics Review Committee
ERC Office, 2nd Floor, Para-clinical Building
Faculty of Medicine and Allied Sciences
Rajarata University of Sri Lanka
Saliyapura, Anuradhapura, Sri Lanka

Tel:+94 252053633
e-mail: ethicsreviewcommittee@gmail.com
website: http://www.rjt.ac.lk/med/index.php/ethic-review-committee