STANDARD OPERATING PROCEDURES

ETHICS REVIEW COMMITTEE

Faculty of Medical Sciences

University of Sri Jayewardenepura

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History

The University originated as Vidyodaya Pirivena in 1873 and was granted university status in 1958. Since then USJ has evolved into one of the leading universities in the country. USJ has eight faculties of study.

The Faculty of Medical Sciences was established in 1993 as the 6th Medical faculty in Sri Lanka. The Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura was established in 1995 to provide ethical oversight for studies done by academics of Faculty of Medical Sciences, University of Sri Jayewardenepura with affiliated as well as non-affiliated members. The scope of review is related to research conducted by academic and non-academic staff of FMS/USJ, students of the Faculty of Graduate Studies, USJ, Medical Officers from the Ministry of Health and undergraduate studies of FMS, USJ.

The objective of the ERC is to maintain ethical standards of practice in research, including protection of potential human participants and other living or genetically modified organisms while taking into account the needs of the researchers and the integrity of FMS/USJP.

Animal research was reviewed till 2018 after which such proposals are referred to the Animal welfare and research subcommittee of the Faculty of Medicine, University of Colombo. ERC/FMS/USJ It is recognized by the Ministry of Health as one of the 9 ERCs empowered to grant ethics approval for Phase 2 and Phase 3 Clinical Trials to be conducted in Sri Lanka. It is also recognized by SLCTR to grant ethics approval for trials that need to be registered in the Clinical trial registry.

The Standard Operational Procedures for ERC was prepared in May 2012 and incorporated changes suggested by SIDCER review in September 2012 as the version 2. Subsequently it was further revised in May 2015 (version 3) after the second SIDCER Review for improving the ERC functions, which is currently being used. The ERC/FMS received the first SIDCER recognition from FERCAP in 2012 and re-recognition in 2015. The ERC was reviewed again in 2019. The current Standard Operational Procedures is version 4, prepared taking into account comments made at that review.

Abbreviations

AEs	Adverse Events
CIOMS	Council for International Organizations of Medical Sciences
Co-PI	Co- principal Investigator
CP	Chairperson
CRF	Case Report Form
CRO	Clinical Research Organization
DoH	Declaration of Helsinki
DSMSC	Date and Safety Monitoring Committee
ERC, FMS/USJ	Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura
FERCSL	Forum of Ethics Review Committees in Sri Lanka
ICH GCP	International Conference on Harmonization, Guidance on good Clinical Practice
IRC	Incident Review Committee
PI	Principal Investigator
SAEs	Serious Adverse Events
SLCTR	Sri Lanka Clinical Trials Registry
SMC	Site Monitoring Committee
SOP	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reactions
TOR	Terms of Reference
VC	Vice Chancellor
WMA	World Medical Assembly

1.1. Purpose

The purpose of SOP is to describe the procedure for the process of preparing, reviewing, distributing and amending SOPs within the ERC FMS/USJ.

1.2. Scope

This SOP covers the procedures of preparing, reviewing, distributing and amending SOPs within the ethics committees of ERC FMS/USJ.

1.3. Responsibility

It is the responsibility of the chairperson of ethics committee to appoint the SOP Team from ERC members, to formulate the SOPs by following the same procedures, format and coding system when drafting or editing any SOP of the institute.

1.4 Detailed instructions

1.4.1 The Standard Operating Procedures shall be reviewed at least every three years and amended as necessary.

1.4.2 The Standard Operating Procedures may be amended for proposals made by an ERC member, proposals made by Dean and faculty board or any other purpose depending on requirements of new guidelines or regulations.

1.4.2.1 For those proposals made by an ERC member:

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

1.4.2.2 For those proposals made by the Dean and Faculty Board:

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

1.4.2.3 Based on new guidelines and regulations nationally and internationally.

2.1 Purpose

The Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura (ERC, FMS/USJ) is established in order to provide independent advice and monitoring on health research or other specific research protocols involving human participants.

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

2.2 Scope

The SOP applies to all activities under the ERC, FMS/USJ.

2.3 Responsibility

It is the responsibility of the ERC, FMS/USJ members to read, understand and respect the policies set by ERC of the Faculty of Medical Sciences, University of Sri Jayewardenepura.

2.4 Detailed instructions

Overall Function:

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

Responsibilities:

2.4.2 ERC, FMS/USJ will

- advise the FMS/USJ on all matters relating to the ethics of human research.
- review proposals for research involving human participant's taking care that all the cardinal principles of research viz. autonomy, beneficence, non-maleficence and justice are adhered to in research proposals.
- make a monthly report to the Faculty Board of the FMS/USJ, which should be made available to the public on request.

2.4.3 ERC, FMS, USJ will not act as a research funding or grant giving committee.

2.4.4 The ERC, FMS/USJ will review all types of research proposals involving human studies conducted by the following;

- staff and students of the University of Sri Jayewardenepura.
- members of the extended Faculty of the FMS, USJ which consists of consultants in the teaching hospital and Institutions attached to the FMS/USJ
- Post Graduate students of University of Sri Jayewardenepura
- Medical officers of the Ministry of Health

2.4.5 All applications will be subject to a handling charge as decided by the Faculty Board of FMS/USJ.

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

2.4.7 ERC, FMS/USJ 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.

2.4.8 ERC, FMS/USJ will not entertain any request by a clinician/s with an ethical problem of medical practice (not pertaining to research) as it falls outside the purview of the ERC.

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3.1. Purpose

To describe the membership composition of the ERC.

3.2. Scope

The ERC, FMS/USJ 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, FMS/USJ.

3.3. Responsibility

The SOP applies to all activities under the ERC, FMS/USJ. ERC members will be appointed by the Vice Chancellor, USJ upon recommendations of the dean/ FMS and will have the authority to review protocols submitted by any member of USJ. Letters of appointment to all members are issued by the Vice Chancellor, USJ.

3.4 Detailed Instructions

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

3.4.2 The committee will comprise of at least eleven (11) and not more than nineteen (19) members.

3.4.3 The membership will comprise of the following categories:

- Members from FMS/USJ – both medical and non-medical members
- Members representing the University of Sri Jayewardenepura (excluding academic members of the FMS)
- Scientific or medical members from institutions other than USJ
- Lay non-scientific members
- A lawyer – essential

3.4.4 The committee strives to ensure that there is a gender balance in its composition.

3.4.5 A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least seven (7) members including Chairperson, Secretary and at least one non-medical and one non-affiliated member are present.

3.4.5 A subject expert roster will be maintained

4.1. Purpose

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

4.2. Scope

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

4.3. Responsibility

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

4.4. Detailed instructions

4.4.1 ERC members will be appointed by the Vice Chancellor (VC), USJ upon recommendations of the Dean, FMS and will have the authority to review protocols submitted by any member of USJ.

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

4.4.3 Prospective members of the ERC, FMS/USJ may be recruited by direct approach, nomination or by advertisement. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their names and professions being made available to the public, including being published on the ERC website.

4.4.4 A selection committee, consisting of the Chairperson and at least one other ERC member shall interview the prospective applicant, consult with the ERC members and make a recommendation to the Dean and the Faculty Board. The letters of appointment will be issued by the Vice Chancellor USJ upon recommendations of the Dean FMS. Prospective members may be invited to attend a meeting of the ERC as observers. Such persons will be expected to sign the confidentiality undertaking as per SOP 004/19 - 4.4.8.

4.4.5 The committee shall **elect** its Chairperson and Secretary from among its members and inform the Dean and Faculty Board for approval. An individual should have at least three years' experience as a member of the FMS/USJ ERC to be eligible to be elected to the post of Chairperson.

An Alternate Chair and Alternate Secretary will be nominated by the committee, to fulfill their duties in case of their absence for the given meeting.

4.4.6 Upon recommendations of the ERC, the Dean and the Faculty Board, the Vice Chancellor will **appoint** the Chairperson and the Secretary. They will receive formal notices of appointment.

4.4.7 The letter of appointment (Annexure 1) shall include the date of appointment, length of tenure, TOR, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as an ERC member, the circumstances whereby membership may be terminated and the conditions of appointment.

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

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

- Appointment letter including the Term of Reference (TOR)
- ERC Standard Operating Procedures (SOPs)

4.4.10 Duration of membership will be for a period of three years. Members are eligible for re-appointment. At the end of three (03) years the committee is reconstituted and the new committee should comprise of at least seven (07) who have a minimum of two years' experience as members of previous ERC"s to maintain the expertise with the view to facilitate the efficient functioning of the ERC.

4.4.11 New members are expected to attend training sessions within 6 months after their appointment.

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

4.4.13 Members may seek a leave of absence from the ERC for extended periods.

4.4.14 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. This should be informed to the ERC in writing prior to commencement of the ERC meeting for which the member is going to be absent.
- The Chairperson will notify the member of such lapse of membership in writing. The Chairperson will also inform the Dean who will recommend to the Vice Chancellor and steps shall be taken to fill the vacancy.

4.4.15 Membership will lapse if a member fails to attend in full at least two thirds of all scheduled ERC meetings in each year, barring exceptional circumstances.

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

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

4.4.18 Vacancies in the ERC will be filled as per SOP/004/19, 4.4.2 and 4. 4.3.

5.1. Purpose

To describe the functions of members of the ERC.

5.2. Scope

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

5.3. Responsibility

It is the responsibility of the ERC, FMS/USJ members to read understand their functions as members of the ERC, FMS/USJ.

5.4 Detailed instructions

The Chairperson and the Secretary of the ERC are expected to perform duties as detailed below:

5.4.1 Chairperson:

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

5.4.2 Secretary

- Organizing the meetings, maintaining records and communicating with all concerned.
- 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.
- Ensure that membership files are current and up to date.
- Assign primary reviewers for applications in consultation with the Chairperson and co-ordinate the review process.
- Provide guidance and supervision to the ERC office staff.
- Perform any other duties of the ERC assigned by the Chairperson.

- Review applications if assigned.

5.4.3 *All members of the ERC, FMS/USJ:*

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

5.4.4 ERC Office Staff:

A designated administrative secretary will be appointed for ERC, and in the absence such staff the functions of the office staff is handled by the Secretary/ERC

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

6.1. Purpose

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

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

6.2. Scope

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

6.3. Responsibility

It is the responsibility of new ERC members of the ERC, FMS/USJ to read and understand their functions as members of the ERC of the Faculty of Medical Sciences, University of Sri Jayewardenepura. It is the responsibility of all members to have themselves educated and trained periodically.

6.4 Detailed instructions

6.4.1 New ERC members must be provided with adequate orientation within 6 months

6.4.2 New member orientation will include the following:

- Introduction to other ERC members prior to the ERC meeting.
- Informal meeting with the Chairperson, Secretary and Officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures.
- An opportunity to sit in on ERC meetings before their appointment takes effect. Priority given to participate in training sessions.

6.4.3 The new members will receive training within 6 months of being appointed in:

- Research ethics and human participant's protection
- Standard Operating Procedures of the committee
- GCP

6.4.4 Obtaining training

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

7.1. Purpose

To provide procedures for engaging the expertise of a professional as a consultant to the ERC, FMS/USJ.

7.2. Scope

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

7.3. Responsibility

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

7.4 Detailed instruction

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

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

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

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

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

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

7. 4.7 A roster of experts will be maintained in the ERC office to select necessary experts.

8.1. Purpose

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

8.2. Scope

This SOP is only meant for new proposals.

8.3. Responsibility

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

8.4. Detailed instructions

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

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

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

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

8.4.4 All applicants will incur a handling charge as decided by the Faculty Board of FMS/USJ. Handling charges for undergraduate student protocols conducted as a direct requirement of course work will be waived at the discretion of the ERC.

8.4.5 All applications for ethical review must be submitted to the office of the ERC by close of business on the last working day of each month.

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

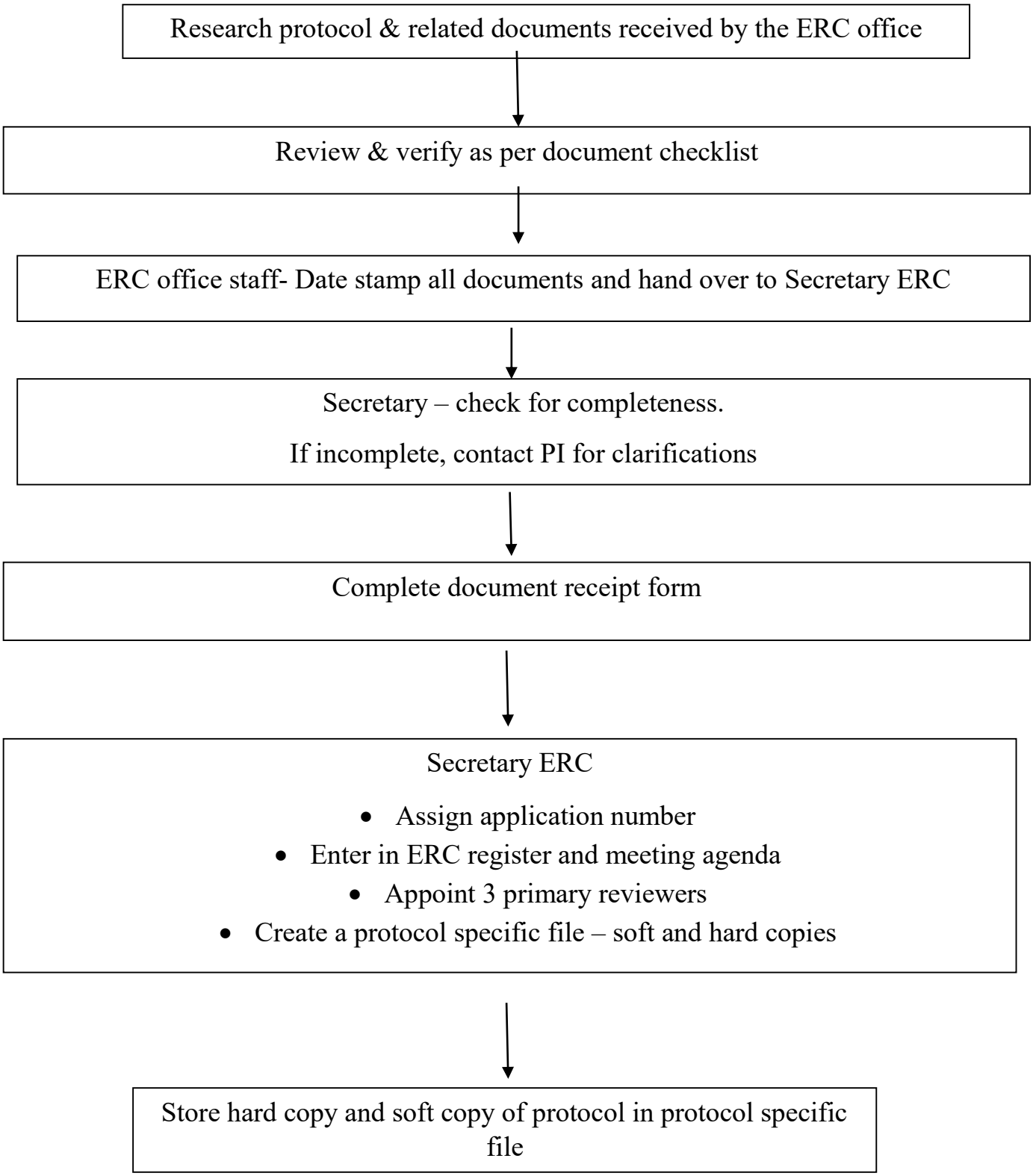
8.4.7 ERC office / Secretary will review and verify documents as per check list. Incomplete applications will be returned to applicant. Once the application is complete, ERC office will date stamp all documents

8.4.8 The ERC office will get the signature of the PI acknowledging the receipt of the application.

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

8.4.10 Secretary shall, in consultation with the Chairperson, appoint 3 primary reviewers for each project. Out of the three primary reviewers two shall be subject experts and the other a non-medical member.

Submission of Procedure of Application



9.1. Purpose

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

9.2. 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

9.3. Responsibility

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

9.4. Detailed instructions

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

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

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

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

9.4.5 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.

9.4.6 Agenda items will include at least the following items (Annex 5):

- Apologies
- Conflict of interest
- Minutes of the previous meeting
- Matters arising from the previous minutes
- New applications
- Expedited Review
- Exempt from Review
- Progress Reports and requests for extension.

- Amendments
- Study completion reports
- SAE/ SUSARs
- Correspondence
- Any other matters
- Close and next meeting

10.1. Purpose

To describe the conduct of ERC meetings.

10.2. Scope

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

10.3. 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.

10.4. Detailed instructions

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

10.4.2 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.

10. 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 seven (7) members including Chairperson, Secretary at least one non-medical and one non-affiliated member are present.

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

10.4.5 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.

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

10.4.7 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.

10.4.8 Notwithstanding item 10.4.7, the ERC may agree to the presence of visitors or observers at a meeting. Visitors or observers will be expected to sign a confidentiality agreement with ERC prior to attending ERC meeting.

10.4.9 Any member of the ERC who has COI in a project or other related matter(s) considered by the ERC must declare such interest beforehand. This will be dealt with in accordance with SOP/011/19.

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

11.1. Purpose

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

11.2. Scope

This SOP covers the agreement on conflict of interest concerning information and procedures at the time of becoming a member of ERC and during the meetings.

11.3. Responsibility

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

11.4 Detailed instruction

11.4.1 An ERC member shall sign a COI agreement upon induction to the committee.

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

11.4.3 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.

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

12.1. Purpose

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

12.2. Scope

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

12.3. Responsibility

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

12.4. Detailed instructions

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

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

12.4.3. Primary reviewers would:

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

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

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

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

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

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

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

12.4.9 Decision making process:

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

12.4.10 Chairperson's approval

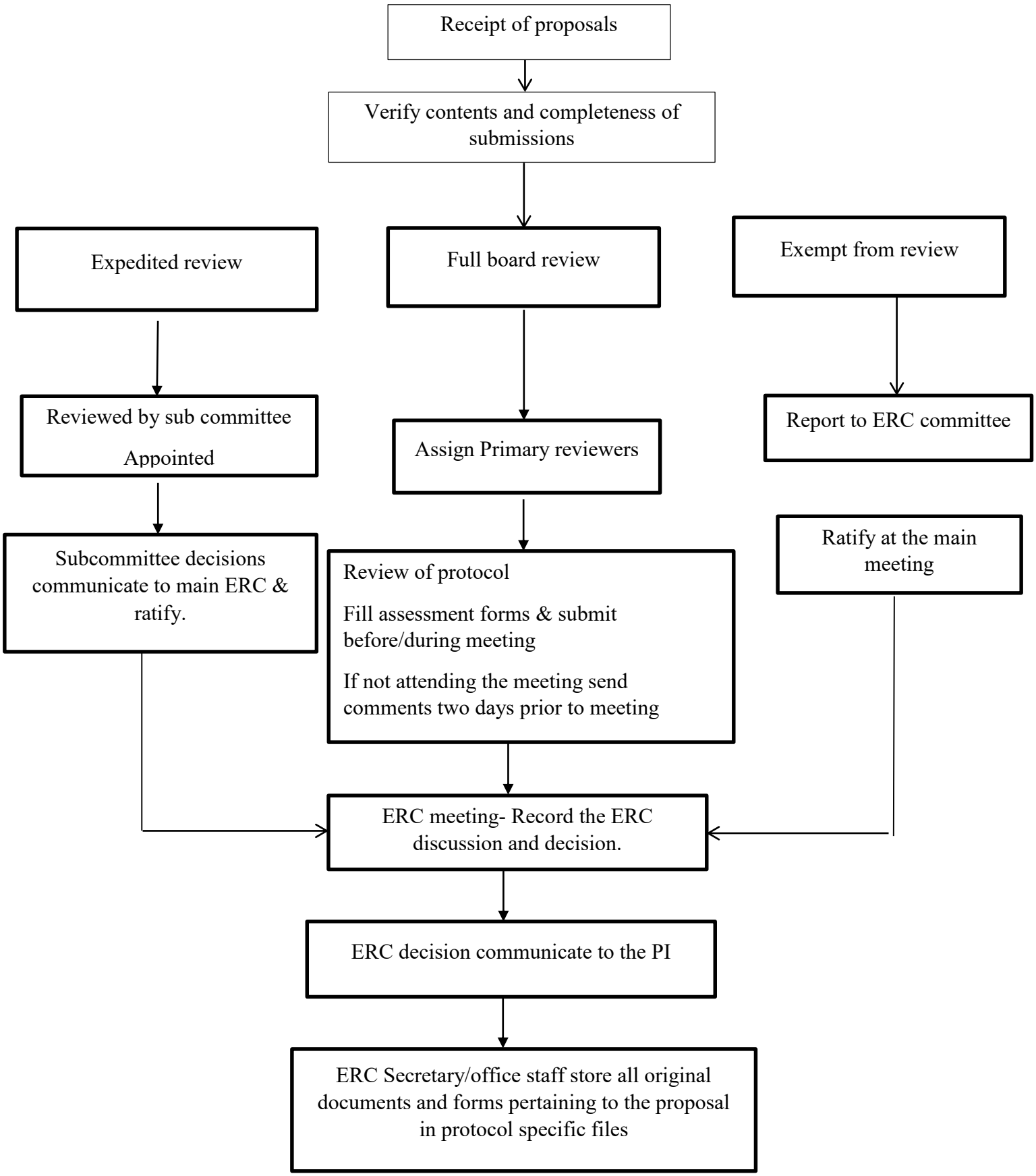
For proposals which the ERC considers ethically acceptable with conditions, it may delegate the authority to review the applicant's response and give final approval to one of the following:

- Minor revisions by Chairperson or designated member/s
- Major revisions full board review

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

12.4.12 The ERC may exempt protocols from review (SOP/014/19) or conduct expedited review of protocols in accordance with SOP/015/19).

Initial Review of Submitted Protocol



13.1. Purpose

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

13.2. Scope

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

13.3. Responsibility

It is the responsibility of the ERC Secretary / Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson. If it is a minor revision re-submitted protocol may be reviewed and approved by either the Chairperson or designated member/s of the ERC and if it is a major revision, full committee will review and approve the protocol. How the protocol will be reviewed should have been determined by the ERC at the time of the initial review.

13.4. Detailed instructions

13.4.1 The received protocol resubmitted package should contain:

- a table indicating the corrections made.
- revised version of protocol with highlighted changes.
- related documents such as the informed consent document, data collection or case report forms.

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

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

Those that do not require full board review will be considered for expedited review.

13.4.4 For protocols which the ERC considers ethically acceptable with conditions / modified documents, the ERC may choose to delegate the authority to review the applicant's response and give final approval for the project to proceed to the Chairperson or designated member/s of the ERC

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

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

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

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

13.4.9 All clarifications should reach the Secretary, ERC on or before 15th day of each month to be considered at the monthly meeting for that month.

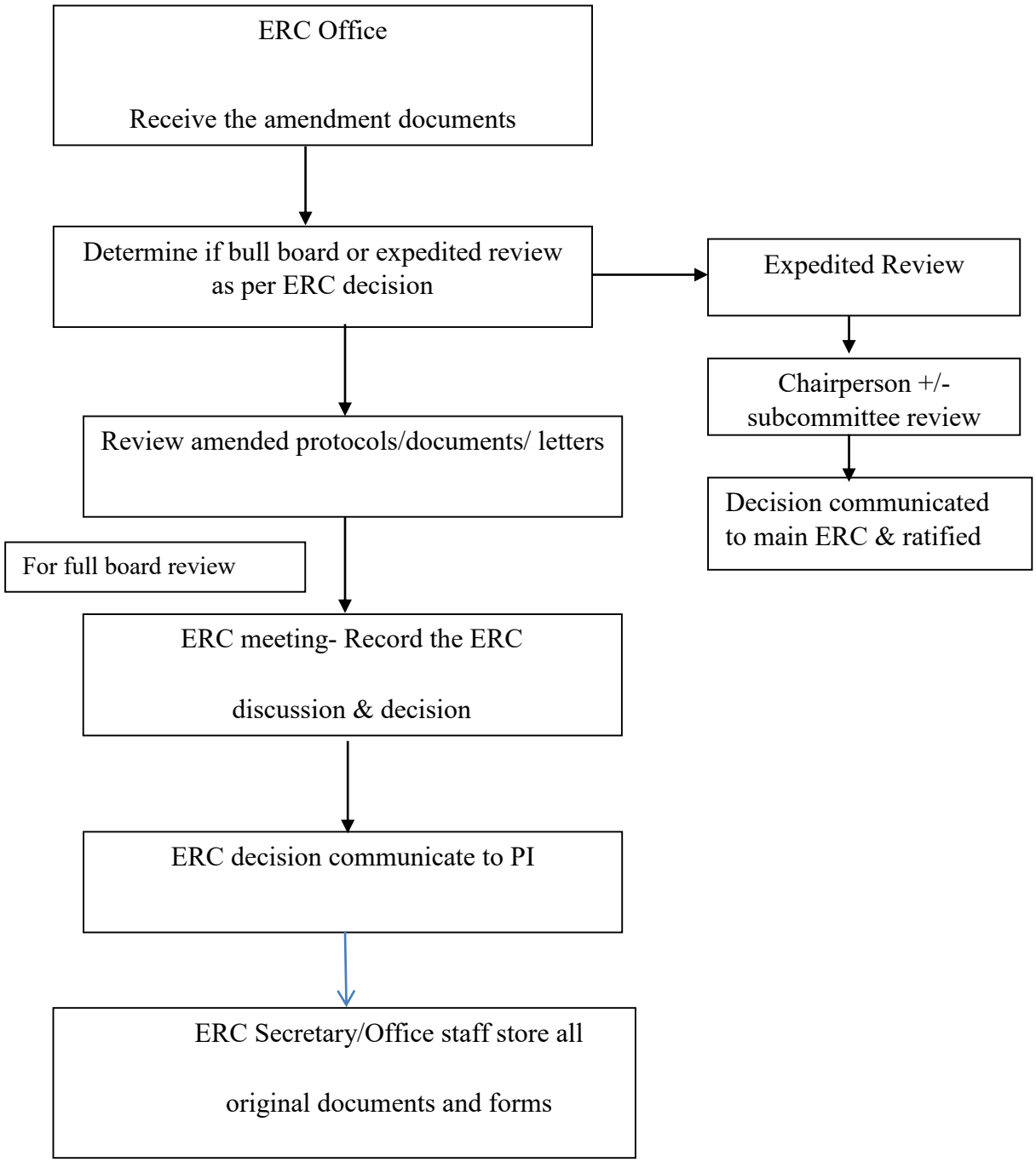
13.4.10 If there is no response from PI after 3 consecutive reminders the file will be closed. The period may be extended upon request by a PI if the ERC considers the reasons for extension valid.

13.4.11 If the ERC previously decided to see the new revision, the revisions will be sent to the original primary reviewers for comments.

13.4.12 The revised protocol will be discussed at the next scheduled ERC meeting where the primary reviewer presents a brief oral or written summary and his/her comments to the ERC members and the Chairperson entertains discussion on the protocol revision. Further recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the Committee are noted in the meeting minutes will be communicated to the Principal Investigator. Once the major revision is accepted by the ERC, then the approval will be communicated to the PI as given in the flow chart.

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

Review of Resubmitted Protocols



14.1. Purpose

The purpose of this SOP is to identify the administrative process for exempting a protocol from ERC review.

14.2. Scope

This SOP applies to protocols that may be exempt from review at a full ERC meeting and to be considered by the Chairperson and Secretary.

14.3. Responsibility

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

14.4 Detailed instructions

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

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

b. Educational research proposals are exempt providing all of the following conditions are met:

- All of the research is conducted in a commonly accepted educational setting (e.g. public school).
- The research involves normal educational practices (e.g. comparison of instructional techniques).
- The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existent at the study site.
- The study procedures involve no increase in the level of risk or discomfort associated with normal, routine educational practices.
- The study procedures do not involve sensitive subjects (e.g. sex education).

- Provisions have been made to ensure the existence of a non-coercive environment for those students who choose not to participate.
- The school or other institution grants written approval for the research to be conducted.

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

14.4.1.1 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(a) information obtained is recorded in such a manner that human participants can be identified, directly, or through identifiers linked to the participants; and

(b) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk for criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

NOTE: Sensitive survey research is not exempted. A sensitive survey is one that deals with sensitive or highly personal aspects of the participant's behaviour, life experiences or attitudes. Examples include chemical substance abuse, sexual activity or attitudes, sexual abuse, criminal behaviour, sensitive demographic data, detailed health history, etc. The principal determination of sensitivity is whether or not the survey research presents a potential risk to the participant in terms of possible precipitation of a negative emotional reaction. An additional risk consideration is, of course, whether or not there is risk associated with a breach of confidentiality should one occur.

With respect to potential psychological risk associated with a survey, the presence or absence of participant identifiers is not necessarily a consideration since the risk may be primarily associated with the sensitive nature of the survey as opposed to being dependent upon confidentiality. Participant identifiers do, however, become a factor when confidentiality is an issue.

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

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

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

14.4.1.3 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, cadavers or death certificates if these sources are publicly available or if the information is recorded by the

investigator in such a manner that participants cannot be identified directly or through identifiers linked to the participants.

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

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

14.4.1.5 Taste and food quality evaluation and consumer acceptance studies:

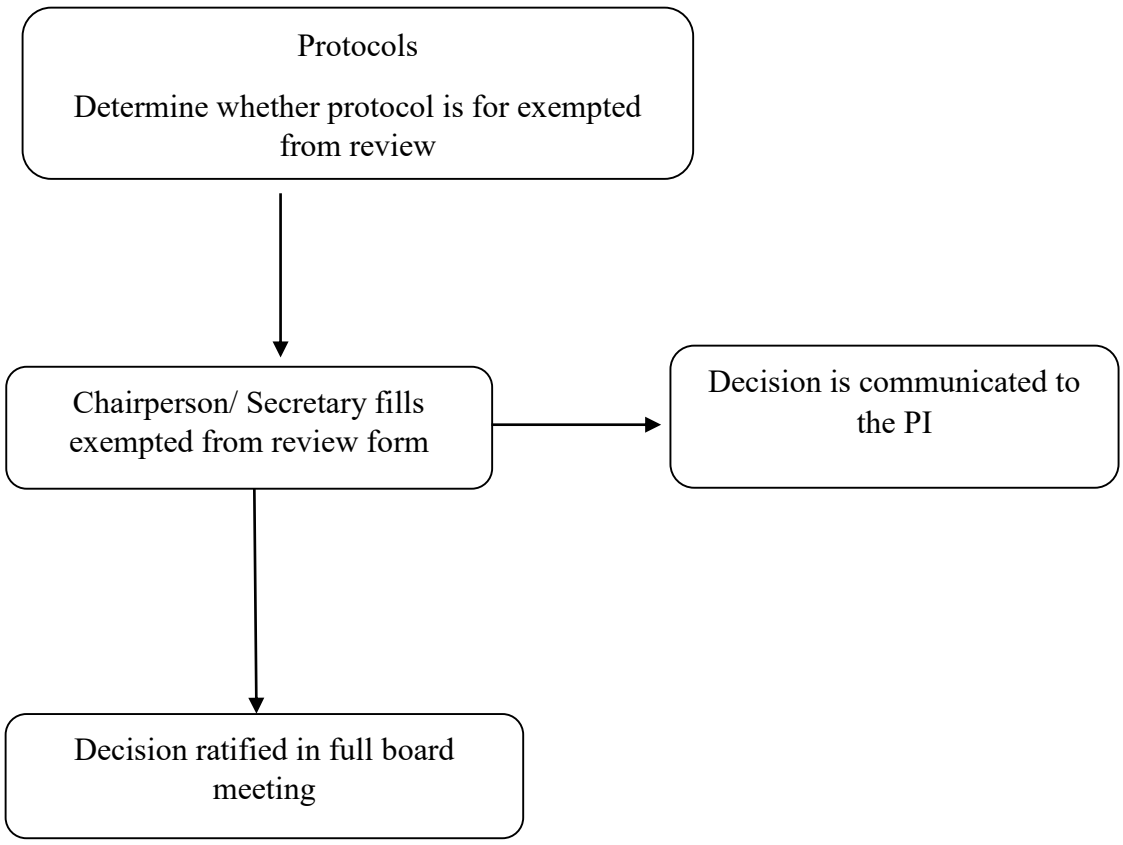
- if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

14.4.1.6 Research on microbes cultured in the laboratory and research on immortalized cells

14.4.2 If the Chairperson or Secretary finds that the protocol needs to be submitted for a full board evaluation, it would be forwarded to the next available meeting and the decision will be conveyed to PI. The protocol will be reviewed as per SOP/013/19

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

Exempted from review



15.1 Purpose

The purpose of this SOP is to identify the administrative process of preparing for an Expedited Review Procedure.

15.2 Scope

This SOP applies for the following instances.

15.2.1 To review protocols identified for expedited reviews, such as those with minimal risk.

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

15.3 Responsibility

The ERC Chairperson will appoint a subcommittee to evaluate such proposals.

15.4 Detailed instructions

15.4.1 Expedited review of research protocols may be undertaken between scheduled meetings, at the discretion of the Chairperson and the Secretary. A subcommittee will be appointed for this purpose and shall consist of either the Chairperson or the Secretary and two other ERC members. The committee may seek views of suitably qualified experts if needed (as per SOP/007/19) before reaching a decision.

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

- Research involving materials (data, documents, records, or 15.specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies where the

investigator does not manipulate the participants behaviour and the research will not involve stress to the participant.

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

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

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

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

15.4.6 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 and the like.

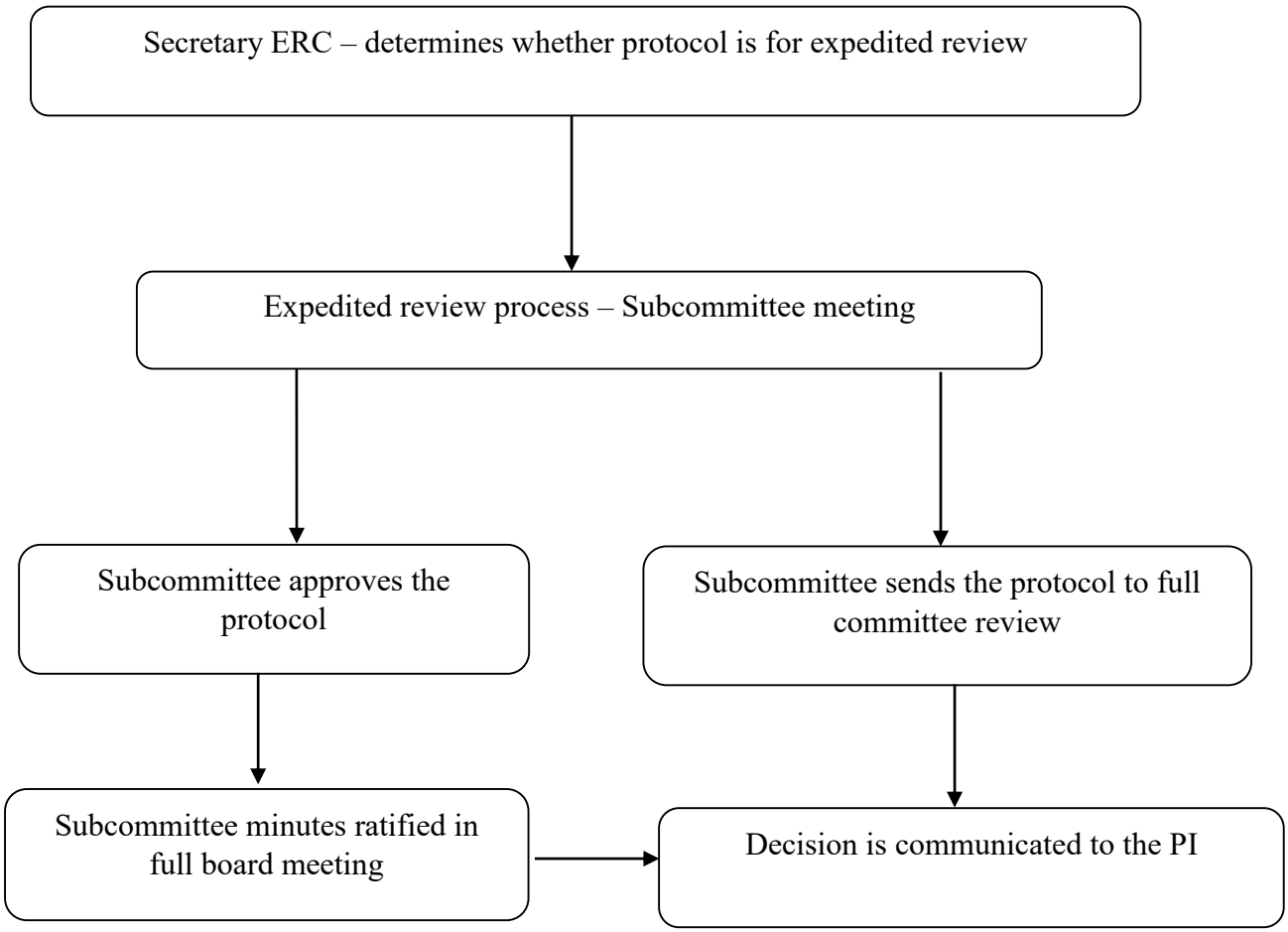
15.4.7 A summary of the matters dealt with at Sub Committee meetings will be included in the agenda for the next ERC meeting.

15.4.8 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.

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

15.4.10 A standard approval letter will be issued.

Expedited Review



16.1 Purpose

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

16.2 Scope

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

16.3. Responsibility

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

16.4 Detailed instructions

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

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

16.4.3 Where an urgent protocol amendment is required for safety reasons, the Chairperson may review and approve the request. In such circumstances, the ERC will review the decision at its next meeting.

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

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

16.4.6 If the ERC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required.

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

17.1 Purpose

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

17.2 Scope

This SOP applies to all communicating activities related to the studies under the approval of the ERC FMS/USJ.

17.3 Responsibility

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

17.4 Detailed instructions

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

17.4.2 If the ERC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the principal investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the FERCSL Guidelines or other relevant documents including legislation. A standard letter will be issued, in the format set out in Annex 10.

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

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

- title of the project
- name of the principal investigator(s), Co-Investigators and Supervisors
- unique ERC project identification number
- version number and date of all documentation reviewed and approved by the ERC including clinical protocols, patient information sheets, consent forms, advertisements, questionnaires etc.
- Date of ERC meeting at which approval was given.
- conditions of the ERC's approval, if any
- duration of the ERC's approval
- frequency of progress reports
- SAE, protocol deviation/protocol violation/noncompliance and

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

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

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

18.1. Purpose

The purpose of this SOP is to describe the procedure for the reporting and handling of serious adverse events (SAEs)

18.2. Scope

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

18.3. 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

18.4. Detailed instructions

18.4.1 The ERC shall require, as a condition of approval of each project that researchers immediately report Suspected Unexpected Serious Adverse Events (SUSAR) or Serious Adverse Events (SAE) to the ERC, including those that have occurred at other institutions participating in the study.

A "serious adverse event" means any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease, whether or not caused by the use of the test material which;

- results in death,
- is life-threatening,
- requires in-patient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability or incapacity, or
- causes any congenital anomaly or birth defect.

18.4.2 As per the current guidelines of the National Medicines Regulatory Authority the following timelines apply for reporting of such events occurring at local trial site to FMS/ERC:

- Death or life threatening event in a patient on a trial or within 30 days off trial: report as soon as possible, but no later than seven calendar days after the sponsor was first aware of such reaction.
- 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 fifteen calendar days after the sponsor was first aware of such reaction

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

- 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.

- 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.

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

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

- Chairperson ERC
- Secretary ERC
- A Clinical Pharmacologist from the Department of Pharmacology, FMS
- A clinician with special training/interest in the clinical discipline/field

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

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

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

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

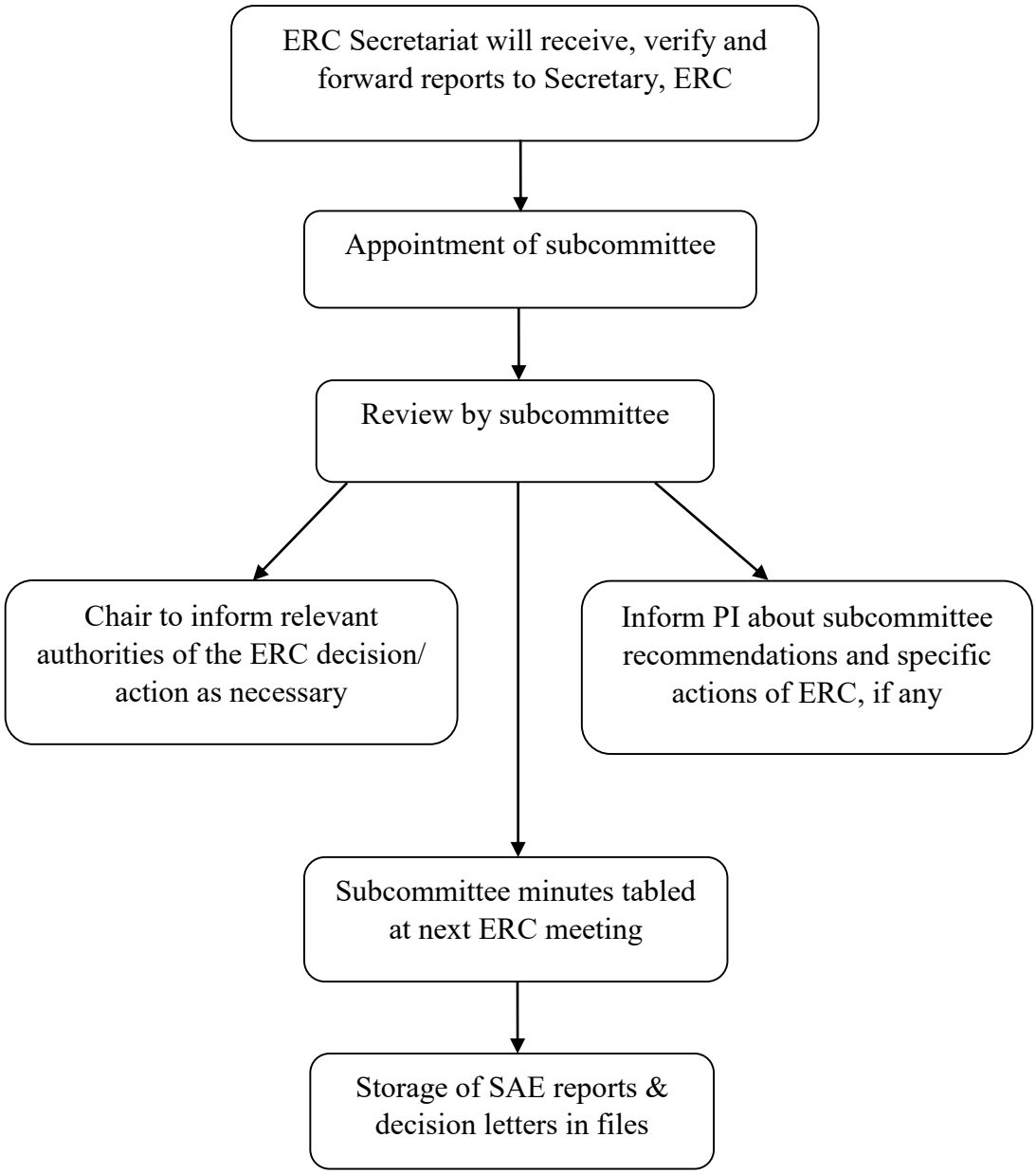
- Referral to the Clinical Trials Sub-committee of the Ministry of Health
- Immediate request for additional information
- Immediate suspension of ethical approval
- Immediate termination of ethical approval.

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

18.4.10 A final resolution report for all SAEs and SUSARs should be submitted to the ERC by the sponsor.

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

Handling of serious adverse events reports



19.1 Purpose

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

19.2 Scope

This SOP applies to all studies under the approval of the ERC, FMS/USJ.

19.3 Responsibility

Principal Investigator should send annual progress reports (Annex 13) and the final report to ERC, FMS/USJ.

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 state all adverse events and the response to those events in the annual progress reports (Annex 13) and final reports (Annex 14) for the project.

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

19.4 Detailed instructions

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

19.4.2 The ERC will require Principal Investigator to provide annual progress reports (Annex 13), and a final report (Annex 4) at the completion of the study. Continuing approval of the research will be subject to the PI submitting the reports as required.

19.4.3 The ERC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:

- periodic written reports;
- random inspections of research sites, data and signed consent forms;
- interview, with their prior consent, of research participants.

19.4.4 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:

- proposed changes in the protocol;
- SAEs/SUSARs
- protocol deviation/ violation/ non-compliance etc.
- any unforeseen events that might affect continued ethical acceptability of the project; and
- 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.

19.4.5 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.

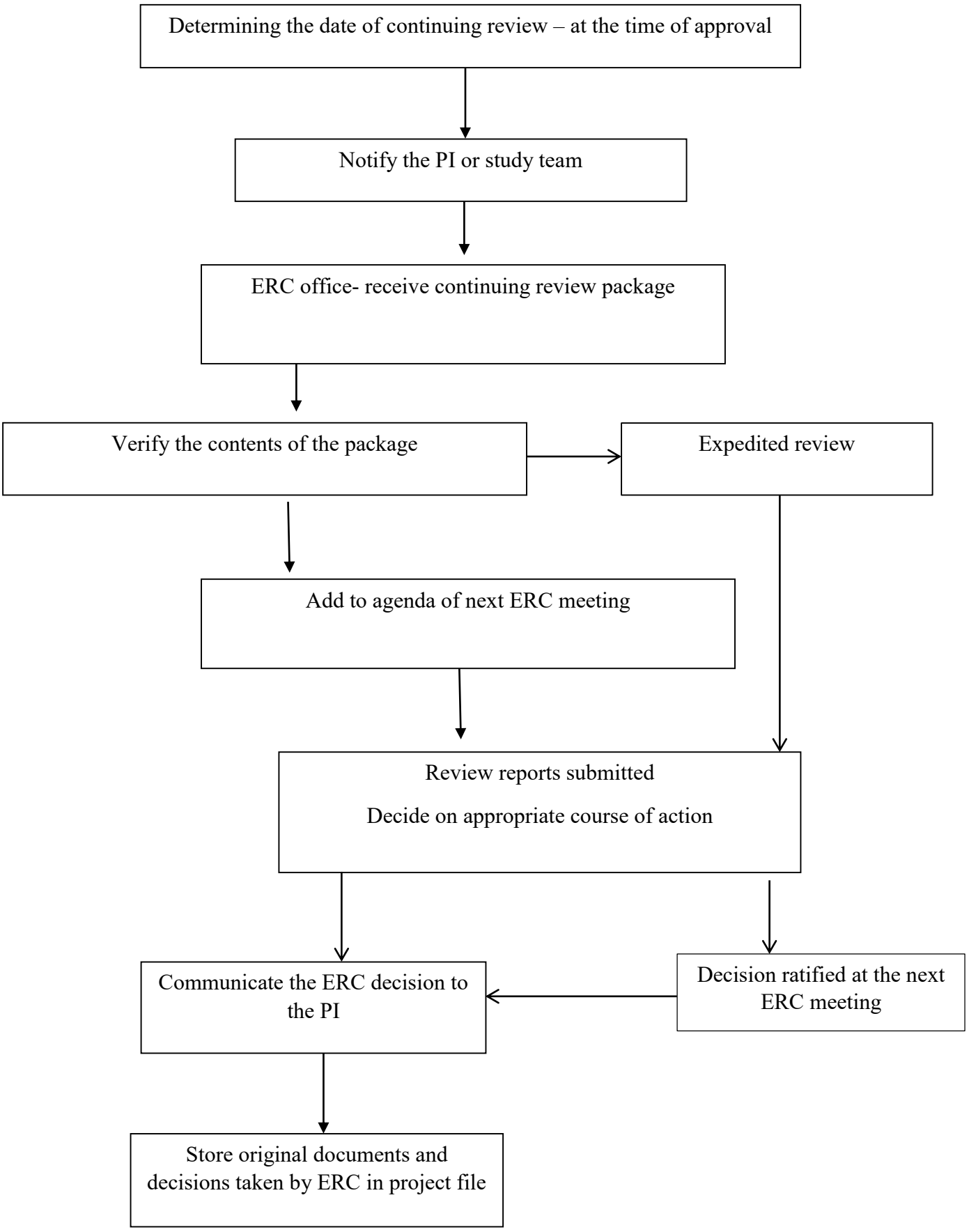
19.4.6 Where the ERC is satisfied that circumstances have arisen which prevent a research project from being conducted in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC shall inform the Principal Investigator and the institution of such withdrawal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

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

19.4.8 In the case of clinical trials the ERC shall require bi-annual reports which shall be reviewed by the Clinical Trials Sub-committee in the first instance. The sub-committee will consist of the following:

- Chairperson ERC
- Secretary ERC
- A Clinical Pharmacologist from the Department of Pharmacology, FMS.
- A clinician with special training/interest in the clinical discipline/field.

Monitoring of approved research protocols



20.1 Purpose

The purpose of this SOP is to describe how the ERC, FMS/USJ 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 participant enrollment and participant follow-up are discontinued before the scheduled completion of the study.

20.2 Scope

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

20.3 Responsibility

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

20.4 Detailed instructions

20.4.1 Receive recommendation for study termination/ suspension/ discontinuation

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

20.4.1.2 **Suspension/Termination/ Discontinuation by ERC**

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

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

20.4.1.3 **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

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

20.4.1.5 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

20.4.2 Review and discuss the Termination / suspension/discontinuation report

20.4.2.1 ERC, FMS/USJ will review the termination report/ suspension/ discontinuation at regular full board meetings.

20.4.2.2The 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.

20.4.2.3 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.

20.4.2.3 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**.**

20.4.2.4 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.

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

20.4.3 When ERC suspends/terminates any study the following will be checked:

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

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

20.4.3.3 Have any adverse events or outcomes reported to the IEC

20.4.4 Notifying the PI

20.4.4.1 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.

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

20.4.4.3 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.

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

20.4.5 Withdrawal of the suspension

20.4.5.1 If a query is sent to PI, he/she should report to ERC on the actions taken as per ERC recommendations within 7 calendar days. This will be reviewed at the next full board meeting.

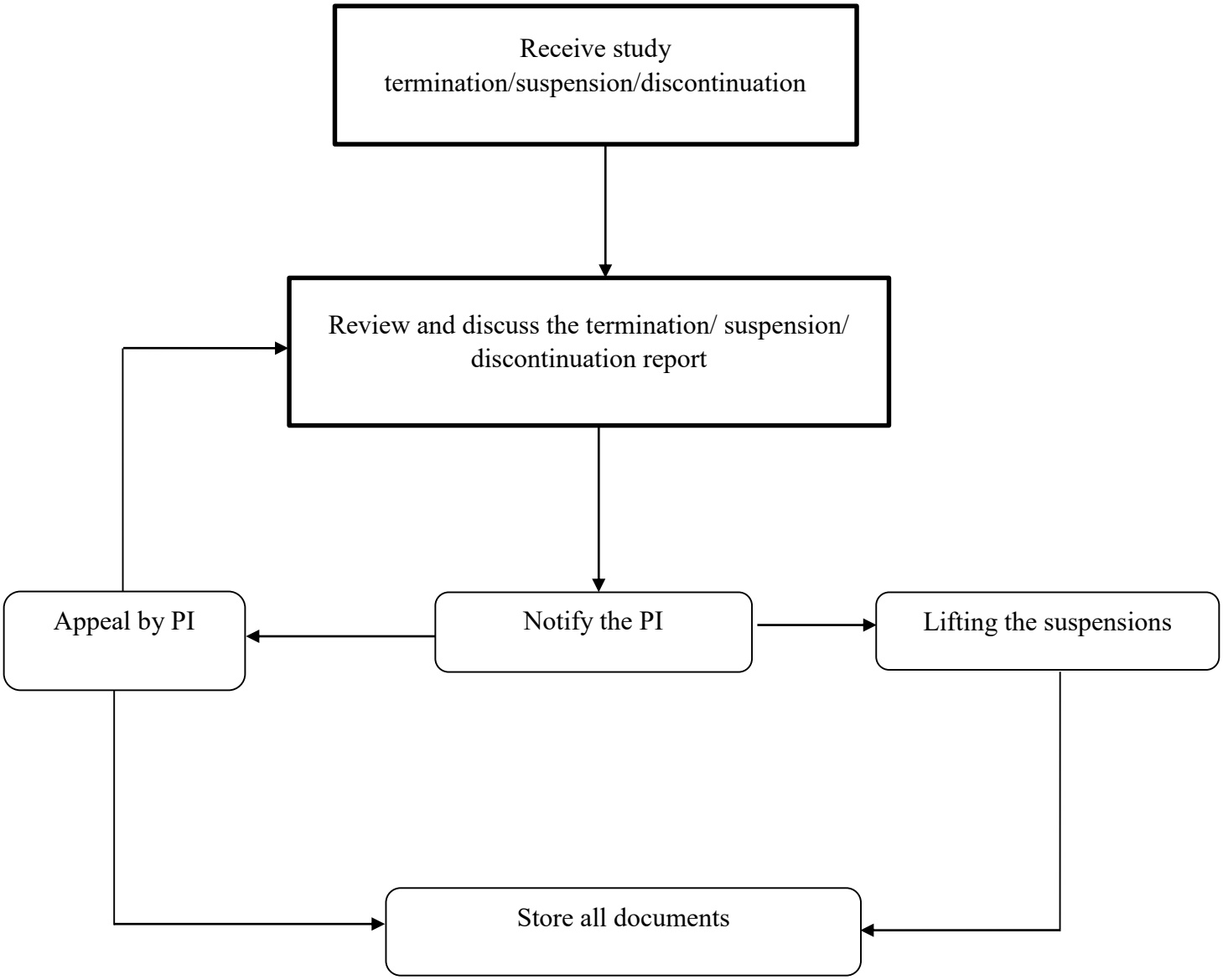
20.4.5.2 The convened ERC then decides to lift the suspension, continue or modify the suspension, or terminate the study.

20.4.6 Storing the Report

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

20.4.6.2 The study documents will be stored as per sponsor requirement.

Premature Study Termination/ Suspension/ Discontinuation



	Ethics Review Committee Faculty of Medical Sciences University of Sri Jayewardenepura	SOP/021/19
	Title : **Review of Protocol Deviation/ Violation/Non-Compliance**	Effective date: 01/01/2020 Page: 50-52

21.1 Purpose

The purpose of this SOP is to describe how the ERC, FMS/USJ provides instructions for taking action and maintaining records, when investigators/ trial sites, fail to –

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

21.2 Scope

This SOP applies to any study approved by ERC, FMS/USJ.

21.3 Responsibility

It is the responsibility of the

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

21.4 Detailed instructions

21.4.1 Detection of Protocol deviation/ non-compliance/ violation
The ERC members performing monitoring of the project at trial site can detect protocol deviation/non-compliance /violation, if the project is

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

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

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

21.4.3 The PI himself / herself may forward protocol deviation / non- compliance/ violation reports to inform the ERC.

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

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

21.4.2 Noting the protocol deviation/ non-compliance/ violation

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

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

21.4.3 Board discussion, decision and actions

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

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

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

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

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

21.4.3.6 The actions taken by the ERC, FMS/USJ could include one of the following:

- Inform the PI that the ERC has noted the deviations / non-compliance/ violation and inform the PI that the deviations / non-compliance/ violation do not occur in the future and follow the ERC recommendations.
- Enlist measures that the PI would undertake to ensure that the deviations / non-compliance/ violation do not occur in future.
- Reprimand the PI.
- Suspend the study till additional information is made available and is scrutinized.
- Suspend the study till recommendations made by the ERC are implemented by the PI and found to be satisfactory by the ERC.
- Suspend the study for a fixed duration of time.
- Revoke the approval of the current study.
- Inform other relevant regulatory authorities.
- Review and/or inspect other studies undertaken by the PI/Co – PI.

21.4.4 Notify the PI

21.4.4.1 The secretary records the ERC decision and drafts and types the notification letters.

21.4.4.2 The chairperson and secretary, and if needed a member/s signs and dates the letter.

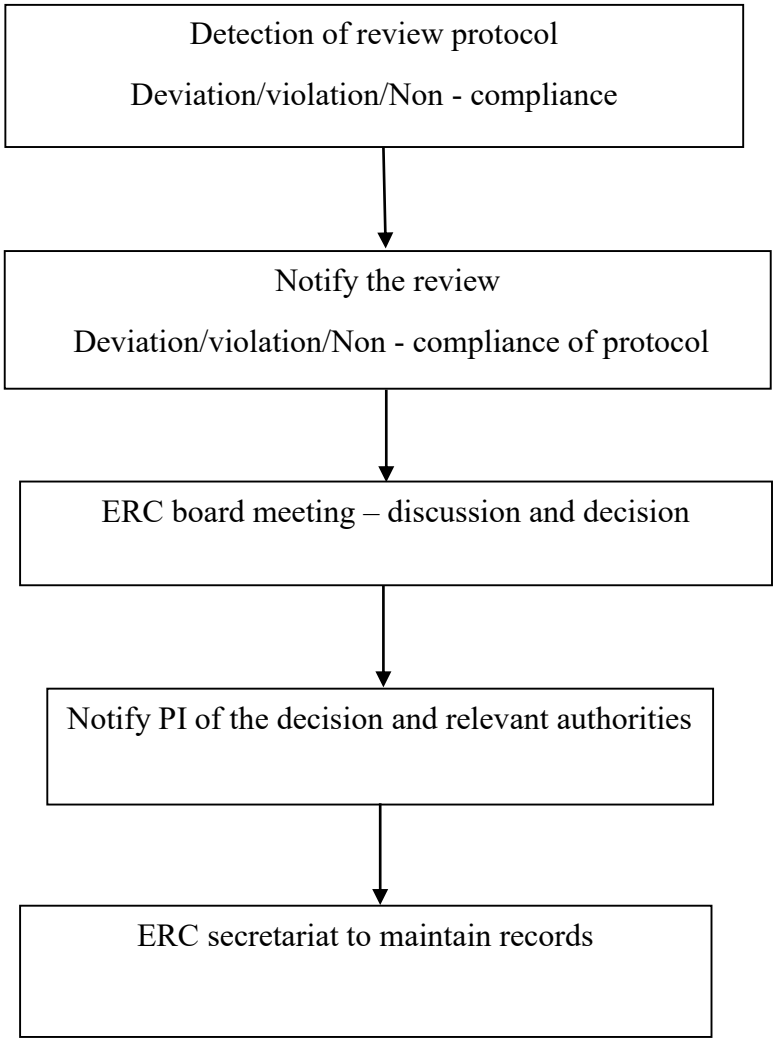
21.4.4.3 The ERC makes copies of the notification letter.

21.4.4.4 The original letter is sent to the PI.

21.4.4.5 Copies of the notification letters are sent to

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

Review of protocol deviation/violation/Non-compliance



22.1 Purpose

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

22.2 Scope

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

22.3 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.

22.4 Detailed instructions

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

22.1.1 The format of the minutes will include at least the following items (Annex 17):

- Apologies
- Conflict of interest
- Minutes of the previous meeting
- Matters arising from the previous minutes
- New applications
- Expedited Review
- Exempt from Review
- Progress Reports and requests for extension.
- Amendments
- Study completion reports
- SAE/ SUSARs
- Correspondence
- Any other matters
- Close and next meeting

22.1.2 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.

22.1.3 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.

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

22.1.5 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.

22.1.6 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.

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

22.1.8 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.

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

22.4.11 The extracts of minutes of each committee meeting shall be forwarded to the Dean and the Faculty Board of FMS. The extracts will consist of the titles of the approved protocols and the names of investigators and any other decision of ERC that would need Faculty Board approval for implementation. A copy of the extract of the minutes sent to the Dean will be filed.

23.1 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

23.2 Scope

This SOP applies to all studies under the approval of the ERC FMS/USJ

23.3 Responsibility

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

23.4 Detailed instructions

23.4.1 The secretariat received the complaints from research participants, researchers or other interested persons about the conduct of approved research. Secretariat is responsible f or obtaining details of the complaint, in writing, especially in the case of verbal complaints, including the grounds for the complaint. In case of COI, another member of ERC can be nominated to receive the complaint.

23.4.2 Any complaints received by the secretariat at ERC office about the conduct of research approved by the ERC should be referred to the chairperson and to member .. secretary.

23.4.3 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.

23.4.4 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.

23.4.5 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.

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

23.4.7 The Chairperson will appoint an Incident Review Committee (IRC) to conduct an investigation of the complaint and its validity, and make a recommendation to the ERC on the appropriate course of action at its next meeting. The investigation will take no longer than 4 weeks from the time of notification for the concern or complaint, unless exceptional circumstances exist. Both the complainant and the PI will be given an opportunity to make submissions. Where the complaint concerns the conduct of any other person the IRC will also provide that person with an opportunity to make submissions.

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

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

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

23.4.10 The possible consequences include the following:

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

23.4.11 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.

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

- the complaint;
- material reviewed in the Chairperson's investigation;
- the results of the Chairperson's investigation; and
- any other relevant documentation.

23.4.13 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.

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

23.4.15 The panel will include, at least, the following members:

- the Dean or his/her nominee, as convener of the panel;
- two nominees of the Dean (not members of the ERC); and
- the ERC Chairperson or his/her nominee.

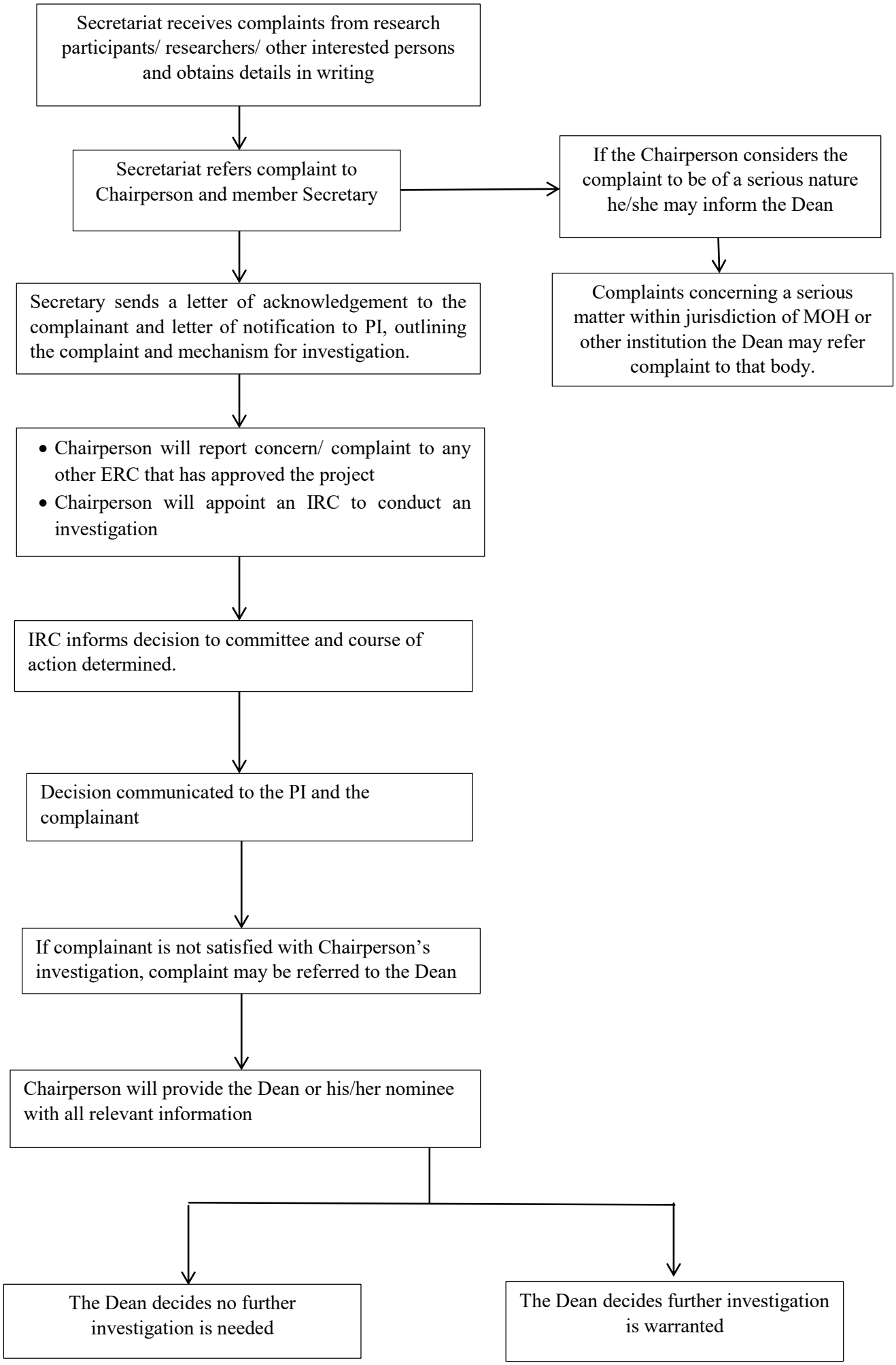
23.4.16 The panel will afford the ERC and the complainant the opportunity to make submissions. Where the complaint concerns the conduct of an investigator or any staff member, the panel shall also provide that person with an opportunity to make submissions.

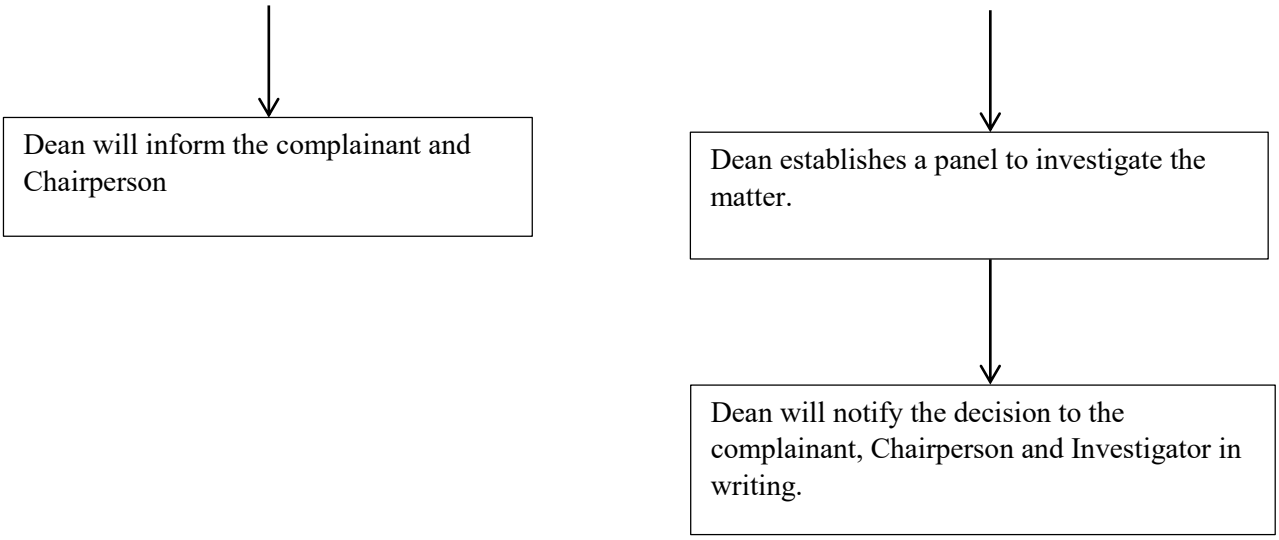
23.4.17 The panel may access any documents relating to the project. The panel may interview other parties, and seek internal and external expert advice, as it sees fit.

23.4.18 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:

- The complaint/concern is dismissed;
- The Dean directs appropriate action to be taken to resolve the complaint.

Complaints about the conduct of a research project.




Dean will inform the complainant and Chairperson
Dean establishes a panel to investigate the matter.
Dean will notify the decision to the complainant, Chairperson and Investigator in writing.

24.1 Purpose

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

24.2 Scope

This SOP applies to the conduct and actions of the ERC FMS/USJ with regards to the review process of applications made.

24.3 Responsibility

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

24.4 Detailed instructions

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

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

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

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

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

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

24.4.7 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.

24.4.8 The panel will include, at least, the following members:

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

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

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

24.4.11 The Dean will notify the appellant and the ERC of the outcome of the investigation. The outcomes of this process may include:

- The concern/appeal is dismissed.
- The concern/appeal is referred back to the ERC for consideration, bearing in mind the findings of the panel
- 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.

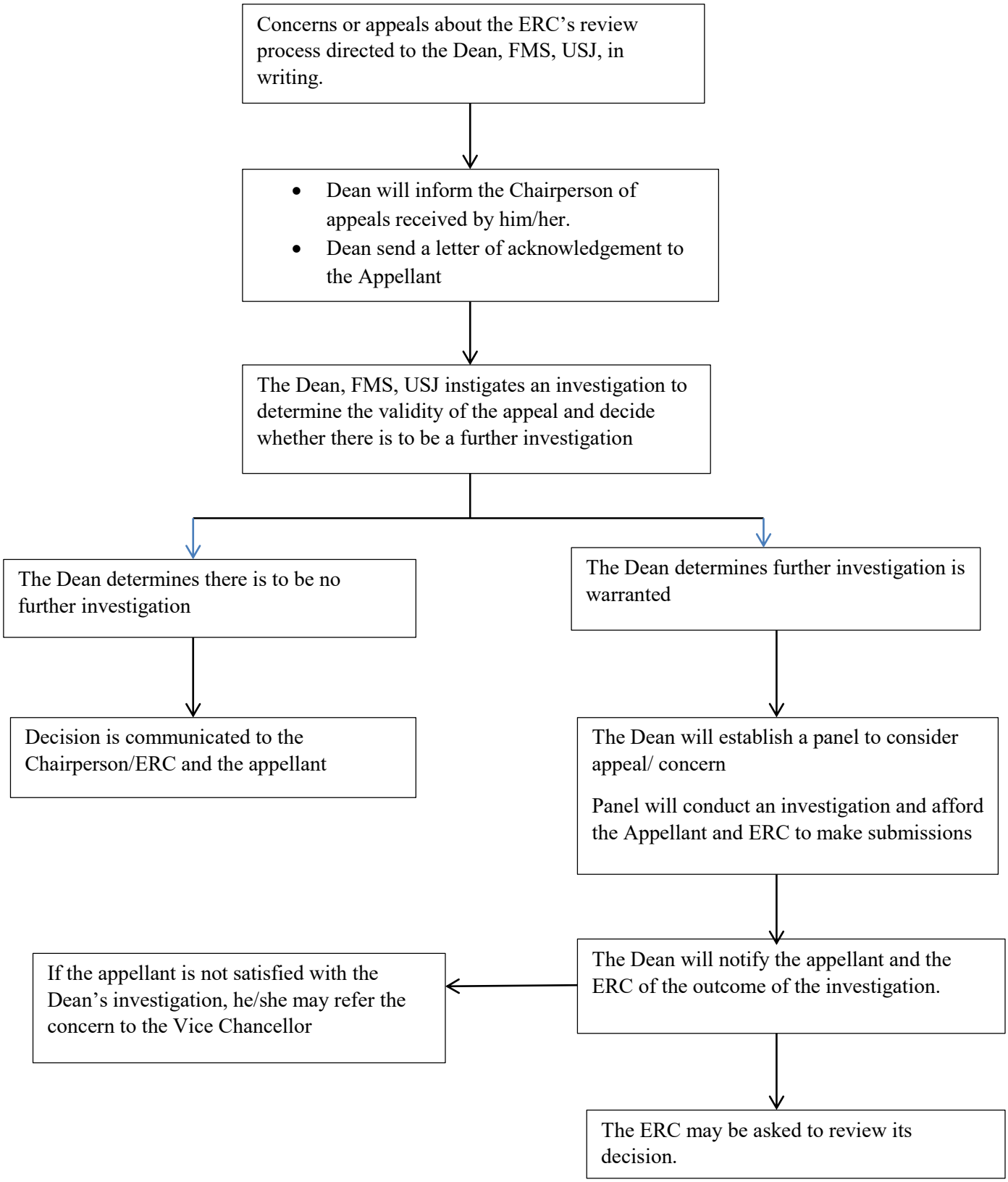
24.4.12 If the ERC is requested to review its decision, then the outcome of this review by the ERC will be final. The panel or the Dean, FMS cannot substitute its approval for the approval of the ERC.

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

24.4.14 The panel may also make recommendations about the operation of the ERC including such actions as:

- a review of the Terms of Reference and Standard Operating Procedures
- a review of the ERC's membership
- other such action, as appropriate.

Appeals concerning the ERC's review process.



25.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the procedures for site monitoring by ERC FMS USJ.

25.2 Scope

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

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

25.3 Responsibility

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

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

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

25.4 Detailed instructions

25.4.1 Selection of study sites

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

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

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

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

25.4.2 Before the visit

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

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

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

25.4.2.4 The chief monitor of SMC

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

25.4.3 During the visit

The SMC will

25.4.3.1 Review the informed consent document to make sure that the site is using the current, approved version

25.4.3.2 Review randomly the participant's source files for proper informed consent documentation. (usually about 10% of enrolled participants, or maybe higher)

25.4.3.3 Observe the informed consent process, if possible

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

25.4.3.5 Observe laboratory and other facilities necessary for the study at the site, if possible.

25.4.3.6 Review the study files to ensure appropriate documentation

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

25.4.3.8 Ensure that the investigator and the investigator's trial staff are adequately informed about the trial.

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

25.4.3.10 Verify that the investigator is enrolling only eligible participants.

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

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

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

25.4.3.14 Collect views of the study participants, if possible.

25.4.3.15 Fill the Site Monitoring Visit Report Form (Annex 18) and write the comments.

25.4.4 After the visit

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

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

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

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

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

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

- Three (3) major violations in the conduct of the study (including serious ERC violations) that result in an unacceptable audit rating.
- The decision to recommend suspension or termination of a clinical trial is carefully considered and takes into account whether corrective actions had been requested at previous reviews and were not implemented.

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

26.1 Purpose

The purpose of this SOP is to describe the mechanism of record keeping for administrative purposes. This include the instructions for archiving and storing both hard and soft copies of the applications, review reports, progress and final reports, minutes and agenda of meetings, SAE, amendments and notification letters of ERC FMS/USJ.

26.2 Scope

This SOP applies to administrative processes concerning the archiving and storage of all documents of ERC FMS/USJ.

26.3 Responsibility

It is the responsibility of the Secretary and the secretariat to maintain all documents pertaining to the ERC.

26.4 Detailed instructions

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

26.4.2 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:

- the unique project identification number
- the principal investigator(s)
- the name of the responsible institution or organization
- the title of the project
- the date of review at a ERC meeting and the decision(s) taken at this meeting
- the ethical approval or non-approval with date
- the date of resubmission
- the approval or non-approval of any changes to the project
- the terms and conditions, if any, of approval of the project
- the type of approval, whether approval was by expedited review
- receipt date of progress and final report, dates of reminders

26.4.3 any relevant correspondence including that between the applicant and the ERC, all approved documents and other material used to inform potential research participants.

Soft copies of the application, proposal and all the relevant correspondence will be stored serially in the computer

26.4.4 All relevant records of the ERC, including applications, membership, minutes and correspondence, extracts of the minutes sent to the faculty board, FMS/USJ will be. kept as confidential files.

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

26.4.6 All records pertaining to research protocols shall be held for sufficient time to allow for future reference. The minimum period for retention will be five (5) years. Files which are no longer required for retention shall be electronically archived.

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

~~26.4.9~~26.4.8 A register of shredded documents/ secure deleted electronic record shall be maintained

27.1 Purpose

The purpose of this SOP is to describe the reporting requirements of the ERC to the faculty board.

27.2 Scope

The purpose of the SOP is to describe the mechanism of reporting extracts of ERC minutes, Standard Operating Procedures and membership of the ERC, and monthly income to the Faculty Board, FMS/USJ.

27.3.1 Responsibility

The extracts of minutes of each Committee meeting shall be forwarded to the Dean and the Faculty Board of FMS by the Secretary ERC. The extracts will consist of the titles of the approved protocols and the names of investigators and any other decision of ERC that would need Faculty Board approval for implementation. Further, the monthly income will be reported to the Faculty Board by secretary as per the requirements of the University Bursa.

27.4 Detailed instructions

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

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

- membership/membership changes
- number of meetings
- number of protocols reviewed, approved and non-approved
- monitoring procedures for ethical aspects of research in progress and any problems encountered by the ERC in undertaking its monitoring role
- description of any complaints received and their outcome
- description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval and
- general issues raised.
- Annual income

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

References

1. WMA declaration of Helsinki – ethical principles for medical research involving human subjects 4th WMA General Assembly, Fortaleza, Brazil, October 2013

2. International Ethical Guidelines for Epidemiological Studies - Prepared by the Council for International Organizations of Medical Sciences (CIOMS) 2009

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

4. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) E6 (R2) 2016

5. FERCSL Operational Guidance for Committees that Review Biomedical Research Proposals 2018

6. International Ethical Guidelines for Health related research involving humans - Prepared by the Council for International Organizations of Medical Sciences (CIOMS) 2016

Glossary

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study
Adverse Event	Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.
Adverse Drug Reaction	In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.
Agenda	A list of things to be done; a program of business for the meeting
Case Report Form	A form on which individual patient data required by the trial protocol are recorded.
Closed Study File	The study which is completed or terminated or discontinued or suspended or not initiated is considered to be closed.
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Minutes	An official record of proceedings at a meeting
Quorum	Number of ERC members required to act on any proposal presented to the committee for action.
Workshop	A group of people engaged in study or work on a creative project or subject

The letter of appointment

Date:

Name:

Address

Dear …….,

Appointment to the Ethics Review Committee

I am pleased to inform you that you have been appointed as the chairperson of the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura for the period of three (3) years effective from …(Date)

As a member of the committee you would be entrusted with the task of reviewing proposals submitted for ethics approval as per the standard procedures of the ERC and relevant national and international guidelines. You are expected to participate in relevant specialized working groups as requested and required to sign confidentiality agreement at the time of appointment and expected to declare any conflict of interest which exist or may arise during his/her tenure. All new members should attend training sessions within 6 months of being appointed. Your membership will lapse if you fail to attend 03 consecutive ERC meetings or more than two thirds of all scheduled ERC meetings as stipulated in the SOPs.
As the chairperson your responsibilities are

- Conduct all meetings of the ERC according to the SOPs.
- Provide guidance to ERC members and office staff.
- Periodically review and formulate existing or new ERC policies and guidelines in consultation with the members of ERC.
- Review applications if assigned.

Faculty of Medical Sciences, University of Sri Jayewardenepura will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. The SOPs are attached herewith. Please sign the attached confidentiality and COI agreements and hand them over to the ERC office.

Yours sincerely

……..
Vice Chancellor

Annexure 1b (SOP/004/19)

The letter of appointment

Date:

Name:

Address

Dear …….,

Appointment to the Ethics Review Committee

I am pleased to inform you that you have been appointed as the secretary of the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura for the period of three (3) years effective from …(Date)

As a member of the committee you would be entrusted with the task of reviewing proposals submitted for ethics approval as per the standard procedures of the ERC and relevant national and international guidelines. You are expected to participate in relevant specialized working groups as requested. All members are required to sign confidentiality agreement at the time of appointment and expected to declare any conflict of interest which exist or may arise during his/her tenure. All new members should attend training sessions within 6 months of being appointed. Your membership will lapse if you fail to attend 03 consecutive ERC meetings or more than two thirds of all scheduled ERC meetings as stipulated in the SOPs.

As the Secretary your responsibilities are:

- Organizing the meetings, maintain records and communicate with all concerned.
- 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.
- Ensure that membership files are current and up to date.
- Assign primary reviewers for applications in consultation with the Chairperson and co-ordinate the review process.
- Provide guidance and supervision to the ERC office staff.
- Perform any other duties of the ERC assigned by the Chairperson.
- Review applications if assigned.

Faculty of Medical Sciences, University of Sri Jayewardenepura will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. The

SOPs are attached herewith. Please sign the attached confidentiality and COI agreements and hand them over to the ERC office.

Yours sincerely

……..

Vice Chancellor

Annexure 1c (SOP/004/19)

The letter of appointment

Date:

Name:

Address

Dear …….,

Appointment to the Ethics Review Committee

I am pleased to inform you that you have been appointed as a member of the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura for the period of three (3) years effective from …(Date).

As a member of the committee you would be entrusted with the task of reviewing proposals submitted for ethics approval as per the standard procedures of the ERC and relevant national and international guidelines. You are expected to participate in relevant specialized working groups as requested. All members are required to sign confidentiality agreement at the time of appointment and expected to declare any conflict of interest which exist or may arise during his/her tenure. All new members should attend training sessions within 6 months of being appointed. Your membership will lapse if you fail to attend 03 consecutive ERC meetings or more than two thirds of all scheduled ERC meetings as stipulated in the SOPs.

As a member your responsibilities are:

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

Faculty of Medical Sciences, University of Sri Jayewardenepura will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. The

SOPs are attached herewith. Please sign the attached confidentiality and COI agreements and hand them over to the ERC office.

Yours sincerely

……..

Vice Chancellor

Annexure 1d(SOP/004/19)

The letter of appointment

Date:

Name:

Address

Dear …….,

Appointment to the Ethics Review Committee

I am pleased to inform you that you have been appointed as a member of the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura for the period of three (3) years effective from …(Date)

As a member of the committee you would be entrusted with the task of reviewing proposals submitted for ethics approval as per the standard procedures of the ERC and relevant national and international guidelines. You are expected to participate in relevant specialized working groups as requested. All members are required to sign confidentiality agreement at the time of appointment and expected to declare any conflict of interest which exist or may arise during his/her tenure. All new members should attend training sessions within 6 months of being appointed. Your membership will lapse if you fail to attend 03 consecutive ERC meetings or more than two thirds of all scheduled ERC meetings as stipulated in the SOPs.

As a member your responsibilities are:

- Review applications assigned to you and lead the discussion on the application at full board meetings
- Complete assessment form for the protocols assigned as primary reviewers prior to the meeting and hand over the completed forms to Secretary at the meeting.
- If you are unable to attend, the forms should be sent to Secretary ERC two (2) working days before the scheduled ERC meeting.
- Perform any other duties assigned to members according to the SOPs.
- Perform any other duties assigned by the Chairperson.
- Look into the Information sheets and the Informed consent forms

Faculty of Medical Sciences, University of Sri Jayewardenepura will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. The

Annexure 1d(SOP/004/19)

SOPs are attached herewith. Please sign the attached confidentiality and COI agreements and hand them over to the ERC office.

Yours sincerely

……..

Vice Chancellor

Annexure 1e(SOP/004/19)

The letter of appointment

Date:

Name:

Address

Dear …….,

Appointment to the Ethics Review Committee

I am pleased to inform you that you have been appointed as a member of the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura for the period of three (3) years effective from …(Date)

As a member of the committee you would be entrusted with the task of reviewing proposals submitted for ethics approval as per the standard procedures of the ERC and relevant national and international guidelines. You are expected to participate in relevant specialized working groups as requested. All members are required to sign confidentiality agreement at the time of appointment and expected to declare any conflict of interest which exist or may arise during his/her tenure. All new members should attend training sessions within 6 months of being appointed. Your membership will lapse if you fail to attend 03 consecutive ERC meetings or more than two thirds of all scheduled ERC meetings as stipulated in the SOPs.

As a member your responsibilities are:

- Review applications assigned to you and lead the discussion on the application at full board meetings.
- Complete assessment form for the protocols assigned as primary reviewers prior to the meeting and hand over the completed forms to Secretary at the meeting.
- If you are unable to attend, the forms should be sent to Secretary ERC two (2) working days before the scheduled ERC meeting.
- Perform any other duties assigned to members according to the SOPs.
- Perform any other duties assigned by the Chairperson.
- Evaluate the legal implications of the study if necessary.

Faculty of Medical Sciences, University of Sri Jayewardenepura will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. The

Annexure 1e(SOP/004/19)

SOPs are attached herewith. Please sign the attached confidentiality and COI agreements and hand them over to the ERC office.

Yours sincerely

……..

Vice Chancellor

Ethics Review Committee
Faculty of Medical Sciences
University of Sri Jayewardenepura
Gangodawila, Nugegoda
Sri Lanka

Confidentiality Agreement

This agreement is made and entered into on this……. day of ……. ……by and between Ethics Review Committee, Faculty of Medical sciences, University of Sri Jayewardenepura (hereinafter referred to as ERC) and ……..…….

…… (holder of NIC number ……

…… ……..)

of……..……

……. (herein after referred to as the "member")

WHEREAS the member has agreed to serve on the aforesaid ERC and in which capacity the member will have access to Confidential Information in the ERC;
AND WHERE AS the Member has acknowledged and agreed that the committee has and shall continue to have sole rights to the Confidential Information and has agreed to hold the same in strict confidence during and after the member's period of service within the ERC.
And it is hereby agreed as follows

1. Interpretation

"Confidential information" shall include all information of a confidential and proprietary nature provided or made available to the member by the ERC. This includes but is not limited to the research proposals and documents, techniques, intellectual property related to the ERC.

2. Obligations of the member

The member hereby undertakes:

a) to maintain the highest degree of secrecy and keep as confidential any Confidential Information which the member may be granted access to and to use such Confidential Information only in duty authorized manner in the interest of the ERC and for the purpose of fulfilling functions and responsibilities arising as a member of the ERC. On termination of the period of membership, the member shall return to the ERC all property, documents and papers in the members possession.

Address all correspondence to: Secretary, Ethics Review Committee, Department of Community Medicine, Faculty of Medical Sciences, University of Sri Jayewardenepura, Gangodawila, Nugegoda, Sri Lanka.
Tel.94-1-2758588, Fax 94-1-811480

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

3. Legal compulsion to disclose

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

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

…….. …….

Signature of the member Date

…….……. ……..

Signature of the Chairperson of the ERC Date

Confidentiality Agreement

This agreement is made and entered into on this……. day of ……. ……by and between Ethics Review Committee, Faculty of Medical sciences, University of Sri Jayewardenepura (hereinafter referred to as ERC) and ……..…….
…… (holder of NIC number …… …… ……)
of……..……
……. (herein after referred to as the "observer/visitor/expert/consultant")

WHEREAS the observer/visitor/expert/consultant has agreed to serve on the aforesaid ERC and in which capacity the observer/visitor/expert/consultant will have access to Confidential Information in the ERC;
AND WHERE AS the observer/visitor/expert/consultant has acknowledged and agreed that the committee has and shall continue to have sole rights to the Confidential Information and has agreed to hold the same in strict confidence during and after the observer/visitor/expert/consultant's period of service within the ERC.
And it is hereby agreed as follows;

1. Interpretation
"Confidential information" shall include all information of a confidential and proprietary nature provided or made available to the member by the ERC. This includes but is not limited to the research proposals and documents, techniques, intellectual property related to the ERC.

2. Obligations of the observer/visitor/expert/consultant
He/she hereby undertakes:

a) to maintain the highest degree of secrecy and keep as confidential any Confidential Information which the observer/visitor/expert/consultant may be granted access to and to use such Confidential Information only in duty authorized manner in the interest of the ERC and for the purpose of fulfilling functions and responsibilities arising as an observer/visitor/expert/consultant of the ERC. On termination of the period of membership, the observer/visitor/expert/consultant shall return to the ERC all property, documents and papers in the observer/visitor/expert/consultant's possession.

Address all correspondence to: Secretary, Ethics Review Committee, Department of Community Medicine, Faculty of Medical Sciences, University of Sri Jayewardenepura, Gangodawila, Nugegoda, Sri Lanka.
Tel.94-1-2758588, Fax 94-1-811480

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

3. Legal compulsion to disclose

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

4. I hereby accept and acknowledge that with regard to the nature of the ERC and the functions and duties of the observer/visitor/expert/consultant of the ERC, the observer/visitor/expert/consultant considers the terms and conditions imposed herein has being fair and reasonable.

…….. …….

Signature of the observer/visitor/expert/consultant Date

……..……. ……..

Signature of the Chairperson of the ERC Date

Ethics Review Committee
Faculty of Medical Sciences
University of Sri Jayewardenepura
Gangodawila, Nugegoda
Sri Lanka

Conflict of Interest Agreement

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

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

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

b) A member is involved in a potentially competing research program.

c) Access to funding or intellectual information that may provide an unfair competitive advantage.

d) Member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

This agreement is made and entered into on this……. day of ……. ……by and between Ethics Review Committee, Faculty of Medical sciences, University of Sri Jayewardenepura (hereinafter referred to as ERC) and ……..…….
…… (holder of NIC number …… …… ……..)
of……..……
……. (herein after referred to as the "member")

Whenever I have a conflict of interest, I shall immediately inform the Chairperson and will not be present for review of the said proposal and will not to count me toward a quorum for voting.

……..

…….

Signature of the member Date

…….…….

……..

Signature of the Chairperson of the ERC Date

Ethics Review Committee
Faculty of Medical Sciences
University of Sri Jayewardenepura
Gangodawila, Nugegoda
Sri Lanka

Conflict of Interest Agreement

1. *Interpretation*

Conflict of Interest

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

It is the policy of the ERC FMS, USJ that no observer/visitor/expert/consultant may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the ERC.

The Undersigned will immediately disclose to the Chairperson of the ERC FMS, USJ any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

When an observer/visitor/expert/consultant has a conflict of interest, the observer/visitor/expert/consultant should notify the Chairperson and may not participate in the ERC FMS, USJ review or approval except to provide information requested by the Committee.

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

a) An observer/visitor/expert/consultant is involved in a potentially competing research program.

b) Access to funding or intellectual information may provide an unfair competitive advantage.

c) Observer/visitor/expert/consultant's personal biases may interfere with his or her impartial judgment

2. Agreement on Conflict of Interest

This agreement is made and entered into on this……. day of ……. ……by and between Ethics Review Committee, Faculty of Medical sciences, University of Sri Jayewardenepura (hereinafter referred to as ERC) and ……..…….
…… (holder of NIC number …… …… ……)
of……..……

……. (herein after referred to as the "observer/visitor/expert/consultant")

Whenever I have a conflict of interest, I shall immediately inform the Chairperson and will not be present for review of the said proposal and will not to count me toward a quorum for voting.

3. ***The observer/visitor/expert/consultant hereby unconditionally accepts and acknowledges that having regard to the nature of the ERC and the functions and duties of the observer/visitor/expert/consultant of the ERC the member considers the terms and conditions imposed herein has being fair and reasonable.***

…….. …….
Signature of the observer/visitor/expert/consultant Date

…….……. ……..
Signature of the Chairperson of the ERC Date

Annexure 3a (SOP/006/19)

Training Record of ……. (Name) ERC FMS, USJ

Name of Training Session	Date	Conducted by

Annexure 3b (SOP/005/19)

Training Record

Name of Training session: .....

Date: .....

Conducted by: .....

Members attended;

Number	Name	Signature

ETHICS REVIEW COMMITTEE
Faculty of Medical Sciences
University of Sri Jayewardenepura

Application No: ……/…… **Date Received: ……. /…../…….**

Version: …….

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

Office use only

APPLICATION FORM – HUMAN RESEARCH

This form should be filled **online** and **signed** by the principal investigator who requests ethical approval for a research project involving **Human Subjects for Observational Studies**.

The spaces in this form are expandable as you type online.

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

PART 1 (Administrative Details)

1. Title of Research Project:

2. Details of Principal Investigator:

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

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

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

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

Please append letter of approval from Board of Study

3.2. Do you have any other active studies at present? Yes ☐ No ☐

3.3. If yes, how many studies are there?

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

4.1. If yes, how many supervisors are there?

Title:	Name:
Department (or organization if not affiliated with FMS/SJP)	
Highest educational qualification	
Mailing address	
Phone:	E-mail:

Title:	Name:
Department (or organization if not affiliated with FMS/SJP)	
Highest educational qualification	
Mailing address	
Phone:	E-mail:

Title:	Name:
Department (or organization if not affiliated with FMS/SJP)	
Highest educational qualification	
Mailing address	
Phone:	E-mail:

Please append additional pages with Supervisors names if necessary

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

5.1. If yes, how many Co-Investigators are there?

Title:	Name:
Department (or organization if not affiliated with FMS/SJP)	
Highest educational qualification	
Mailing address	
Phone:	E-mail:

Title:	Name:
Department (or organization if not affiliated with FMS/SJP)	
Highest educational qualification	
Mailing address	
Phone:	E-mail:

Annexure 4a (SOP/008/19)

Title:	Name:
Department (or organization if not affiliated with FMS/SJP)	
Highest educational qualification	
Mailing address	
Phone:	E-mail:

Please append additional pages with co-investigators names if necessary

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

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

6.2 Specify all study sites

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

Type of site (Hospital/Clinic/School/Community, etc.)	Details

7. Other Research Ethics Board Approval(s):

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

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

8. Funding of this Project:

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

PART 11 (Research Proposal)

9. Project Start and End Dates

Annexure 4a (SOP/008/19)

9.1 Estimated date of commencement that involves human participants or data:

9.2 Estimated date of completion that involves human participants or data for this project:

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

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

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

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

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

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

10.6	Fair Participant Selection	Applicable		Section & Page in Protocol
		Yes	No	
1.	The justification for the selection of the study population	☐	☐	
2.	The inclusion and exclusion criteria	☐	☐	

10.7	Responsibilities of the Researcher	Applicable		Section & Page in Protocol
		Yes	No	
1.	The provision of medical services to research participants	☐	☐	
2.	The provisions for continuation of care after the research is completed	☐	☐	
3.	Declaration of conflicts of interests and how the investigators plan to manage the conflicts	☐	☐	
4.	The ethical/legal/social and financial issues relevant to the study	☐	☐	

10.8	Vulnerable Populations	Applicable		Section & Page in Protocol
		Yes	No	
1.	Justification for conducting the study in this population	☐	☐	

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

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

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

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

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

**** Attach an assent form for children aged 12-18 years**

11. Data Collection

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

Page Number/s	
Section/s	

12. Experience of Investigators with this type of research

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

PART III (Description of the Risks and Benefits)

13. Possible Risks

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

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

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

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

14. Possible Benefits

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

15. Compensation

15.1 Will participants receive compensation for participation?

1. Financial Yes ☐ No ☐
2. In-kind Yes ☐ No ☐
3. Other Yes ☐ No ☐

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

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

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

16. Feedback/ Debriefing/ Referral/ After-Care

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

17. Do you think that the project has a Conflict of Interest?

17.1 Commercially

17.2 Financially

17.3 Intellectually

17.4 Other (Explain)

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

Yes ☐ No ☐

If yes, please explain:

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

20. Declaration of Applicant

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

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

Full name of Principal Investigator:

21. Consent from all Investigators

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

Name	Qualifications	Institutional Affiliations	Signature

Annexure 4a (SOP/008/19)

CHECK LIST (Please mark all documents submitted)

			To be marked by the applicant	To be marked by ERC office
One copy each of the following				
1.	Covering letter signed by the applicant		☐	☐
2.	Letter from supervisor (If relevant)		☐	☐
3.	Bank receipt		☐	☐
4.	Copy of approval letter from Board of Study (*for postgraduate students only*)		☐	☐
5.	Curriculum Vitaes of all the investigators		☐	☐
6.	Letter signed by all investigators confirming their participation		☐	☐
Four copies each of the following				
7.	Completed application form		☐	☐
The following documents (where relevant) must be submitted. They must be stapled or bound together to form 07 complete sets of documents. All documents must carry the Title and Version Number as a header (E.g. Version 1).				
8.	Proposal (*postgraduate students must submit a copy identical to that approved by the board of study*)		☐	☐
9.	Study Instruments	English	☐	☐
		Sinhala	☐	☐
		Tamil	☐	☐
10.	Information Sheet	English	☐	☐
		Sinhala	☐	☐
		Tamil	☐	☐
11.	Consent Forms	English	☐	☐
		Sinhala	☐	☐
		Tamil	☐	☐
12.	Assent Forms	English	☐	☐
		Sinhala	☐	☐
		Tamil	☐	☐
13.	Advertisement for Recruitment	English	☐	☐
		Sinhala	☐	☐
		Tamil	☐	☐
14.	Email a complete set of all documents submitted (include one copy of your application, protocol, instruments and forms in **all languages)** as **pdf files** to erc.fms.usjp@gmail.com at the time of submission		☐	☐

Annexure 4a (SOP/008/19)

PLEASE NOTE

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

……..

Signature of Principal Investigator Date: _____ /_____/_____

(E- Signatures are not accepted)

ERC/FMS/USJ Application form – Human studies
Clinical Trials (Version 6.0) April 2015
ETHICS REVIEW COMMITTEE
Faculty of Medical Sciences
University of Sri Jayewardenepura

Application No: ……/…… **Date received: ……./……/…….**

Version: …….

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

Office use only

APPLICATION FORM – HUMAN RESEARCH – Clinical Trials

This form should be filled **online** and **signed** by the principal investigator who requests ethical approval for a research project involving **human subjects for Clinical Trials**.

The spaces in this form are expandable as you type online

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

PART 1 (Administrative details)

1. **Title of Research Project:**

2. Details of principal investigator

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

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

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

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

Please append letter of approval from Board of Study

3.2 Do you have any other active studies at present? Yes ☐ No ☐

3.3 If yes, how many studies are there?

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

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

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

Please append additional pages with Supervisors names if necessary

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

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

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

Please append additional pages with Co-investigators names if necessary

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

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

6.2 Specify all study sites

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

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

7. Other research ethics board approval(s)

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

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

8. Funding of this project Is this study approved by a Board of Study Yes ☐ No ☐

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

.

9. Funding of this project

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

ERC/FMS/USJ Application form – Human studies
Clinical Trials (Version 6.0) April 2015

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

Phase I ☐
Phase II ☐
Phase III ☐
Phase IV (post marketing) ☐
Other ☐

If OTHER specify:

10.2 Is it a multicentre trial?

Yes ☐ No ☐

If yes, list the other trial sites

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

10.3 Is the clinical trials registered with a clinical trials registry?

Yes ☐ No ☐ Pending ☐

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

If No, give reasons

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

Yes ☐ No ☐ Pending ☐

If yes, give details of Approval Number

If No, give reasons

10.5 Data Safety Monitoring Board (only if available)

Name and Designation of Members*	Role

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

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

PART 11 (Research Proposal)

11 Project start and end dates

Estimated date of commencement that involves human participants or data:
Estimated date of completion that involves human participants or data for this project:

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

12. 1 Collaborative partnership		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The collaborations you have established with institutions where the study is to be conducted	☐	☐	
2.	The collaborations you have established with the community where the study is to be conducted	☐	☐	
3.	The benefits to institutions, communities, and participants in your research	☐	☐	

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

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

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

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

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

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

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

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

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

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

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

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

* **Attach a copy of all posters, advertisements, flyers, letters to be used for recruitment.**
**** Attach an assent form for children aged 12-18 years**

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

Page Number/s	
Section/s	

14. Experience of Investigators with this type of research
Please provide a brief description of previous experience with this type of research by either the principal investigator or the research team or the people who will have direct contact with the participants. If there has not been previous experience, please describe how the principal investigator/research team will be trained/prepared.

PART III – (Description of the risks and benefits)

15. Possible Risks
15.1 Please indicate all potential risks to participants that may arise from this research:

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

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

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

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

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

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

16. Possible Benefits

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

17. Compensation

17.1 Will participants receive compensation for participation?
Financial Yes ☐ No ☐ In-kind Yes ☐ No ☐
Other Yes ☐ No ☐

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

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

17.4 if participants choose to withdraw, how will compensation be affected?

18. Feedback/debriefing/referral/after care

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

19. Do you think that the project has a conflict of interest?

19.1 Commercially

19.2 Financially

19.3 Intellectually

19.4 Other (Explain)

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

Yes ☐ No ☐

If yes, please explain:

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

22. Declaration of applicant

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

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

Full name of Principal Investigator :

23. Consent from all Investigators

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

Name	Qualifications	Institutional Affiliations	Signature

ERC/FMS/USJ Application form – Human studies
Clinical Trials (Version 6.0) April 2015

ERC/FMS/USJ Application form – Human studies
Clinical Trials (Version 6.0) April 2015

CHECK LIST (Please mark all documents submitted)

One copy each of the following		**To be marked by the applicant**	**To be marked by ERC office**
1.	Covering letter signed by the applicant	☐	☐
2.	Letter from supervisor (if relevant)	☐	☐
3.	Bank receipt	☐	☐
4.	Copy of approval letter from Board of Study (*for postgraduate students only*)	☐	☐
5.	Curriculum Vitae of Principal Investigator	☐	☐
6.	Letter signed by all investigators confirming their participation	☐	☐
7.	**Four copies** of the application form	☐	☐
The following documents (where relevant) must be submitted They must be stapled or bound together to form **07 complete sets** of documents. All documents must carry the date and version number as a header			
8.	Proposal (*postgraduate students must submit a copy identical to that approved by the board of study*)	☐	☐
9.	Study instruments **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
10.	Information Sheet **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
11.	Consent forms **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
12.	Assent forms **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
13.	Advertisement for recruitment **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
14.	Email a complete set of all documents submitted (include one copy of your application, protocol, instruments and forms in **all languages)** as *pdf* files to erc.fms.usjp@gmail.com at the time of submission	☐	☐

PLEASE NOTE:
Your application will not be processed until all required documents are received by the ERC office.

……..
Signature of Principal Investigator
(e signatures are not accepted)

Date :___ /____/_____

Annexure 5 (SOP/009/19)

Date:	**MEETING AGENDA OF THE ETHICS REVIEW COMMITTEE, FACULTY OF MEDICAL SCIENCES, UNIVERSITY OF SRI JAYEWARDENEPURA** **To be held on (Date) at the ERC Office of the Faculty of Medical Sciences, University of Sri Jayewardenepura at (Time).**	
To members of the ERC		
Please Note	You have been selected as a primary reviewer for the following project proposal/s. All primary reviewers are required to submit their written comments on the allocated proposals. If you are unable to attend, please submit your WRITTEN comments in writing to the Secretary/ERC at least 2 DAYS PRIOR TO THE MEETING DATE.	
1. Apologies		
2. Conflicts of Interest		
3. Minutes of the Previous Meeting	Corrections:	Approved:

4. Matters arising from the Previous Minutes

4.1	**Application Number:**		**Date Received:**								
Title											
Primary reviewers											
Applicant											
Supervisors/ Co-investigators											
Meeting Date											
Documents Perused	Application	Protocol	Instruments			ICF			ASSENT		
			English	Sinhala	Tamil	English	Sinhala	Tamil	English	Sinhala	Tamil
Date											
Version											

5. New Applications

5.1	**Application Number:**		**Date Received:**								
Title											
Primary reviewers											
Applicant											
Supervisors/ Co-investigators											
Meeting Date											
Documents Perused	Application	Protocol	Instruments			ICF			ASSENT		
			English	Sinhala	Tamil	English	Sinhala	Tamil	English	Sinhala	Tamil
Date											
Version											

6. Expedited Review

7. Exempt from Review

8. Progress Reports and requests for extension

9. Amendments

10. Study completion reports

11. SAEs/ SUSARs

12. Correspondence

13. Any other matters

14. Close and next meeting

Secretary,
ERC/FMS.

Ethics Review Committee

Faculty of Medical Sciences, University of Sri Jayewardenepura

Study Assessment Form – for research involving humans

Instructions to reviewers:

1. Sections 1- 5 should be filled for ALL protocols

2. Section 6 – should only be filled if the study is externally sponsored

3. Section 7 – should only be filled for clinical trials and is in addition to sections 1-6

4. Section 8 - should only be filled for all others – e.g. Community based/ Observational/Qualitative research - and is in addition to sections 1-6

5. Please type your review, sign and send to Secretary ERC.

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

Assessment of Protocol

1. Social/Scientific value

		Yes	No	NA	Comment:
1.1	Will the study lead to improvements in human health and wellbeing or increase knowledge?				
1.2	Does the literature review provide adequate information to justify the study?				
1.3	Is there provision for dissemination of results (reporting and publishing) of the research?				
1.4	Are there any conflicts of interest, including payments and other rewards?				

2. Scientific validity

2.1	Is the title reflective of the study?				
2.2	Are general and specific objectives clearly stated?				
2.3	Is the study design appropriate to achieve the stated objectives?				
2.4	Are inclusion and exclusion criteria appropriate to achieve given objectives?				

2.5	Is the methodology clear?				
2.6	Is the sample size adequate?				
2.7	Is the sampling technique appropriate?				
	Are the statistics used appropriate?				
2.8	Is there a plausible data analysis plan?				
3. Fair subject selection					
3.1	Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?				
3.2	Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				
3.3	Does the selection of participants stigmatize any group?				
3.4	Does selection of subjects favour any group?				
3.5	Is the initial contact and recruitment appropriate?				
3.6	Is the research conducted on vulnerable individuals or groups?				
****** If research is to be carried out in vulnerable groups, assess following. (a-g)**					
a	Can the research be equally well carried out in another, less vulnerable, group?				
b	Will the study result in new knowledge relevant to the health needs of this population?				
c	Is the procedure for obtaining (proxy) consent adequate?				
d	Will the subject's withdrawal from research due to refusal (dissent) be always upheld?				
e	Is there a favourable risk benefit ratio?				
f	Is the medical and psychological support adequate?				
g	Will the benefit of the research be made reasonably available to this group?				

4. Risk benefit assessment					
4.1	Is the need for human participants justified?				
4.2	Are the inclusion criteria appropriate?				
4.3	Are the exclusion criteria appropriate?				
4.4	Is recruitment of participants voluntary and non-coercive?				
4.5	Is the intervention to be used in the research acceptable?				
4.6	Is the risks and benefits assessment by investigator acceptable?				
4.7	Are the facilities at the site adequate to support the study?				
4.8	Have provision been made for treatment of study-related injuries and if so are they adequate?				
4.9	Are the provisions for medical/psychosocial support adequate?				
4.10	Have adequate provisions been made for safety monitoring and termination of the research project?				
4.11	Is there provision for the subjects to be informed of results of clinical research?				
4.12	If biological samples are being collected, is the fate of the sample mentioned and appropriate?				
4.13	Are qualification and experience of the Participating Investigators appropriate? **(Check CVs)**				

5. Respect for participants					
	Informed consent				
5.1	Is the process for obtaining informed consent appropriate (written/verbal)?				
5.2	Are the participants competent?				
5.3	Is the justification for the intention to include individuals who cannot consent appropriate?				
5.4	If participants are not competent, is the procedure for obtaining proxy consent appropriate?				
5.5	Will dissent be respected?				
5.6	Are incentives offered and if so do you approve those offered?				

5.7	Will fresh informed consent be obtained if the procedures are changed during the research?				
6	**Informed consent forms**				
6.1	Is the written and oral information to be given to the research participants appropriate, adequate and complete?				
6.2	Is the language used in information sheets clear and understandable? **NB check use of scientific words.**				
6.3	Are translations of all forms consistent?				
6.4	Is there an opportunity for the participant to ask questions regarding the research?				
6.5	Is there provisions for the participant to withdraw unconditionally from research without penalty or loss of care?				
6.6	If biological samples are being collected, are the participants informed about - What is being collected - What tests will be done with them - Whether they will be stored for future studies - If stored for how long and what is expected to be done with samples				
6.7	Consent form – has the participant consented for all procedures planned? Eg. Immediate activities of study, storing of samples, recording of interviews etc				
6.8	Are contact details of PI and other appropriate investigator for site given in the information sheet?				
6.9	Is there provisions for study participants to make complaints if needed? E.g. ERC contact details				
7. Confidentiality (Check both protocol and ICF)					
7.1	Will the researcher collect only the minimum information/samples required to fulfill the study objectives?				
7.2	Is the privacy of the research participant safeguarded?				
7.3	Is the place for data collection appropriate?				
7.4	Are data/sample storage and disposal procedures adequate?				

8. For Externally sponsored research					
		Yes	No	NA	Comments
8.1	Is there a local collaborator?				
8.2	Has the research project been approved by a ERC/ IRB in the sponsoring country?				
8.3	Is the research also being carried out in the Sponsor's country?				
8.4	Is the justification for the research to be carried out in Sri Lanka and not in the sponsoring country adequate?				
8.5	Is the research relevant to Sri Lanka?				
8.6	Are the post-research benefits to the country acceptable?				
8.7	For any trial drug or device, is it registered in the country of origin?				
8.8	Are relevant local laws/ regulations/guidelines of each country adhered to?				
8.9	Is the research responsive to cultural/social differences?				
8.10	Are the provisions for intellectual property sharing fair?				
8.11	If the data/biological samples are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights? i.e material transfer agreement				
8.12	Is there provision for results of research to be conveyed to relevant authorities in Sri Lanka?				
8.13	Are any conflicts of interest resolved?				
8.14	Is there a written agreement between the collaborators?				

9. For clinical trials – ie any research that has an intervention					
		Yes	No	NA	Comments
9.1	Have adequate animal toxicity and teratogenecity trials been carried out? **(Check background and justification section)**				
9.2	Is there sufficient justification for using a control arm?				
9.3	Are there any plans to withdraw or withhold standard therapy for the purpose of research and if so is such action justified?				
9.4	Is the treatment given to control group appropriate?				
9.5	Is the standard of care the best available locally?				
9.6	Are all participants treated equally?				
9.7	Is the site including support staff, facilities and emergency procedures adequate?				
9.8	Have provision been made for treatment of study-related injuries and if so are they adequate?				
9.9	Is there provision for compensation (where applicable) and if so is it adequate?				
9.10	Have adequate provisions been made for dealing with and reporting adverse effects?				
9.11	Have provisions been made for the continuing care of those that withdraw consent and if so is it adequate?				
9.12	Is there a possibility of an intervention being available to the population/trial participants if found effective? (i.e. post-trial access)				
9.13	Are the criteria for termination of the trial detailed?				
9.14	Is there provision for insurance of trial participants? If yes, is it adequate?				
9.15	If it is a multicentre trial, are all centres following the same protocol?				

Decision – Approved/ Minor modifications needed/ Major modifications needed/ Disapproved

Any other comments (Append extra sheets as needed)

10. For Community based/ Observational/Qualitative research					
		Yes	No	NA	Comments
10.1	Is the impact and relevance of the research on the community in which it is to be carried out acceptable?				
10.2	Has the concerned community been consulted during the design of the study?				
10.3	Is community consent obtained?				
10.4	Is individual consent obtained?				
10.5	Is the privacy of the participants safeguarded?				
10.6	If the intervention is shown to be beneficial will the researcher/ sponsor continue to provide it to participants after conclusion of the study?				
10.7	Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the population?				
10.8	Does the research contribute to capacity building of the community?				
10.9	Will the results of the research be made available to the concerned community?				

Decision – Approved/ Minor modifications needed/ Major modifications needed/ Disapproved

Any other comments (Append extra sheets as needed)

Exempted from Review

Check whether research involves any of the following:

- Audits of educational practices
- Research on regular or special education instructional strategies
- Research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods
- Research on microbes cultured in the laboratory
- Research on immortalized cell lines
- Research on cadavers or death certificates provided such research reveals no identifying personal data
- Analysis of data freely available in public domain

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

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

Check whether following documents are submitted and acceptable:

1. Participant Letter/ Parental Participant Letter and Assent Letter
   Note: Research w/ minors is rarely exempt.
2. Permission letter for access to data or recruitment of participants
3. Survey instruments, interview questions or data collection forms

a. Rationale for selection of standardized instruments provided

4. For researcher-developed instruments or questions, evidence of piloting OR pre-testing
5. Recruitment materials: advertisements, brochures, flyers, e-mail solicitation messages or other recruitment materials

Check List for protocols Exempted from Review

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

Does the data provide identification of subjects? ☐ ☐

Would the information if disclosed outside research reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation? ☐ ☐

If No to all of the above → **Exempt from review**

…… ……

Chairperson, ERC FMS/USJ
(or nominee)

Secretary, ERC FMS/USJ
(or nominee)

N.B. Secretary must be one of the reviewers.

Annexure 8 (SOP/014/19)

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Chairperson

Secretary

Committee Members

Date: Our ref:

ERC meeting date:

Name of Principal Investigator

Address of Principal Investigator

Dear …,

Application Number:

Title:

Principal Investigator:

Co-investigators/ Supervisors:

The FMS, USJP ERC at its meeting held on the (Date) has reviewed your application and considers it exempt from review for the following reasons:

1.
2.

The Following documents have been reviewed by the committee.

Document	**Version**	**Date of submission**
Project proposal		
Study instrument		

Please note that this exception is pertaining to the submitted protocol and any alteration or deviation should be notified to the ERC.

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Chairperson

Thank you.

Yours Sincerely,

Secretary

Chairperson **Secretary**

Committee Members

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Chairperson

Secretary

Committee Members

Date:

ERC meeting date:

Name of Principal Investigator

Address of Principal Investigator

Dear ...

Application Number:

Title:

Principal Investigator:
Co-investigators/ Supervisors:

am pleased to inform you that the FMS/USJP ERC at its meeting held on the above mentioned date has granted ethical approval for your project as per details given below.

Document	**Version No**	**Date of submission**
Project proposal		
Participant consent forms - English		
Participant consent forms - Sinhala		
Participant consent forms - Tamil		
Participant information sheet - English		
Participant information sheet - Sinhala		
Participant information sheet – Tamil		
Study instrument- English		
Study instrument- Sinhala		
Study instrument-Tamil		

The ethical approval for your project is effective from the above mentioned ERC meeting date.
We affirm that none of the proposed study team members were present during the decision making process of the ERC. The quorum requirements were met.

The **approval is valid until one year from the date of sanction**. You may make a written request for renewal / extension of the validity, along with the submission of annual status report. **Please note that ethical approval would be revoked if any alteration is made to the project without obtaining prior written consent from the ethics review committee.**

As the Principal Investigator, you are expected to ensure that procedures performed under the project will be conducted in accordance with all relevant national and international

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

policies and regulations that govern research involving human participants.

Please note that this approval is subjected to the following condition:

- An ERC approved stamped ICFs are attached herewith. Please ensure that the stamped ICF are provided to the participants.
- Progress reports to be submitted annually.
- All serious adverse events (SAEs) that may occur in Sri Lanka should be reported within 07 calendar days of their occurrence to the ERC, FMS USJ
- Any serious adverse event, which has arisen during the clinical trial or which has come to your knowledge from reports other participating trial sites should be informed in writing to ERC FMS, USJ within 30 working days.
- The adverse events should be reported in the format of the attached adverse events reporting form.
- The final report to be submitted at the completion of the study.
- In the event of any complaints from the participants, these should be reported to the Secretary, ERC FMS USJ.
- In the events of any protocol amendments, ERC must be informed and the amendments should be highlighted in clear terms as follows:
  a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. etc.)
  b. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval

Thank you.

Yours Sincerely,

Chairperson **Secretary**

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Date: Our ref:

ERC meeting date:

Name of Principal Investigator

Address of Principal Investigator

Dear…

Application No... /..

Title

Principal Investigator:
Co-investigators/ Supervisors:

Thank you for submitting the above amendment to the ERC, FMS/USJ. We are pleased to inform you that the ERC, FMS/USJ has granted approval effective from … for the following amendments.

1.
2.

Thank you.

Yours Sincerely,

Chairperson **Secretary**

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Chairperson

Secretary

Committee Members

Date: Our ref:

ERC meeting date:

Name of Principal Investigator

Address of Principal Investigator

Dear ...,

Application Number:

Title:

Thank you for submitting the above study to the ERC/FMS, USJ. The ERC made the following observations and recommendations regarding;

1.
2.
3.

Please clarify the above and resubmit **four sets of the documents on or before … (date) for processing.**

The corrections done should be given in a **separate document as a table with 4 columns. This table should include the comments given by the ERC, the statement in the old document, the change made in the new document and the relevant page numbers**.

Please be kind enough to submit four sets of this table, corrected proposal and all other required documents as hard copies. Highlight the changes made on the pages concerned. Email a soft copy of your resubmission to the ERC email (erc.fms.usjp@gmail.com).

Please state clearly the version numbers, page numbers and date along with the title in the header of all documents submitted.

Thank you.

Yours Sincerely,

Chairperson **Secretary**

Annexure 11 (SOP/017/19)

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Chairperson

Secretary

Committee Members

Date: Our ref:

ERC meeting date:

Name of Principal Investigator

Address of Principal Investigator

Dear...,

Application Number ../..

Title:

The FMS/ USJ ERC at its meeting held on (date) has reviewed your application and has not granted approval for the following reasons;

1.
2.

If you have any further queries, please write Chairperson ERC, FMS/USJ citing the application number above.

Thank you.

Yours Sincerely,

Chairperson **Secretary**

Annexure 12 (SOP/018/19)

Serious Adverse Events (SAE) report form (version 2 effective from August 2019)

Ethics Review Committee, FMS, USJ.

<table>
<tr><td>Principal Investigator:

Study title:

Name of the study medicine/device:

Sponsor</td><td colspan="2">Application number:

Protocol number:

Report date

Initial ☐ ☐ follow up

Onset date:

Date of first use:</td></tr>
<tr><td>Subjects initial number:</td><td>Age</td><td>☐ Male ☐ female</td></tr>
<tr><td>Subjects history:</td><td colspan="2">Laboratory findings:</td></tr>
<tr><td>SAE:</td><td colspan="2">Management if any:

Outcome: resolved ☐ on going ☐</td></tr>
<tr><td colspan="3">Seriousness

<table>
<tr><th>Seriousness</th><th>Relation to drug/device/study</th></tr>
<tr><td>☐ death</td><td>☐ not related</td></tr>
<tr><td>☐ Life threatening</td><td>☐ Possibly</td></tr>
<tr><td>☐ Hospitalization initial/prolong</td><td>☐ Probably</td></tr>
<tr><td>☐ Disability/incapacity</td><td>☐ Definitely related</td></tr>
<tr><td>☐ Congenital anomaly</td><td>☐ Unknown</td></tr>
<tr><td>☐ Other</td><td></td></tr>
</table>

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

Changes in the informed consent form recommended ☐ No ☐ Yes, attach proposal</td></tr>
<tr><td colspan="3">Received by…… Date……

Comment…….. Action ……..</td></tr>
</table>

Ethics Review Committee

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Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Progress Report Form

FMS ERC protocol:

Study title:

Principal Investigator:

Sponsor:

Duration of the study:

Study start date:

Summary of Protocol Participants:

- Total number of participants approved by ERC …….
- Screened……
- Screen failures …….
- Enrolled ……..
- Consent withdrawn…….. Reason
- Withdrawn by PI……..Reason
- Active on treatment ……..
- Completed treatment…….
- Patients on follow up…….
- Patients lost to follow up……
- Any other……

Presentation/publication related to the data generated in this trial:

SAE's at approved study center (Total number and type):

Whether all SAE's were intimated to the ERC: Yes/No

SAE management initiated: Yes/No If yes, Management procedure:

Protocol deviation/violations/noncompliance (Number and nature):

Conclusion:

Signature of PI:

Date:

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Study Completion Report Form

FMS ERC protocol No:

Study title:

Principal Investigator:

Sponsor:

Duration of the study: Study Start date: Study Completion date:

Summary of protocol Participants:

- Total accrual of study ……..
- Total patients to be recruited at approve study site (ERC ceiling)……
- Screened……
- Screen failures…….
- Enrolled…….
- Consent withdrawn…….. Reason
- Withdrawn by PI……..Reason
- Active on treatment……..
- Completed treatment…….
- Patients on follow up…….
- Patients lost to follow up……
- Any other……

Number of study arms:

Results (brief) (use extra blank sheets, if more space is required):

Presentation/publication related to the data generated in this study:

SAE's at approved study center (Total number and type):

Whether all SAE's were intimated to the ERC: Yes/No

SAE management initiated: Yes/No If yes, Management procedure:

Protocol deviation/violations/noncompliance (Number and nature):

Any ethical issues encountered:

Brief description of the study:

Conclusions:

Signature of PI:

Date:

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Premature study termination report

Application number:	
Title:	
Name of PI:	
Contact number & e-mail 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 failure:
- Enrolled:
- Consent withdrawn and reasons:
- Withdrawn by PI and reasons:
- Withdrawn by sponsor and reasons:

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Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

• Active on treatment: • Completed treatment: • Patients on follow up: • Patients lost to follow up: • Any other
Any impaired participants (provide numbers) • None: • Physically • Mentally/Cognitively • Both
SAE total number:
SAE events:
Study terminated by: PI ☐ Reasons: Sponsor ☐ Reasons:

PI signature	Date:

Ethics Review Committee

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Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Reporting form for violations and deviations

Specify if it is a violation or deviation:
Nature; Minor ☐ Major ☐ Other ☐ If others please specify:
Date of occurrence:
Number of similar events during the same study:
Patient ID number:
Project number:
Details of violation or deviation:
Action taken by the PI/Co –PI's:
Impact on study subjects:
Signature: Date:

Annexure 17 (SOP/022/19)

MINUTES OF THE ETHICS REVIEW COMMITTEE

Meeting held on (**Date**) at the ERC Office of the Faculty of Medical Sciences, University of Sri Jayewardenepura

Meeting start: (Time)

1. Attendance
Members present
Members excused

2. Declaration of conflict of interest

3. Confirmation of minutes.

Corrections.

4. Resubmissions.

4.1	**Application Number:**										
Title											
Primary reviewers											
Applicant											
Supervisors/ Co-investigators											
Meeting Date											
Documents Perused	Application	Protocol	Instruments			ICF			ASSENT		
			English	Sinhala	Tamil	English	Sinhala	Tamil	English	Sinhala	Tamil
Date											
Version											
Decision:			**Discussion:**								
Follow up:			**Recommendation to the Principal Investigator:**								

5. New Applications.

<table>
<tr><td>5.1</td><td colspan="4">Application Number:</td><td colspan="5">Date Received:</td></tr>
<tr><td>Title</td><td colspan="9"></td></tr>
<tr><td>Primary reviewers</td><td colspan="9"></td></tr>
<tr><td>Applicant</td><td colspan="9"></td></tr>
<tr><td>Supervisors/
Co-investigators</td><td colspan="9"></td></tr>
<tr><td>Meeting Date</td><td></td><td></td><td colspan="3"></td><td colspan="3"></td><td colspan="3"></td></tr>
<tr><td rowspan="2">Documents Perused</td><td rowspan="2">Application</td><td rowspan="2">Protocol</td><td colspan="3">Instruments</td><td colspan="3">ICF</td><td colspan="3">ASSENT</td></tr>
<tr><td>English</td><td>Sinhala</td><td>Tamil</td><td>English</td><td>Sinhala</td><td>Tamil</td><td>English</td><td>Sinhala</td><td>Tamil</td></tr>
<tr><td>Date</td><td></td><td></td><td colspan="3"></td><td colspan="3"></td><td colspan="3"></td></tr>
<tr><td>Version</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">ERC discussion:</td><td colspan="5">Recommendations to the Principal Investigator:</td></tr>
<tr><td colspan="5">Decision on components of the protocol:</td><td colspan="5">Reasons given/ details:</td></tr>
</table>

6. Expedited Review

7. Exempt from Review

8. Progress Reports and requests for extension.
All the above mentioned progress reports were accepted and minuted.

9. Amendments.

10. Study completion reports.
All the Above-mentioned Study Completion Reports were accepted and minuted.

11. SAEs/ SUSARs

12. Correspondence.

13. Any other matters.

14. Meeting close time: **Next meeting:**

Secretary
ERC/ FMS/ USJ

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

Site Monitoring Visit Report

1. ERC Project number:
2. Title:
3. Principal Investigator:
4. Institute:
5. Type of study;
    a. Investigator initiated:
    b. Pharma:
6. Source of funding:
7. Date of ERC approval:
8. Start date of study:
9. Duration of study:
10. Date of monitoring visit:
11. Reasons for monitoring;
    a. Routine
    b. For causes
        i. Protocol violation/deviation
        ii. SAE reporting
        iii. Recruitment rate
        iv. Other
12. Last monitoring done
    a. Yes ☐ Date of last monitoring:
    b. No ☐
13. Project status
    a. Ongoing ☐
    b. Completed ☐
    c. Accrual completed ☐
    d. Follow up ☐
    e. Suspended ☐

Ethics Review Committee
A SIDCER *(Strategic Initiative for Developing Capacity in Ethical Review) recognized ERC*
Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

f. Terminated ☐

g. Closed ☐

h. Closed prematurely ☐

i. In case of the responses to options e, f or h kindly provide reasons:

14. Recruitment status;

a. Total patients to be recruited:

b. Screened:

c. Screen failure:

d. Enrolled:

e. Withdrawn: Reasons:

f. Discontinued: Reasons:

g. Completed:

h. Active:

15. Is the recruitment on schedule Yes ☐ No ☐

a. If not is it acceptable Yes ☐ No ☐

b. If not state reasons /steps taken by the PI to improve recruitment:

16. Protocol;

a. Have there been any amendments to the protocol? Yes ☐ No ☐

b. If yes state the steps:

c. Is the protocol version approved by the ERC Yes ☐ No ☐

d. Is the latest version of the protocol being used for the study Yes ☐ No ☐

17. Informed consent

a. Is informed consent obtained from all enrolled participants Yes ☐ No ☐

b. Have there been any amendments to the ICF Yes ☐ No ☐

c. If so state the changes:

d. Is the latest ICF version approved by the ERC Yes ☐ No ☐

e. Is the latest version of the ICF being used for the study Yes ☐ No ☐

f. Have all the deviations/Violations/noncompliance notified to the ERC Yes ☐ No ☐

Ethics Review Committee

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

Faculty of Medical Sciences, University of Sri Jayewardenepura
Gangodawila, Nugegoda, Sri Lanka

g. Comments if any:

18. Have the eligibility, inclusion, exclusion criteria been adhered to Yes ☐ No ☐
19. Have there been any AE/SAE on the study Yes ☐ No ☐ N/A ☐
    If yes

    a. No. of adverse effects
    b. No. of serious adverse effects
    c. No. of deaths reported
        i. Deaths unrelated to the participants in the trial
        ii. Deaths possibly elated to the participants in the trial
        iii. Deaths related to the participants in the trial
    d. Were all SAE reports notified and submitted to the DSMSC within 7 days and deaths within 24 hours of the knowledge of the PI Yes ☐ No ☐
    e. Comments if any:

20. Are the investigational drugs accountability and prescription procedure performed and documented Yes ☐ No ☐

21. Are there any changes to the study personnel Yes ☐ No ☐ N/A ☐
    If yes state
    Is the change notified to the ERC? Yes ☐ No ☐ N/A ☐

22. Number of patients monitored during the visit

23. Duration of the visit

24. Any outstanding tasks/actions from the visit

Signature and date	Signature and date
Name of ERC member	Name of ERC member
Signature and date	Signature and date
Name of ERC member	Name of ERC member