Standard Operating Procedures

Ethics Review Committee

Version 4

Faculty of Medicine

University of Jaffna

2021

Standard Operating Procedures

Ethics Review Committee (ERC)

Faculty of Medicine, University of Jaffna

Editors

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Approved by the ERC, Faculty of Medicine, University of Jaffna

ERC members

	Name	Designation
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9	Dr. T. Thileepan	Senior Lecturer, Unit of Siddha Medicine, University of Jaffna
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12	Mr. V. Gowthaman	Attorney-at-Law
13	Dr. R. Gajanthan	Consultant Resident Physician, Teaching Hospital Jaffna
14	Dr. Aru Thirumurugan	Founder and Director, Sivapoomi Trust, Jaffna

Approved by the Faculty Board, Faculty of Medicine, University of Jaffna, at its 369th meeting held on 21.04.2021.

Approved by the Senate of the University of Jaffna at its 455th meeting held on 18.05.2021.

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History of the Ethics Review Committee of the Faculty of Medicine, University of Jaffna

The first Ethics Review Committee (ERC) of Faculty of Medicine, University of Jaffna (FM, UJ) was established in 1985 and functioned based on the national and international ethical guidelines that existed at the time. Following the establishment of the Forum for Ethics Review Committees of Sri Lanka (FERCSL), the ERC, FM, UJ was reconstituted in 2008 based on the FERCSL guidelines of 2007.

The ERC has held regular board meetings since March 2009. The ERC's operations followed the FERCSL guidelines of 2007 during its initial years. Later the ERC developed its own Terms of Reference (TOR) and Standard Operating Procedures (SOP). The document history of the ERC is given below.

All SOPs and TORs were approved by the Faculty Board, FM, UJ, and the Senate of the University of Jaffna. Members were appointed by the Faculty Board, FM, UJ.

Based on the recommendation of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) survey conducted in August 2017, the ERC revised its SOP (Version 2) to incorporate the SIDCER survey recommendations given by the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP). The SOP (Version 3) became effective in February 2018, and was updated to the current Version 4 in May 2021.

Description	Name and version of the document	Implementation
First guideline developed by the ERC	TOR Version 1	October 2012
Revised guideline developed during the development of SOP	TOR Version 2	February 2014
First SOP developed by the ERC	SOP Version 1	February 2014
Revision of SOP and TOR	TOR Version 3	April 2016
Revision of SOP and TOR	SOP Version 2	April 2016
Revision of SOP as per recommendations of the SIDCER survey	SOP Version 3	February 2018
Revision of SOP	SOP Version 4	May 2021

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 01/ V4
	Title: Functions of the ERC	Effective date: 18/05/2021 Page: 2-3

1.1 Purpose

The purpose of this SOP is to describe the functions and responsibilities of the ERC, FM, UJ.

1.2 Scope

This SOP provides the TOR for the responsibility and activities of the ERC, FM, UJ.

1.3 Responsibility

It is the responsibility of the ERC to ensure that the welfare of participants of research projects submitted to ERC, FM, UJ, is protected by providing an updated ethical framework, guidance and consultation to researchers in order to facilitate adherence to ethical principles and practice in research.

1.4 Functions of the ERC

1.4.1 The ERC, FM, UJ accepts applications for review of research protocols that involve human participants directly or indirectly, which are conducted:

1.4.1.1 by staff and students of the University of Jaffna

1.4.1.2 in the Northern Province of Sri Lanka.

1.4.2 An application fee approved by the Faculty Board of FM, UJ, is charged for all applications except undergraduate projects of the UJ.

1.4.3 The ERC provides independent, competent and timely review on ethical and scientific aspects of the projects involving human participants to ensure the protection of research participants.

1.4.4 The ERC reviews the research projects according to institutional, FERCSL and other national and international guidelines on ethics review.

1.4.5 The ERC will send applications to external subject experts when it lacks the required expertise among its members to review specific subject/technical areas.

1.4.6 The ERC will follow up and monitor approved research projects. As such, the ERC will receive regular progress reports, completion reports and reports on serious adverse effects (SAE) and, when the necessity arises, visit the study site to monitor performance/compliance with the approved protocol. The details of follow up and monitoring procedures are described in SOP18/ V4, 19/ V4 and 20/ V4.

1.4.7 The ERC provides an ethical framework and guidance to improve the standards of biomedical research.

1.4.8 The ERC meets every month to discuss the research projects submitted to the ERC and for other activities. Details of conduct of the ERC meetings are described in SOP 13/ V4.

1.4.9 The ERC will review the SOP at least every three years or whenever necessity arises. The procedure for reviewing the SOP is described in SOP 26/ V4.

1.4.10 The ERC will conduct training programmes/workshops on the SOP and research ethics annually, preferably soon after the appointment of new members. Details of the training for members are described in SOP 5/ V4.

1.5 Accountability

1.5.1 The ERC is accountable to the Faculty Board, FM, UJ and the Senate, UJ. Extracts of the confirmed minutes of the ERC meeting will be sent to the Faculty Board.

1.5.2 The ERC will submit an Annual Report on the activities of the ERC to the Faculty Board at the end of each calendar year.

1.5.3 The ERC maintains financial records and will submit an Annual Financial Report to the Faculty Board at the end of each calendar year.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 02/ V4
	Title: Composition of the ERC	Effective date: 18/05/2021 Page: 4-5

2.1 Purpose

The purpose of this SOP is to describe the composition of the ERC of FM, UJ.

2.2 Scope

The ERC is composed of experts from diverse fields to provide a more comprehensive review of research protocols. This SOP describes the TOR for the composition of the ERC.

2.3 Responsibility

It is the responsibility of the ERC to maintain the composition of the ERC to enable independent and competent review.

2.4 Composition of the ERC

2.4.1 The composition of the ERC is in accordance with FERCSL and other relevant guidelines.

2.4.2 The ERC will comprise of 15-20 members.

2.4.3 The composition should provide the required expertise to review the protocols submitted to the ERC.

2.4.4 The ERC composition should reflect balance between:

- 2.4.4.1 Males and females
- 2.4.4.2 Scientists and community representatives
- 2.4.4.3 Clinicians and medical basic scientists
- 2.4.4.4 Medical and non-medical basic scientists
- 2.4.4.5 Affiliated and non-affiliated members

2.4.5 The ERC will comprise the following categories of members:

- 2.4.5.1 Clinicians from FM, UJ
- 2.4.5.2 Clinicians from institutions other than FM, UJ
- 2.4.5.3 Medical basic scientists from FM, UJ
- 2.4.5.4 Non-medical basic scientists from FM, UJ
- 2.4.5.5 Members from UJ excluding FM
- 2.4.5.6 Experts in statistics
- 2.4.5.7 A legal expert
- 2.4.5.8 Community representatives

2.4.6 The term of ERC members is three years.

2.4.7 At the end of the term, members may be reappointed for a maximum of two more terms or replaced by new members.

2.4.8 The Chairperson, Member Secretary, Vice-Chairperson and Assistant Secretary are elected from among existing ERC members and their names are forwarded to the Faculty Board.

2.4.9 On the recommendation of the Faculty Board of FM, UJ, the Dean appoints the Chairperson, Vice-Chairperson, Member Secretary and Assistant Secretary for a period of three years, unless a necessity arises due to some exigencies. The template of the appointment letter is annexed as Annexure 1/ SOP3/ V4.

2.4.10 The Chairperson and Member Secretary should have a minimum of three years of experience and the Vice-Chairperson and Assistant Secretary should have a minimum of one year of experience as a member of the ERC of FM, UJ.

2.4.11 The ERC has a permanent Administrative Secretary at the ERC Office designated by the Dean, FM, UJ.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 03/ V4
	Title: Appointment of ERC members	Effective date: 18/05/2021 Page: 6-7

3.1 Purpose

The purpose of this SOP is to describe the procedures of appointing and reappointing members to the ERC of FM, UJ.

3.2 Scope

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

3.3 Responsibility

Dean of the FM, UJ appoints the ERC members based on the recommendation of the Faculty Board of FM, UJ, according to the requirements of composition of the ERC and the SOP of the ERC of FM, UJ.

3.4 Procedures for appointment and reappointment of ERC members

3.4.1 The ERC nominates prospective ERC members and forwards the nominations to the Faculty Board.

3.4.2 The selection of members is based on their personal capacities, qualifications, knowledge, experience and expertise in their respective fields, and with consideration to the composition requirements of the ERC.

3.4.3 The Dean, FM, appoints the ERC members based on the recommendation of the Faculty Board, according to the requirements of composition of the ERC and the SOP of ERC, FM, UJ, for a period of three years. The letter of appointment is issued by the Dean of FM, UJ.

3.4.4 The letter of appointment will include the date of appointment, tenure, terms of reference, and conditions of appointment. The template of the appointment letter is annexed as Annexure 1/ SOP3/ V4.

3.4.5 At the time of appointment, members should provide their curriculum vitae (CV; signed paper version and soft copy via email) and they should sign a confidentiality agreement undertaking that

3.4.5.1 all matters of which he/she becomes aware during the course of his/her work in the ERC will be kept confidential.

3.4.5.2 any conflicts of interest which exist or may arise during his/her tenure in the ERC will be declared at the earliest opportunity.

3.4.5.3 he/ she has not been subjected to any criminal conviction or disciplinary action which may prejudice his/her standing as an ERC member.

The confidentiality and conflict of interest agreement is attached as Annexure 2/ SOP3/ V4.

3.4.6 Upon appointment, members will be provided with the following documents:
- 3.4.6.1 Current SOP of the ERC.
- 3.4.6.2 An up-to-date list of members and their contact information, including that of the Dean, FM.

3.4.7 Members must agree to their names, designations and affiliations, being made available to the public including by publishing them on the website of FM, UJ.

3.4.8 Members should complete their training on research ethics, Good Clinical Practice (GCP) and the SOP within 6 months of appointment, or at the earliest available opportunity. Members who fail to complete the above training will be replaced at the end of the term with the appointment of new members.

3.4.9 Members may be re-appointed for a maximum of two additional consecutive terms. After two consecutive reappointments, the member may be reappointed after a break of a period of at least one term (3 years).

3.4.10 If a member fails to attend three consecutive ERC meetings without a letter of excuse, the membership lapses. The Chairperson/Vice-Chairperson will notify the member in writing of such lapse of membership and steps will be taken to fill the vacancy of such a member for the rest of the term, as described in sections 3.4.1, 3.4.2 and 3.4.3 of SOP 03/ V4.

3.4.11 Membership will also lapse if a member fails to attend (with or without excuses) at least two-thirds of all scheduled ERC meetings in a given year, barring exceptional circumstances.

3.4.12 Members may seek a leave of absence from the ERC for up to 3 months. If this period exceeds 3 months, steps will be taken to fill the vacancy of such a member for the rest of the term, as described in sections 3.4.1, 3.4.2 and 3.4.3 of SOP 03/ V4.

3.4.13 A member may resign from the ERC at any time upon giving notice in writing through the Chairperson/ERC to the Dean/FM. The effective date of resignation will be the date in which the resignation is formally accepted by the Faculty Board of FM, UJ. Steps will be taken to fill the vacancy as described above in sections 3.4.1, 3.4.2 and 3.4.3 of SOP 03/ V4.

3.4.14 A member will lose his/her membership in the following circumstances:
- 3.4.14.1 Disclosure of confidential information
- 3.4.14.2 Utilizing proprietary information
- 3.4.14.3 Failure to declare conflict of interest (COI)
- 3.4.14.4 Evidence of personal or professional misconduct

The vacancy of a disqualified member will be filled as described in sections 3.4.1, 3.4.2 and 3.4.3 of SOP 03/ V4.

3.5 Annexure

3.5.1 Annexure 1/ SOP3/ V4 – Letter of appointment for ERC members

3.5.2 Annexure 2/ SOP3/ V4 – Confidentiality and conflict of interest agreement

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 04/ V4
	Title: Functions of ERC members	Effective date: 18/05/2021 Page: 8 - 10

4.1 Purpose

The purpose of this SOP is to describe the functions of members of the ERC.

4.2 Scope

This SOP provides the job description and TOR for the functions of ERC members of FM, UJ.

4.3 Responsibility

4.3.1 Members are responsible for the protection, safety and rights of the participants of the projects reviewed by the ERC.

4.3.2 Members should read, understand and abide by the guidelines and procedures set by the ERC of FM, UJ.

4.3.3 Members should maintain confidentiality.

4.3.4 Members should engage in continuous education / training in their respective fields of expertise, biomedical research and research ethics.

4.4 Functions of ERC members

4.4.1 All members of the ERC of FM, UJ should

4.4.1.1 review applications assigned to them within the stipulated time period and contribute to the discussion on the application at full board meetings.

4.4.1.2 review all applications submitted for full board review and contribute to the discussion on the applications at full board meetings.

4.4.1.3 return the completed review form along with the protocol and supporting documents to the Secretary of the ERC at least two working days before the scheduled meeting.

4.4.1.4 perform any other duties assigned to members according to the SOP and also any other duties assigned by the Chairperson/Vice-Chairperson.

4.4.1.5 disclose conflicts of interest and, where one exists with respect to a study protocol, abstain from reviewing the protocol and leave the room during discussion of and voting on the protocol.

4.4.1.6 remain impartial and objective when reviewing protocols.

4.4.1.7 respect other members' views.

4.4.1.8 keep up-to-date with national and international research ethics and regulatory guidance.

4.4.1.9 undergo periodic training on research ethics according to the following requirements of the ERC of FM, UJ.

4.4.1.9.1 Training on research ethics and GCP at least every 3 years.
4.4.1.9.2 SOP training when a new SOP is implemented.
4.4.1.10 attend ERC meetings regularly except under unavoidable circumstances.

4.4.2 In addition to the functions described in section 4.4.1 of SOP04/ V4, the Chairperson of the ERC is expected to perform the following duties.
4.4.2.1 Conduct the meetings of the ERC according to the SOP.
4.4.2.2 Provide guidance to ERC members and office staff.
4.4.2.3 Periodically review ERC policies and guidelines in consultation with ERC members.

4.4.3 In addition to the functions described in section 4.4.1 of SOP 04/ V4, the Member Secretary of the ERC is expected to perform the following duties.
4.4.3.1 Organize ERC meetings, maintain records and communicate with all concerned.
4.4.3.2 Prepare the minutes of ERC meetings and general correspondence with applicants and obtain approval for these documents/letters from the Chairperson/ Vice-Chairperson before communication.
4.4.3.3 Prepare extracts of the minutes, and after the approval of the Chairperson/ Vice-Chairperson, forward them to the Faculty Board, FM.
4.4.3.4 Ensure the membership files are up-to-date.
4.4.3.5 Arrange sub-committee meetings to assign primary reviewers for applications.
4.4.3.6 Provide guidance and supervise the ERC office staff.
4.4.3.7 Perform any other ERC duties assigned by the Chairperson/ Vice-Chairperson.

4.4.4 In addition to the functions described in section 4.4.1 of SOP 04/ V4, the specific functions of the Vice-Chairperson include
4.4.4.1 carrying out the functions of the Chairperson as described in 4.4.2, in the absence of the Chairperson.

4.4.5 In addition to the functions described in section 4.4.1 of SOP 04/ V4, the specific functions of the Assistant Secretary include
4.4.5.1 Assisting the Member Secretary to prepare the agenda, minutes, communications etc., and organising ERC meetings and training.
4.4.5.2 Carrying out the functions of the Member Secretary as described in 4.4.3, in the absence of the Member Secretary.
4.4.5.3 Performing any other ERC duties assigned by the Chairperson/Vice-Chairperson/Member Secretary.

4.4.6 The specific functions of community representatives include
4.4.6.1 Representing the interests of the community/participants at large.
4.4.6.2 Evaluating the community utility of a project
4.4.6.3 Reviewing the informed consent process.
4.4.6.4 Evaluating benefits and risks to research participants.
4.4.6.5 Ensuring that language and other aspects of a study are appropriate for the study participants.

4.4.7 The functions of the Administrative Secretary include

4.4.7.1 Maintaining confidentiality in all aspects of work related to the ERC; the Administrative Secretary will sign a confidentiality agreement on appointment to the position.

4.4.7.2 Coordinating and processing the ethics review process of applications from the time of submission till the file is closed.

4.4.7.3 Receiving applications and checking all applications for completeness.

4.4.7.4 Sending and receiving communications.

4.4.7.5 Coordinating organizational aspects of the ERC meetings.

4.4.7.6 Preparing the meeting agenda according to the standard format described in SOP 13/ V4 as guided by the Member Secretary/Assistant Secretary.

4.4.7.7 Sending the approved minutes and agenda to all ERC members.

4.4.7.8 Reserving a place for meetings on the scheduled dates and times.

4.4.7.9 Sending the approved extracts of the minutes to the Faculty Board, FM.

4.4.7.10 Practicing the procedures set by the ERC to maintain confidentiality of ERC documents.

4.4.7.11 Recordkeeping and archiving, including maintenance of the registry of applications and the electronic database of the ERC.

4.4.7.12 Organizing training programmes/workshops conducted by the ERC.

4.4.7.13 Performing any other duties assigned by the Chairperson/ Vice-Chairperson and Member Secretary/Assistant Secretary.

In the absence of the Administrative Secretary, the above functions will be covered by the Member Secretary/Assistant Secretary.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 05/ V4
	Title: Orientation of new ERC members and training	Effective date: 18/05/2021 Page: 11–12

5.1 Purpose

The purpose of this SOP is to describe the procedures for orientation of new members and continuous training in research ethics for all members of the ERC of FM, UJ.

5.2 Scope

This SOP provides the TOR for orientation of new members and providing continuous training for ERC members of FM, UJ.

5.3 Responsibility

5.3.1 It is the responsibility of the ERC to provide opportunities for its members to receive the required training in research ethics within the stipulated time period.

5.3.2 It is the responsibility of all members to obtain the required training within the specified timeframe and keep themselves regularly updated and periodically trained on research ethics.

5.4 Procedures for orientation of new members and the provision of training

5.4.1 Adequate orientation should be given to new ERC members before they start functioning as ERC members. The orientation of a new member includes the following:

5.4.1.1 Introduction to other ERC members at the commencement of the ERC meeting.

5.4.1.2 Informal meeting with the Chairperson/Vice-Chairperson and Member Secretary/Assistant Secretary to explain the responsibilities of an ERC member, the ERC procedures and processes.

5.4.1.3 Providing the opportunity to observe an ERC meeting before the new member starts functioning as a reviewer.

5.4.1.4 The ERC will organize training sessions for new members on:

5.4.1.4.1 Research ethics

5.4.1.4.1.1 Periodical in-house training

5.4.1.4.1.2 Annual workshop

5.4.1.4.2 SOP of the ERC of FM, UJ.

5.4.2 Training on research ethics

5.4.2.1 The ERC will organize training programmes on research ethics annually.

5.4.2.2 Members who fail to attend the training organized by the ERC of FM, UJ, should attend a training programme on research ethics organized by FERCSL, other ERCs/ Institutions/ Organisations within the stipulated timeframe (within 6 months of appointment for new members and every 3 years for existing members) in order to retain their membership.

5.4.2.3 A certificate of training on research ethics needs to be submitted by new members within 6 months of appointment to the ERC.

5.4.3 Training on SOP

5.4.3.1 The ERC of FM, UJ will organize SOP training within one month of appointment of new members.

5.4.3.2 The ERC will conduct training on the SOP for all members when a new SOP is implemented or the existing SOP is amended.

5.4.3.3 If a member is not able to attend the SOP training for valid reasons (professional commitments/ illness/ important personal commitments), on the written request of such member to the Chairperson, an additional SOP training session may be conducted.

5.4.3.4 A certificate of training on the SOP needs to be submitted by new members within a month of appointment.

5.4.4 Training on GCP

5.4.4.1 The ERC of FM, UJ will arrange for its members to attend the GCP training programme conducted by FERCSL annually.

5.4.4.2 Members who fail to attend the GCP training conducted by FERCSL must attend training programmes on GCP organized by other ERCs / Institutions/ Organisations or complete an online GCP training within the stipulated timeframe (within 6 months of appointment for new members and every 3 years for existing members) in order to retain their membership.

5.4.4.3 A certificate of GCP training needs to be submitted by new members within 6 months of appointment.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 06/ V4
	Title: External subject experts	Effective date: 18/05/2021 Page: 13 – 14

6.1 Purpose

The purpose of this SOP is to describe the procedure of appointing external subject experts for review of applications submitted to the ERC of FM, UJ, and their role in ethics review.

6.2 Scope

This SOP provides the TOR for appointing an external subject expert when a project involves information or procedures outside the expertise of members of ERC of FM, UJ or a member/s with the required expertise to review such project has/ have COI. This SOP also describes the role of external subject experts in ethics review.

6.3 Responsibility

6.3.1 It is the responsibility of the Chairperson and Member Secretary to identify external subject experts with appropriate expertise when a project involves information or procedures outside the expertise of members of ERC of FM, UJ.

6.3.2 The Chairperson and Member Secretary should ensure that the external subject expert understands the procedures and process of ethics review.

6.4 Procedure for appointment of external subject experts and their role

6.4.1 The ERC should have a panel of external subject experts anticipating the expertise that would be required outside that of the ERC members.

6.4.2 The pool of external subject experts will include language experts to review translations.

6.4.3 The Dean will appoint the external subject experts nominated by the ERC on the recommendation of Faculty Board of FM, UJ.

6.4.4 External subject experts should receive a letter of appointment signed by the Dean of FM, UJ. The template of the letter of appointment of external subject experts is annexed as Annexure 3/ SOP6/V4.

6.4.5 External subject experts are appointed for a period of three years.

6.4.6 The conditions of appointment for external subject experts include

6.4.6.1 Signing a confidentiality agreement

6.4.6.2 Disclosure of conflict of interest

6.4.6.3 Willingness to publicize his/her full name, designation and affiliation to the public including by publishing these details in the website of FM, UJ.

6.4.7 If the required expertise is not available among the existing panel of external subject experts, the Chairperson in consultation with the Member Secretary and/ or other member/s will nominate a person with the required expertise outside the panel of external subject experts. Covering approval from the ERC and Faculty Board, FM, UJ will be obtained.

6.4.8 The Chairperson and/or Member Secretary will describe the specific duties, review process and responsibilities to all external subject experts.

6.4.9 Once an external subject expert is nominated for reviewing a specific protocol, the Member Secretary/Assistant Secretary will contact the external subject expert and send the relevant documents for review.

6.4.10 The external subject expert must review the protocol and send the completed protocol review form to the Member Secretary at least two working days before the next scheduled ERC meeting. The review report of the external subject expert will be taken up at the discussion of the protocol concerned.

6.4.11 If required, the ERC may invite the external subject expert to participate in the discussion regarding the protocol at the ERC meeting.

6.4.12 The external subject expert will not participate in the decision-making process of the protocol under review or on any other ERC matter.

6.4.13 External subject experts will not have voting rights at the ERC meeting.

6.5 Annexure

6.5.1 Annexure 3/ SOP6/ V4 – Letter of appointment for external subject experts

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 7/ V4
	Title: Conflict of interest	Effective date: 18/05/2021 Page: 15 – 16

7.1 Purpose

Purpose of this SOP is to describe the procedures for declaring and handling conflicts of interest (COI).

7.2 Scope

This SOP covers the procedures for declaring COI by the ERC members, office staff, external subject experts and guest attendees/PI and handling COI by the ERC of FM, UJ.

7.3 Responsibility

7.3.1 It is the responsibility of the ERC to instruct its members, office staff, external subject experts and guest attendees regarding disclosure of COI.

7.3.2 It is the responsibility of the ERC members to declare COI before the protocol/ matter concerned is taken up for review.

7.4 Procedures for declaration and handling of COI

7.4.1 COI should be declared in the following circumstances;

- 7.4.1.1 Direct COI
  - 7.4.1.1.1 Being the PI or one of the co-investigators/supervisors.
  - 7.4.1.1.2 Being part of the research team as a consultant /member of monitoring committee /in-charge for recruitment /data collector etc.
  - 7.4.1.1.3 Being a potential participant of the project concerned.
  - 7.4.1.1.4 Receiving financial benefits from the project concerned.
- 7.4.1.2 Indirect COI
  - 7.4.1.2.1 Being a reviewer of another committee /sponsor /funding agency for the review of the protocol concerned.
  - 7.4.1.2.2 Involved in another project in the same research area as the protocol concerned.
  - 7.4.1.2.3 When a first degree relative is in the research team of the protocol under review.

7.4.2 Members/ office staff/ external subject experts/ guest attendees should declare if they have a direct or indirect COI and refrain from involving in any matters related to the protocol/ matter concerned (Annexure 2/ SOP3/ V4).

7.4.3 The ERC will determine if the declared COI could potentially result in a COI for the member and, if so, the member will withdraw from the meeting until the

ERC's consideration of the relevant matter is completed. The member will not be permitted to adjudicate on the project.

7.4.4 All declarations of COI and their resolution will be recorded in the minutes.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 8/ V4
	Title: Submission of applications for ethics review	Effective date: 18/05/2021 Page: 17 - 19

8.1 Purpose

The purpose of this SOP is to describe the procedure for submission of new applications for ethics review.

8.2 Scope

This SOP provides the TOR for the procedures for submission of new applications for ethics review to the ERC of FM, UJ.

8.3 Responsibility

It is the responsibility of the Administrative Secretary to receive, register and process the applications submitted to the ERC Office of FM, UJ.

8.4 Procedure for submission of new applications for ethics review

8.4.1 Applications along with the relevant documents must be submitted to the ERC Office of FM, UJ. The ERC accepts applications from Monday to Friday during office hours.

8.4.2 The Administrative Secretary will receive the applications, check them for completeness, and then process the applications.

8.4.3 All applications submitted before the close of business of the last working day of the month will be taken up at the next scheduled meeting.

8.4.4 All new applications must be submitted in the prescribed format by the ERC of FM, UJ. The Application Form for Ethics Review and the Guide to Applicants are available at the faculty website at this link. The application form and guide are annexed as Annexure 4/ SOP8/ V4 and Annexure 5/ SOP8/ V4, respectively.

8.4.5 The application form must be duly filled, signed and submitted along with one (01) copy of the following documents;

8.4.5.1 Complete research protocol.

8.4.5.2 Information sheets and consent forms in English with Tamil and Sinhala translations where applicable.

8.4.5.3 Other relevant documents such as questionnaires, data sheets, checklists etc. in English with Tamil and Sinhala where applicable.

8.4.5.4 The updated CV of the Principal Investigator (PI) and CV of the Chief Supervisor of postgraduate studies.

8.4.5.5 If scientific review of postgraduate research proposals has been undertaken, a letter from the relevant postgraduate institute / Board of Study stating that the proposal has been reviewed and approved.

8.4.5.6 Soft copies of all the above in word file and PDF format by email to …….

8.4.6 The initial protocol and all supporting documents must indicate Version 1 in the header/footer of all pages of all documents.

8.4.7 A non-refundable application fee will be charged for all new applications except undergraduate research projects of UJ.

8.4.7.1 The fee structure is available in the Guide to Applicants (Annexure 5/SOP8/V4)

8.4.7.2 The authorized counter copy of the completed paying in voucher (available at this link) for the payment of the application fee should be submitted along with the application. The paying in voucher is annexed as Annexure 6/ SOP8/ V4.

8.4.7.3 The payment may be made by cash/money order/postal order (in favour of ERC, Faculty of Medicine, University of Jaffna) at the Shroff Counter of the University of Jaffna or at any branch of the Bank of Ceylon to the credit of the account number provided in the paying in voucher.

8.4.8 The applications will be checked for completeness by the Administrative Secretary with the help of a checklist.

8.4.9 The Administrative Secretary will accept complete applications, date stamp all enclosed documents, and issue a copy of the checklist as proof of receipt to the PI. The document receipt check list is attached as Annexure 7/ SOP8/ V4.

8.4.10 Once a completed application is accepted for ethics review, the Administrative Secretary will assign a unique reference number to the application, and enter the application details into the ERC's register for applications.

8.4.11 The accepted applications along with all relevant documents and soft copies will be filed. Each protocol will have a specific protocol file and all documents and communications related to the protocol will be added to the protocol file.

8.4.12 The Member Secretary will categorize all the new proposals within the first week of the next month, and will call for a sub-committee meeting. The sub-committee comprising the Chairperson/Vice-Chairperson or nominee, Member Secretary/Assistant Secretary or nominee and another ERC member will decide the type of review required for the protocols submitted in the previous month.

8.4.13 For applications requiring full board review, the subcommittee will appoint at least three (03) primary reviewers per application. Primary reviewers will include a subject expert (or more if necessary), an expert in statistics (to review the appropriateness of methodology and sample size) and a community representative. Primary reviewers will be selected from among the ERC members if the required expertise is available. If not, primary reviewers may be invited from the pool of external subject experts.

8.4.14 Submission of undergraduate projects

8.4.14.1 Undergraduate research projects should be submitted under the responsibility of Heads of departments.

8.4.14.2 Such protocols should be forwarded through the Head of the department concerned.

8.4.14.3 A subcommittee comprising the Chairperson/nominee, Secretary /nominee and Head/nominee of the department concerned will review undergraduate projects.

8.4.15 Submission of collaborative research projects

In the case of international collaborative research, the following documents should be submitted with the application;

8.4.15.1 Evidence of prior written agreement between the local and foreign collaborators on the following;

8.4.15.1.1 Fate of data and samples/ specimens.

8.4.15.1.2 Ownership of data, publication and intellectual property rights.

8.4.15.1.3 Nature of benefits and their distribution.

8.4.15.2 An ethical clearance certificate from the country/countries of the collaborators.

8.4.15.3 Transfer of biological or genetic materials should follow national standards and the relevant supporting documents should be submitted.

8.5 Annexure

8.5.1 Annexure 4/ SOP8/ V4 – Application for Ethics review

8.5.2 Annexure 5/ SOP8/ V4 – Guide to Applicants

8.5.3 Annexure 6/ SOP8/ V4 – Paying in voucher

8.5.4 Annexure 7/ SOP8/ V4 – Document Receipt Checklist

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 9/ V4
	Title: Exemption from ethics review	Effective date: 18/05/2021 Page: 20 – 21

9.1 Purpose

The purpose of this SOP is to describe the procedure of identifying the protocols that are eligible for exemption from ethics review, and providing such exemptions.

9.2 Scope

This SOP provides the criteria and standards for exempting from ethics review.

9.3 Responsibility

It is the responsibility of a subcommittee comprising the Chairperson/ Vice-Chairperson (or nominee), Member Secretary/Assistant Secretary (or nominee), and another ERC member to assess and decide on exempting from ethics review using the criteria set by the ERC of FM, UJ.

9.4 Procedure for exemption from ethics review

9.4.1 The ERC will consider research projects that fall into any one of the following categories for exemption from ethics review;

9.4.1.1 Research that relies exclusively on secondary use of anonymous information (i.e., data that does not identify subjects directly or through identifiers linked to them), provided the research does not generate any identifiable findings/results.

9.4.1.2 Research that involves analysis of data freely available in the public domain, provided the findings do not constitute an invasion of privacy.

9.4.1.3 Studies that are conducted on educational activities (teaching techniques, curricula, class room management, etc.) that do not involve deviation from routine education practices at the specific educational settings, provided no identifiable information is used and the researchers do not intend to make public/publish the results.

9.4.1.4 Professional development activities that involve others (e.g. colleagues, students) to solicit information that can be used for self-evaluation or improvement, provided no information collected is identifiable and the researchers do not intend to make public/publish the results.

9.4.1.5 Projects aimed at monitoring or improving performance of an organization/ institution, provided no information about the participants is identifiable and the researchers do not intend to make public/publish the results.

9.4.2 The sub-committee comprising the Chairperson/ Vice-Chairperson (or nominee), Member Secretary/Assistant Secretary (or nominee) and an ERC member will assess the protocols for eligibility to exempt from ethics review as per the Checklist for Exemption from Ethics Review (Annexure 8/ SOP9/ V4).

9.4.3 When a proposal is exempted from ethics review, the Chairperson/Vice-Chairperson will communicate the decision to grant exemption at the next ERC meeting. The formal letter of exemption from ethics review will be issued after ratification at the next ERC meeting.

9.4.4 All documents and communications related to the protocol will be filed in a specific protocol file.

9.5 Annexure

9.5.1 Annexure 8/ SOP9/ V4 – Checklist for Exemption from Ethics Review

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 10/ V4
	Title: Expedited ethics review	Effective date: 18/05/2021 Page: 22 – 23

10.1 Purpose

The purpose of this SOP is to describe the procedures to be followed for expedited review of applications submitted for ethics review.

10.2 Scope

This SOP provides criteria and standards for expedited ethics review.

10.3 Responsibility

It is the responsibility of a subcommittee comprising the Chairperson/ Vice-Chairperson (or nominee), Secretary/Assistant Secretary (or nominee) and an ERC member to assess and decide on expedited ethics review using the criteria set by the ERC of FM, UJ.

10.4 Procedure for expedited review

10.4.1 The ERC of FM, UJ may undertake expedited review of research protocols between scheduled meetings by a subcommittee comprising the Chairperson/ Vice-Chairperson (or nominee), Member Secretary/Assistant Secretary (or nominee) and an ERC member.

10.4.2 The committee may seek views of suitably qualified experts if needed before reaching a decision.

10.4.3 Research protocols could be considered for expedited review if they carry minimal risk and are on non-sensitive topics, in the following circumstances;

10.4.3.1 Research that involves non-sensitive information using secondary data where the subjects involved are likely to be identified directly or indirectly (e.g. reviewing prescriptions, bed head tickets, etc.).

10.4.3.2 Observational studies to assess the effectiveness or quality assurance of an existing programme that will not manipulate the participants' behaviour or cause stress to the participants.

10.4.3.3 Studies related to sudden disease outbreaks that are expected to exist for a short period.

10.4.4 Research proposals involving the following will not be considered for expedited review;

10.4.4.1 Clinical trials

10.4.4.2 Invasive physical procedures

10.4.4.3 Sensitive personal or cultural issues

10.4.4.4 Vulnerable groups (children <12 years, pregnant women, war-affected persons, prisoners, etc.).

10.4.5 At the sub-committee meeting, the Chairperson/Vice-Chairperson (or nominee), Member Secretary/Assistant Secretary (or nominee) and an ERC member will assess the protocol for eligibility for expedited review.

10.4.6 If eligible for expedited review, an ERC member or an external subject expert will be appointed to review the protocol in full.

10.4.7 Once the reviewer is appointed, the Member Secretary/Administrative Secretary will send the following documents to the reviewer;

10.4.7.1 Copy of the application form

10.4.7.2 Protocol and supporting documents

10.4.7.3 Protocol review form and, when applicable, the informed consent review form

10.4.8 The review should be completed within two (02) weeks of the subcommittee meeting.

10.4.9 Once the reviewer's report is received, the Chairperson in consultation with the reviewer and Member Secretary will arrive at a decision. If the Chairperson/ Member Secretary is the reviewer, the decision will be taken by the Vice-Chairperson/Assistant Secretary and the reviewer. The decision could be;

10.4.9.1 Approve the proposal.

10.4.9.2 Minor revisions needed.

10.4.9.3 Full board review needed.

10.4.10 The ERC will be informed regarding the details of any proposals that have undergone expedited review, including the decision, at the next regular meeting. Ethical clearance will be sent to the PI after ratification at the meeting.

10.4.11 If minor revisions are needed, the Member Secretary/Assistant Secretary will communicate with the PI as soon as possible, and request the PI to resubmit the revised version. If the Chairperson/Vice-Chairperson and Member Secretary /Assistant Secretary are satisfied with the revisions, the Chairperson/Vice-Chairperson will approve the proposal and the decision will be communicated to the ERC.

10.4.12 If any ERC member raises concerns about expedited review, then, based on the decision of the ERC, the proposal may need to undergo full board review.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 11/ V4
	Title: Full board review of new applications	Effective date: 18/05/2021 Page: 24 – 25

11.1 Purpose

The purpose of this SOP is to describe the procedures to be followed when a new application is submitted to the ERC of FM, UJ, and is subjected to full board review.

11.2 Scope

This SOP provides the standards and timelines for the procedures to be followed when a new application is subjected to full board review.

11.3 Responsibility

11.3.1 It is the ERC's responsibility to ensure the protection of the rights and welfare of research participants by providing independent, competent and timely review.

11.3.2 Reviewers are responsible for reading, understanding, and adhering to the procedures and standards set by the ERC of FM, UJ for reviewing protocols.

11.3.3 The Member Secretary/Assistant Secretary and Administrative Secretary should make sure that review processes take place according to the standards and timelines set by the ERC of FM, UJ.

11.4 Procedures for full board review of new applications

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

11.4.2 At the sub-committee meeting, the Chairperson/ Vice-Chairperson (or nominee), Member Secretary/Assistant Secretary (or nominee) and an ERC member will appoint 3 primary reviewers for each new application that requires full board review as described in section 8.4.13, of SOP 8/ V4.

11.4.3 On the instruction of the Member Secretary, the Administrative Secretary will send the following documents to the primary reviewers, in hard or soft copy (based on the preference of reviewers), as early as possible, not later than three (03) working days after the subcommittee meeting;

- 11.4.3.1 Copy of application form
- 11.4.3.2 Curriculum vitae
- 11.4.3.3 Protocol
- 11.4.3.4 Supporting documents including Tamil and Sinhala translations
- 11.4.3.5 Review forms
  - 11.4.3.5.1 Protocol Review Form; or
  - 11.4.3.5.2 Form to Assess Community Acceptability

The Protocol Review Form and the Form to Assess Community Acceptability are annexed as Annexures 9/ SOP 11/ V4 and 10/ SOP11/ V4, respectively.

11.4.4 Primary reviewers should

11.4.4.1 review the application in detail prior to the meeting.

11.4.4.2 return the completed review form to the Member Secretary at least two working days prior to the scheduled meeting.

11.4.4.3 when necessary, request the applicant to submit additional documents or information through the ERC.

11.4.5 All proposals will be circulated by soft/hard copy to all members of the ERC for review at least 7 days prior to the scheduled meeting, generally along with the minutes and agenda for the next meeting. All ERC members are expected to be familiar with the proposals to be taken up for full board review, and contribute to the discussion at the meeting. Written submissions made by those not present will be considered.

11.4.6 The ERC will assess proposals submitted for review in accordance with institutional, FERCSL and other national and international guidelines, and national and international law to determine their acceptability on matters of ethics. Thus, ERC members must ensure that they are sufficiently informed on all aspects of a research proposal, including its scientific validity, to make an assessment.

11.4.7 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 participants' language(s) and that the translations convey the same message as the English version.

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

11.4.9 After considering an application at a meeting, the ERC will make a decision on whether to approve the protocol, request for minor revisions, request for resubmission with major corrections, or disapprove the protocol, as described in section 13.4.9 of SOP 13/ V4.

11.4.10 Decision making

11.4.10.1 The ERC will endeavor to reach a decision concerning the ethical acceptability of a protocol by consensus.

11.4.10.2 Any significant dissenting view or concern will be noted in the minutes.

11.4.10.3 Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members, provided that the majority includes at least one community representative.

11.4.10.4 The decision of the ERC will be communicated to the PI in writing.

11.5 Annexure

11.5.1 Annexure 9/ SOP11/ V4 – Protocol Review Form

11.5.2 Annexure 10/ SOP11/ V4 – Informed Consent Review Form

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 12/ V4
	Title: Preparation of the agenda for ERC meetings	Effective date: 18/05/2021 Page: 26 – 27

12.1 Purpose

The purpose of this SOP is to describe the procedure for preparing the agenda for the ERC meeting of the ERC of FM, UJ.

12.2 Scope

This SOP provides the TOR for preparing the agenda for the forthcoming meeting of the ERC based on matters of the previous minutes, new applications, follow up and any other matters to be discussed.

12.3 Responsibility

12.3.1 It is the responsibility of the of the Member Secretary/Assistant Secretary to prepare the agenda and get the approval of the Chairperson / Vice-Chairperson.

12.3.2 It is the responsibility of the Administrative Secretary to circulate the approved agenda along with other relevant documents among the members of the ERC within the stipulated timeframe.

12.4 Description of the procedures for preparing the agenda for the ERC meeting

12.4.1 The Member Secretary/Assistant Secretary will prepare the agenda for the forthcoming meeting of the ERC and get it approved by the Chairperson/Vice-Chairperson.

12.4.2 The agenda of the ERC meeting will be prepared considering the following;

- 12.4.2.1 Matters to be raised from minutes of the previous meeting.
- 12.4.2.2 New applications
- 12.4.2.3 Follow up of reviewed and approved projects
- 12.4.2.4 Any other matters to be discussed

12.4.3 New applications that are submitted on or before the closing of the last working day of the previous month will be included in the agenda.

12.4.4 Other documents including those pertaining to previously reviewed / approved projects also will be included in the agenda.

12.4.5 Contents of the agenda include

- 12.4.5.1 Date, time and venue of the meeting
- 12.4.5.2 Preliminaries
  - 12.4.5.2.1 Excuses
  - 12.4.5.2.2 Announcements
- 12.4.5.3 Declarations of conflict of interest

12.4.5.4 Conformation of the minutes of the previous meeting
12.4.5.5 Matters arising from the minutes
12.4.5.5.1 Protocols awaiting revisions and/ or clarifications
12.4.5.6 New applications
12.4.5.6.1 Exempted from ethics review
12.4.5.6.1.1 Title of the project
12.4.5.6.1.2 Full name of the PI
12.4.5.6.1.3 Reference number
12.4.5.6.2 Expedited review
12.4.5.6.2.1 Title of the project
12.4.5.6.2.2 Full name of the PI
12.4.5.6.2.3 Reference number
12.4.5.6.3 Full board review
12.4.5.6.3.1 Title of the project
12.4.5.6.3.2 Full name of the PI
12.4.5.6.3.3 Reference number
12.4.5.6.3.4 Names of the primary reviewers
12.4.5.6.4 Undergraduate projects
12.4.5.7 Follow up
12.4.5.7.1 Amendments
12.4.5.7.2 Request for extension of ethical clearance
12.4.5.7.3 Progress reports
12.4.5.7.4 Completion reports
12.4.5.7.5 Reports on adverse events
12.4.5.7.6 Reports on site visits
12.4.5.7.7 Protocol Deviation and violation
12.4.5.7.8 Other communications related to approved protocols
12.4.5.8 Correspondence
12.4.5.9 Any other business
12.4.5.10 Close and date of next meeting

Template for the agenda of the meeting is attached as Annexure 11/ SOP12/ V4.

12.4.6 The Administrative Secretary will circulate the approved agenda along with the minutes and other documents to all ERC members 7 days before the next scheduled meeting of the ERC.

12.5 Annexure

12.5.1 Annexure 11/ SOP12/ V2 – Agenda of the meeting

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 13/ V4
	Title: Conduct of ERC meetings	Effective date: 18/05/2021 Page: 28 – 29

13.1 Purpose

The purpose of this SOP is to describe the procedure for conducting ERC meetings.

13.2 Scope

This SOP provides the TOR for the procedure to be followed in conducting the scheduled meetings of the ERC of FM, UJ.

13.3 Responsibility

13.3.1 It is the responsibility of the Chairperson/ Vice-Chairperson and Member Secretary/Assistant Secretary to schedule the monthly meetings of the ERC, as well as special meetings, if necessary.

13.3.2 The Administrative Secretary is responsible for organizing the meeting and informing the ERC members.

13.4 Procedure for conducting scheduled ERC meetings

13.4.1 The ERC generally meets on the fourth Tuesday of the month. Dates of the ERC meetings for the year will be pre-decided and be publicly available in the website and notice board of the ERC.

13.4.2 Members attend the meeting in person; those who are unable to attend the meeting must inform their excuses in writing to the Member Secretary prior to the meeting. Such excuses will be recorded in the minutes.

13.4.3 A quorum must be present for the ERC to arrive at a final decision on any agenda item. A quorum for the meeting of the ERC is at least five (05) members, among whom should be the Chairperson/Vice-chairperson, Member Secretary /Assistant Secretary, and a community representative.

13.4.4 If the meeting does not meet the quorum requirements, the Chairperson/ Vice-Chairperson will cancel it and the ERC will convene another meeting within ten (10) working days of the cancelled meeting.

13.4.5 Meetings will usually continue until all agenda items have been considered. In the event that the meeting has to be concluded before this, the ERC will reconvene within 10 working days of the meeting to complete the agenda.

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

13.4.7 Guest attendees/PIs may be invited to the meetings to discuss protocols or for expert opinion. Such attendees must declare COI and sign a confidentiality

agreement before attending the meeting. Guest attendees will not be involved in decision making.

13.4.8 Any member of the ERC who has any potential COI must declare such interest beforehand. This will be dealt with in accordance with SOP 7/ V4.

13.4.9 After reviewing each (new/revised/amended) proposal, the ERC will make one of the following decisions:

13.4.9.1 Approve the proposal: as being ethically acceptable without revision.

13.4.9.2 Revision with minor correction: eligible for expedited review on resubmission.

13.4.9.3 Resubmission with major correction: requires full board review on resubmission; the revised protocol will be re-reviewed by the same primary reviewers.

13.4.9.4 Disapprove the proposal: as being ethically unacceptable; reasons for disapproval will be conveyed to the applicant.

13.4.10 At the closure of the meeting, the date for the next meeting will be confirmed/ decided.

13.4.11 Special meetings of the ERC

13.4.11.1 Special meetings may be conducted in between regular ERC meetings.

13.4.11.2 The Member Secretary in consultation with the Chairperson/ Vice-Chairperson will call for a special meeting.

13.4.11.3 Special meetings of the ERC may be called

13.4.11.3.1 when a regular meeting of the ERC is cancelled due to a lack of quorum.

13.4.11.3.2 when all agenda items of a regular meeting could not be considered.

13.4.11.3.3 for some specific purpose such as revision of the SOP.

13.4.11.4 The minutes of the special meeting will be circulated and taken up at the next regular meeting of the ERC.

13.4.12 Emergency meeting

13.4.12.1 The Chairperson/ Vice-Chairperson of the ERC may direct the Member Secretary to call for an emergency meeting of the ERC in situations where urgent decisions of the ERC are needed such as reports of death or serious adverse events (SAE) associated with an approved protocol.

13.4.12.2 The emergency meeting should be held as soon as possible, not later than three (03) days from the date of receiving a report of such an event.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 14/ V4
	Title: Minutes of ERC meetings	Effective date: 18/05/2021 Page: 30 – 31

14.1 Purpose

The purpose of this SOP is to describe the format and procedure for preparing the minutes of the meetings of the ERC of FM, UJ.

14.2 Scope

This SOP provides the administrative framework for preparing the minutes of meetings of the ERC of FM, UJ.

14.3 Responsibility

14.3.1 It is the responsibility of the Member Secretary/Assistant Secretary to prepare the minutes of the meetings according to the format set by the ERC of FM, UJ.

14.3.2 The Chairperson/ Vice-Chairperson will review and approve the minutes before circulating it among members.

14.4 Format and procedure for preparing the minutes of ERC meetings

14.4.1 The Member Secretary/Assistant Secretary will prepare the meeting minutes.

14.4.2 The minutes of the ERC should include the following;

- 14.4.2.1 Attendance
- 14.4.2.2 Preliminaries
- 14.4.2.3 Conflicts of interest
- 14.4.2.4 Confirmation of minutes of the previous meeting
- 14.4.2.5 Matters arising from the minutes
- 14.4.2.6 New applications
  - 14.4.2.6.1 Exemption from ethics review
  - 14.4.2.6.2 Expedited review
  - 14.4.2.6.3 Full board review
  - 14.4.2.6.4 Undergraduate projects
- 14.4.2.7 Follow up
  - 14.4.2.7.1 Amendments
  - 14.4.2.7.2 Extension of ethical approval
  - 14.4.2.7.3 Reports on SAE
  - 14.4.2.7.4 Progress reports
  - 14.4.2.7.5 Completion report
  - 14.4.2.7.6 Protocol violation or deviation
  - 14.4.2.7.7 Other communications related to approved protocols
- 14.4.2.8 General correspondence

14.4.2.9 Any other business

14.4.2.10 Close and date and time of the next meeting

The template for the meeting minutes is annexed as Annexure 12/ SOP14/ V4.

14.4.3 The minutes should include

14.4.3.1 A summary of the discussion including reference to views expressed in writing by absent members

14.4.3.2 The decision of the ERC

14.4.4 The following needs to be recorded for review of new protocols and amendments

14.4.4.1 The decision of the ERC

14.4.4.2 Clarifications /additional information requested, when applicable

14.4.4.3 Views or concerns of reviewers and other members

14.4.5 In the record of review comments, names of members will not be quoted unless a member specifically asks to have his/her opinion or objections recorded by name.

14.4.6 Declarations of COI by members, and their absence during the discussion of the protocol concerned, must be recorded.

14.4.7 The Member Secretary will prepare the minutes after the meeting and they will be reviewed and approved by the Chairperson.

14.4.8 The minutes along with the agenda for the next meeting, and the new applications requiring full board review, will be circulated among members at least 7 days prior to the meeting.

14.4.9 All members shall be given the opportunity to seek amendments to the minutes prior to their confirmation.

14.4.10 The original version of the minutes will be kept in the minutes file.

14.4.11 Extracts of minutes of each meeting will be sent to the Faculty Board, FM, UJ. The template for the extracts of minutes is annexed as Annexure 13/ SOP14/ V4.

14.5Annexure

14.5.1 Annexure 12/ SOP14/ V4 – Minutes of ERC meetings

14.5.2 Annexure 13/ SOP14/ V4 – Extract of minutes of ERC meetings

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 15/ V4
	Title: Communication of decisions of the ERC	Effective date: 18/05/2021 Page: 32 – 34

15.1 Purpose

The purpose of this SOP is to describe the procedures for communicating the decisions of the ERC concerning a new application/ resubmission / amendment.

15.2 Scope

This SOP provides the standards and procedures for communicating the decisions of the ERC regarding a new application/ resubmission / amendment to the PI.

15.3 Responsibility

15.3.1 It is the responsibility of the Chairperson/ Vice-Chairperson/ and Member Secretary/Assistant Secretary to communicate the decision of the ERC concerning a new application/ resubmission/ amendment to the PI according to the standard format and timelines set by the ERC of FM, UJ.

15.3.2 The Administrative Secretary is responsible for sending the correspondence to the PI within the stipulated timeframe and recording the same in the appropriate register/ record.

15.4 Procedure for the communication of ERC decisions

15.4.1 The decision of the ERC should be communicated to the PI in writing within seven (07) working days of the monthly ERC meeting.

15.4.2 The Member Secretary /Assistant Secretary will prepare such communications.

15.4.3 Correspondence regarding the decision of the ERC will be signed by the Chairperson/ Vice-Chairperson or the Member Secretary/Assistant Secretary (with the approval of Chairperson/ Vice-Chairperson).

15.4.4 The Administrative Secretary will send the correspondence to the PI and also enter the details of such communication in the appropriate registry/ record.

15.4.5 The decision to solicit further clarifications from the PI should be communicated in writing and signed by the Chairperson/Vice-Chairperson/Member Secretary/Assistant Secretary.

15.4.5.1 If the ERC decides to request the PI for further information, clarification or modification, the correspondence to the PI should be in the standard format and include the following;

15.4.5.1.1 Date of communication

15.4.5.1.2 Reference number
15.4.5.1.3 Title of project
15.4.5.1.4 Date of submission
15.4.5.1.5 Name and address of the PI
15.4.5.1.6 Date of the ERC meeting
15.4.5.1.7 Type of decision
15.4.5.1.8 Reasons for this decision
15.4.5.1.9 Request for additional information/ clarification/ modification if needed

The template for requesting further clarification/ information is annexed as Annexure 14/ SOP17/ V4.

15.4.5.2 If the ERC decides to exempt the protocol from ethics review, the decision should be communicated in the standard format and signed by the Chairperson/Vice-Chairperson and Member Secretary/ Assistant Secretary. The template for this correspondence is given in Annexure 15/ SOP17/ V4.

15.4.5.3 Communication of ethical approval will be in writing and signed by the Chairperson/Vice-Chairperson and Member Secretary/Assistant Secretary, and will contain the following;

15.4.5.3.1 Date of communication
15.4.5.3.2 Reference number
15.4.5.3.3 Title of the project
15.4.5.3.4 Version number of the protocol
15.4.5.3.5 Date of submission
15.4.5.3.6 Name and address of PI
15.4.5.3.7 Names of co-investigators with affiliations
15.4.5.3.8 Date of ERC meeting at which approval was granted
15.4.5.3.9 Conditions, if any, to which ERC approval is subject
15.4.5.3.10 Period of validity of ethical approval
15.4.5.3.11 Frequency of progress reports
15.4.5.3.12 Instructions for submission of the final report.

The template for ERC approval is annexed as Annexure 16/ SOP17/ V4.

15.4.5.4 Data collection should not commence until written notification has been received by the applicant confirming ethical approval.

15.4.5.5 For interventional studies, the conditions for reporting SAE should be included in the approval letter.

15.4.5.6 For researches that involve international collaboration, the condition of approval should include a clause to protect the rights of the local collaborator. The following should be included;

15.4.5.6.1 The ownership of the data and right of publication should lie with the researcher who collects the data.

15.4.5.6.2 In the case of multicenter research, data must be pooled for publication, but, researchers from Sri Lanka should be allowed to publish data collected by them that are of relevance to this country.

15.4.6 If the ERC determines that a protocol is disapproved on ethical or other grounds, the communication of the ERC's decision will include the reason for disapproval with reference to the FERCSL guidelines or other relevant legislation. A standard letter will be issued, in the format set out by the ERC of FM, UJ, and will be signed by the Chairperson and Member Secretary. In situations when both Chairperson and Member Secretary have COI, the Vice-Chairperson and Assistant Secretary will sign the letter. The template for disapproval of protocols is annexed as Annexure 17/ SOP17/ V4.

15.4.7 Office copies of all communications will be filed in the respective protocol files and the status of the protocol will be updated in appropriate registries / records.

15.4.8 Communications related to undergraduate projects will be done through the Heads of the respective departments. Once ethical approval is given, the department concerned will be responsible for the conduct and monitoring of the project.

15.5 Annexure

15.5.1 Annexure 14/ SOP17/ V4 – ERC review comments to PI

15.5.2 Annexure 15/ SOP17/ V4 – Exemption from ethics review

15.5.3 Annexure 16/ SOP17/ V4 – ERC approval

15.5.4 Annexure 17/ SOP17/ V4 – ERC disapproval

15.5.5 Annexure 18/ SOP17/ V4 – Approval for amendments to protocol

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 16/ V4
	Title: Review of resubmitted protocols	Effective date: 18/05/2021 Page: 35 – 36

16.1 Purpose

The purpose of this SOP is to describe the procedures to manage, re-review and approve resubmitted protocols.

16.2 Scope

This SOP provides the standards and timelines for the procedures to be followed when reviewing protocols which have been resubmitted after initial review by the ERC.

16.3 Responsibility

16.3.1 It is the responsibility of the Member Secretary/Assistant Secretary and Administrative Secretary to ensure the completeness of the resubmitted documents and notify the Chairperson/ Vice-Chairperson of receipt.

16.3.2 It is the responsibility of the Chairperson/ Vice-Chairperson and Member Secretary/Assistant Secretary to process the resubmission based on the decision of the ERC.

16.4 Procedures for management of resubmitted protocols

16.4.1 The resubmission should include the following documents;

16.4.1.1 Duly signed cover letter indicating the changes made in the protocol with page number and/ or supporting documents, according to the recommendations of the ERC.

16.4.1.2 Revised protocol with the version of the protocol indicated on each page of the protocol (one copy)

16.4.1.3 Supporting documents with the version of the protocol indicated on each page of the documents (one copy).

16.4.1.4 Soft copies of all the above documents in word/pdf by email to ……

16.4.2 The Administrative Secretary should date stamp the documents on receipt.

16.4.3 The Member Secretary/Assistant Secretary should scrutinize the resubmission and process it in consultation with the Chairperson/ Vice-Chairperson according to the decision of the ERC regarding the protocol concerned.

16.4.3.1 Minor revision: expedited review by Chairperson/Vice-Chairperson (or nominee) and Secretary/Assistant Secretary (or nominee) in between ERC meetings.

16.4.3.2 Major revision: full board review.

16.4.4 Resubmission with minor revision will go through expedited review as described in SOP 10/V4.

16.4.4.1 If the Chairperson/Vice-Chairperson and Member Secretary /Assistant Secretary are satisfied with the revisions made, the Chairperson/Vice-Chairperson will approve the proposal, and the decision will be communicated to the ERC. Formal ethical approval will be issued after ratification at the next ERC meeting.

16.4.5 Resubmissions with major revision will be sent to the primary reviewers. The Administrative Secretary should send the following documents to the reviewers;

16.4.5.1 Cover letter

16.4.5.2 Revised protocol along with supporting documents

16.4.5.3 Recommendations and comments of the ERC as communicated to the PI

16.4.5.4 The relevant review form

16.4.6 Resubmitted protocols with major revision, along with the reviewers' reports, will be subjected to full board review. The ERC will make its decision as described in section 13.4.9 of SOP 13/ V4. The decision will be communicated to the PI.

16.4.7 If the PI fails to send the corrections, monthly reminders will be issued after the 1st and 2nd month. Those failing to reply within 3 months of the date of communicating the ERC comments will be removed from the meeting agenda. The period may be extended upon request by a PI, if the ERC considers the reasons for extension valid.

16.4.8 If ethical clearance is desired for a lapsed protocol, a fresh application needs to be submitted.

16.4.9 Revised protocols and supporting documents, re-review reports and communications with PI will be filed in the protocol file along with the original documents and initial communication, in chronological order.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 17/ V4
	Title: Amendments to approved protocols	Effective date: 18/05/2021 Page: 37 – 38

17.1 Purpose

The purpose of this SOP is to describe the procedures to be followed for reviewing amendments to an approved protocol including requests for extending ethical approval.

17.2 Scope

This SOP provides the standards and procedures for reviewing amendments to approved protocols, including extensions.

17.3 Responsibility

It is the responsibility of the Member Secretary/Assistant Secretary to process the amendments for review as per the standards and procedures set by the FM, UJ.

17.4 Procedures for managing amendments to approved protocols

17.4.1 The PI may seek approval for amendments to approved protocols. Such requests must be made in writing and should include;

17.4.1.1 A duly signed cover letter with details of the

17.4.1.1.1 protocol, including its title and ERC reference number

17.4.1.1.2 nature of the proposed amendments

17.4.1.1.3 assessment of the ethical implications, if any, of the proposed amendment

17.4.1.2 The amended protocol and supporting documents with revised version number, date, and the amended sections highlighted.

17.4.2 Depending on the nature of the amendments, the ERC will decide on whether the amended protocol needs to undergo expedited or full board review.

17.4.2.1 Major amendments will be reviewed by the primary reviewers of the initial protocol before being subjected to full board review.

17.4.2.2 Minor amendments shall undergo expedited review as described in SOP13/V4.

17.4.3 Amendments such as those listed below may be considered as minor amendments and subjected to expedited review;

17.4.3.1 Inclusion or exclusion of investigators

17.4.3.2 Changes in study setting

17.4.3.3 Changes in the duration of the study

17.4.3.4 Extension of ethical approval

17.4.4 The decision regarding the amendment(s) will be communicated to the PI in the standard format set by the ERC of FM, UJ. The template for the approval of amendments to a protocol is attached as Annexure 18/ SOP 17/ V4.

17.4.5 All amendments, reviewers' reports of amendments, and communications regarding amendments will be added to the document of protocol file of the project concerned.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 18/ V4
	Title: Monitoring of approved research projects	Effective date: 18/05/2021 Page: 39 – 41

18.1 Purpose

The purpose of this SOP is to describe the procedures for reporting and monitoring approved research projects for compliance to the conditions of ethical approval.

18.2 Scope

This SOP provides the requirements, timelines and procedures for reporting and monitoring research projects approved by the ERC of FM, UJ for compliance to the conditions of ethical approval.

18.3 Responsibility

18.3.1 It is the responsibility of the ERC to ensure compliance to the conditions of ethical approval by investigators of the approved research protocols.

18.3.2 The PI is responsible for complying with the conditions of ethical approval and reporting to the ERC as per the conditions of the ERC.

18.4 Procedures for the monitoring of approved research projects

18.4.1 The ERC follows up approved research protocols to ensure compliance to the conditions of ethical approval and the safety of participants by;

- 18.4.1.1 reviewing progress and completion reports
- 18.4.1.2 requesting information on relevant aspects
- 18.4.1.3 reviewing reports on SAE (described in SOP 19/ V4).
- 18.4.1.4 conducting site visits (described in SOP 20 / V4)

18.4.2 The PI should submit periodic progress reports to the ERC. The follow-up interval, not less than every 6 months, will be decided by the ERC considering the nature of the project.

18.4.3 The PI should submit a completion report at the conclusion of the study.

18.4.4 If the PI does not submit the progress/final report, new applications from the PI will not be processed for review until such report/s is/are submitted.

18.4.5 The following information must be contained in the progress/ completion report;

- 18.4.5.1 progress to date or outcome in the case of completed research
- 18.4.5.2 maintenance and security of records
- 18.4.5.3 compliance with the approved protocol
- 18.4.5.4 compliance with any conditions of approval

The template for progress reports and the completion report are annexed as Annexure 19/ SOP 18/ V4 and Annexure 20/SOP18/ V4, respectively.

18.4.6 Any request for extension of ethical approval will be considered by the ERC only on receiving the progress reports.

18.4.7 Prospective applications of the PI will be considered by the ERC for review only on receiving the progress/ completion reports of the PI's approved protocol(s).

18.4.8 The ERC will send reminders to the PI regarding progress/completion reports one month before the due date of submission.

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

18.4.10 The ERC will determine the type and frequency of monitoring required for approved studies, considering the degree of risk to participants in the research. The ERC may adopt the measures it deems as appropriate for monitoring, such as:

18.4.10.1 written reports on the following;

18.4.10.1.1 inspections of research sites, data and signed consent forms, etc.

18.4.10.1.2 interviews with research participants, with their prior consent

18.4.11 In the case of clinical trials, the ERC will require six monthly reports, which will be reviewed by a special subcommittee called the Clinical Trials Subcommittee. The progress reports of clinical trials must contain at least the following information;

18.4.11.1 Progress to date or outcome in the case of completed research

18.4.11.2 Statements regarding maintenance and security of records

18.4.11.3 Statements supporting compliance with the approved protocol

18.4.11.4 Statements supporting compliance with any conditions of approval

18.4.12 The Clinical Trials Subcommittee consists of the following members;

18.4.12.1 Chairperson/ Vice-Chairperson or nominee

18.4.12.2 Member Secretary/Assistant Secretary or nominee

18.4.12.3 A clinical pharmacologist

18.4.12.4 A clinician with special training/interest in the clinical discipline/field

18.4.12.5 A statistical expert

18.4.13 The ERC will require, as a condition of approval, that investigators immediately report any circumstances that may warrant review of the ethical approval of the protocol, including;

18.4.13.1 proposed changes to the protocol

18.4.13.2 unforeseen event(s) that may affect the ethical acceptability of the project

18.4.13.3 new information from published or unpublished studies that may have an impact on the continued ethical acceptability of a clinical trial, or indicate the need for amendments to the trial protocol.

18.4.14 When circumstances have prevented a study from being conducted in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC will inform the PI and the relevant authorities of such withdrawal of approval in writing, and recommend the PI and the institution to take steps to discontinue or suspend the research study.

18.5Annexure

18.5.1 Annexure 19/ SOP18/ V4 – Progress report

18.5.2 Annexure 20/SOP18/ V4 – Completion report

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 19/ V4
	Title: Handling Serious Adverse Events	Effective date: 18/05/2021 Page: 42 – 44

19.1 Purpose

The purpose of this SOP is to describe the procedures for the reporting and handling of Serious Adverse Events (SAE).

19.2 Scope

This SOP defines SAE and provides the standards and procedures for reporting and handling SAE of protocols approved by the ERC of FM, UJ.

19.3 Responsibility

19.3.1 It is the responsibility of the PI to report any adverse events immediately in compliance with the conditions set by the ERC of FM, UJ.

19.3.2 The PI should include all adverse events and responses to such events in the progress and completion reports.

19.3.3 It is the responsibility of the Chairperson/ Vice-Chairperson to take appropriate action as early as possible to address adverse events deemed to be serious and/or requiring immediate attention.

19.4 Procedures for reporting and handling SAE

19.4.1 The ERC requires, as a condition of approval of each proposal, that researchers immediately report Serious Adverse Events (SAE), including Serious Adverse Reactions (SAR) and Suspected Unexpected Serious Adverse Reactions (SUSAR) to the ERC.

19.4.1.1 This requirement includes SAE that have occurred at other sites in the case of multicenter studies.

19.4.2 SAE are defined to include those that result in;

19.4.2.1 Death

19.4.2.2 Life threatening adverse events

19.4.2.3 Hospitalization

19.4.2.4 Disability

19.4.2.5 Congenital abnormalities

19.4.3 SAR are reactions that are likely to be a harmful effect of the product/intervention.

19.4.4 SUSAR are reactions that occur during or soon after the study but have not been previously reported in relation to the particular drug/intervention and are not included in the product information sheet.

19.4.5 The timeline for reporting adverse events for interventional studies approved by the ERC of FM / UJ are as follows;

19.4.5.1 Fatal or life threatening expected/unexpected reactions occurring in a patient on a trial should be reported to the ERC within 24 hours.

19.4.5.2 All other adverse reactions, other than fatal or life threatening, in a participant on a trial are to be reported as soon as possible, but not later than fifteen (15) days after the event.

19.4.5.3 Any other timeframe required by national regulations, if any, but not later than fifteen (15) days after the event.

19.4.6 SAE should be reported in the format prescribed by the ERC of FM, UJ, which is available at the faculty website at this link and the ERC office. The adverse event reporting form is annexed as Annexure 21/ SOP19/ V4.

19.4.7 The following documents must be submitted to the ERC along with the Adverse Event Reporting Form;

19.4.7.1 A statement from the PI 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.

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

19.4.8 Adverse events will be reviewed by the Clinical Trials Subcommittee (section 18.4.14 of SOP 18/V4), which is empowered to review such events, to determine the appropriate course of action.

19.4.9 The review shall take place as soon as possible, not later than one week after notification of the event. The Clinical Trials Subcommittee will determine the appropriate course of action depending on the nature and seriousness of the event and inform the ERC of its recommendation, which may include;

19.4.9.1 a notation on the protocol file of the occurrence

19.4.9.2 a request to increase monitoring of the research

19.4.9.3 a request for an amendment to the protocol and/or patient information sheet /consent form.

19.4.9.4 suspension of ethics approval

19.4.9.5 withdrawal of ethics approval

19.4.10 Based on the recommendation of the Clinical Trials Subcommittee, the Chairperson/ Vice-Chairperson may take a course of action following adverse events deemed serious and requiring immediate attention, including;

19.4.10.1 Referral to the Subcommittee on Clinical Trials (SCOCT) of the Ministry of Health

19.4.10.2 Immediate request for additional information

19.4.10.3 Immediate suspension of ethics approval

19.4.10.4 Immediate termination of ethics approval

19.4.11 All adverse events reviewed, the recommendations of the Clinical Trials Subcommittee and the Chairperson's/Vice-Chairperson's decision will be reported to the ERC at the next meeting.

19.4.12 If the Chairperson/Vice-Chairperson feels that a decision of the full board is immediately required, he/she will instruct the Member Secretary to call for an emergency meeting.

19.4.13 The ERC will inform the PI that it has received notification of the serious adverse event, and the course of action it has deemed necessary to take.

19.4.14 The Chairperson/Vice-Chairperson will immediately notify the relevant authorities if a decision is made to suspend or terminate a project due to a SAE.

19.5Annexure

19.5.1 Annexure 21/ SOP19/V4 – Adverse Event Reporting Form

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 20/ V4
	Title: Site visits	Effective date: 18/05/2021 Page: 45 – 46

20.1 Purpose

The purpose of this SOP is to describe the circumstances and procedures for visiting the study site(s) of approved projects for monitoring purposes.

20.2 Scope

This SOP provides the criteria and procedures for the ERC to carry out site visits to the study sites of approved projects as part of continuous monitoring of approved projects.

20.3 Responsibility

It is the responsibility of the ERC to have a mechanism to identify approved projects that require site visits and carry out visits to the relevant study site(s) as part of continuous monitoring of approved projects.

20.4 Criteria and procedures for site visits

20.4.1 Sites requiring visits will be identified based on the degree of intervention, sample size, complexity of the study, and the risk involved.

20.4.2 Approved projects that require site visits will be decided based on the following criteria;

- 20.4.2.1 Unrealistically high number of projects carried out in a study site
- 20.4.2.2 Non-compliance or suspicious conduct
- 20.4.2.3 Failure to submit progress/ completion reports
- 20.4.2.4 Based on a report of the SAE subcommittee
- 20.4.2.5 Reported violations of protocol

20.4.3 Sites will be selected for visits at the ERC meeting.

20.4.4 A 3-member site monitoring subcommittee will be appointed to carry out site visits; the subcommittee's composition will depend on the nature of the project.

20.4.5 Before each visit, the ERC will

- 20.4.5.1 contact the site and notify them about the visit
- 20.4.5.2 make appropriate travel arrangements
- 20.4.5.3 review the ERC files at the office and make appropriate notes

20.4.6 Site monitoring will be guided by a checklist formulated by the ERC. The site monitoring checklist is annexed as Annexure 22/ SOP20/ V4

20.4.7 During the site visit, the site monitoring subcommittee will

- 20.4.7.1 verify and review the documents for compliance to the protocol and conditions of the ERC
- 20.4.7.2 specifically review the following documents
  - 20.4.7.2.1 informed consent forms

20.4.7.2.2 randomly selected subject files to ensure that

20.4.7.2.2.1 the subjects have signed the correct informed consent forms

20.4.7.2.2.2 only eligible subjects are recruited

20.4.7.3 observe the laboratory and/or other facilities

20.4.8 After each site visit, the site monitoring subcommittee will

20.4.8.1 write a report within 2 weeks of the visit

20.4.8.2 forward a copy of the site visit report for full board review

20.4.8.3 the site visit report should be filed in the site monitoring file

20.4.8.4 send a copy of the report to the PI

20.5 Annexure

20.5.1 Annexure 22/ SOP20/ V4 – Site Monitoring Checklist

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 21/ V4
	Title: Handling protocol deviation, non-compliance and violation	Effective date: 18/05/2021 Page: 47 – 48

21.1 Purpose

The purpose of this SOP is to describe the procedures for reporting and handling protocol deviation, non-compliance and violation of the approved projects.

21.2 Scope

This SOP provides standards and procedures for reporting and handling protocol deviation, non-compliance and violation of approved projects by the ERC of FM, UJ.

21.3 Responsibility

21.3.1 It is the responsibility of the ERC to review protocol deviation/ non-compliance /violation reports and take appropriate action on these reports.

21.3.2 The Member Secretary/Assistant Secretary is responsible for including protocol deviation/ non-compliance/ violation reports in the agenda and making sure that the ERC reviews such reports without delay.

21.4 Procedures for reporting and handling protocol deviation, non-compliance and violation

21.4.1 When a protocol deviation/ non-compliance/violation report is received, the Member Secretary/Assistant Secretary should immediately inform the Chairperson/Vice-Chairperson and include it in the agenda of the next scheduled meeting.

21.4.2 Protocol deviation/ non-compliance/ violation may be reported to the ERC by

- 21.4.2.1 monitoring subcommittees of the ERC
- 21.4.2.2 investigator / trial site / sponsor / study monitor / contract research organization (CRO)
- 21.4.2.3 research participants who have been enrolled or any individual who has been approached for enrollment

21.4.3 Protocol deviation/ non-compliance / violation may be detected

- 21.4.3.1 when scrutinizing progress reports or SAE reports
- 21.4.3.2 during site monitoring visits
- 21.4.3.3 when a communication related to protocol deviation/ non-compliance / violation is brought to the notice of ERC by the research team/ participants/ third party

21.4.4 Review of reports / communications regarding protocol deviation/ non-compliance / violation

- 21.4.4.1 Protocol deviations / non-compliance/ violations will be scrutinized for gravity and implications at the ERC meeting.

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

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

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

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

21.4.4.6 Based on the seriousness of the protocol deviation/ non-compliance / violation one of the following decisions will be taken.

21.4.4.6.1 Temporary suspension

21.4.4.6.2 Termination of the approval of the current study

21.4.4.6.3 Refusal to accept and review subsequent applications from the PI, if the violations were not reported to the ERC.

21.4.5 The letter of notification of the decision of the ERC on protocol deviation/ non-compliance / violation will be prepared by the Member Secretary/Assistant Secretary and signed by the Chairperson and Member Secretary.

21.4.6 The original letter will be sent to the PI and copies of the letter will be

21.4.6.1 filed in the protocol file and non-compliance file in the ERC office

21.4.6.2 sent to the relevant national authorities, institutes and the sponsor of the study

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 22/ V4
	Title: Suspension / termination of an approved project	Effective date: 18/05/2021 Page: 49 – 50

22.1 Purpose

The purpose of this SOP is to describe the procedures to be followed when suspending / terminating an approved project before the scheduled date of completion.

22.2 Scope

This SOP provides the conditions and procedures for suspending or terminating projects approved by the ERC of FM, UJ before the scheduled date of completion.

22.3 Responsibility

22.3.1 It is the responsibility of the ERC to suspend / terminate approved projects when the benefit to or safety of the study participants is doubtful or at risk.

22.3.2 It is the responsibility of the PI to inform the ERC about an investigator-initiated suspension/ termination of an approved project, with reason/s.

22.4 Procedures for suspension / termination of approved projects

22.4.1 Suspension / termination by ERC

The ERC will suspend/ terminate approved projects under the following circumstances;

22.4.1.1 Protocol non-compliance/violation

22.4.1.2 Significantly high SAEs that raise safety concerns

22.4.1.3 Violations of ERC approval conditions

22.4.2 On receiving a recommendation to suspend/terminate an approved project from a monitoring subcommittee of the ERC, the sponsor or other authorized bodies, the Member Secretary will notify the Chairperson/ Vice-Chairperson regarding the recommendation for suspension / termination within 24 hours.

22.4.3 The Chairperson/Vice-Chairperson will review the results, reasons and accrual data.

22.4.4 The Chairperson/ Vice-Chairperson will instruct the Member Secretary to call for an emergency meeting as early as possible, not later than 3 working days from receipt of the recommendation, to discuss and make a final decision on the recommendation.

22.4.5 The decision of the ERC to suspend /terminate the project with reason/s for such a decision will be communicated to the PI in writing with the letter signed by the Chairperson/ Vice-Chairperson and Member Secretary/Assistant Secretary, within 7 working days of making the final decision.

22.4.6 The memorandum of suspension /termination will be filed in the protocol file and kept in the ERC office indefinitely.

22.4.7 Copies will be sent to appropriate authorities, when applicable.

22.4.8 Suspension / termination by PI

22.4.8.1 The PI may suspend/ terminate an ongoing project/approved project.

22.4.8.2 The PI should submit the suspension or termination report along with other relevant documents to the ERC.

22.4.8.3 The Member Secretary will inform the Chairperson and acknowledge the report.

22.4.8.4 The suspension/termination will be included in the agenda of the next meeting.

22.4.8.5 The suspension/termination report will be filed in the protocol file.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 23/ V4
	Title: Complaints concerning conduct of approved projects	Effective date: 18/05/2021 Page: 51 – 52

23.1 Purpose

The purpose of this SOP is to describe procedures for handling complaints concerning conduct of projects approved by the ERC of FM, UJ.

23.2 Scope

This SOP provides the administrative and ethical framework for handling complaints concerning conduct of projects approved by the ERC of FM, UJ.

23.3 Responsibility

It is the responsibility of the Chairperson/ Vice-Chairperson and Member Secretary/Assistant Secretary to process complaints concerning conduct of approved projects.

23.4 Procedures for handling complaints concerning conduct of approved projects

23.4.1 The contact details of the ERC must be included in the participant information sheet and consent forms as outlined in Annexure 5/ SOP8/ V4.

23.4.2 When a complaint is received, the Member Secretary/Assistant Secretary will notify the Chairperson as soon as possible. Under the instruction of the Chairperson/ Vice-Chairperson, the Member Secretary will send an acknowledgement to the complainant and a letter of notification briefing the nature of the complaint and investigation procedure to the PI.

23.4.3 The Chairperson/ Vice-Chairperson will appoint a three-member committee to investigate the complaint.

23.4.4 Both the complainant and PI will be given an opportunity to make submissions.

23.4.5 The investigation committee will submit its report and recommendation within 4 weeks, barring exceptional circumstances.

23.4.6 The report and recommendations will be discussed at the next scheduled meeting of the ERC. The Chairperson may call for an emergency meeting if the complaint is serious in nature.

23.4.7 If the complaint is substantiated the ERC could take one of the following decisions based on the severity of the matter;

23.4.7.1 Intensify monitoring by the ERC of compliance to the approved protocol

23.4.7.2 Suspension of research till remedial action has been taken.

23.4.7.3 Termination of the study

23.4.7.4 Any other action to address the issues raised by the complainant.

23.4.8 If the Chairperson/Vice-Chairperson considers the complaint to be of a sufficiently serious nature, they will bring it to the attention of the Dean as soon as possible. The Dean may inform other appropriate authorities, as and when applicable.

23.4.9 If the complainant is not satisfied with the outcome of the Chairperson's inquiry, the complainant may appeal against the decision with reasons to the Dean of FM, UJ. In such circumstances the Chairperson must provide the following information to the Dean;

23.4.9.1 Nature of the complaint

23.4.9.2 Material reviewed during the investigation

23.4.9.3 Decision of the ERC

23.4.9.4 Any other relevant information.

23.4.10 The Dean, FM, UJ will review the appeal and the information provided by the Chairperson, determine whether further investigation is needed, and inform the decision in writing to the complainant and the Chairperson.

23.4.11 If the Dean decides to further investigate into the matter, he/she may form a panel of investigators comprising

23.4.11.1 Dean / nominee

23.4.11.2 two nominees from the Faculty Board (who are not ERC members)

23.4.11.3 Chairperson of the ERC.

23.4.12 The panel shall have access to all documents related to the project and may interview other parties, and seek internal and external expert advice, if necessity arises. The members of the panel should sign a confidentiality agreement.

23.4.13 Based on the decision of the panel, the Dean may dismiss the appeal or take necessary action to resolve the issue/s raised by the complainant.

23.4.14 The Dean will communicate the decision of the panel to the complainant.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 24/ V4
	Title: Complaints concerning the ERC review process	Effective date: 18/05/2021 Page: 53 – 54

24.1 Purpose

The purpose of this SOP is to describe procedures for handling complaints concerning the review process of the ERC of FM, UJ.

24.2 Scope

This SOP provides the standards and procedures to be followed when handling complaints concerning the review process of the ERC of FM, UJ.

24.3 Responsibility

24.3.1 It is the responsibility of Chairperson/ Vice-Chairperson to process any complaints concerning the review process of the ERC.

24.3.2 The preliminary investigation is the responsibility of the Chairperson/ Vice-Chairperson of the ERC of FM, UJ.

24.4 Procedures for handling complaints concerning the review process of the ERC

24.4.1 Any concern or complaint about the ERC's review process should be directed in writing to the attention of the Chairperson. Complaints may be made to the Dean of FM, UJ, only in case of inaction of ERC or when potential COI exists.

24.4.2 The Chairperson will notify such complaint to the Dean as soon as possible.

24.4.3 If the complaint is directed to the Dean, he/ she will notify the Chairperson as soon as possible.

24.4.4 The Chairperson / Dean will send an acknowledgement letter to the complainant.

24.4.5 The Chairperson/ Dean will decide if further inquiry is necessary.

24.4.6 If further investigation is needed, the Dean will appoint an 3-member appeal panel comprising

24.4.6.1 the Dean / nominee

24.4.6.2 two faculty board members (who are not ERC members).

24.4.7 The appeal panel will ask the ERC and complainant for clarifications and / or further information.

24.4.8 The panel will have access to all documents related to the project and may interview other parties, and seek internal and external expert advice, if necessary.

24.4.9 The panel will check whether the ERC has acted according to the SOP and FERCSL guidelines.

24.4.10 The decision of the panel could be

24.4.10.1 Dismissal of appeal

24.4.10.2 Recommendations to the ERC

24.4.11 The panel will send the recommendations to the ERC on the appropriate course of action within 4 weeks of notification of the complaint.

24.4.12 The decision will be communicated to the complainant by the Chairperson / Dean in writing.

24.4.13 If the complainant was made to the Chairperson, and the complainant is not satisfied with the Chairperson's decision, he/she may appeal to the Dean.

24.4.14 If the complainant is not satisfied with the decision of the Dean, he/she may appeal to the Vice Chancellor of the University of Jaffna.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 25/ V4
	Title: Record keeping and archiving	Effective date: 18/05/2021 Page: 55 – 56

25.1 Purpose

The purpose of this SOP is to describe the procedures for record keeping and documenting the activities of the ERC and archiving the protocols submitted to the ERC.

25.2 Scope

This SOP provides the administrative framework for procedures for record keeping and documenting the ERC activities and archiving the protocols submitted to the ERC.

25.3 Responsibility

25.3.1 It is the responsibility of the Member Secretary/Assistant Secretary to oversee the Administrative Secretary and to ensure all the records of the ERC are in order.

25.3.2 The Administrative Secretary is responsible for maintaining the ERC records.

25.4 Procedures for record keeping

25.4.1 The Member Secretary/Assistant Secretary with the assistance of the Administrative Secretary will prepare and record all the activities of the ERC including the agenda, meeting minutes, and communications.

25.4.2 The Administrative Secretary, under the supervision of the Member Secretary, will maintain all the records in the appropriate files and/or database.

25.4.3 The following documents are maintained at the ERC office

25.4.3.1 ***Non-confidential documents***

25.4.3.1.1 SOP and TOR

25.4.3.1.2 National and international guidelines on ethics review

25.4.3.1.3 Registry for ERC applications

25.4.3.1.4 Delivery book

25.4.3.1.5 Extracts of minutes to the Faculty Board

25.4.3.2 ***Confidential documents***

25.4.3.2.1 Personal files of the members, including the following;

25.4.3.2.1.1 Appointment letter as ERC member

25.4.3.2.1.2 Acceptance letter

25.4.3.2.1.3 Curriculum vitae

25.4.3.2.1.4 Confidentiality agreement

25.4.3.2.1.5 Certificate of training in research ethics and GCP

25.4.3.2.1.6 Other correspondence to and from the member

25.4.3.2.2 Agenda and minutes of ERC Meeting
25.4.3.2.3 Annual reports of the ERC
25.4.3.2.4 Financial reports of the ERC
25.4.3.2.5 Other financial records
25.4.3.2.6 General correspondence
25.4.3.2.7 Protocol files

Each application will be filed separately and will contain the following documents

25.4.3.2.7.1 Duly signed application form
25.4.3.2.7.2 Copy of paying in voucher
25.4.3.2.7.3 Protocol and supporting documents
25.4.3.2.7.4 Office copy of the checklist
25.4.3.2.7.5 Reviewers' reports
25.4.3.2.7.6 Copy of the review comments sent to PI
25.4.3.2.7.7 Response of PI to the ERC comments, including revised versions of the protocol and supporting documents
25.4.3.2.7.8 Copy of ethical clearance letter / ERC decision
25.4.3.2.7.9 Progress reports
25.4.3.2.7.10 Completion reports
25.4.3.2.7.11 Other communications / documents related to the project, if any

Documents will be filed in chronological order and numbered. An indexed sheet will be pasted on each protocol file.

25.4.4 The following will be stored in a password-protected computer with regular back ups

25.4.4.1 Protocol database
25.4.4.2 Soft copies of
25.4.4.2.1 Agenda
25.4.4.2.2 Minutes
25.4.4.2.3 Extracts of minutes
25.4.4.2.4 Correspondence

25.4.5 Confidential documents may be accessed only by the Chairperson, Vice-Chairperson, Member Secretary, Assistant Secretary and Administrative Secretary.

25.4.6 When a completion report is received, the protocol file will be closed. Once closed, the protocol file will be maintained at the ERC office for five (05) years. After five years, protocol files will be disposed of in a secure manner.

25.4.7 Files that need to be maintained indefinitely will be archived.

25.4.8 All confidential documents that are no longer required will be disposed of in a secure manner using a shredder by the Chairperson/Secretary and Administrative Secretary.

	Ethics Review Committee Faculty of Medicine University of Jaffna	SOP Code: SOP 26/ V4
	Title: Review of SOP	Effective date: 18/05/2021 Page: 57

26.1 Purpose

The purpose of this SOP is to describe the procedures to be followed when reviewing the SOP of the ERC of FM, UJ.

26.2 Scope

This SOP provides the administrative framework for reviewing and amending the SOP of the ERC of FM, UJ.

26.3 Responsibility

It is the responsibility of the ERC to appoint a team to review or amend the SOP.

26.4 Procedures for reviewing or amending the SOP

26.4.1 The SOP of the FM, UJ is reviewed at least every three years and whenever the necessity arises.

26.4.2 The ERC will appoint a team to review and revise the SOP of the ERC.

26.4.2.1 The revised SOP will be reviewed and approved by the ERC and forwarded for approval to the Faculty Board, FM, UJ

26.4.2.2 Once approved by the Faculty Board, the revised SOP will be forwarded to the Senate of the University Jaffna.

26.4.2.3 The new version of the SOP will be effective from the date of Senate approval.

26.4.3 The SOP could be revised before three years if the necessity arises as

26.4.3.1 Proposed by ERC members

26.4.3.2 Proposed by the Faculty Board, FM, UJ

26.4.3.3 Proposed by an accrediting/ recognizing body

References

Council for International Organizations of Medical Sciences and World Health Organization (2016). *International Ethical Guidelines for Health-related Research Involving Humans.* https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (2002). *International Ethical Guidelines for Biomedical Research Involving Human Subjects.* https://media.tghn.org/medialibrary/2011/04/CIOMS_International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf

Forum for Ethics Review Committees of Sri Lanka (FERCSL) (2018). Ethics Review Committee Guidelines. http://fercsl.lk/wp/wp-content/uploads/2018/12/FERCSL-Guideline-2018.pdf

Good Clinical Practice Network (n.d.). Guideline for Good Clinical Practice ICH E6 (R2) ICH Consensus Guideline. https://ichgcp.net/

Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) (2010). SIDCER Survey Standard Operating Procedures. Geneva: SIDCER Secretariat.

World Health Organization (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant. https://www.who.int/activities/ensuring-ethical-standards-and-procedures-for-research-with-human-beings#guidelines

World Medical Association (2013). Declaration of Helsinki. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

ANNEXURE

Annexure 1/ SOP3/ V4: Letter of appointment - ERC members

Date:
Name:
Address

Dear …….,

Appointment as a member of the Ethics Review Committee (ERC) of Faculty of Medicine, University of Jaffna

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

As a member of the ERC you are expected to

1. Review proposals submitted for ethics approval as per the Standard Operating Procedures (SOP) of the ERC and relevant national and international guidelines.
2. Regularly attend the monthly ERC meetings.
3. Undergo periodic training on research ethics.
4. *Perform the duties described in the SOP4/V4 (pp. 8-10) in addition to the above.*

The SOP (Version 4) is attached herewith.

Kindly sign the attached confidentiality and conflict of interest agreement and acceptance letter and hand it over to the ERC office on or before ……. Please also email a soft copy of your CV to…….

Thank you

The Dean
Faculty of Medicine
University of Jaffna

Annexure 2/ SOP3/ V4: Confidentiality and conflict of interest agreement

Ethics Review Committee
Faculty of Medicine, University of Jaffna

Confidentiality and Conflict of Interest Agreement

I, …… the undersigned member/ office staff / external subject expert / guest attendee of the Ethics Review Committee of Faculty of Medicine of University of Jaffna, agrees not to disclose or utilize, directly or indirectly, any confidential or proprietary information belonging to a third party outside the committee's mandate.

I also assure that whenever I have a conflict of interest under any of the following circumstances, I shall inform the Chairperson of the ERC as soon as possible and not participate in any discussion and/or decision-making related to the matter concerned.

Direct conflict of interest (COI)

- Being the PI or one of the co-investigators/ supervisors.
- Being part of the research team as a consultant/ member of a monitoring committee/ in-charge for recruitment, data collector etc.
- Being a potential participant of the project concerned.
- Getting any financial benefit from the project concerned.

Indirect COI

- Being a reviewer of another committee / sponsor/ funding agency of the protocol concerned.
- Involved in another project in the same research area as the project concerned.
- Being a first degree relative of a member of the research team.

I also declare that I have not been subjected to any criminal conviction or disciplinary action.

…… Date:
Signature of the Member
Name & designation of the member:

…… Date:
Signature of the Chairperson

Annexure 3/ SOP6/ V4 – Letter of appointment – External subject experts

Date:
Name:
Address:

Dear ……..,

Appointment as an external subject expert of the Ethics Review Committee of the Faculty of Medicine, University of Jaffna

I am pleased to inform you that you have been appointed as an external subject expert to the Ethics Review Committee (ERC) of the Faculty of Medicine, University of Jaffna, for a period of three years from ……..

As an external subject expert of the ERC you are expected to review protocols submitted for ethics approval as per the Standard Operating Procedures (SOP) of the ERC and relevant national and international guidelines.

The SOP is attached herewith.

Kindly sign the attached confidentiality and conflict of interest agreement with the acceptance letter and hand it over to the ERC office, Faculty of Medicine.

Thank you

The Dean
Faculty of Medicine
University of Jaffna

Annexure 4/ SOP8/ V4 – Ethics review application form

APPLICATION FOR ETHICS REVIEW
Faculty of Medicine, University of Jaffna

(Please read the GUIDE TO APPLICANTS before filling the application form)

For office use only

Reference number	**J/**	**ERC/**								**Date received**			**/**			**/**				

Reviewer 1 (Name and field of expertise)	
Reviewer 2 (Name and field of expertise)	
Reviewer 3 (Name and field of expertise)	

ERC decision	

ERC Meeting Date			**/**			**/**					**ERC decision informed on**			**/**			**/**				

Part I – Project Information

1. **Title of the project**

……

……

2. **Type of project**

Undergraduate ☐

Postgraduate degree (specify) ☐ ……..

……..

Clinical trial ☐

Other (specify) ☐ ……..

……..

3. Investigators

3.1. Principal investigator

Name	
Qualification/s	
Area of specialisation	
Designation	
Institution	
Contact Address	
Contact number	
E-mail	
Signature	

3.2. Co-investigator / Supervisor (indicate the status)

Name	
Qualification/s	
Area of specialisation	
Designation	
Institution	
Contact Address	
Contact number	
E-mail	
Signature	

3.3. Co-investigator / Supervisor (indicate the status)

Name	
Qualification/s	
Area of specialisation	
Designation	
Institution	
Contact Address	
Contact number	
E-mail	
Signature	

3.4. Co-investigator / Supervisor (indicate the status)

Name	
Qualification/s	
Area of specialisation	
Designation	
Institution	
Contact Address	
Contact number	
E-mail	
Signature	

Attach extra sheet if necessary.

4. **Proposed date of commencement and completion of the study**

   Date of commencement ☐ Date of completion ☐

5. **Proposed data collection period (from the initial recruitment of participants / data collection until the completion of all data collection)**

   Date of commencement ☐ Date of completion ☐

6. **Has this study been submitted to any other ERC or similar committee for ethical clearance?**

   Yes ☐ No ☐

If yes,

Name of the committee	
Decision *	
Date	

* Attach documentary evidence.

7. **Has this project been subjected to scientific review?**

   Yes ☐ No ☐

If yes,

Name and address of committee/board of study	
Decision *	
Date	

* Attach the copy of communication of the above decision.

8. **Funding**

Name and address of funding agency	
Amount	

9. Have you submitted any application to this ERC before? (attach extra sheets if necessary)

Yes ☐ No ☐

If yes,

Title	
Reference number of project	
Decision *	
Date	
Current status of the project	

* Attach copy of communication of the above decision.

Attach additional sheet if required

10. If yes to 9, have you submitted the progress / completion report/s for the above project/s

Yes ☐ No* ☐

*** If you have not submitted the progress / completion reports, this application will be processed by the ERC after the progress / completion reports are received.**

11. **Collaborative research** Not applicable ☐

11.1. Does the project involve international (non-Sri Lankan citizens/residents) researchers?

Yes***** ☐ No ☐

*** For projects involving international researcher/s, attach the agreement between the local and international collaborators on the following;**

a. Fate of data and, if applicable, samples/ specimens.
b. Ownership of data, publication and intellectual property rights.
c. Nature of benefits and their distribution.

(For further information refer the SOP 7 / V4)

11.2. List the collaborating institutions

1.	
2.	
3.	
4.	
5.	
6.	

11.3. Has this study been submitted to any ERC / similar body in the country/ countries of the international collaborator/s?

Yes ☐ No ☐

If yes,

Name and address of the committee(s)	Decision*	Date

* Attach evidence of the above decision.

If no, give reason/s

11.4. What is the relevance of this study to this country?

11.5. Are biological samples to be transferred abroad?

Yes ☐ No ☐

If yes, attach the material transfer agreement.

12. Clinical trials Not applicable ☐

12.1. Which phase of the trial is being conducted?

Phase I ☐

Phase II ☐

Phase III ☐

Phase IV ☐

Others (specify) ☐ ……

……

12.2. Is the clinical trial registered with a clinical trial registry?

Yes ☐ No ☐

If yes*,

Name of the registry	
Registration number	

* Attach evidence.

12.3. Is the drug/ product/device registered in Sri Lanka?

Yes ☐ No ☐

If no, submit the approval from the National Medicines Regulatory Authority

12.4. Is the new intervention, or any intervention that is to be tested outside its approved use, registered and approved by the Sub-committee of Clinical Trials of the Ministry of Health?

Yes ☐ No ☐

If, yes attach the copy of the approval.
If, no please obtain the approval before submitting to ERC.

12.5. Is this a multicenter trial?

Yes ☐ No ☐

If yes, list the other centers.

12.6. Are the participants to be compensated for participation?

Yes ☐ No ☐

If yes, compensation per participant in Sri Lanka Rupees.

12.7. Are the investigators to be paid?

Yes ☐ No ☐

If yes, by whom?

12.8. Please provide details of the Trial Monitoring Committee / Data Safety Monitoring Board (if applicable).

Name of member	**Designation**	**Role**

12.9. Please provide details of insurance coverage for participants, investigators and the ERC.

13. Conflicts of interest (please declare)**.**

14. Declare any objection you have for this protocol to be sent for review to any particular reviewer/s with reasons**.**

……

……

Part II – Protocol Checklist

No.		**Page No.**	**NA***
1	Summary of the project		
2	Introduction/ background		
3	Justification		
4	Review of literature		
5	Objectives		
	Methodology		
6	Study design		
7	Study setting		
8	Study duration (and data collection period)		
9	Study population		
10	Sample size and calculation of sample size		

11	Inclusion criteria		
12	Exclusion criteria		
13	Study instrument/s		
14	Pilot study		
15	Sampling/ recruitment procedure		
16	Data collection		
17	Data analysis		
	Ethical issues		
18	Assessment of risks/ benefits		
19	Procedure for obtaining consent		
20	Informed consent form		
21	Justification for including a vulnerable population		
22	Procedures to protect the rights of participants		
23	Confidentiality		
24	Maintenance and fate of data		
25	Safety monitoring		
26	Provision of medical and psychological support to participants		
27	Dissemination of results		
	Biological Samples		
28	Justification for using biological sample/s		
29	Procedures for collection, storage and disposal of biological sample/s		
30	Consent for collecting biological sample/s		
	Collaborative research		
31	Justification and benefits of collaboration with foreign investigators		
32.	Protection of the rights of local collaborator and participants		
33.	Justification for transfer of data and /or biological/ genetic materials to the country of foreign collaborator		
34.	Fate of transferred data and biological/ genetic material		

	Clinical trials		
35.	Criteria for termination of participants from the trial		
36.	Criteria for termination of the trial		
37.	Adverse event monitoring, management and reporting		
38.	Justification for withholding/ withdrawing standard therapy		
39.	Provision for making the trial drug available after completion		

*** NA – Not applicable**

Part III – Application Checklist

I declare that I have attached the following documents.
(Please tick the appropriate check box)

No.	Document	Check box
1	Application form – 1 copy	
2	Signed and dated CV of PI and postgraduate research supervisor/s – 1copy	
3	Summary of the project – 1 copy	
4	Research protocol – 1 copy	
5	Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 1 copy each	
6	Questionnaire (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 1 copy each	
7	Data record booklet/ event record diary/data record sheet or form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil & Sinhala, if self-administered by participants) – 1 copy each	
8	Approval from National Drug Regulatory Authority (for clinical trials)	
9	Approval from SCOCT (to test new interventions/ interventions outside approved use in clinical trials)	
10	Insurance coverage (for clinical trials)	
11	Ethical clearance from the country of international collaborator(s), if applicable	

12	Evidence of scientific review, if available	
13	Soft copies of all documents other than the application form (by email)	
14	Receipt for payment of application fee to Shroff Counter, University of Jaffna or any branch of the People's Bank	
15	Administrative approval/s, if available (permission letters from heads of institution or authorized officers/ in-charge of the study site(s), etc.). Specify ……..	
16	Material transfer agreement	
17	Font size -12pt	
18	Line space between sentences- 1.5	
19	Other (Specify ……)	

I understand that the application for ethics clearance will not be accepted unless all necessary documents are submitted and that at least 6 weeks are required for ethics review.

I declare that:

- I am not seeking approval for a study that has commenced or been completed.
- all the information given is correct to the best of my knowledge.

…… Date:
Signature of Principal Investigator

……. Date:
Signature of Chief Supervisor
(If applicable)

……. Date:
Signature of Head of the Department/ Unit
(If applicable)

……. Date:
Signature of Dean/Head of the Institution
(if applicable)

Annexure 5/ SOP8/ V4 – Guide to applicants

GUIDE TO APPLICANTS

Ethics Review Committee

Faculty of Medicine, University of Jaffna

1. Research projects involving human subjects conducted by students and staff of the University of Jaffna and other projects conducted in the Northern Province are eligible to be submitted for ethical clearance to the Ethics Review Committee (ERC), Faculty of Medicine, University of Jaffna.
2. The Application for Ethics Review may be downloaded from the Faculty of Medicine website at this link.

   Sections of the application form that are not applicable to the proposal may be skipped.
3. Along with the completed original application form, a hard copy of the project summary, protocol, and annexures should be submitted to the Office of the Ethics Review Committee, Faculty of Medicine, University of Jaffna. Except the application form, soft copies of all documents should be emailed to ……
4. If the application form contains erroneous information OR progress/completion reports are pending from the Principal Investigator (PI), new applications will be processed once corrections are made and/or the relevant report(s) is/are submitted.
5. The summary should not exceed 500 words and should include an introduction (with justification for the research), objectives, methods, and any anticipated ethical concerns. The protocol should cover all applicable areas in the 'Protocol Checklist' in the application form, and be formatted according to ERC requirements (Times New Roman, 12 pt, 1.5 spacing). Please use double-sided printing and normal binding.
6. Protocols that involve electronic informed consent procedures and/or data collection will be assessed for risk on a case-by-case basis. The sensitivity of the topic, the researcher's experience, whether identifiable data are to be collected, data security, and the possibility of coercive data collection (such as requiring responses for questions in online questionnaires) will be considered in the risk assessment. Researchers should outline the measures taken to minimize these risks and cover these aspects in the information sheet. Screen shots of all pages of the web interface, including those to obtain informed consent and elicit data, must be annexed.

7. The authorized copy of the completed paying in voucher (available at the Faculty website at this link) should be handed over along with the application. Payment can be made by cash/money order/postal order/ cheque (in favour of the **Ethics Review Committee, University of Jaffna**) at the Shroff Counter of the University of Jaffna or at any branch of People's Bank (in favour of the **Ethics Review Committee, University of Jaffna**) to the credit of the account number in the paying in voucher.
8. Undergraduate student proposals should be submitted through the relevant Head of the Department.
9. Proposals for postgraduate degrees should be submitted under the responsibility of a qualified supervisor (unless the researcher is exempted from working under a supervisor) with a covering letter indicating:
    8.1 Degree to be obtained
    8.2 Institution where the candidate is registered and, if scientific review has been undertaken, a letter from the relevant postgraduate institute / Board of Study stating that the research proposal has been approved for postgraduate study.
10. Applicants for ethical review of protocols involving research with international collaborators are directed to the instructions in the application form and the SOP available at the Faculty of Medicine website at this link (Section 8.4.15 of SOP8 / V4).
11. Completed applications submitted before the close of business of the last working day of the month will be taken up at the next scheduled meeting and the ERC's decision will be communicated to the PI/ Head of the Department. This process will take a minimum of 6 weeks.
12. The ERC will disapprove all projects that have already started participant recruitment, data collection, or any projects that are completed before obtaining ethical clearance.
13. If the protocol is to be amended after submission for review or after obtaining ethical clearance, such amendments should be communicated to the ERC and effected only after ERC approval.
14. After obtaining ethical clearance, researchers are responsible for adhering to the protocol. The ERC has the right to withdraw clearance if there is evidence of non-compliance with an approved protocol and/or ERC guidelines.
15. All researchers whose projects have been granted ethical clearance are obliged to send progress reports every 6 months (or more frequently if requested to do so by the ERC)

and a completion report on completing the project, in the format prescribed by the ERC in its Standard Operating Procedures.

16. Please quote the reference number assigned to the project in all future communications.
17. For further information, refer the Standard Operating Procedure (SOP) available on the Faculty of Medicine website at this link.
18. If you need any further clarifications, please call 021 2222073; extension 342.
19. If you want to make any complaints about the ERC, please write to the Chairperson, ERC, Faculty of Medicine, University of Jaffna.
20. Details of application fees for protocols submitted for ethical clearance:

Personal research	***Payment to ERC***
Grants less than (Rs. 300,000.00)	**Rs. 2500.00**
Grants more than (Rs. 300,000.00)	**Rs. 5000.00**
Research with international collaboration	
Sri Lankan PI	**Rs. 10,000.00**
Non-Sri Lankan PI	**Rs. 50,000.00**
Sponsored clinical trials	**USD 1000**
Undergraduate projects of others universities	**Rs. 500.00**
Undergraduate projects of the UJ	**No fee**

GUIDANCE FOR PREPARATION OF INFORMED CONSENT FORM

The informed consent form(s) should cover the following areas:

- Introduction to the Principal Investigator (name, designation, affiliated institution) and the research project, including the objective(s) and research setting
- Reasons for selecting the participant
- Statement regarding voluntary participation
- Study duration
- Study procedures (including details of data collection methods or interventions)
- Risk-benefit assessment
- Reimbursements (if any)
- Measures to protect privacy and confidentiality
- Data security concerns (if any)
- Contact details of research team for additional information
- Contact details of ERC for complains (if any)
- Consent forms, and, if applicable, assent forms, including, for illiterate participants (if necessary)

Please note: Separate informed consent forms must be developed if a study protocol includes: 1) several research activities that involve different groups of participants (e.g., participants of surveys, interviews, and focus groups in a mixed methods study) or 2) recruitment of minors when informed consent/assent needs to be obtained from parents and minors.

A sample informed consent form is provided below. Some sections of this form may not be relevant to your project. Please include only the sections that are applicable to your project.

The informed consent form must be translated in the local language/s of the participants based on their language preferences and competencies.

SAMPLE INFORMED CONSENT FORM

Part I: Information sheet

Title:……
…….

Part I – Information sheet

1. **Introduction**

   I/We *(name of PI/investigators)* attached to *(institute)* as *(designation)* are doing research on *(field/discipline)* at (*site of the study*) to (*aim of the study*). I wish to give you information about the research and invite you to participate in this research.

   If you do not understand any words, you can stop me and ask for explanation. You need not necessarily decide now whether to participate or not. Before you decide you may talk to anyone you feel comfortable with about the research. If you have any questions /doubts about the research/ procedures, you may ask me or anyone from the research team you are comfortable with now or later.

2. **Participant selection**

   The reason for considering you suitable for this research is ……

3. **Voluntary participation**

   You are free not to participate or withdraw from the study at any time *(of the study/during data collection)* without any loss of or compromise in *(medical care/other services)* to which you are otherwise entitled. If you decide to participate, you are not

required to provide any information, and may skip any part of the research that makes you feel uncomfortable.

4. Duration of the study

The study will begin on *(DD/MM/YYYY)* and ends on *(DD/MM/YYYY).* Data will be collected from *(DD/MM/YYYY)* to *(DD/MM/YYYY).*

5. Procedures of the study and participant responsibilities

(Explain what is expected from the participants in relation to research and the time that the participant would need to dedicate towards the research. If a questionnaire is to be used, the nature and purpose of questions, and the information and data to be collected. If any intervention study, explain how it differs from routine medical care / procedures).

6. Intervention

7. *(Explain the type of intervention to be studied and currently available established standard intervention/treatment and other alternatives, if any).*

8. Clinical trial (if applicable)

The following need to be clearly explained:

a. Phase of the trial with detailed description of procedures.
b. Reason for development of a new drug
c. Treatment and manufacture information of drug/device
d. Known experience with the new drug, if any.
e. Known and potential adverse effects of the drug/device and other drugs/devices.
f. Unfamiliar procedures such as randomization, blinding, placebo etc. Participants should be informed about the meaning of placebo, the chances of getting the test/standard drug/placebo and that they may not know whether they will be receiving the test/standard drug/placebo till data collection is over.

9. Nature of benefits, risks/hazards/discomforts, and risk-benefit assessment

(Mention actual and potential benefits, any potential or actual risks, hazards and/or discomforts, including any sensitive questions/topics; weigh the benefits of the study against its risks for the individual and / or community in simple language).

10. Reimbursements

You will be paid for expenses incurred as a result of participation, including *(travel costs, money for wages lost, etc.)*

11. Privacy

I will make sure that data will be collected discreetly so that your privacy is not compromised in any way.

(Mention the measures taken to ensure privacy).

12. Confidentiality

The information collected will be kept confidentially. Personal details, if collected, and any information that may identify you will not be disclosed or published.

13. **Data storage and security**

(If data or biological samples are to be stored for some time or are likely to be used for another purpose, provide information and obtain consent specifically for such storage and use; mention possibilities of third-party use of electronic data, if applicable)

14. Additional information regarding this research

Please feel free to contact any member of the research team to obtain additional information regarding this research.

(List name and contact details of PI and other members of the research team)

15. Complaints

If you have any complaints regarding the conduct of this research, please inform…

(Provide the contact information of the ERC for participants who may want to express their concerns or make complaints regarding the study.)

Part II –Consent Form

Title: ……

I have read the above information / the above information has been read to me and I understand it thoroughly. I have been allowed to ask questions regarding this study and all the questions have been answered satisfactorily. I am aware of the benefits and risk of this study and the confidentiality of my details. I voluntarily give my consent to participate in this study and understand that I have the right to withdraw from the study at any time without loss of benefit to which I am otherwise entitled.

……. Date:

Signature of the participant

Name of the participant:

I confirm that the participant was given an opportunity to ask questions about the study and all the questions asked by the participant have been answered to the satisfaction of the participant.
I confirm that consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

……. Date:

Signature of the investigator

Name of the investigator:…….

Format for assent from a child/minor (<18 years)

I have read this information (or have had the information read to me). I have had my questions answered and know that I can ask questions later if I have any.
I agree to take part in the research.

Print name of the child …….
Signature of the child: ……
Date:…….

Format for consent form from parent or legally acceptable representative

I have read the above information / the above information has been read to me and I understand it thoroughly. I was allowed to ask questions regarding this study and all the questions have been answered satisfactorily. I voluntarily give my consent for my child (name of the participant) to participate in this study and understand that I have the right to withdraw her/his participation from the study at any time without loss of benefit to which he/ she is otherwise entitled.

……. Date:

Signature of the parent/ legally acceptable representative

Name of the parent/ legally acceptable representative:……..

Relationship to the participant: ……

Format for consent from illiterate participants

I have witnessed that the above information are clearly and accurately read to the participant and he/ she has understood it thoroughly. The participant was allowed to ask questions and all the questions have been answered to the satisfaction of the participant. I confirm that the participant has given the consent voluntarily to participate in this study and has understood that that he/ she has the right to withdraw from the study at any time without loss of benefit otherwise he/ she is entitled.

……. Date:

Signature of the witness

Name of the witness:

Name of the participant: Thumb print of participant

I have read the information sheet to the participant clearly and accurately. I confirm that the participant was given an opportunity to ask questions about the study and that all the questions have been answered to the satisfaction of the participant. I confirm that consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

……. Date:

Signature of the investigator

Name of the investigator:

Annexure 6/ SOP 8/ V4 – Paying in voucher

University of Jaffna
PAYING IN VOUCHER

1. Account to be credited: **Ethics Review Committee**
Faculty of Medicine

2. Name of the Payer: …….....

3. Address of the Payer: …….

…….…….....

4. Reason for payment: Rs. Cts.

1. Application fee ....
2. ……. ....
3. ……. ..... …… ……

_____

Total _____

5. Total amount (in words):

…….....

6. Mode of payment: Cash/ Cheque/ Money order/ Postal order

(No:……..)

7. Signature;……

8. Date:

Received by Cash/ Cheque/ Money order/ Postal order the above sum for credit of the People's Bank, Branch University of Jaffna, ***Account No.: 162-1-001-8-0000902.***

Shroff…… *Date:*

Annexure 7/ SOP 8/ V4 – Document receipt checklist

Document Receipt Checklist
(Applicant's copy)

(This document will be filled and handed over to the applicant by the Administrative Secretary of the ERC)

Reference number	**J/**	**ERC/**								**Date received**			/			/				

Title of the project

This confirms that the applicant has handed over the following documents;
(Please tick the appropriate check box)

No.	**Document**	**Check box**
1	Application form – 1 copy	
2	Signed and dated CV of PI and postgraduate research supervisor/s – 1copy	
3	Summary of the project – 1 copy	
4	Research protocol – 1 copy	
5	Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 1 copy each	
6	Questionnaire (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 1 copy each	
7	Data record booklet/ event record diary/data record sheet or form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil & Sinhala, if self-administered by participants) – I copy each	
8	Approval from National Drug Regulatory Authority (for clinical trials)	
9	Approval from SCOCT (to test new interventions/ interventions outside approved use in clinical trials)	
10	Insurance coverage (for clinical trials)	
11	Ethical clearance from the country of international collaborator(s), if applicable	

12	Evidence of scientific review, if available	
13	Soft copies of all documents other than the application form (by email)	
14	Receipt for payment of application fee to Shroff Counter, University of Jaffna or any branch of the People's Bank	
15	Administrative approval/s, if available (permission letters from heads of institution or authorized officers/ in-charge of the study site(s), etc.). Specify ……..	
16	Material transfer agreement	
17	Font size -12pt	
18	Line space between sentences- 1.5	
19	Other (Specify ……)	

The reference number on the top of this page is assigned for this application. Please quote this number in all correspondence with the ERC.

If you have any clarification or need to complain about the review process, you may contact:

The Chairperson/Secretary

The Ethic Review Committee

Faculty of Medicine

University of Jaffna

0212222073 extension: 342

…….. Date:

Signature of Administrative Secretary
(ERC secretariat)

Document Receipt Checklist
(Office copy)

Reference number	**J/**	**ERC/**								**Date received**			/			/				

Title of the project

This confirms that the applicant has handed over the following documents;

(Please tick the appropriate check box)

No.	**Document**	**Check box**
1	Application form – 1 copy	
2	Signed and dated CV of PI and postgraduate research supervisor/s – 1copy	
3	Summary of the project – 1 copy	
4	Research protocol – 1 copy	
5	Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 1 copy each	
6	Questionnaire (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 1 copy each	
7	Data record booklet/ event record diary/data record sheet or form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil & Sinhala, if self-administered by participants) – 1 copy each	
8	Approval from National Drug Regulatory Authority (for clinical trials)	
9	Approval from SCOCT (to test new interventions/ interventions outside approved use in clinical trials)	
10.	Insurance coverage (for clinical trials)	
11	Ethical clearance from the country of international collaborator(s), if applicable	
12	Evidence of scientific review, if available	
13	Soft copies of all documents other than the application form (by email)	

14	Receipt for payment of application fee to Shroff Counter, University of Jaffna or any branch of the People's Bank	
15	Administrative approval/s, if available (permission letters from heads of institution or authorized officers/ in-charge of the study site(s), etc.). Specify ……..	
16	Material transfer agreement	
17	Font size -12pt	
18	Line space between sentences- 1.5	
19	Other (Specify ……)	

……. Date:
Secretary/Administrative Secretary
(ERC secretariat)

……
Signature of PI/Co-investigator Date:
Name:…….

Annexure 8/ SOP9/ V4: Check list for exemption from ethics review

Ethics Review Committee
Faculty of Medicine, University of Jaffna

Check list for exemption from ethics review (Office use only)

Reference number	**J/**	**ERC/**	/							**Date received**			/			/				
Title of the Project																				

Principal Investigator:		
Institute:		**Contact No:**
Duration of the Study		
Type of Study	Educational ☐ Audit ☐ Survey ☐ Study using secondary data ☐	

No.		**Yes**	**No**	**NA**	**Comments**
Section A					
1.	Qualification of investigators are appropriate to conduct the study				
2.	Research falls into one of the exemption categories listed in SOP 9 (V4)				
Section B					
1.	Research involves vulnerable groups				
2.	Research involves interviews				
3.	Study deals with sensitive information				
4.	Study involves collecting personally identifiable data				

5.	Data from biological samples are used				
6.	Places subjects at risk for criminal or civil liability or is damaging to the subjects' financial standing, employability, or reputation				
Exemption from ethics review		**<u>If "Yes" for all responses in section A and "No" or "NA" for all responses in section B, an exemption can be granted</u>** **Exempted** ☐ **Not exempted** ☐			

…….
Chairperson/Vice-Chairperson
Ethics Review Committee

Date:

…….
Secretary/Assistant Secretary
Ethics Review Committee

Date:

Annexure 9/ SOP11/ V4: Protocol review form

Ethics Review Committee
Faculty of Medicine, University of Jaffna

Protocol Review Form

Office use only

Reference number	**J/**	**ERC/**	**/**							**Date received**			**/**			**/**				
Title of the Project																				

Principal Investigator:		
Institution:		**Contact No:**
Duration of the Study		
Status	New ☐ Revised ☐ Amended ☐	
Type of the Study	Observational ☐ Interventional ☐ Document based ☐ Other (specify) ……	
Reviewer 1 (name and field of expertise)		
Reviewer 2 (name and field of expertise)		
Reviewer 3 (name and field of expertise)		

No.		Yes	No	NA	Comments
1.	All necessary documents are provided				
2.	Evidence of approval/s from relevant authorities is/ are provided				
3.	Investigator/s has/have scientific, clinical or other relevant qualifications that are appropriate for the study				
4.	Title is appropriate				
5.	Background appropriate				
6.	Justification is sufficient				
7.	Objectives are clear				
8.	Review of literature is appropriate				
9.	Study design is appropriate				
10.	Study setting is appropriate				
11.	Facilities and infrastructure of the site are appropriate				
12.	Involvement of human subjects is needed				
13.	Study population is appropriate				
14.	Inclusion criteria are appropriate				
15.	Exclusion criteria are appropriate				
16.	Sample size is appropriate				
17.	Sampling technique is appropriate				
18.	Study instrument(s) is/are appropriate				
19.	Recruitment of participants is appropriate				
20.	Voluntary participation is ensured				
21.	Participants have the right to withdraw unconditionally at any time of the study without penalty or loss of benefit.				
22.	Participants are allowed to ask questions and register complaints				
23.	Procedure for obtaining consent is appropriate				
24.	Contents of information sheet and consent form(s) are adequate and clear				
25.	Translations of all forms are consistent				

26.	Risk-benefit assessment is acceptable				
27.	Confidentiality is ensured				
28.	Privacy of the participants is protected				
29.	Provision for compensation is appropriate				
30.	No inducement for participants				
31.	Provision of adequate medical and psychological support is planned				
32.	Statistical or other analytical methods are appropriate				
33.	Fate of data is mentioned				
	Plan to disseminate the study findings is appropriate				
34.	Details of budget and source(s) of funding are declared				
35.	Gantt chart is appropriate				
	Research involving biological samples				
36.	Justification for collecting biological samples is provided				
37.	Standards procedures will be adopted in sample collection				
38.	Procedures for disposal of sample are appropriate				
39.	Consent procedure for storage and future usage of sample is described				
40.	Justification for transfer of biological materials is adequate				
41.	Procedure for transfer of biological materials is appropriate				
42.	The above details are included in the information sheet				
	Vulnerable populations				
43.	Adequate justification is given for studying a vulnerable population				
44.	Procedures for obtaining consent from vulnerable population are appropriate				

45.	Measures to protect the rights and prevent exploitation of vulnerable populations are adequate				
	Clinical trials				
46.	Registered with clinical trial registry				
47.	Clearance from National Drug Regulatory Authority is annexed				
48.	Approval from the Sub-committee of Clinical trials (SCOCT) for new interventions/ interventions outside approved use is annexed				
49.	Adequate information is provided on the intervention/drug/device				
50.	Evidence for safe use of the drug/s in humans is provided				
51.	Adequate justification is provided for stopping the standard therapy				
52.	Provisions for monitoring and handling adverse events are stated				
53.	Procedure for reporting adverse events is appropriate				
54.	Criteria for withdrawal of participants are appropriate.				
55.	Criteria for termination of the trial are appropriate				
56.	Provisions for insurance coverage for trial participants and investigators are stated				
57.	Provisions for continuing access of subjects to the investigational treatment after the study are stated				
58.	Provisions for continuing access to the drug/device (investigational treatment) after the completion of the study are stated				
59.	Provisions for continuing access to medical treatment after the termination/completion of the study are stated				
60.	Details of sponsor are provided				
61.	Investigator's brochure is annexed				
	Collaborative research				
62.	Collaboration with international researchers is justified				

63.	Adequate justification is provided for doing the research in Sri Lanka				
64.	Nature of benefits and their distribution are appropriate/ acceptable				
65.	Ownership and fate of data are acceptable				
66.	Publication rights are stated and appropriate				
67.	Rights of the local collaborator are protected				
68.	Approval from the collaborating country/countries is annexed				
69.	Transfer of biological and/ or genetic materials is justified				
70.	Transfer of such materials follows national regulations				

Additional comments:

……

……

……

……

……

……

……

Approved ☐

Revision with minor corrections ☐

Resubmission with major corrections ☐

Disapprove ☐

……. Date:

Signature

Name of the reviewer:

Annexure 10/ SOP11/ V4: Form to assess community acceptability

Ethics Review Committee
Faculty of Medicine, University of Jaffna

Form to Assess Community Acceptability

Office use only

Reference number	**J/**	**ERC/**	**/**							**Date received**			**/**			**/**				
Title of the Project																				

Principal Investigator:		
Institution:		**Contact No:**
Duration of the Study		
Status	New ☐ Revised ☐ Amended ☐	
Type of Study	Observational ☐ Interventional ☐ Document based ☐ Other (specify) ……	
Reviewer 1 (name and field of expertise)		

Reviewer 2 (name and field of expertise)	

Reviewer 3 (name and field of expertise)	

No.		Yes	No	NA	Comments
1.	Information given in the ICF to the research participants is appropriate, adequate and complete				
2.	Language/s used is/ are simple and understandable by the participants				
3.	Language in the ICF is culturally appropriate and sensitive				
4.	Voluntary participation is ensured				
5.	Participants have the right to withdraw unconditionally at any time of the study without penalty and/ or loss of benefit.				
6.	Participants are allowed to ask questions and register complaints				
7.	All procedures are explained clearly in the information sheet				
8.	If biological samples are being collected, participants are informed about the type of samples to be collected				
	What tests will be done on the samples				
	Whether the samples will be stored for future studies				
	If stored, for how long and what will be done with the samples eventually				
9.	Translation/s of all forms is/ are consistent and accurate.				
10.	Assent form has been included				
11.	Contact details of PI and other investigators are given in the information sheet				
12.	Contact details of the ERC are given in the information sheet.				
13.	Justification to conduct the study is sufficient				
14.	Adequate justification is given for studying vulnerable populations				
15.	Risk and benefit of the study are explained				

Additional comments:

……
……
……
……
……
……
……
……
……
……
……
……

Approved: ☐

Revision with minor corrections: ☐

Resubmission with major corrections: ☐

Disapprove: ☐

……. Date:

Signature

Name of the reviewer:

Annexure 11/ SOP12/ V4 – Agenda of ERC meetings

Office of the ERC
Faculty of Medicine
University of Jaffna
Date:……..

Name list of the members

Dear Sir/Madam,

<u>…….Meeting of the Ethics Review Committee</u>

The …… meeting of the Ethical Review Committee will be held on **……. (Tuesday)** at **2.00 pm** in the Board Room of the Faculty of Medicine.

<u>Agenda of the ……..meeting of the ERC</u>

ERC/…/1. Preliminaries
ERC/…/1.1. Excuses
ERC/…/1.2. Announcements
ERC/…/2. Declaration of conflict of interest

ERC/…/3. Conformation of the minutes of the previous meeting

ERC/…/4. Matters arising from the minutes
Protocols awaiting revisions and/ or clarifications
Other matters under each categories of Exempted from ethics review, Expedited review and Full board review

ERC/…/5. New applications
ERC/…/5.1. Exempted from ethics review
Title of the project
Full name of the PI
Reference number

ERC/…/5.2.Expedited review
Title of the project
Full name of the PI
Reference number

ERC/…/5.3.Full board review
Title of the reject
Full name of the PI
Reference number
Names of the primary reviewers

ERC/…/5.4.Undergraduate projects

ERC/…/6. Follow up
ERC/…/6.1. Amendments
ERC/…/6.2. Request for extension of ethical clearance
ERC/…/6.3. Progress reports
ERC/…/6.4. Completion reports
ERC/…/6.5. Reports on adverse event
ERC/…/6.6. Reports on site visit
ERC/…/6.7. Protocol deviation/violation
ERC/…/6.8. Other communications related to approved protocols

ERC/…/7. Correspondence

ERC/…/8. Any other business

ERC/…/9. Close and date of next meeting

Kindly be present for this meeting.

Yours sincerely,

……..
Secretary/Ethics Review Committee
Date:

Annexure 12/ SOP14/ V4: Minutes of ERC meetings

Minutes of the ……th Meeting of the Ethics Review Committee held at 2.00 P.M on …..….(date) in the Board Room of the Faculty of Medicine

Name	Months						
	January	February	March	May	June	July	August
1.							
2.							

P – Present E - Excuse A – Absent

ERC/86/1 Confirmation of the minutes of the ..th meeting held on …….
The minutes of the …th meeting of the ERC were confirmed subject to the following amendments:

Preliminaries

Confirmation of agenda

Announcements

Conflicts of interest

The following members of the ERC declared conflict of interest

1. ……. – PI/Co-investigator/Supervisor/Consultant/data collector/first degree relative of the PI of the Research Project titled "…….." submitted by ……(name of PI)
2. …….
3. …….

ERC/…/… Matters arising from the minutes

ERC…/…./… Research protocol titled "……..." submitted by …….. – Reference No…….

(Details including version numbers, the due date of the revised version, and that the ERC is awaiting reply from the Principal Investigator should be documented).

ERC/…./….. New proposals submitted for ethical clearance

Exempted from ethics review

ERC…./…/.. Research protocol titled "……" submitted by ……. – Reference …….
At the …the subcommittee meeting held on ….. it was decided to exempt the proposal from ethics review.

The Ethics Review Committee at its … meeting held on … granted an exemption for the above protocol.

Expedited review

ERC…./…/.. Research protocol titled "……" submitted by ……. – Reference …….
At the …the subcommittee meeting held on…., it was decided to expedite the review of the above protocol.

Reviewer:
Name, designation and affiliation

At the ..th meeting held on …….. , the ERC decided to request **…… (name of PI)** to fulfill the following:

Full board review

Research protocol titled "……" submitted by ……. – Reference …….

Reviewers:

1. Name, designation and affiliation
2. ……
3. …….

The above proposal was reviewed by the Ethics Review Committee at its ..th meeting held on …….. The Committee decided to request **…… (name of PI)** to fulfill the following:

It was decided that the clarifications and revised protocol could undergo expedited review by the Chairperson and Secretary.

ERC/…/.. Undergraduate research proposal

ERC/…/.. Follow up

ERC/…/. Amendments

ERC/…/. Extension of ethical clearance

ERC/…/. Progress reports

The Chairperson informed that progress reports have been received from:

1. …….(Name of PI and Reference Number)
   Title "……..'

ERC/…/. Completion reports

The Chairperson informed that completion reports have been received from:

1. …….(Name of PI and Reference Number)
   Title "……..'

ERC/…/. Reports on adverse events

ERC/…/. Reports on site visits

ERC/…/…Protocol deviation/violation

ERC/…/. Other communications related to approved protocols

ERC/…/.. Any other business - Nil

ERC/…/.. The next meeting will be held on ……

Secretary/Ethics Review Committee
Date:

Annexure 13/ SOP14/ V4: Extracts of minutes

Minutes of the ……th Meeting of the Ethics Review Committee held at 2.00 P.M on ……., …….in the Board Room of the Faculty of Medicine

ERC/…./1 Confirmation of the Minutes of the ….th meeting held on (Date)

The Minutes of the ….. meeting of the ERC were confirmed.

Preliminaries

ERC/84/2 Matters arising from the minutes

ERC…….. Research protocol titled "……." submitted by …… (name of the PI) – Reference No……

Decision…….

ERC……. ……

ERC…. …….

ERC/84/3 New proposals submitted for ethical clearance

ERC…….. Research protocol titled "……." by …….. (Name of PI – Reference No…….

Decision……..

ERC/…./…. Follow up

ERC/…./…. Correspondence

ERC/…./…. Any other business

Secretary/Ethics Review Committee

Date:

Annexure 14/ SOP17/ V4: ERC review comments to PI

Office of the ERC
Faculty of Medicine
University of Jaffna
Date:

Name of the PI

Designation

Address

Dear …….,

(Title of the project)

(Reference No.)

The above protocol/ clarifications/ amendments was/were reviewed by the ERC at its…… meeting held on ……. It was decided that the protocol requires revision with minor corrections/resubmission with major corrections of version …… of the protocol. The ERC made the following observations and recommendations.

1. ……
2. …….

Kindly submit your clarifications and revised protocol as early as possible (on or before DATE). Please tabulate your responses to the ERC in the format below.

No.	Comments of the ERC	Existed as	Corrected as	Page Nos. of the Proposal (Version…..)
1.				
2.				
….				

If you fail to submit the clarifications within 3 months from …... the application will lapse. In such case, a new application would need to be submitted to the ERC to obtain ethical clearance for this project from our ERC.

Chairperson/ Vice-Chairperson/ Secretary/Assistant Secretary
Ethics Review Committee
Faculty of Medicine
University of Jaffna

Annexure 15/ SOP17/ V4: Exemption from ethics review

Office of the ERC
Faculty of Medicine
University of Jaffna
Date:

Name of the PI
Designation
Address

(Title and the reference number of the project)

(Co-investigators)

Dear …….,

The ERC at its …… meeting held on …….. decided to exempt Version ….. of the study protocol titled "……." from ethics review with following reasons.

1……

2……..

Please note: The exemption pertains to this version of the protocol; any amendments /deviations should be informed to the ERC.

Chairperson/ Vice-Chairperson
Ethics Review Committee

Secretary/Assistant Secretary
Ethics Review Committee

Annexure 16/ SOP17/ V4: ERC approval

Office of the ERC
Faculty of Medicine
University of Jaffna

Date:

Name of the PI
Designation
Address

Dear …….,

(Title and the date of submission of the application)

(Reference number)

(Co-investigators)

The ERC at its …… meeting held on …….. decided to grant ethical clearance for Version……. of the above project for a period of one year from ……. with the following conditions;

1. Progress reports must be submitted 6-monthly unless informed otherwise (refer SOP 17/V4).
2. If the study extends beyond a year, ethical clearance must be extended/renewed at the end of one year.
3. If extension/renewal is needed, a request for extension/ renewal of ethical clearance must be submitted at the end of one year along with the progress report.
4. A completion report must be submitted at the conclusion of the study (refer SOP 17/V4).
5. Any amendments to the protocol should not be carried out without prior approval from the ERC (refer SOP 15/V4).
6. The following must be submitted when/if applicable
   a. Report on serious adverse events (refer SOP 18/V4)
   b. Protocol violation report (refer SOP 20/V4)
   c. Suspension/ termination of the project (refer SOP 21/V4)

Chairperson/Vice-Chairperson
Ethics Review Committee

Secretary/Assistant Secretary
Ethics Review Committee

Annexure 17/ SOP17/ V4: ERC disapproval

Office of the ERC
Faculty of Medicine
University of Jaffna
Date:

Name of the PI
Designation
Address

Dear …….,

(Title and the date of submission of the project)

(Application number)

The ERC at its …… meeting held on …….. reviewed the application and has decided to disapprove the proposal for following reasons;

1…..
2…..

If you have any further clarifications/queries or would like to appeal this decision, please write to the Chairperson ERC, Faculty of Medicine, University of Jaffna.

Chairperson/Vice-Chairperson
Ethics Review Committee

Secretary/Assistant Secretary
Ethics Review Committee

Annexure 18/ SOP17/ V4: Approval to amendments to protocol

Office of the ERC
Faculty of Medicine
University of Jaffna
Date:

Name of the PI
Designation
Address

Dear …….,

(Title and the date of submission of the proposal)

(Application number)

(Co-investigators)

The ERC at its …… meeting held on …….. decided to grant approval for the amendment of Version ……. of the above project for a period of one year from ……. with the following conditions;

……..
……..

Chairperson/Vice-Chairperson
Ethics Review Committee

Secretary/Assistant Secretary
Ethics Review Committee

Annexure 19/ SOP18/ V4: Progress report

Progress Report Form
Ethics Review Committee
Faculty of Medicine, University of Jaffna

Reference number:

Principal investigator:

Telephone:

Email:

Protocol title:

Date of commencement of the study:

Number of participants enrolled:

Number of participants who withdrew:

Number of participants lost to follow-up (if applicable):

Adverse events (if any):

Protocol violation/ deviation (if any):

Any deviations from the Gantt Chart:

Any ethical issues encountered and action taken:

A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last version of the protocol submitted to the Ethics Review Committee (not more than 500 words):

Publications/ presentations related to the study:

Signature of the PI:

Date:

Annexure 20/SOP18/ V4: Completion report

Completion Report Form

Ethics Review Committee

Faculty of Medicine, University of Jaffna

Reference number:

Protocol title:

Principal investigator:

Telephone:

Email:

Date of start:

Date of completion:

Study site(s):

Total number of study participants:

Objective(s):

Study materials and method:

Results and conclusions:

Adverse events (if any):

Protocol violation/ deviation (if any):

Any ethical issues encountered and action taken:

Publications (if any):

Signature of Principal Investigator:

Date:

Annexure 21/ SOP19/ V4: Adverse event reporting form

ADVERSE EVENT REPORTING FORM

Reference number:

Protocol title:

Principal investigator:

Sponsor's name:

Study site(s):

Patient identification number:

2. Suspected adverse drug reaction

Date of onset:	**Date of recovery:**
Description of the event:	

Outcome (tick the appropriate box)

Recovered	Recovering	Continuing	Hospitalised	Fatal

Laboratory reports

Seriousness (tick the appropriate box)			
Life threatening		Death	
Results in hospitalisation		Birth defect	
Prolongation of hospitalisation expected		Other (specify)	
Permanent disability			
Impairment or damage to organs			
Relevant medical history			

3. Study drug / device

Batch no.:				**Expiry date:**
Date started:				**Date stopped:**
Dosage form	**Route**	**Dose**	**Frequency**	

Other drugs used						
Name	**Dosage form**	**Route**	**Dose & frequency**	**Date started**	**Date stopped**	**Reason for using**

Adverse event on discontinuation of the drug/ reduction of dose (tick the appropriate box)					
Drug stopped (date)	Dose reduced (indicate the reduced dose) (date)				
Status of adverse event (tick the appropriate box)					
Disappeared	Improved	Persisted	Not known		
Reappearance of adverse events on reintroduction (tick the appropriate box)					
Yes		No		Not known	

4. Reporting person

Name:

Address:

Designation:

Status in the research team:

Contact number:

Date of reporting:

Signature:

Date:

Annexure 22/ SOP20/ V4: Site monitoring checklist

Site Monitoring Checklist
Ethics Review Committee
Faculty of Medicine, University of Jaffna

Reference number:

Study title:

Date of visit:

Reason for the visit:

Name of Principal Investigator:

Address:

Telephone:

Name of the sponsor:

Address of the sponsor:

Date of ERC approval:

Date of commencement of the study:

Total number of subjects expected:

Total number of subjects enrolled:

Are site facilities appropriate as stated in the proposal? □ Yes □ No
Comments:

Is informed consent obtained appropriately and filed? □ Yes □ No
Comments:

Any adverse events found? □ Yes □ No
Comments:

Any protocol non-compliance/violations detected? □ Yes □ No
Comments:

Are all case record forms up to date? □ Yes □ No
Comments:

Are storage of data and investigating products kept under lock and key? □ Yes □ No
Comments:

Is participant protection: □ Good □ Fair □ Poor

Comments:

Details of action or results of the visit:

Duration of visit:……hours. Starting from:

Names and signatures of the ERC members

1.

2.

3.

Date: