

Standard Operating Procedures

Ethics Review Committee

Version 3



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Standard Operating Procedures

Ethics Review Committee (ERC)

Faculty of Medicine, University of Jaffna

Editors

Dr. K. Kandeepan, Secretary, ERC

Dr. T. S. Navaratinarajah, Member, ERC

Dr. T. Chenthuran, Member, ERC

Approved by the ERC, Faculty of Medicine, University of Jaffna held on 26.10.2017

Details of members

| | Name | Designation |
|----|--------------------------------|---|
| 1 | Dr. K. Sivapalan (Chairperson) | Visiting Professor in Physiology, Faculty of Medicine, University of Jaffna |
| 2 | Dr. K. Kandeepan (Secretary) | Senior Lecturer in Biochemistry, Faculty of Medicine, University of Jaffna |
| 3 | Dr.Ms. S. Ambikaipakan | Senior Lecturer in Anatomy, Faculty of Medicine, University of Jaffna |
| 4 | Dr. T. Chenthuran | Senior Lecturer in Anatomy, Faculty of Medicine, University of Jaffna |
| 5 | Dr. T. Eswaramohan | Senior Lecturer in Zoology, Faculty of Science, University of Jaffna |
| 6 | Dr. S. Kannathasan | Senior Lecturer in Parasitology, Faculty of Medicine, University of Jaffna |
| 7 | Dr. K. Muhunthan | Senior Lecturer in Obstetrics and Gynaecology, Faculty of Medicine, University of Jaffna |
| 8 | Mr. S. Pathmanathan | Retired Principal |
| 9 | Dr. Mrs.J. Pratheepan | Senior Lecturer in Medicine, Faculty of Medicine, University of Jaffna |
| 10 | Dr. S. Rajendra | Senior Lecturer in Surgery, Faculty of Medicine, University of Jaffna |
| 11 | Mrs. Kokila Mehaendraraja | Retired Deputy Director of Education, Valikamam zone. |
| 12 | Dr. S. Sivaganesh | Registrar and former Regional Epidemiologist, Jaffna |
| 13 | Mr. V. T. Sivalingam | Attorney at Law |
| 14 | Dr. S. Sivansuthan | Consultant Physician, Teaching Hospital, Jaffna |
| 15 | Dr. S. Sivashamugarjah | Senior Lecturer in Siddha Medicine, Unit of Siddha Medicine, University of Jaffna |
| 16 | Dr. Mrs. T. S. Navaratinaraja | Senior Lecturer in Pharmacology, Faculty of Medicine, University of Jaffna |
| 17 | Dr. Mrs. N. Umashankar | Senior Lecturer in Paediatrics, Faculty of Medicine University of Jaffna |
| 18 | Dr. R. Surenthirakumaran | Senior Lecturer in Community and Family Medicine, Faculty of Medicine, University of Jaffna |

**Approved by the Faculty Board of the Faculty of Medicine, University of Jaffna held on
27.12.2017**

.....
Dean
Faculty of Medicine
University of Jaffna
Date:

Approved by the Senate of the University of Jaffna held on 20.02.2018

.....
Vice chancellor
University of Jaffna
Date:

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History of 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 was functioning based on the national and international ethical guidelines that existed at that time. Following the establishment of Forum of Ethics Review Committees in Sri Lanka (FERCSL), ERC of Faculty of Medicine, University of Jaffna was reconstituted in 2008 based on the FERCSL guidelines of 2007. The ERC started having regular board meetings since March 2009. During the initial years the ERC has followed FERCSL guidelines 2007 for its operations. Later on the ERC developed its own Terms of Reference (TOR) and Standard Operating Procedures (SOP). Document history of the ERC is given below.

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

Based on the recommendation on the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) survey conducted in August 2017, the ERC has revised its SOP (Version 2) to incorporate the SIDCER survey recommendation given by Forum for Ethic Review Committees in Asian and Western Pacific Region (FERCAP).

| Description | Name and version of the document | Implementation |
|---|---|-----------------------|
| First guideline developed by the ERC | TOR version 1 | October 2012 |
| Revised 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 the recommendations of SIDCER survey | SOP version 3 | February 2018 |

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|---|---|---|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 01/ V3 |
| | Title: Functions of ERC | Effective date: 01.02.2018 Page: 2-3 |

1.1 Purpose

The Purpose of this standard operating procedure (SOP) is to describe the functions and responsibilities of the Ethics Review Committee (ERC) of the Faculty of Medicine, University of Jaffna (FM, UJ). This SOP provides the terms of reference (TOR) for the constitution, responsibility and activities of ERC of the FM, UJ.

1.2 Scope

- 1.2.1 The primary objective of the ERC of the FM, UJ is to protect the welfare, rights, dignity and the safety of the research participants.
- 1.2.2 The secondary objective is to provide an updated ethical frame work, guidance and consultation to the researchers conducting research in Northern Province of Sri Lanka including University of Jaffna.
- 1.2.3 The sub-committee of the ERC will review research involving animals according to the separate SOP developed by ERC of FM, UJ to protect the care/welfare of the animals.


1.3 Responsibility

- 1.3.1 It is the responsibility of the ERC to ensure that the welfare of the participants and animals of the research projects submitted to ERC, FM, UJ is protected and it facilitates the researchers to adhere to ethical principles and practice.
- 1.3.2 The ERC is responsible for its decisions.

1.4 Description of functions of ERC

- 1.4.1 The ERC of FM, UJ accept applications for review of research projects in which human participants involve directly or indirectly that are conducted
 - 1.4.1.1 by students and staff of the University of Jaffna
 - 1.4.1.2 in the Northern Province of Sri Lanka.
- 1.4.2 The ERC will charge an application fee as approved by the Faculty Board of FM, UJ for all the applications except undergraduate projects of the UJ.
- 1.4.3 It will provide independent, competent and timely review on ethical and scientific aspects for the projects involving human participants and animals to ensure the protection of welfare of participants and animals.
- 1.4.4 The ERC of FM, UJ accept applications for review of research projects involving animals.

- 1.4.5 The ERC will review the research projects according to the institutional, FERCSL and other national and international guidelines on ethics review.
- 1.4.6 The ERC will send the application to an external subject expert when the committee lacks the expertise among its members to review specific subject/technical areas.
- 1.4.7 It is the duty of the ERC to follow up and monitor the research projects approved by it. The ERC will receive regular progress report, completion report and report on serious adverse effects (SAE) and also will visit the study site to monitor the performance / compliance with the approved protocol. The details of follow up and monitoring procedures are described in SOP18/ V3, 19/ V3 and 20/ V3.
- 1.4.8 The ERC will provide an ethical frame work and guidance to promote the standards of biomedical researches.
- 1.4.9 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/ V3.
- 1.4.10 It is the responsibility of the ERC to review the SOP at least every three years or whenever necessity arises. Procedure for reviewing SOP is described in SOP 26/ V3.
- 1.4.11 The ERC will conduct training programme/ workshop on Research Ethics and SOP annually soon after the appointment of new members. Details of the training to members are described in SOP 5/ V3.
- 1.4.12 Accountability
 - 1.4.12.1 The ERC is accountable to the Faculty Board of FM, UJ and the Senate of University of Jaffna. Extracts of the confirmed minutes of the ERC meeting are sent to the Faculty Board.
 - 1.4.12.2 It provides annual report on the activities of the ERC at the end of each calendar year to the Faculty Board.
 - 1.4.12.3 The ERC maintains financial record and provides an annual financial report to the Faculty Board.

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 02/ V3 |
| | Title: Composition of ERC | Effective date: 01.02.2018 Page: 4-5 |

2.1 Purpose

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

2.2 Scope

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


2.3 Responsibility

The composition of ERC should enable independent and competent review.

2.4 Description of composition of ERC

- 2.4.1 The composition of the ERC is in accordance with the FERCSL and other relevant guidelines.
- 2.4.2 The ERC will comprise of 15-20 members.
- 2.4.3 Composition of the ERC should ensure that it has the expertise to review the protocols submitted to the ERC.
- 2.4.4 The ERC composition should reflect the balance between the following;
 - 2.4.4.1 Male:Female
 - 2.4.4.2 Scientist: non-scientist
 - 2.4.4.3 Clinician: medical basic scientist
 - 2.4.4.4 Medical: non-medical basic scientist
 - 2.4.4.5 Affiliated: non-affiliated members
- 2.4.5 The ERC will comprise the following category of members.
 - 2.4.5.1 Clinicians from FM, UJ
 - 2.4.5.2 Clinician from institutions other than FM, UJ
 - 2.4.5.3 Medical basic scientist from FM, UJ
 - 2.4.5.4 Non-medical basic scientist from FM, UJ
 - 2.4.5.5 Members from UJ excluding FM
 - 2.4.5.6 Expert in statistics
 - 2.4.5.7 Legal expert
 - 2.4.5.8 Veterinary Surgeon
 - 2.4.5.9 Non-scientific members

- 2.4.6 The term of the ERC members will be three years.
- 2.4.7 At the end of the term, members may be reappointed for maximum of two terms or replaced by new members.
- 2.4.8 The chairperson, member secretary/ joint secretaries, vice-chairperson and assistant secretary will be elected from among its existing members of ERC and their names will be forwarded to the Faculty Board.
- 2.4.9 Upon the recommendation of the Faculty Board of FM, UJ, the Dean will appoint the chairperson, vice-chairperson, member secretary/ joint secretaries and assistant secretary for the period of three years unless a necessity arises due to some exigencies. Template of the appointment letter is annexed as Annexure 1/ SOP3/ V3.
- 2.4.10 The chairperson and member secretary/joint secretaries should have a minimum of three years of experience and vice-chairperson and assistant secretary should have a minimum of one year of experience in the existing committee as a member of the ERC of FM, UJ.
- 2.4.11 The ERC will also have a permanent administrative secretary for the ERC office who will be designated by the Dean, FM, UJ.

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 03/ V3 |
| | Title: Appointment of ERC members | Effective date: 01.02.2018 Page: 6-7 |

3.1 Purpose

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

3.2 Scope

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

3.3 Responsibility

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

3.4 Description of procedures for appointment/reappointment of ERC members


- 3.4.1 The ERC committee nominates prospective ERC members and forwards it to the Faculty Board.
- 3.4.2 The selection of members is based on their personal capacities, qualifications, knowledge, experience and expertise in their fields in considering the composition of the ERC.
- 3.4.3 The Dean, Faculty of Medicine appoints the ERC members based on recommendation of the Faculty Board of FM according to the requirement of composition of the ERC and the guidelines set by ERC, FM, UJ for the period of three years. Letter of appointment will be issued by the Dean of Faculty of Medicine, University of Jaffna.
- 3.4.4 The letter of appointment shall include date of appointment, tenure, terms of reference, conditions of appointment, and the circumstances whereby membership may be terminated. Template of the appointment letter is annexed as Annexure 1/ SOP3/ V3.
- 3.4.5 At the time of appointment members should provide their curriculum vitae with signature and 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 on the ERC shall be kept confidential.
 - 3.4.5.2 any conflicts of interest which exist or may arise during his/her tenure in the ERC shall 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 a ERC member.

The confidentiality and conflict of interest agreement is attached as Annexure 2/ SOP3/ V3.

- 3.4.6 Upon appointment, members shall be provided with the following documents:
 - 3.4.6.1 Latest SOP of the ERC.
 - 3.4.6.2 An up-to-date list of members and contact information including that of the Dean.
- 3.4.7 Members must agree to their names, designations and affiliations being made available to public including publishing on the website of FM, UJ.
- 3.4.8 Members should complete their training on research ethics, Good Clinical Practices (GCP) and SOP within 6 months of appointment. Members who fail to complete the above training will be replaced at the appointment of members.
- 3.4.9 Members can be re-appointed at the end of their term. The number of times of reappointments is limited to two terms for a member. After consecutive two reappointments the member could be reappointed after a break for a period of at least one term (3years).
- 3.4.10 If a member fails to attend three consecutive meetings of the ERC without 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 member for the rest of the terms described in sections 3.4.1, 3.4.2 and 3.4.3 of SOP 03/ V3.
- 3.4.11 Membership also will lapse if a member fails to attend (with or without excuses) at least two thirds of all scheduled ERC meetings in each 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/ V3.
- 3.4.13 A member may resign from the ERC at any time upon giving notice in writing to the Chairperson/ERC and 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. The vacancy will be filled as described above in sections 3.4.1, 3.4.2 and 3.4.3 of SOP 03/ V3.
- 3.4.14 A member will lose membership in the following circumstances:
 - 3.4.14.1 Disclosure of confidential information
 - 3.4.14.2 Utilizing the proprietary information
 - 3.4.14.3 Fails to declare conflict of interest (COI)
 - 3.4.14.4 Evidence for personal or professional misconduct
- 3.4.15 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/ V3.

3.5 Annexure

- 3.5.1 Annexure 1/ SOP3/ V3 – Letter of appointment for ERC members
- 3.5.2 Annexure 2/ SOP3/ V3 – Confidentiality and conflict of interest agreement

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 04/ V3 |
| | Title: Functions of ERC members | Effective date: 01.02.2018 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 the TOR for the functions of the 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 they reviewed.
- 4.3.2 It is the responsibility of the members to read, understand and abide by the guidelines and procedures set by the ERC of FM, UJ.
- 4.3.3 Members should maintain the confidentiality.
- 4.3.4 Members should be able to be engaged in continuous education / training in their fields of expertise, biomedical researches and research ethics.


4.4 Description of functions of ERC members

- 4.4.1 All the members of the ERC of FM, UJ should
 - 4.4.1.1 review applications assigned to them within the stipulated time and contribute to the discussion on the application at full board meetings.
 - 4.4.1.2 complete the review forms and return the completed review form along with protocol and supporting documents to the secretary of ERC at least two days before the scheduled meeting.
 - 4.4.1.3 perform any other duties assigned to members according to the SOPs and duties assigned by the chairperson/vice-chairperson.
 - 4.4.1.4 disclose conflict of interests and where a conflict does exist with respect to a study abstain from reviewing the protocol and leave the room during discussion of and voting on the protocol.
 - 4.4.1.5 remain impartial and objective when reviewing protocols
 - 4.4.1.6 respect others' views.
 - 4.4.1.7 keep up-to-date with national and international research ethics and regulatory guidance.
 - 4.4.1.8 Undergo periodic training on research ethics according to the following requirements of ERC of FM, UJ.
 - 4.4.1.8.1 Training on research ethics and GCP at least every 3 years.

- 4.4.1.8.2 SOP training when new SOP is implemented.
- 4.4.1.9 attend the ERC meeting regularly except unavoidable circumstances.
- 4.4.2 In addition to functions described in section 4.4.1 of SOP04/ V3, the Chairperson of the ERC is expected to perform the following additional duties.
 - 4.4.2.1 Conducting the meetings of the ERC according to the SOPs.
 - 4.4.2.2 Providing guidance to ERC members and office staff.
 - 4.4.2.3 Periodically review / revise ERC policies and guidelines in consultation with the members of ERC.
- 4.4.3 In additions to functions described in section 4.4.1 of SOP 04/ V3, the member secretary/joint secretaries of the ERC is expected to perform following additional duties.
 - 4.4.3.1 Organizing the meetings, maintaining records and communicating with all concerned.
 - 4.4.3.2 Preparing the minutes of the meetings and the general correspondence with applicants and getting approval for these documents/ letters from the chairperson/ vice-chairperson before communicating.
 - 4.4.3.3 Preparing extract of minutes and after the approval of the chairperson/ vice-chairperson forwarding to faculty board.
 - 4.4.3.4 Ensuring the membership files are up-to-date.
 - 4.4.3.5 Arranging sub-committee meetings to assign primary reviewers for applications.
 - 4.4.3.6 Providing guidance to the ERC office staff and supervising ERC office and the office staff.
 - 4.4.3.7 Performing any other duties of the ERC assigned by the Chairperson/vice-chairperson.
- 4.4.4 Specific functions of non-scientific member include
 - 4.4.4.1 representing the interests of the community/participant at large.
 - 4.4.4.2 reviewing informed consent process to ensure participant protection.
 - 4.4.4.3 evaluating benefits and risks to research participants
 - 4.4.4.4 reviewing protocols helping to ensure that language and other aspects of a study make sense to laypersons.
- 4.4.5 Specific functions of vice-chairperson in additions to functions described in section 4.4.1 of SOP 04/ V3
 - 4.4.5.1 In the absence of the chairperson, the vice-chairperson will carry out the functions of the chairperson as described in 4.4.2.
- 4.4.6 Specific functions of assistant secretary in addition to functions described in section 4.4.3 of SOP 04/ V3
 - 4.4.6.1 Assisting the member secretary in preparation of agenda, minutes, communications with PI etc. and organising ERC meetings and training.
 - 4.4.6.2 In the absence of the member secretary, the assistant secretary will carry out the functions of the member secretary as described in 4.4.3.

- 4.4.6.3 Performing any other duties of the ERC assigned by the Chairperson/vice-chairperson/member secretary.
- 4.4.7 Functions of administrative secretary include
 - 4.4.7.1 the administrative secretary needs to sign a confidentiality agreement.
 - 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 the applications and checking all applications for completeness.
 - 4.4.7.4 sending and receiving communications.
 - 4.4.7.5 coordinating ERC meeting.
 - 4.4.7.6 preparing the meeting agenda according to the standard format as described in SOP 13/ V3 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 the scheduled meeting on scheduled date and time.
 - 4.4.7.9 sending approved extract of minutes to the faculty board.
 - 4.4.7.10 practicing the procedures that are set by the ERC to maintain confidentiality of ERC documents.
 - 4.4.7.11 maintaining registry of applications.
 - 4.4.7.12 maintaining the electronic database of the ERC.
 - 4.4.7.13 record keeping and archiving.
 - 4.4.7.14 organizing training programmes/ workshops conducted by the ERC.
 - 4.4.7.15 performing any other duties assigned by the chairperson/vice-chairperson and member secretary/assistant secretary.

(In the absence of the administrative secretary the these functions will be covered by the member secretary/assistant secretary)

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 05/ V3 |
| | Title: Orientation of new members and training | Effective date: 01.02.2018 Page: 11–12 |

5.1 Purpose

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

5.2 Scope

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


5.3 Responsibility

- 5.3.1 It is the responsibility of the ERC to give the opportunities to its members to get the necessary training in research ethics within the stipulated time.
- 5.3.2 It is the responsibility of all members to get necessary training within the timeline and keep them regularly and periodically trained on research ethics.

5.4 Description of the procedures for orientation of new members and training

- 5.4.1 Adequate orientation should be given to new ERC members before they start functioning as ERC member. The orientation of a new member includes the following.
- 5.4.1.1 Introduction to other ERC members prior to the ERC meeting.
- 5.4.1.2 Informal meeting with the Chairperson/vice-chairperson and Member Secretary/assistant secretary to explain their responsibilities as an ERC member, the ERC processes and procedures.
- 5.4.1.3 Giving opportunity to observe an ERC meeting before they start functioning as reviewer.
- 5.4.1.4 The ERC will organize training sessions to new members on the following.
- 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 training program on research ethics organized by FERCSL, other ERCs / Institutions/ Organisations with in the stipulated time (new members within 6 months of appointment and existing members every 3 years) in order to retain their membership.
- 5.4.2.3 Certificate of training on research ethics need to be submitted by new members within 6 months of appointment.
- 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 SOP to all of its members when a new SOP is implemented or 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 commitment), on written request of such member to the chairperson of the ERC an additional SOP training session may be conducted.
 - 5.4.3.4 Certificate of training on SOP need 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 do the necessary arrangements to send its members to the GCP training programme conducted by FERCSL annually.
 - 5.4.4.2 Members who fail to attend the GCP training conducted by FERCSL attend training programmes on GCP organized by other ERCs / Institutions/ Organisations or complete an online GCP training within the stipulated time (new members within 6 months of appointment and existing members every 3 years) in order to retain their membership.
 - 5.4.4.3 Certificate of training on GCP need to be submitted by new members within 6 months of appointment.

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 06/ V3 |
| | Title: External subject experts | Effective date: 01.02.2018 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.

6.2 Scope

This SOP provides the terms of reference 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 a required expertise to review such project has/ have COI.

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 understand the process and procedures of reviewing.

6.4 Description of the procedures for appointment of external subject experts


- 6.4.1 The ERC should have a panel of external subject experts anticipating the expertise that would be required outside the ERC members.
- 6.4.2 The pool of external subject experts will include language experts to review the translations.
- 6.4.3 On the recommendation of the ERC, the Dean will appoint the external subject experts on the recommendation of Faculty Board of FM, UJ and they receive letter appointment signed by the Dean of FM, UJ. Template of appointment of external subject experts is attached as Annexure 3/ SOP6/V3.
- 6.4.4 External subject experts are appointed for the period of three years.
- 6.4.5 The conditions of appointment for external subject experts include
- 6.4.5.1 signing and disclosing confidentiality and conflict of interest agreement.
- 6.4.5.2 willingness to publicize his/her full name, designation and affiliation to public including publishing in the website of FM, UJ.
- 6.4.6 If the required expertise is not available among the panel of external subject experts, the chairperson in consultation with the member secretary and / or other member/s will nominate a person with required expertise outside the panel of

external subject experts. Covering approval from ERC and Faculty board, FM, UJ will be obtained.

- 6.4.7 Chairperson and /or member Secretary will describe the specific duties, review process and responsibilities to the external subject experts.
- 6.4.8 The Member Secretary/assistant secretary will contact the external subject expert and send the relevant documents for review.
- 6.4.9 The external subject expert must complete and send completed protocol review form to the secretary at least two days before the scheduled meeting. Review report of the external subject expert will be taken at the discussion of the project concerned.
- 6.4.10 If required ERC could invite the external subject expert to participate in the discussion about the project at the ERC meeting.
- 6.4.11 The external subject expert will not participate in the decision making process of the project under review or on any other matter of ERC and they don't have the voting rights.

6.5 Annexure

- 6.5.1 Annexure 3/ SOP6/ V3 – Letter of appointment for external subject expert

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 7/ V3 |
| | Title: Conflict of interest | Effective date: 01.02.2018 Page: 15 – 16 |

7.1 Purpose

Purpose of this SOP is to describe the procedures for declaring and handling COI.

7.2 Scope

This SOP covers the procedures for declaring COI by the 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 the members, office staff, external subject expert and guest attendee regarding disclosure COI.
- 7.3.2 It is the responsibility of the ERC members to declare the COI before the project/ matter concerned is taken for review.

7.4 Description of procedures for declaration and handling COI

- 7.4.1 Conflict of interest 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 Getting any financial benefit 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 project concerned.
- 7.4.1.2.2 Involved in another project in the same research area as the project concerned.
- 7.4.1.2.3 First degree relative of member/ office staff / external subject expert / guest attendee is in the research team.
- 7.4.2 Member/ office staff/ external subject expert/ guest attendee should declare if they have direct or indirect COI and refrain from involving in any matters related to the project/ matter concerned (Annexure 2/ SOP3/ V3).
- 7.4.3 The ERC will determine if this results 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 has been completed. The member shall not be permitted to adjudicate on the project.

- 7.4.4 All declarations of conflict of interest and the resolutions of same will be recorded in the minutes.

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 8/ V3 |
| | Title: Submission of applications for ethics review | Effective date: 01.02.2018 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 terms of reference for the procedures for submission of new application for ethics review to the ERC of FM, UJ.

8.3 Responsibility

It is the responsibility of administrative secretary to receive, register and process the submitted applications to ERC office of FM, UJ.

8.4 Description of the procedures for submission of new applications for ethics review


- 8.4.1 Applications along with 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 Administrative secretary will receive, check for completeness and then process the applications.
- 8.4.3 All the applications that are submitted before the close of business of last working day of the month will be taken up at the next schedule meeting.
- 8.4.4 All the new applications must be submitted in the prescribed format by the ERC of FM, UJ. The application form of ERC of FM, UJ and guide to applicant are available at the faculty website at <http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>. The ERC application form and guide to applicant are attached as Annexure 4/ SOP8/ V3 and Annexure 5/ SOP8/ V3 respectively. Applicant should use the latest application form.
- 8.4.5 Application form must be duly filled and signed and submitted along with four (04) copies of the following documents.
- 8.4.5.1 Complete research protocol.
- 8.4.5.2 Information sheets and consent forms - in English, Tamil and Sinhala where appropriate.
- 8.4.5.3 Other relevant documents such as questionnaires, data sheet, check lists etc. in English, Tamil and Sinhala where appropriate.

- 8.4.5.4 Updated Curriculum Vitae (CV) of the Principal Investigator (PI) and CV of the chief-supervisor for undergraduate and postgraduate studies.
- 8.4.5.5 For postgraduate study projects – a letter from the relevant postgraduate Institute / Board of Study stating that the research proposal has been approved for postgraduate study.
- 8.4.5.6 Soft copies of all the above documents in word file/PDF format in a CD.
- 8.4.6 Initial protocol and all supporting documents must be indicated in the pages (header/footer) as version 1.
- 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 Fee structure is given in the guide to applicant (Annexure 5/SOP8/V3)
 - 8.4.7.2 The authorized counter copy of the completed paying in voucher (can be downloaded from the faculty website at <http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>) for the payment of application should be submitted along with the application. Paying in voucher is attached as Annexure 6/ SOP8/ V3.
 - 8.4.7.3 Payment can be made by cash/money order/postal order (in favor of ERC, Faculty of Medicine, University of Jaffna) at the shroff's counter of the University of Jaffna or at any branch of Bank of Ceylon to the credit of the account number given in the paying in voucher.
- 8.4.8 Applications will be checked by the Administrative secretary of the ERC using a checklist and all documents will be date stamped. All incomplete applications will be returned to the applicant immediately.
- 8.4.9 For complete applications, the administrative secretary will issue a copy of the checklist as receipt to the PI. Document receipt check list is attached as Annexure 7/ SOP8/ V3
- 8.4.10 Once a completed application is accepted for ethics review, the ERC shall assign a unique reference number to the application. Then details of application will be entered in the ERC's register for applications.
- 8.4.11 The accepted applications along with all relevant documents and soft copy will be filed. Each protocol will have a specific protocol file and all the documents and communications related to the protocol will be added to the protocol file.
- 8.4.12 Member Secretary will categorize the new proposals that are submitted to ERC, FM, UJ and on the first working day of a month will call for a sub-committee meeting. The sub-committee comprising the chairperson/vice-chairperson or nominee, member secretary/assistant secretary or nominee and an ERC member will decide the type of review of submitted protocols in previous month.

- 8.4.13 For applications requiring full board review, the chairperson/ vice chairperson and member secretary/assistant secretary and designated one member of ERC, appoint at least 3 primary reviewers for each application. Primary reviewers shall include a subject expert (or more if necessary), expert in statistics (to review the appropriateness of methodology and sample size before review to comments) and a non-scientific member. Primary reviewers can be from ERC members if they are suitable to review the proposal, if not the primary reviewers can be external subject experts 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 responsible of Head of the departments.
- 8.4.14.2 Such research projects should be forwarded through the Head of the Department concerned.
- 8.4.14.3 A subcommittee will review undergraduate projects. The subcommittee shall comprise of the chairperson/ nominee, secretary/ nominee and Head or nominee of the department concerned.
- 8.4.15 Submission of collaborative research projects; In the case of international collaborative researches following documents should be submitted with the application;
- 8.4.15.1 Evidences for prior written agreement between the local and foreign collaborator on the following;
- 8.4.15.1.1 Fate of data and samples/ specimens.
- 8.4.15.1.2 Ownership of the data and publication and intellectual property rights.
- 8.4.15.1.3 Nature of benefits and their distribution.
- 8.4.15.2 Ethical clearance certificate from the country of collaborator.
- 8.4.15.3 Transfer of biological or genetic materials should follow the standards drawn by this country and supporting documents should be submitted.

8.5 Annexure

- 8.5.1 Annexure 4/ SOP8/ V3 – Ethics review application form
- 8.5.2 Annexure 5/ SOP8/ V3 – Guide to applicants
- 8.5.3 Annexure 6/ SOP8/ V3 – Paying in voucher
- 8.5.4 Annexure 7/ SOP8/ V3 – Document Receipt Checklist

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|---|---|---|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 9/ V3 |
| | Title: Exemption from ethics review | Effective date: 01.02.2018 Page: 20 – 21 |

9.1 Purpose

The purpose of this SOP is to describe the procedures to identify the protocols that could be exempted from ethics review.

9.2 Scope

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

9.3 Responsibility

It is the responsibility of the chairperson/ vice-chairperson (or nominee) and member secretary/assistant secretary (or nominee) to assess and decide on exempting from ethics review using the set criteria by the ERC of FM, UJ.

9.4 Description of procedures for exemption from ethics review

9.4.1 The ERC of FM, UJ will consider research projects that fall into one of the following category for exemption from ethics review;

9.4.1.1 Educational researches (research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom, management methods, etc.) that fulfill the following criteria;

9.4.1.1.1 All research is conducted in a commonly accepted educational setting (e.g. school or university).

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

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

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


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

9.4.1.1.6 Provisions are made to ensure the existence of a non-coercive environment for students who choose not to participate.

- 9.4.1.1.7 The school or other institution grants written permission for the research to be conducted.
- 9.4.1.1.8 Study should not involve vulnerable population (children, individuals with disability etc.)
- 9.4.1.2 Audit, survey and research involving the use of secondary data or educational tests (cognitive, diagnostic, aptitude, achievement) provided that information obtained
 - 9.4.1.2.1 is recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects.
 - 9.4.1.2.2 do not have any sensitive information such as substance abuse, sexual activity or attitudes, sexual abuse, criminal behaviour, sensitive demographic data, detailed health history, etc.
- 9.4.2 At the sub-committee meeting the chairperson/ vice-chairperson (or nominee), member secretary/assistant secretary (or nominee) and an ERC member will assess protocol for eligibility to exempt from ethics review as per the check list for exemption from ethics review. The check list for exemption from ethics review is attached as Annexure 8/ SOP9/ V3.
- 9.4.3 When a proposal is exempted from ethical review the chairperson/ vice-chairperson shall communicate to the next ERC that the proposal is exempted from ethics review and the formal letter of exemption from ethics review will be issued after ratification at the next ERC meeting.
- 9.4.4 All the documents and communication related to the protocol will be filed in a specific protocol file.

9.5 Annexure

- 9.5.1 Annexure 8/ SOP9/ V3 – Check list for exemption from ethics review

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|---|---|---|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 10/ V3 |
| | Title: Expedited ethics review | Effective date: 01.02.2018 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 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 set criteria by the ERC of FM, UJ.

10.4 Description of procedures for expedited review

- 10.4.1 The ERC of FM, UJ may under take expedited review of research protocols between scheduled meetings and reviewed by subcommittee comprising chairperson/ vice-chairperson or a nominee, member Secretary/assistant secretary or a 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 proposal could be considered for expedited review which carry minimal risk and on non-sensitive topics in the following circumstances;
- 10.4.3.1 Researches involving non-sensitive information using secondary data where the human 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 and the research will not cause stress to the participants.
- 10.4.4 Research proposals involving the following will not be considered for expedited review;
- 10.4.4.1 clinical trial.
- 10.4.4.2 research involving invasive physical procedures.

- 10.4.4.3 research exploring sensitive personal or cultural issues and research dealing with vulnerable groups.
- 10.4.5 At the sub-committee meeting chairperson/vice-chairperson (or nominee), member secretary/assistant secretary (or nominee) and an ERC member will assess protocol for eligibility to expedited review.
- 10.4.6 Once the decision is made, the administrative secretary will send the following documents to the reviewer;
 - 10.4.6.1 Copy of the application form
 - 10.4.6.2 Protocol and supporting documents
 - 10.4.6.3 Protocol review form and when applicable informed consent review form
- 10.4.7 Review should not take more than 2 weeks.
- 10.4.8 Once reviewer's report is received, chairperson in consultation with the reviewer and member secretary could arrive at a decision. If the chairperson/member secretary is the reviewer, the decision will be taken by the vice-chairperson in consultation with assistant secretary and another member of the ERC. Decision could be
 - 10.4.8.1 Approve the proposal.
 - 10.4.8.2 Minor revision needed.
 - 10.4.8.3 Full board review needed.
- 10.4.9 The board will be informed the details of proposals that have undergone expedited review and the decision at its next regular meeting. Ethical clearance will be sent to the PI after ratification at full board meeting.
- 10.4.10 If minor revision needed, secretary will communicate to the PI as soon as possible.
- 10.4.11 If any ERC member raises concern about expedited review, then based on the decision of the ERC board, the proposal may undergo full board review.

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 11/ V3 |
| | Title: Full board review of new applications | Effective date: 01.02.2018 Page: 24 – 26 |

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 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 responsibility of the ERC to providing independent, competent and timely review and make sure that rights and welfare of the participants are protected.
- 11.3.2 Reviewers are responsible to read and understand the procedures and standards set by the ERC of FM, UJ for reviewing protocols and should strictly follow them.
- 11.3.3 Member Secretary/assistant secretary and the administrative secretary should make sure that review processes are according to the standards and timelines set by the ERC of FM, UJ.

11.4 Description of procedures for full board review of new application

- 11.4.1 The ERC shall consider a new application at its next monthly meeting provided that the completed application is received on or before the last working day of the 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 are subjected to full board review as described in section 8.4.13, of SOP 8/ V3.
- 11.4.3 On the instructions of the member secretary, the administrative secretary will send the following documents to the primary reviewers as early as possible and not later than three working days from the date of 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 All supporting documents including Tamil and Sinhala translations

11.4.3.5 Review forms

11.4.3.5.1 Protocol review form to scientific reviewers

11.4.3.5.2 Informed consent review form to non-scientific primary reviewer

Protocol review form and informed consent review forms are attached as Annexure 9/ SOP 11/ V3 and Annexure 10/ SOP11/ V3 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 days prior to the scheduled meeting.

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

11.4.5 All proposals shall be circulated both soft and/or hard copies 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. Applications will be discussed at the meeting by all members present. Written submissions made in lieu of attendance by those not present will be considered.

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

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 and the translations convey the same message as 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 The ERC, after considering an application at a meeting, will make decision as approve the proposal or revision with minor correction or resubmission with major correction or disapprove the proposal as describe in section 13.4.9 of SOP 13/ V3.

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 shall 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 non-scientific member.

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

11.5 Annexure

11.5.1 Annexure 9/ SOP11/ V3 – Protocol review form

11.5.2 Annexure 10/ SOP11/ V3 – Informed consent review form

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 12/ V3 |
| | Title: Preparation of agenda for ERC meetings | Effective date: 01.02.2018 Page: 27 – 28 |

12.1 Purpose

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

12.2 Scope

This SOP provides the terms of reference 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 from 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 ERC within stipulated time.

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

- 12.4.1 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 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 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 Declaration 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
 - 12.4.5.6 Protocols awaiting revisions and/ or clarifications
 - 12.4.5.7 Other matters
 - 12.4.5.8 New applications
 - 12.4.5.8.1 Exempted from ethics review
 - 12.4.5.8.1.1 Title of the project
 - 12.4.5.8.1.2 Full name of the PI
 - 12.4.5.8.1.3 Reference number
 - 12.4.5.8.2 Expedited review
 - 12.4.5.8.2.1 Title of the project
 - 12.4.5.8.2.2 Full name of the PI
 - 12.4.5.8.2.3 Reference number
 - 12.4.5.8.3 Full board review
 - 12.4.5.8.3.1 Title of the project
 - 12.4.5.8.3.2 Full name of the PI
 - 12.4.5.8.3.3 Reference number
 - 12.4.5.8.3.4 Names of the primary reviewers
 - 12.4.5.8.4 Undergraduate projects
 - 12.4.5.9 Follow up
 - 12.4.5.10 Amendments
 - 12.4.5.11 Request for extension of ethical clearance
 - 12.4.5.12 Progress reports
 - 12.4.5.13 Completion reports
 - 12.4.5.14 Reports on adverse events
 - 12.4.5.15 Reports on site visit
 - 12.4.5.16 Other communications related to approved protocols
 - 12.4.5.17 Protocol Deviation and violation
 - 12.4.5.18 Correspondents
 - 12.4.5.19 Any other business
 - 12.4.5.20 Close and date of next meeting

Template for the agenda of the meeting is attached as Annexure 11/ SOP12/ V3.

- 12.4.6 Administrative secretary will circulate the approved agenda along with minutes and other documents to all the 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

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 13/ V3 |
| | Title: Conduct of meetings | Effective date: 01.02.2018 Page: 29 – 30 |

13.1 Purpose

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

13.2 Scope

This SOP provides the terms of reference for the procedures to be followed in conducting the 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 regular meetings of the ERC as well as special meetings if necessary.
- 13.3.2 Administrative secretary is responsible for organizing the meeting and informing the ERC members.

13.4 Description of the procedures for conducting ERC meeting

- 13.4.1 The ERC shall generally meet on the 4th Tuesday of the month. Dates of ERC meetings for the year shall 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 and those who are unable to attend the meeting must inform their excuses in writing to the member secretary prior to the meeting which 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 (5) members to be present including chairperson/ vice-chairperson and member secretary / assistant secretary with a non-scientific member to arrive at a decision.
- 13.4.4 If the meeting does meet the quorum requirements, the Chairperson/ vice-chairperson shall cancel it and the ERC will convene a 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 prior to all agenda items being considered, the ERC will reconvene within 10 working days 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/PI may be invited to the meeting to discuss the protocol or for expert opinion. Such attendees must declare COI and sign a confidentiality

- agreement before attending the meeting. Guest attendees will not involve in decision making.
- 13.4.8 Any member of the ERC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the ERC must declare such interest beforehand. This will be dealt with in accordance with SOP 7/ V3.
- 13.4.9 After reviewing of each proposal (new/revised/amended), ERC board will make one of the following decisions:
- 13.4.9.1 **Approve the proposal:** as being ethically acceptable, no changes requested
- 13.4.9.2 **Revision with minor correction:** would be eligible for expedited review of resubmissions.
- 13.4.9.3 **Resubmission with major correction:** which would require full board review once the revisions are done and the revised proposal will be re-reviewed by the same primary reviewers.
- 13.4.9.4 **Disapprove the proposal:** as being ethically unacceptable and reasons for disapproval will be conveyed to the applicant.
- 13.4.10 At the closure of the meeting date for the next meeting will be confirmed/ decided.
- 13.4.11 Special meeting of the ERC
- 13.4.11.1 Special meetings will be conducted in between regular ERC meetings.
- 13.4.11.2 Member Secretary in consultation with the chairperson/ vice-chairperson will call for a special meeting.
- 13.4.11.3 Special meeting of the ERC could be called
- 13.4.11.3.1 when a regular meeting of the ERC is cancelled because of lack of quorum.
- 13.4.11.3.2 when all the agenda items of the regular meeting could not be considered.
- 13.4.11.3.3 for some specific purpose such as revision of SOP.
- 13.4.11.4 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 for situation where urgent decision of the ERC is needed such as death or serious adverse event (SAE) reported for an approved project.
- 13.4.12.2 Emergency meeting should be held as soon as possible not later than 3 days from the day of reporting of such SAE.

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 14/ V3 |
| | Title: Minutes of Meetings | Effective date: 01.02.2018 Page: 31 – 32 |

14.1 Purpose

The purpose of this SOP is to describe format and procedures 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 meeting 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 the members.

14.4 Description of format and procedures for preparing the minutes of ERC meetings

- 14.4.1 Member Secretary/assistant secretary will prepare the minutes of all the meetings of the ERC.
- 14.4.2 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 Amendments
 - 14.4.2.8 Extension of ethical approval
 - 14.4.2.9 Reports on SAE
 - 14.4.2.10 Progress reports
 - 14.4.2.11 Completion report
 - 14.4.2.12 Protocol violation or deviation
 - 14.4.2.13 General correspondents
 - 14.4.2.14 Any other business

14.4.2.15 Close and date and time for the next meeting

Template for the minutes of the meeting is attached as Annexure 12/ SOP14/ V3.

14.4.3 Minutes should include

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

14.4.3.2 Decision of the ERC

14.4.4 The following need to be recorded for review of new protocol and amendments

14.4.4.1 Decision of the ERC

14.4.4.2 Clarifications / additional information requested when applicable

14.4.4.3 Significant dissenting view or concern of member/s

14.4.5 Generally in the record of review comments, name/s of member/s will not be quoted in the minutes unless a member seeks to have his/her opinions or objections recorded by name.

14.4.6 Declaration of COI by member and his/ her absence during the discussion of the project concerned must be recorded.

14.4.7 Member Secretary will prepare the minutes after the meeting and it will be reviewed and approved by the chairperson.

14.4.8 Minutes will be circulated along with agenda for the next meeting and new applications among the 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 Original copy 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. Template for extracts of minutes is attached as Annexure 13/ SOP14/ V3.

14.5 Annexure

14.5.1 Annexure 12/ SOP14/ V3 – Minutes of the meeting

14.5.2 Annexure 13/ SOP14/ V3 – Extract of Minutes

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 15/ V3 |
| | Title: Review of resubmitted protocols | Effective date: 01.02.2018 Page: 33 – 34 |

15.1 Purpose

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

15.2 Scope

This SOP provides the standards and timelines for the procedures to be followed when reviewing resubmitted protocols which are already subjected to initial review by the ERC.


15.3 Responsibility

- 15.3.1 It is the responsibility of the member secretary/assistant secretary and administrative secretary to ensure the completeness and of the resubmitted documents and to notify the chairperson/ vice-chairperson.
- 15.3.2 It is the responsibility of the chairperson/ vice-chairperson and member secretary/assistant secretary to process the resubmission based on the ERC decision.

15.4 Description of procedures for management of resubmitted protocols

- 15.4.1 Resubmission should include the following documents.
- 15.4.1.1 Duly signed cover letter indicating the changes made in the protocol with page number and/ or supporting documents according to recommendations of the ERC.
- 15.4.1.2 Revised protocol – version of the protocol must be indicated on each page of the protocol (if the decision is minor correction, one copy; if the decision is resubmission with major correction four copies are needed)
- 15.4.1.3 Supporting documents - version of the protocol must be indicated on each page of these documents (if the decision is a minor correction, one copy; if the decision is resubmission with major corrections, four copies are needed).
- 15.4.1.4 all the above documents in word/pdf written in CD
- 15.4.2 The administrative secretary should date stamp upon receiving the packages.
- 15.4.3 Member Secretary/assistant secretary should scrutinize the resubmission and processes it in consultation with chairperson/ vice-chairperson according to the decision of the ERC regarding the project concerned.

- 15.4.3.1 Minor revision: expedited review by Chairperson/ vice-chairperson or nominee and Secretary/Assistant secretary or nominee in between the ERC meetings.
- 15.4.3.2 Major revision: full board review.
- 15.4.4 Resubmission with minor revision will go through the expedited review as described in SOP 10/V3.
 - 15.4.4.1 If the chairperson/ vice-chairperson and member secretary/Assistant secretary are satisfied with the revision made, chairperson/vice-chairperson shall approve the proposal. The decision shall be communicated to the ERC. The formal ethical approval will be issued after ratification at the next ERC meeting.
- 15.4.5 Resubmissions with major revision will be sent to the primary reviewers. Administrative Secretary should send the following documents to the reviewers;
 - 15.4.5.1 Cover letter
 - 15.4.5.2 Revised protocol along with supporting documents
 - 15.4.5.3 Recommendations and comments of ERC
 - 15.4.5.4 Relevant Review form (s)
- 15.4.6 With the reviewers' report resubmitted protocols with major revision will be subjected full board review. The ERC will make the decision as described in section 13.4.9 of SOP 13/ V3 and the decision will be communicated to PI.
- 15.4.7 If the PI fails to send the corrections, reminders will be sent after 1st and 2nd month and those failing to reply within 3 months of the date of communicating the 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.
- 15.4.8 If the PI does not respond within 3 months the application concerned will lapse. In such a case if ethical clearance is desired for the same project a fresh application has to be submitted.
- 15.4.9 Revised protocol and supporting documents, re-review reports and communication to PI will be filed in the protocol file along with the original documents and initial communication in chronological order.

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 16/ V3 |
| | Title: Amendments to approved protocols | Effective date: 01.02.2018 Page: 35 – 36 |

16.1 Purpose

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

16.2 Scope

This SOP provides standards and procedures for reviewing amendments to an approved protocol.

16.3 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.

16.4 Description of procedures for managing amendment to approved protocols

16.4.1 The principal investigator may seek approval for amendments to proposals that have been approved and such requests shall be in writing and include

16.4.1.1 A duly signed cover letter with details of the

16.4.1.1.1 title of the protocol with its ERC reference number

16.4.1.1.2 nature of the proposed amendments

16.4.1.1.3 assessment of the ethical implications, if any, that arise as a result of the amendment

16.4.1.2 Protocol and supporting documents incorporating the amendments with revised version numbers and dates. The amended sections should be highlighted.

16.4.2 The ERC of FM, UJ depending on the nature of the amendments will decide on the type of review, either expedited or full board review.

16.4.2.1 Major amendments will be subjected to full board review and will be reviewed by


16.4.2.1.1 the same primary reviewers who reviewed the initial protocol.

16.4.2.1.2 the ERC board.

16.4.2.2 Minor amendments shall undergo expedited review as described in SOP13/V3.

16.4.3 Following will be considered as minor amendments and are eligible for expedited review.

- 16.4.3.1 Inclusion or exclusion of investigators
- 16.4.3.2 Changes in study setting
- 16.4.3.3 Changes in the duration of the study
- 16.4.3.4 Extension of ethical approval
- 16.4.4 Decision regarding amendment shall be communicated in to the PI in a standard format set by the ERC of FM, UJ. Template for approval of amendments to protocol is attached as Annexure 18/ SOP 17/ V3.
- 16.4.5 All the amendments, review report of amendments and communications shall be added to the document of protocol file of the project concerned.

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 17/ V3 |
| | Title: Communication of decisions of the ERC | Effective date: 01.02.2018 Page: 37 – 39 |

17.1 Purpose

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

17.2 Scope

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

17.3 Responsibility

- 17.3.1 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.
- 17.3.2 Administrative secretary is responsible to send the correspondence to the PI within stipulated time and record them in appropriate register/ record.

17.4 Description of procedures for communication of ERC decisions

- 17.4.1 The decision of the ERC should be communicated to the PI in writing within seven (07) working days of monthly ERC meeting.
- 17.4.2 Member Secretary/assistant secretary will prepare such communications.
- 17.4.3 Correspondence regarding the decision of the ERC will be signed by the chairperson/ vice-chairperson or member secretary/assistant secretary (after the approval of chairperson/ vice chairperson).
- 17.4.4 Administrative secretary will send the correspondence to the PI and also enter the details of such communication in appropriate registry / record.
- 17.4.5 The decision of the ERC board for further clarifications from PI should be communicated in writing and will be signed by the chairperson/vice-chairperson/member secretary/assistant secretary.
- 17.4.5.1 If the ERC decides to request the PI for further information, clarification or modification, the correspondence to the PI should be in a standard format including the following;
- 17.4.5.2 Date of communication
- 17.4.5.3 Reference number
- 17.4.5.4 Title of the project
- 17.4.5.5 Date of submission

- 17.4.5.6 Name and address of the PI
- 17.4.5.7 Date of the ERC meeting
- 17.4.5.8 Type of decision
- 17.4.5.9 Reasons for this decision
- 17.4.5.10 Request for additional information/ clarification/ modification if needed

Template for requesting further clarification/ information is attached as Annexure 14/ SOP17/ V3.

- 17.4.5.11 If the ERC decides to exempt the project from ethics review the decision should be communicated in the standard format and will be signed by the chairperson/vice-chairperson and member secretary/ assistant secretary. It given in the Annexure 15/ SOP17/ V3.
- 17.4.5.12 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 information:
 - 17.4.5.12.1 Date of communication
 - 17.4.5.12.2 Reference number
 - 17.4.5.12.3 Title of the project
 - 17.4.5.12.4 Date of submission
 - 17.4.5.12.5 Name and address of the PI
 - 17.4.5.12.6 Names of collaborating investigators with affiliations;
 - 17.4.5.12.7 Version number of the protocol.
 - 17.4.5.12.8 The date of the ERC meeting at which approval is given
 - 17.4.5.12.9 The conditions, if any, to which the ERC approval is subject;
 - 17.4.5.12.10 The period of validity of the ERC's approval;
 - 17.4.5.12.11 The frequency of progress reports
 - 17.4.5.12.12 Date of submission of the final report and instructions for submission of the final report.
- 17.4.5.13 Data collection for research protocols should not commence until written notification has been received by the applicant confirming approval. Template for ERC approval is attached as Annexure 16/ SOP17/ V3.
- 17.4.5.14 For interventional studies condition for reporting SAE should be included in the approval letter.
- 17.4.5.15 For researches with international collaboration the condition of the approval should include clause to protect the rights of the local collaborator. Following will be considered for the considered for collaborative researches;
 - 17.4.5.15.1 The ownership of the data and right of publication should lie with the researcher who collects the data.

- 17.4.5.15.2 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 of relevance to this country.
- 17.4.6 If the ERC determines that a proposal is disapproved on ethical or other grounds, the communication of the ERC's decision will include the reason for disapproval of the proposal with reference to the FERCSL Guidelines or other relevant legislation. A standard letter will be issued, in the standard 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 can sign. Template for disapproval of applications is attached as Annexure 17/ SOP17/ V3.
- 17.4.7 Office copy of all communications will be filed in the respective protocol files and also status of the protocol will be updated in appropriate registries / records.
- 17.4.8 Communications related to undergraduate projects will be done through the Head of the respective departments. Once the ethical approval is given the department concerned will be responsible for the conduct and monitoring of the project.

17.5 Annexure

- 17.5.1 Annexure 14/ SOP17/ V3 – ERC review comments to PI
- 17.5.2 Annexure 15/ SOP17/ V3 – Exemption from ethics review
- 17.5.3 Annexure 16/ SOP17/ V3 – ERC approval
- 17.5.4 Annexure 17/ SOP17/ V3 – ERC disapproval
- 17.5.5 Annexure 18/ SOP17/ V3 – Approval to amendments to protocol

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|---|---|---|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 18/ V3 |
| | Title: Monitoring of approved research projects | Effective date: 01.02.2018 Page: 40 – 42 |

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 of 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 the compliance of approved research projects to the conditions of ethical approval.

18.3.2 Principal investigator should comply with the conditions of ethical approval and send reports to the ERC as per the conditions of the ERC.

18.4 Description of procedures for Monitoring of approved research projects

18.4.1 The ERC will follow up the research projects that are approved to ensure the adherence of researchers to the conditions of ethical approval and to ensure the safety of the participants by

18.4.2 reviewing progress and completion reports.

18.4.3 requesting information on relevant aspect.

18.4.4 reviewing reports on SAE (described in SOP 19/ V3).

18.4.5 site visits (described in SOP 20 / V3)

18.4.6 Principal investigator should provide periodic progress reports to the ERC. The follow-up intervals will be decided by the ERC considering the nature of the project, at least every 6 months and completion report at the conclusion of the study. If PI do not submit the progress/final report, new applications will not be processed for review until such report/s is/ are submitted.

18.4.7 The ERC shall require the following information in the progress/ completion report;

18.4.7.1 progress to date or outcome in the case of completed research

18.4.7.2 maintenance and security of records

18.4.7.3 compliance with the approved protocol

18.4.7.4 compliance with any conditions of approval

Template for progress report and completion reports are attached as Annexure 19/ SOP 18/ V3 and Annexure 20/SOP18/ V3 respectively.


- 18.4.8 Request for extension of ethical approval will be considered by the ERC on receiving the progress reports.
- 18.4.9 Prospective applications of the PI will be considered by the ERC for review on receiving the progress/ completion reports of the approved projects of the PI.
- 18.4.10 The ERC will send reminders to PI for progress or completion reports one month before the due date for the submission of progress or completion reports.
- 18.4.11 The ERC may request, at any time, information on any relevant aspects of the study and discuss any issue of relevance with the researchers.
- 18.4.12 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 those measures it considers appropriate for monitoring, such as:
- 18.4.12.1 written reports;
 - 18.4.12.1.1 random inspections of research sites, data and signed consent forms etc.
 - 18.4.12.1.2 interviews, with their prior consent, of research participants.
- 18.4.13 In the case of clinical trials the ERC shall require six monthly reports which shall be reviewed by the special subcommittee (or the Clinical Trials Sub-committee) The progress reports shall contain at least the following information:
- 18.4.13.1 Progress to date or outcome in the case of completed research
 - 18.4.13.2 Statements regarding maintenance and security of records
 - 18.4.13.3 Statements supporting compliance with the approved protocol
 - 18.4.13.4 Statements supporting compliance with any conditions of approval
- 18.4.14 Clinical trial subcommittee consists of following members
- 18.4.14.1 The Chairperson/ vice-chairperson or nominee
 - 18.4.14.2 Member Secretary/Assistant Secretary or nominee
 - 18.4.14.3 A Clinical Pharmacologist
 - 18.4.14.4 A clinician with special training/interest in the clinical discipline/field
 - 18.4.14.5 A statistical expert
- 18.4.15 The ERC shall require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of the ethical approval of the protocol, including:
- 18.4.15.1 proposed changes in the protocol;
 - 18.4.15.2 any unforeseen events that might affect continued ethical acceptability of the project
 - 18.4.15.3 new information from other published or unpublished studies
 - 18.4.15.4 which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.

18.4.16 When circumstances have prevented a research study from being conducted in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC shall inform the Principal Investigator and the institution of such withdrawal of approval in writing, and recommend to the institution that the research study be discontinued or suspended, or that other necessary steps be taken.

18.5 Annexure

18.5.1 Annexure 19/ SOP18/ V3 – Progress report

18.5.2 Annexure 20/SOP18/ V3 – Completion report

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 19/ V3 |
| | Title: Handling of Serious Adverse Events | Effective date: 01.02.2018 Page: 43 – 46 |

19.1 Purpose

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

19.2 Scope

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

19.3 Responsibility

- 19.3.1 It is the responsibility of the PI to report immediately all the adverse events according to the conditions set by to the ERC of FM, UJ.
- 19.3.2 The PI should include all the adverse events and responses to those events in the progress and completion reports.
- 19.3.3 It is the responsibility of the chairperson/ vice-chairperson to take appropriate course of action as early as possible for those adverse events deemed serious and requiring immediate attention.

19.4 Description of procedures for reporting and handling SAE


- 19.4.1 The ERC shall require, as a condition of approval of each proposal, that researchers immediately report Suspected Unexpected Serious Adverse Reactions (SUSAR) and Serious Adverse Events (SAE) to the ERC.
- 19.4.2 This requirement includes those that have occurred at other sites in the case of multicenter studies.
 - 19.4.2.1 Serious Adverse Event; the following are considered as serious adverse events,
 - 19.4.2.1.1 Death
 - 19.4.2.1.2 Life threatening adverse events
 - 19.4.2.1.3 Hospitalization
 - 19.4.2.1.4 Disability
 - 19.4.2.1.5 Congenital abnormalities
- 19.4.3 Unexpected adverse events: Unexpected adverse events are the events that occurred during or soon after the study that are not reported earlier with the particular drug or intervention and are not included in the product information sheet.
- 19.4.4 Time line for reporting adverse events for the interventional studies approved by the ERC of FM / UJ;

- 19.4.4.1 Fatal or life threatening expected/unexpected reactions occurring in a patient on a trial should be reported to the ERC within 24 hours.
- 19.4.4.2 All other adverse reactions, other than fatal and life threatening, in a participant on a trial: report as soon as possible, but not later than fifteen (15) days.
- 19.4.4.3 Or some other time frame as required by Sri Lankan Regulations, if any.
- 19.4.5 Reporting of SUSAR and SAE should be submitted in the prescribed format by the ERC of FM, UJ and available at the faculty website (<http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>) and ERC office of FM, UJ. The adverse event reporting form is attached as Annexure 21/ SOP19/ V3.
- 19.4.6 Along with adverse event reporting form following documents also must be submitted to the ERC;
 - 19.4.6.1 A statement from the principal investigator as to whether, in his/her opinion, the adverse event was related to the protocol or in the case of a drug/device trial, whether the adverse event was related to the study drug/device.
 - 19.4.6.2 A statement from the principal investigator as to whether, in his/her opinion, the adverse event necessitates an amendment to the protocol and/or the patient information sheet/consent form.
- 19.4.7 Adverse events may be reviewed by a special subcommittee of the ERC (or Clinical Trials Subcommittee) empowered to review such events, which shall determine the appropriate course of action.
- 19.4.8 Composition of clinical trial subcommittee is provided in section 18.4.14 of SOP18/ V3.
- 19.4.9 The review shall take place as soon as possible, not later than one week of notification of the event. The special subcommittee shall determine the appropriate course of action depending on nature and seriousness of the event and inform the ERC of its recommendations which may include
 - 19.4.9.1 a notation on the proposal file of the occurrence.
 - 19.4.9.2 increased 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 trial sub-committee chairperson/ vice-chairperson may take a course of action for those adverse events deemed serious and requiring immediate attention and decision could be;
 - 19.4.10.1 Referral to the Sub-committee of 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 special committee and chairperson's decision shall be reported to the ERC at the next meeting.
- 19.4.12 If chairperson feels that a decision of the full board is required, he/ she shall instruct the member secretary to call for an emergency meeting.
- 19.4.13 The ERC shall 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 shall immediately notify the Dean and/ or Head of the institution where PI is attached to, if a project is suspended or terminated because of a serious adverse event.

19.5Annexure

- 19.5.1 Annexure 21/ SOP19/V3 – Adverse event reporting form

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 20/ V3 |
| | Title: Site visit | Effective date: 01.02.2018 Page: 46 – 47 |

20.1 Purpose

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

20.2 Scope

This SOP provides the criteria and procedures for site visit of the ERC to the study sites of approved projects by the ERC of FM / UJ as a part of continuous monitoring.

20.3 Responsibility

It is the responsibility of the ERC to have a mechanism to identify the approved projects that require site visits and carry out site visits of such projects as a part of continuous monitoring of approved project.


20.4 Description of criteria and procedure for site visit

- 20.4.1 Criteria for site visit
- 20.4.2 Sites will be identified based on the degree of intervention, sample size and complexity of the study and risk involved.
- 20.4.3 Approved projects that require site visits by the ERC shall be decided according to the following criteria;
 - 20.4.3.1 Nature of the report of the SAE committee
 - 20.4.3.2 Nature of the violations of protocol reported
 - 20.4.3.3 Unrealistically high number of projects carried out in a study site
 - 20.4.3.4 Non-compliance or suspicious conduct
 - 20.4.3.5 Failure to submit progress/ completion reports
- 20.4.4 The ERC has formulated a check list for site monitoring visits. The site monitoring check list is attached as Annexure 22/ SOP20/ V3.
- 20.4.5 Sites will be selected for visit at the ERC meeting and appoint a 3 member site monitoring committee. The composition of the committee will be decided based on the nature of the project.
- 20.4.6 Before the visit ERC will
 - 20.4.6.1 contact the site and notify them about the visit.
 - 20.4.6.2 make appropriate travel arrangements.
 - 20.4.6.3 review the ERC files at the office and make appropriate notes.
- 20.4.7 During the site visit monitoring committee will

- 20.4.7.1 verify with the research team and review the documents for adherence 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 the subject files to ensure that
 - 20.4.7.2.2.1 the subjects are signing the correct informed consent forms
 - 20.4.7.2.2.2 only eligible subjects are recruited
- 20.4.7.3 observe the laboratory and other facilities for the study
- 20.4.8 After the visit the committee will
 - 20.4.8.1 write a report within 2 weeks.
 - 20.4.8.2 forward a copy of the site visit report to the 'site monitoring file' for full board
 - 20.4.8.3 review.
 - 20.4.8.4 send a copy of the report to the PI.

20.5 Annexure

- 20.5.1 Annexure 22/ SOP20/ V3 – Site monitoring check list

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|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 21/ V3 |
| | Title: Handling protocol deviation, non-compliance and violation | Effective date: 01.02.2018 Page: 48 – 49 |

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 of 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 actions on these reports.

21.3.2 Member secretary/assistant secretary is responsible to include protocol deviation/ non-compliance / violation reports in the agenda and make sure that the ERC reviews such reports without delay.

21.4 Description of 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 should immediately inform the chairperson/vice-chairperson and include it in the agenda of the next schedule meeting.

21.4.2 Protocol deviation/ non-compliance / violation could be informed to the ERC by

21.4.2.1 monitoring committees of the ERC.

21.4.2.2 investigator / trial site / sponsor / study monitor / CRO.

21.4.2.3 research participants who have been enrolled or any individual who has been approached for enrollment.

21.4.3 The can detect protocol deviation/ non-compliance / violation


21.4.3.1 when scrutinizing annual / periodic reports / SAE reports.

21.4.3.2 during site monitoring visit.

21.4.3.3 when communication related to protocol deviation/ non-compliance / violation 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

- 21.4.5 Protocol deviations / non-compliance/ violation/ waiver will be scrutinized for gravity and implications at the ERC meeting.
- 21.4.6 The ERC will review the information available and take a decision depending on the seriousness of the violation.
- 21.4.7 If unable to come to a decision, ERC will call for additional information.
- 21.4.8 The decision will be taken by consensus and if no consensus is arrived at, a voting will be conducted.
- 21.4.9 The decision will be taken to ensure that the safety and rights of the research participants are safe guarded.
- 21.4.10 Based on the seriousness of the protocol deviation/ non-compliance / violation one of the following decisions will be taken.
 - 21.4.10.1 Temporary suspension
 - 21.4.10.2 Termination of the approval of the current study
 - 21.4.10.3 Refusal to accept and review subsequent applications from the investigator cited for major violations without informing the ERC.
- 21.4.11 The letter of notification of the decision of the ERC on protocol deviation/ non-compliance / violation will be prepared by the member secretary and signed by the chairperson and member secretary.
- 21.4.12 Original letter will be sent to the PI.
- 21.4.13 Copies of letters will be
 - 21.4.13.1 filed in protocol file and non-compliance file in the ERC office.
 - 21.4.13.2 sent to relevant national authorities and institutes and to the sponsor of the study.

| | | |
|---|---|---|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 22/ V3 |
| | Title: Suspension / termination of Approved project | Effective date: 01.02.2018 Page: 50 – 51 |

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 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 the approved projects when the benefit or safety of the study participants is doubtful or at risk.
- 22.3.2 It is the responsibility of the principal investigator to inform the ERC about investigator initiated suspension/ termination of approved projects, giving reason/s.


22.4 Description of procedures for suspension / termination of approved projects**22.4.1 Suspension / termination by ERC**

The ERC shall suspend/ / terminate approved projects under following circumstances;

- 22.4.1.1 If protocol non-compliance/violation is detected
- 22.4.1.2 Significantly high SAEs which arise concerns of safety of the participants
- 22.4.1.3 Violations of ERC approval conditions
- 22.4.2 On receiving recommendations for suspension / termination of an approved protocol from monitoring committee of the ERC, the sponsor or other authorized bodies, member secretary will notify the chairperson/ vice-chairperson regarding the recommendation for suspension / termination within 24 hours.
- 22.4.3 Chairperson/vice-chairperson will reviews the results, reasons and accrual data.
- 22.4.4 Chairperson/ vice-chairperson will instruct themember secretary to calls for an emergency meeting as early as possible not later than 3working days to discuss the recommendation.
- 22.4.5 The decision by the ERC to suspend /terminate the project with reason/s for such decision will be communicated to PI in writing signed by chairperson/

vice-chairperson and member secretary/assistant secretary within 7 working days.

- 22.4.6 The memorandum for 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 principal investigator
 - 22.4.8.1 An investigator may also 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 It will be included in the agenda of the next meeting.
 - 22.4.8.5 Termination report will be kept in the respective protocol file.

| | | |
|---|---|---|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 23/ V3 |
| | Title: Complaints concerning conduct of approved projects | Effective date: 01.02.2018 Page: 52 – 53 |

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 the complaints concerning conduct of projects approved the ERC of FM, UJ.


23.3 Responsibility

It is the responsibility of chairperson/ vice-chairperson and member secretary/assistant secretary to process the complaints concerning conduct of approved projects.

23.4 Description of procedures for handling complaints concerning conduct of approved projects

- 23.4.1 The contact details of the ERC shall be included in the participant information sheet and consent forms.
- 23.4.2 When complaint is received the member secretary/assistant secretary shall notify the chairperson as soon as possible and under the instruction of the chairperson/ vice-chairperson member secretary will send acknowledgement to the complainant and letter of notification briefing the nature of the complaint and investigation procedure to the PI.
- 23.4.3 Chairperson/ vice-chairperson will appoint three membered committee to investigate the complaint. The investigation committee will submit the report and recommendation within 4 weeks, unless exceptional circumstances exist.
- 23.4.4 Both the complainant and the PI will be given an opportunity to make submissions.
- 23.4.5 The report and recommendations will be discussed at the next scheduled meeting of the ERC. If the complaint is serious in nature chairperson could call for an emergency meeting.
- 23.4.6 If the complaint is substantiated the ERC could take one of the following decisions based on the severity of the matter;
- 23.4.6.1 Increased monitoring by the ERC as to whether investigators are adhering strictly to the approved protocol
- 23.4.6.2 Suspension of the research till remedial action has been taken.

- 23.4.6.3 Termination of the study.
- 23.4.6.4 Any other action to address issues raised by the complainant.
- 23.4.7 If the Chairperson/ vice-chairperson considers the complaint to be of a sufficiently serious nature, he/she will bring it to the attention of the Dean as soon as possible and Dean may inform other appropriate authorities as and when applicable.
- 23.4.8 If the complainant is not satisfied with the outcome of the Chairperson's inquiry, then the complainant can appeal against the decision with reasons to the Dean of FM, UJ. In such circumstances the chairperson will provide the following information to the Dean;
 - 23.4.8.1 Nature of the complaint;
 - 23.4.8.2 Material reviewed during the investigation
 - 23.4.8.3 Decision of the ERC
 - 23.4.8.4 Any other relevant information.
- 23.4.9 The Dean, FM, UJ will review the appeal and the information provided by the chairperson and will determine the whether further investigation is needed or not and will inform his decision in writing to the complainant and to the chairperson.
- 23.4.10 If the Dean decides to have further investigation into the matter he/ she could form a panel of investigators comprising
 - 23.4.10.1 the Dean / nominee
 - 23.4.10.2 two nominees from the Faculty Board (who are not ERC members)
 - 23.4.10.3 the chairperson of the ERC.
- 23.4.11 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 the confidentiality agreement.
- 23.4.12 Based on the decision of the panel, Dean may dismiss the appeal or take necessary action to resolve the issue/s raised by the complainant.
- 23.4.13 The Dean will communicate the decision of the panel to the complainant and the chairperson of the ERC.

| | | |
|---|---|---|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 24/ V3 |
| | Title: Complaints concerning review process of the ERC | Effective date: 01.02.2018 Page: 54 – 55 |

24.1 Purpose

The purpose of this SOP is to describe procedures for handling complaints concerning 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 the complaints concerning the review process of the ERC.
- 24.3.2 Preliminary investigation is the responsibility of the chairperson/ vice-chairperson of the ERC of FM, UJ.

24.4 Description of procedures for handling complaints concerning review process of the ERC

- 24.4.1 Any concern or complaint about the ERC's review process will be directed to the attention of the chairperson of the ERC, detailing it in writing. Complaints may also be made to the Dean of FM, UJ only in case of inaction of ERC or COI.
- 24.4.2 The Chairperson will notify such complaint to the Dean as soon as possible (if the complaint is directed to Dean, he/ she will notify the chairperson as soon as possible).
- 24.4.3 Chairperson / Dean will send the acknowledgement letter to the complainant.
- 24.4.4 Chairperson/ Dean will decide if a further inquiry is necessary or not.
- 24.4.5 If further investigation is needed, Dean will appoint an appeal panel comprising
- 24.4.5.1 Dean / nominee and
- 24.4.5.2 two faculty board members (who are not members of ERC).
- 24.4.6 The appeal panel will ask ERC and complainant for clarifications and / or further information.
- 24.4.7 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 necessary arises.
- 24.4.8 The Panel will check whether the ERC has acted according to the SOP and FERCSL guidelines.
- 24.4.9 Decision of the panel could be

24.4.9.1 Dismissal of appeal


24.4.9.2 Recommendations to ERC

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

24.4.11 Decision will be communicated to the complainant by the chairperson / Dean in writing.

24.4.12 If the complainant is not satisfied with the decision of the chairperson, he/she can appeal to the Dean.

24.4.13 Complainant can be appealed to the Vice Chancellor of University of Jaffna if he/she is not satisfied the decision of Dean, FM, UJ.

| | | |
|---|---|---|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 25/ V3 |
| | Title: Record keeping and archiving | Effective date: 01.02.2018 Page: 56 – 58 |

25.1 Purpose

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

25.2 Scope

This SOP provides the administrative framework for procedures for record keeping documenting the ERC activities and archiving the projects 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 Administrative secretary is responsible for maintaining the records of the ERC.

25.4 Description of procedures for record keeping

- 25.4.1 Member Secretary/assistant secretary with the assistance of administrative secretary will prepare and record all the activities of the ERC including agenda, minutes of the meetings and communications.
- 25.4.2 The administrative secretary under the supervision of member secretary will maintain all the records in the appropriate files or database.
- 25.4.3 The following documents are maintained at ERC secretariat
 - 25.4.3.1 ***Non confidential documents***
 - 25.4.3.1.1 SOPs
 - 25.4.3.1.2 Other national and international guidelines on ethics review
 - 25.4.3.1.3 Registry for ERC application
 - 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: should have following documents
 - 25.4.3.2.1.1 Appointment letter as member of the ERC
 - 25.4.3.2.1.2 Acceptance letter
 - 25.4.3.2.1.3 Curriculum Vitae of the member


- 25.4.3.2.1.4 Certificate of training in research ethics and GCP
- 25.4.3.2.1.5 Confidentiality agreement
- 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 record
- 25.4.3.2.5 General correspondents
- 25.4.3.2.6 Protocol files: each application will be filed separately and will have following documents
 - 25.4.3.2.6.1 Duly signed application form
 - 25.4.3.2.6.2 Copy of paying in voucher
 - 25.4.3.2.6.3 Protocol and supporting documents
 - 25.4.3.2.6.4 Office copy of the check list
 - 25.4.3.2.6.5 Reviewers' reports
 - 25.4.3.2.6.6 Copy of the review comments sent to PI
 - 25.4.3.2.6.7 Response of PI to the ERC comments including revised version of the protocol
 - 25.4.3.2.6.8 Copy of ethical clearance letter / ERC's decision
 - 25.4.3.2.6.9 Progress reports
 - 25.4.3.2.6.10 Completion reports
 - 25.4.3.2.6.11 Any other communications / documents related to the project

Documents in will be filed in the 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
 - 25.4.4.1 Protocol database
 - 25.4.4.2 Soft copies of
 - 25.4.4.2.1 SOP
 - 25.4.4.2.2 TOR
 - 25.4.4.2.3 application form
 - 25.4.4.2.4 ethics review form
 - 25.4.4.2.5 agenda
 - 25.4.4.2.6 minutes
 - 25.4.4.2.7 extracts of minutes
 - 25.4.4.2.8 correspondence
- 25.4.5 Confidential documents are accessible only to chairperson/ vice-chairperson, member secretary/joint secretary, assistant secretary and administrative secretary.
- 25.4.6 When the completion report is received the protocol file will be closed. Once a protocol file is closed, it will be maintained at the office of the ERC for 5 years.

After that it will be destroyed in a secured manner. Files that need to be maintained indefinitely will be archived.

- 25.4.7 All the confidential documents that are no longer required will be disposed in a secured procedure using shredder by the chairperson/secretary and administrative secretary.

| | | |
|---|---|--|
|  | Ethics Review Committee Faculty of Medicine University of Jaffna | SOP Code: SOP 26/ V3 |
| | Title: Review of SOP | Effective date: 01.02.2018 Page: 59 |

26.1 Purpose

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

26.2 Scope

This SOP provides the administrative framework for reviewing and amending 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 SOP.

26.4 Description of procedures for reviewing or amending SOP

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

26.4.2 Every three years 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 board and forwarded to the approval of the Faculty Board

26.4.2.2 After the approval of Faculty Board it will be forwarded to the Senate of the University Jaffna.

26.4.2.3 The new version of SOP will be effective only after obtaining the Senate approval.

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

26.4.3.1 Proposed by ERC members

26.4.3.2 Proposed by Faculty Board

26.4.3.3 Proposed by accrediting/ recognizing body

26.4.4 Standard Operating Procedures may be amended consequent to proposals made by ERC members.

26.4.4.1 Proposal of amendment/s will be forwarded to the Faculty Board for approval and then to Senate of the University Jaffna.

26.4.4.2 Amendments will be effective after the approval of senate.

Reference

1. 'International Ethical Guidelines for Health-related Research Involving Humans', Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), 2016.
2. Council for International Organizations of Medical Sciences (CIOMS), World Health Organization (WHO). International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002.
3. Declaration of Helsinki , World Medical Assembly, 2013
4. Ethics Review Committee Guidelines, Forum of Ethics Review Committees, Sri Lanka, 2007
5. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) E6 (R1) 1996
6. International Organizations of Medical Sciences (CIOMS), in collaboration with the WorldHealth Organization (WHO). Geneva, 2008.
7. SIDCER Survey Standard Operating Procedures, approved version, 2010
8. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organization, 2011

ANNEXURE

Annexure 1/ SOP3/ V3: 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 that you have been appointed as a member to the ERC of the Faculty of Medicine, University of Jaffna for a period of three years from.....

As a member of the committee you are expected to

1. review proposals submitted for ethics approval as per the standard operating procedures of the ERC and relevant national and international guidelines.
2. regularly attend the ERC meetings.
3. undergo periodic training on research ethics.
4. *perform the jobs described in the SOP4/V3 (Page 8-10) in addition to the above specific job descriptions.*

The standard operating procedure (SOP Version 3) 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

Thank you

The Dean
Faculty of Medicine
University of Jaffna

Annexure 2/ SOP3/ V3: 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 the directly or indirectly any confidential or proprietary information belong to a third party outside the committee mandate.

I also assure that whenever I have a conflict of interest under any of the following circumstances, I shall inform the chairperson as soon as possible and will not participate in the discussion and decision making of the matter concerned.

Direct conflict of interest

- Being the PI or one of the co-investigators/ supervisors.
- Being part of the research team as a consultant/ member of 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 for the review of project concerned.
- Being in the same department/ unit where member/s of research is currently attached.
- Involved in another project in the same research area as the project concerned.
- First degree relative of member/ office staff / external subject expert / guest attendee is in 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/ V3 – Letter of appointment for external subject experts

Date:

Name:

Address

Dear

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

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

As an external subject expert of the committee you are expected to review proposals submitted for ethics approval as per the standard operating procedures of the ERC and relevant national and international guidelines.

The standard operating procedure is attached herewith.

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

Thank you

The Dean
Faculty of Medicine
University of Jaffna

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 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 the committee | |
| Decision * | |
| Date | |

* Attach the copy of communication of the above decision.

8. Funding

| | |
|-----------------------------------|--|
| Name and address of funding agent | |
| Amount | |

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

Yes No

If yes,

| | |
|---------------------------------|--|
| Title | |
| reference number of the 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 yet, this application will not processed by the ERC until progress / completion reports are submitted for your previous project/s approved by this ERC.**

11. Collaborative research

11.1. Does the project involve foreign researcher?

Yes* No

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

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

(For further information refer the SOP 7 / V3)

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 foreign collaborator/s?

Yes

No

If yes,

| | |
|-----------------------------------|--|
| Name and address of the committee | |
| Decision * | |
| Date | |

* Attach copy of communication of the above decision.

If no, give reason/s

11.4. Why this project is carried out in Sri Lanka and not in the sponsoring country?

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

11.6. Are biological samples transferred abroad?

Yes

No

If yes, attach the material transfer agreement.

12. Clinical trial

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 the documentary evidence.

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

12.4. If no submit the approval from National Medicines Regulatory Authority

12.5. Is new interventions/ interventions outside approved use registered and approved by the Sub-committee of Clinical trials?

Yes No

12.5.1. If, yes attach the copy of the approval.

12.5.2. If, no please obtain the approval before submitting to ERC.

12.6. Is it a multicenter trial?

Yes No

If yes, list the other centers.

| |
|--|
| |
|--|

12.7. Are the participants paid?

Yes No

If yes, amount of money per participant?

| |
|--|
| |
|--|

12.8. Are the investigators paid?

Yes No

If yes, by whom?

| |
|--|
| |
|--|

13. Trial monitoring committee / Data Safety Monitoring Board (if applicable).

| Name of member | Designation | Role |
|----------------|-------------|------|
| | | |
| | | |
| | | |

14. Details of insurance coverage for participants, investigators and the ERC.

| |
|--|
| |
|--|

15. Conflict of interest (please declare).

| |
|--|
| |
|--|

16. Declare your objection to send this project for review to any particular reviewer/s if any.

Part II – Protocol Checklist

| No. | | Page No. | NA* |
|-----|--|----------|-----|
| 1 | Summary of the project | | |
| 2 | Introduction/ background | | |
| 3 | Justification | | |
| 4 | Review of literature | | |
| 5 | Objectives of the study | | |
| | Methodology | | |
| 6 | Study design | | |
| 7 | Place of study | | |
| 8 | Duration of the study | | |
| 9 | Study population | | |
| 10 | Inclusion criteria | | |
| 11 | Exclusion criteria | | |
| 12 | Sample size and calculation of sample size | | |
| 13 | Study instrument/s | | |
| 14 | Pilot study | | |

| | | | |
|-----|---|--|--|
| 15 | Sampling/ recruitment procedure | | |
| 16 | Data collection | | |
| 17 | Data analysis | | |
| 18 | Maintenance and fate of data | | |
| 19 | Dissemination of results | | |
| | Ethical issues | | |
| 21 | Assessment of risks/ benefits | | |
| 22 | Procedure for obtaining consent | | |
| 23 | Informed consent form | | |
| 24 | Justification for including vulnerable population | | |
| 25 | Procedures to protect the rights of participants | | |
| 26 | Confidentiality | | |
| 27 | Safety monitoring | | |
| 28 | Provision of medical and psychological support to participants | | |
| | Biological Samples | | |
| 29 | Justification for using biological sample/s | | |
| 30 | Procedures for collection, storage and disposal of biological sample/s | | |
| 31 | Consent for collecting biological sample/s | | |
| | Collaborative research | | |
| 32 | Justification and benefits of collaboration with foreign investigators | | |
| 33. | Protection of the rights of local collaborator and participants | | |
| 34. | Justification for transfer of data and /or biological/ genetic materials to the country of foreign collaborator | | |
| 35. | Fate of transferred data and biological/ genetic material | | |
| | Clinical trial | | |
| 36. | Criteria for termination of participants from the trial | | |
| 37. | Criteria for termination of the trial | | |
| 38. | Adverse event monitoring, management and reporting | | |

| | | | |
|-----|---|--|--|
| 39. | Justification for withholding/ withdrawing standard therapy | | |
| 40. | Provision for making the trial drug available after completion of the trial | | |

* 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 | CV of PI and supervisor/s (with date and sign) – 1 copy | |
| 3 | Summary of the project – 4 copies | |
| 4 | Research protocol – 4 copies | |
| 5 | Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4copies | |
| 6 | Questionnaire (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4 copies | |
| 7 | Data record booklets/ 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) – 4 copies | |
| 8 | Approval from Drug Regulatory Authority (for clinical trials) | |
| 9 | Approval from SCOTT ((for clinical trials) | |
| 10 | Insurance coverage (for clinical trials) | |
| 11 | Ethical clearance from the country of foreign collaborator if applicable | |
| 12 | Soft copies of all documents (CD) | |
| 13 | Receipt for payment of application to the Finance Branch, University of Jaffna | |
| 14 | Administrative approval/s if any specify (permission letter from the head of the institution or authorized officer/ in-charge of the site of study etc.). | |
| 15 | Material transfer agreement | |

| | | |
|-----|-----------------------------------|--|
| 15 | Font size-12pt | |
| 16. | Line space between sentences- 1.5 | |
| | | |

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

I declare that:

- **I am not seeking approval for a study that has already commenced or has already been completed.**
- **all the information given are 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

Annexure 5/ SOP8/ V3 – Guide to applicants
GUIDE TO APPLICANTS
Ethics Review Committee
Faculty of Medicine, University of Jaffna

1. Research projects involving humans to be conducted by the students and staff of University of Jaffna and in the Northern Province could be submitted for ethical clearance.
2. Ethics review application form can be downloaded from the following link; <http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>
3. With completed original application form, four (04) hard copies of project protocol, four copies of summary of the protocol and all relevant documents along with soft copy of all the documents in a CD should be submitted to the Ethics Review Committee, Faculty of Medicine, University of Jaffna, Adiyapatham Road, Kokuvil. *In the application form, sections that are not applicable to the proposal can be skipped.*
4. The summary should not exceed 500 words and should include the following: background, justification, objectives, methodology and ethical issues.
5. The contents of the protocol should be based on the ‘Protocol Checklist’ of the application form. The font size and space between sentences should be in 12pt and 1.5 lines respectively. Submit the protocol as Printed in both pages with normal binding.
6. The authorized copy of the completed paying in voucher for the appropriate payment (can be downloaded from the link;<http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>) should be handed over along with the application. Payment can be made by cash/money order/postal order/ cheque (in favor of **Ethics Review Committee, University of Jaffna**) at the shroff counter of the University of Jaffna or at any branch of People’s Bank (in favor of **Ethics Review Committee, University of Jaffna**) to the credit of the account number given in the paying in voucher.
7. Undergraduate student proposals should be submitted through the relevant Head of the Department.

8. 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 the degree to be obtained
 - 8.2 the institution where the candidate is registered and a letter from the relevant postgraduate Institute / Board of Study stating that the research proposal has been approved for postgraduate study.
9. Applications for research with foreign collaborators: please read instructions in the application form and also refer section of SOP 8 / V3 on collaborative research.
10. Completed applications submitted before the close of business of last working day of the month will be taken up at the next schedule meeting and the decision of the ERC will be communicated to the PI/ Head. This process will take minimum of 6 weeks.
11. The ERC will disapprove all projects that have already started recruitment of participants or collection of data and that are completed before obtaining the ethical clearance.
12. If the protocol to be amended after submission or after obtaining ethical clearance, such amendments should be communicated to the ERC and effected only after approval by the ERC.
13. After obtaining ethical clearance, the researchers are responsible to adhere to the protocol and the ERC has the right to withdraw the clearance if there is evidence for not complying with approved protocol and ERC guidelines.
14. All researchers whose projects have been granted ethical clearance are obliged to send progress report every 6 month as requested format by the ERC and at the end a completion report. Please quote the reference number assigned to the project in all future communications.
15. For further information, refer to the Standard Operating Procedure (SOP) at the following link: <http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>
16. If you need any further clarifications, please call 021 2222073; extension 342.
17. If you want to make any complaints about the ERC, please write to the Chairperson, ERC, Faculty of Medicine, University of Jaffna.

18. Details of application fee for proposals submitted for ethical clearance:

| | |
|---|------------------------------|
| Personal research | <i>Payment to ERC</i> |
| <i>Grants less than (Rs. 300,000.00)</i> | Rs.1500.00 |
| <i>Grants more than (Rs. 300,000.00)</i> | Rs. 3000.00 |
| Research with foreign collaboration | |
| <i>Sri Lankan PI</i> | Rs. 5,000.00 |
| <i>Non-Sri Lankan PI</i> | Rs. 50,000.00 |
| Sponsored clinical trials | Rs. 200,000.00 |
| Undergraduate projects of others Universities | Rs. 500.00 |
| Undergraduate projects of the UJ | No fee |

GUIDANCE FOR PREPARATION OF INFORMED CONSENT FORM (ICF)

We recommend you to use the following format in the preparation of ICF for the projects that are submitted to this ERC. Some sections of this ICF may not be relevant to your project. You can skip the sections that are not applicable to your project. The ICF must be translated in the local language/s of the participants.

INFORMED CONSENT FORM***Part I: Information sheet***

Title:.....

Part I – Information sheet

1. Introduction

I (name of PI) attached to (institute) as (designation). I am / we are (state the name and designation of other investigators) doing a research on (field) at (site of the study) to (aim of the study). I wish to give you the 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. You are free not to

participate or withdraw from the study at any time of the study without any loss of or compromise in medical care/ other services otherwise you are entitled.

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. (Name and contact details of PI and other members of research team from whom the participant can ask questions and clarify)

2. Participant selection

The reason for considering you suitable for this research is

3. Duration of the study

The study will begin on (DD/MM/YYYY) and ends on (DD/MM/YYYY).

4. Nature of the benefits; Participation in this study may benefit you and/ or others by (mention all the actual and potential benefits).

5. Nature of the risk, potential hazards and discomforts: Any potential or actual risks, hazards and discomforts should be clearly mentioned.

6. Procedures of the study and participants responsibilities

(Explain how it differs from the routine medical care / procedures, nature and purpose of questions to be asked, time needs to be spent for each interview and information and data to be collected. Explain what is expected from the participants in relation to research).

7. Intervention

(Explain the type of intervention and currently available established standard intervention or treatment and other alternatives if any).

8. Reimbursements

You could be paid for expenses incurred as a result of participation in the research e.g. travel costs and money for wages lost, etc.

9. Confidentiality

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

10. Clinical trial

Following need to be clearly explained:

9.1 Phase of the trial and its detailed description.

9.2 Reason for development of new drug/ treatment and manufacture information of drug/device

- 9.3 Explanation on known experience with the new drug if any.
- 9.4 Explanation on known and potential adverse effects of this drug/device and other drugs used in the trial.
- 9.5 Explanation of unfamiliar procedures such as randomization, blinding and involving placebo etc. - the participants should be told what that means and what chance they have of getting test/ standard drug or placebo drug and they also should be informed that they may not know the drug they will be on till the data collection is over.
11. Risk benefit assessment: explain the risks and benefits (for the individual and / or community at large) of the study in simple language.
12. If data or biological samples will be stored for a duration longer or is likely to be used for another purpose, provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study.
13. Contact information (Personal Mobile Number, Office Number and contact Address of the all investigator/s including the PI
14. Contact information of the ERC which approves the project if participants 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 have been read to me and I understand it thoroughly. I have been allowed to ask questions regarding this study and all the questions are being answered satisfactorily. I am aware of the benefits and risk of this study and 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 otherwise I am 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 the 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 the child

I have read this information (or had the information read to me). I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

Print name of child

Signature of child:

Date:.....

Format for consent form from parent or legally acceptable representative

I have read the above information / the above information have been read to me and I understand it thoroughly. I am 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/him from the study at any time without loss of benefit otherwise he/ she is 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 all the questions asked by the participant have been answered to the satisfaction of the participant. I confirm that the 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/ V3 – 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/ V3 – Document Receipt Check List

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

| |
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**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 | CV of PI and supervisor/s (with date and sign) – 1 copy | |
| 3 | Summary of the project – 4 copies | |
| 4 | Research protocol – 4 copies | |
| 5 | Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4copies | |
| 6 | Questionnaire (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4 copies | |
| 7 | Data record booklets/ 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) – 4 copies | |
| 8 | Approval from National Drug Regulatory Authority (for clinical trials) | |
| 9 | Approval from the Sub-committee of Clinical trials (SCOCT) for new interventions/ interventions outside approved use | |
| 10 | Insurance coverage (for clinical trials) | |
| 11 | Ethical clearance from the country of foreign collaborator if applicable | |

| | | |
|----|---|--|
| 12 | Soft copies of all documents (CD) | |
| 13 | Receipt for payment of application to the Finance Branch, University of Jaffna | |
| 14 | Administrative approval/s if any specify (permission letter from the head of the institution or authorized officer/ in-charge of the site of study etc.). | |
| 15 | Material transfer agreement | |
| 16 | Font size-12pt | |
| 17 | Line space between sentences- 1.5 | |
| | | |
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The reference number on the top of this page is assigned for this application. Please quote this number in all correspondents with ERC. You are requested to maintain the confidentiality.

If you have any clarification or need to send violation of ethical principles and human rights violation you may contact the following address:

The Chairperson/Secretary
The Ethic Review Committee
Faculty of Medicine
University of Jaffna
0212222073 extension: 342

.....
Signature of Administrative secretary
(ERC secretariat)

Date:

Document Receipt Checklist
(Office copy)

| | | | | | | | | | | | | | | | | | | | |
|-------------------------|-----------|-------------|--|--|--|--|--|--|--|----------------------|--|--|---|--|--|---|--|--|--|
| Reference number | J/ | ERC/ | | | | | | | | Date received | | | / | | | / | | | |
|-------------------------|-----------|-------------|--|--|--|--|--|--|--|----------------------|--|--|---|--|--|---|--|--|--|

Title of the project

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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 | CV of PI and supervisor/s (with date and sign) – 1copy | |
| 3 | Summary of the project – 4 copies | |
| 4 | Research protocol – 4 copies | |
| 5 | Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4copies | |
| 6 | Questionnaire (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4 copies | |
| 7 | Data record booklets/ 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) – 4 copies | |
| 8 | Approval from National Drug Regulatory Authority (for clinical trials) | |
| 9 | Insurance coverage (for clinical trials) | |
| 10. | Approval from the Sub-committee of Clinical trials (SCOCT) for new interventions/ interventions outside approved use | |
| 11 | Ethical clearance from the country of foreign collaborator if applicable | |
| 12 | Soft copies of all documents (CD) | |
| 13 | Receipt for payment of application to the Finance Branch, University of Jaffna | |
| 14 | Administrative approval/s if any specify (permission letter from the head of | |

| | | |
|----|--|--|
| | the institution or authorized officer/ in-charge of the site of study etc.). | |
| 15 | Material transfer agreement | |
| 16 | Font size-12pt | |
| 17 | Line space between sentences- 1.5 | |
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.....
 Secretary/Administrative Secretary
 (ERC secretariat)

Date:

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

Date:

| | | | | | |
|------------------|---|--|--|--|--|
| 4.. | Study procedures do not cause any deviation in time or effort from the usual educational practices at the study site | | | | |
| 5. | Study procedures involve no increase in the level of risk or discomfort associated with routine educational practices | | | | |
| 6. | Study procedures do not involve sensitive subject area/s | | | | |
| 7. | Provisions are made to ensure the existence of a non-coercive environment for students who choose not to participate | | | | |
| 8. | School or other institution grants written approval for the research to be conducted | | | | |
| | | | | | |
| Section B | | | | | |
| 1. | Does the research involve vulnerable groups? | | | | |
| 2. | Does the research involve interviews? | | | | |
| 3. | Study deals with sensitive information such as substance abuse, sexual activity or attitudes, sexual abuse, criminal behaviour, sensitive demographic data, detailed health history, etc. | | | | |
| 4. | Does the data provide identification of subjects? | | | | |
| 5. | Data from biological samples are used without consent | | | | |
| 6. | place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation? | | | | |

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| | | | | | |
| Exemption from ethics review | | <p><u>If “Yes or NA” for all response in section A and “No or NA” for all response in section B, it can be exempted</u></p> <p><u>Exempted</u> <input type="checkbox"/></p> <p><u>Not exempted</u> <input type="checkbox"/></p> | | | |

Chairperson/vice-chairperson
Ethics Review Committee

Secretary/assistant secretary
Ethics Review Committee

| No. | | Yes | No | NA | Comments |
|-----|---|-----|----|----|----------|
| 1. | All the necessary documents are provided. | | | | |
| | Evidence for appropriate approval/s from relevant authorities is/ are provided. | | | | |
| 2. | Background appropriate | | | | |
| 3. | Justification is sufficient. | | | | |
| 4. | Objectives are clear. | | | | |
| 5. | Review of literature is appropriate. | | | | |
| 6. | Investigator/s has/have scientific, clinical or other relevant qualification/s that is/are appropriate for the study. | | | | |
| 6. | Study design is appropriate. | | | | |
| 7. | Involvement of human participants is necessary for this study. | | | | |
| 8. | Study population is appropriate for this study. | | | | |
| 9. | Inclusion criteria are appropriate. | | | | |
| 10. | Exclusion criteria are appropriate. | | | | |
| 11. | Sample size is appropriate. | | | | |
| 12. | Statistics used is appropriate. | | | | |
| 13. | Recruitment of participants is appropriate. | | | | |
| 14. | Voluntary participation is ensured. | | | | |
| 15. | Participants have the right to withdraw unconditionally at any time of the study without penalty and/ or loss of benefit. | | | | |
| 16. | Participants are allowed to ask questions and register complaints. | | | | |
| 17. | Procedure for obtaining consent is appropriate. | | | | |
| 18. | Contents of information sheet and consent form are adequate and clear. | | | | |
| 19. | Translations of all forms are consistent. | | | | |
| 20. | Risk-benefit assessment is acceptable. | | | | |
| 21. | Confidentiality is ensured. | | | | |
| 22. | Privacy of the participants is protected. | | | | |
| 23. | Provision for compensation is appropriate | | | | |

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|-----|---|--|--|--|--|
| 24. | No inducement for participants. | | | | |
| 25. | Provision of adequate medical and psychological support. | | | | |
| 26. | Facilities and infrastructure of the site are appropriate. | | | | |
| 27. | Analysis is appropriate. | | | | |
| 28. | Dissemination and fate of data are mentioned. | | | | |
| 29. | Details of budget including source of funding and Gantt chart appropriate | | | | |
| | Researches involving biological samples | | | | |
| 30. | Justification for collecting biological samples | | | | |
| 31. | Standards procedures are adopted in sample collection | | | | |
| 32. | Procedures for disposal of sample are appropriate | | | | |
| 33. | Consent procedure for storage and future usage of sample is described | | | | |
| 34. | Justification for transfer of biological materials is adequate | | | | |
| 35. | Procedure for transfer of biological materials is appropriate, does the informed consent form have the above relevant details | | | | |
| | Vulnerable population | | | | |
| 36. | Adequate justification is given for studying the vulnerable population. | | | | |
| 37. | Procedures for obtaining consent for vulnerable population are appropriate. | | | | |
| 38. | Measures to protect the rights and prevent exploitation of vulnerable population are adequate. | | | | |
| | Clinical trial | | | | |
| 39. | Registered with clinical trial registry. | | | | |
| 40. | Clearance from National Drug Regulatory Authority is attached. | | | | |

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| 41. | Approval from the Sub-committee of Clinical trials (SCOCT) for new interventions/ interventions outside approved use. | | | | |
| 42. | Adequate information given on drug/device | | | | |
| 43. | Evidences for safe use of the drug/s in human are provided. | | | | |
| 44. | Adequate justification is given for stopping the standard therapy. | | | | |
| 45. | Provision for monitoring and handling adverse events. | | | | |
| 46. | Procedure for reporting adverse events is appropriate. | | | | |
| 47. | Criteria for withdrawal of a participant are appropriate. | | | | |
| 48. | Criteria for termination of the trial are appropriate. | | | | |
| 49. | Provision of insurance coverage for trial participants and investigators. | | | | |
| 50. | Provision for continuing access of subjects to the investigational treatment after the study | | | | |
| 51. | Provision for continuing access of drug/device (investigational treatment) after the completion of the study | | | | |
| 52. | Provision for continuing access of medical treatment after the termination/completion of the study | | | | |
| 53. | Details of sponsor are given. | | | | |
| 54. | Investigator's Brochure is attached. | | | | |
| | Collaborative research | | | | |
| 55. | Collaboration with foreign researchers is justified. | | | | |
| 56. | Adequate justification for doing it in Sri Lanka is provided. | | | | |
| 57. | Nature of benefits and their distribution are appropriate/ acceptable. | | | | |
| 58. | Ownership and fate of data are acceptable. | | | | |
| 59. | Publication rights are appropriate. | | | | |

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|-----|---|--|--|--|--|
| 60. | Rights and welfare of the participants are protected. | | | | |
| 61. | Rights of the local collaborator are protected. | | | | |
| 61. | Approval from the collaborating country is provided. | | | | |
| 62. | Transfer of biological and/ or genetic materials is justified. | | | | |
| 63. | Transfer of such materials follows the standards drawn by this country. | | | | |

Additional comments:

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Approved

Revision with minor corrections:

Resubmission with major corrections:

Disapprove:

.....

Date:

Signature

Name of the reviewer:

Annexure 10/ SOP11/ V3: Informed consent review form



Ethics Review Committee
Faculty of Medicine, University of Jaffna

Informed consent review formOffice use only

| | | | | | | | | | | | | | | | | | |
|-----------------------------|----|------|---|--|--|--|--|--|--|----------------------|--|---|--|---|--|--|--|
| Reference number | J/ | ERC/ | / | | | | | | | Date received | | / | | / | | | |
| Title of the Project | | | | | | | | | | | | | | | | | |

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|---|---------------|--------------------------|----------------|--------------------------|----------------|--------------------------|------------------------|--|--|--|--|--------------------|--|--|--|--|--|
| Principal Investigator: | | | | | | | | | | | | | | | | | |
| Institute: | | | | | | | | | | | | Contact No: | | | | | |
| Duration of the Study | | | | | | | | | | | | | | | | | |
| Status | New | <input type="checkbox"/> | Revised | <input type="checkbox"/> | Amended | <input type="checkbox"/> | | | | | | | | | | | |
| Type of the Study | Observational | <input type="checkbox"/> | Interventional | <input type="checkbox"/> | Document based | <input type="checkbox"/> | Others (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 appropriate, adequate and complete? | | | | |
| 2. | Language/s used is/ are simple and understandable by the participants. | | | | |
| 3. | Voluntary participation is ensured. | | | | |
| 4. | Participants have the right to withdraw unconditionally at any time of the study without penalty and/ or loss of benefit. | | | | |
| 5. | Participants are allowed to ask questions and register complaints. | | | | |
| 6. | If biological samples are being collected, are the participants informed about - What type of samples are collected - What tests will be done with them - Whether they will be stored for future studies - If stored for how long and what is expected to be done with samples | | | | |
| 7. | Provision given in the consent form to consent for all procedures planned. | | | | |
| 8. | Translation/s of all forms is/ are consistent and accurate. | | | | |
| 9. | Assent form is provided. | | | | |
| 10. | Contact details of PI and other investigators are given in the information sheet. | | | | |
| 11. | Contact details of the ERC are given in the information sheet. | | | | |
| 12. | Justification to conduct the study is sufficient (optional) | | | | |
| 13. | Adequate justification is given for studying the vulnerable population (optional). | | | | |
| 14. | Risk and benefit of the study are given | | | | |

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| | adequately (optional) | | | | |
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Additional comments:

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Approved:

Revision with minor corrections:

Resubmission with major corrections:

Disapprove:

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Signature

Date:

Name of the reviewer:

Annexure 11/ SOP12/ V3 – Agenda of the meeting

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

Name list of the members

Dear Sir/Madam,

.....Meeting of the Ethics Review Committee

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.

Agenda ofmeeting of the ERC

ERC/.../1. Preliminaries

- ERC/.../1.1. Excuses
- ERC/.../1.2. Announcements
- ERC/.../1.3. Declaration of conflict of interest

ERC/.../2. Conformation of the minutes of the previous meeting

ERC/.../3. 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/.../4. New applications

ERC/.../4.1. Exempted from ethics review

- Title of the project
- Full name of the PI
- Reference number

ERC/.../4.2. Expedited review

- Title of the project
- Full name of the PI
- Reference number

ERC/.../4.3. Full board review

- Title of the reject
- Full name of the PI
- Reference number
- Names of the primary reviewers

ERC/.../4.4. Undergraduate projects

ERC/.../5. Follow up

ERC/.../5.1. Amendments

ERC/.../5.2. Request for extension of ethical clearance

ERC/.../5.3. Progress reports

ERC/.../5.4. Completion reports

ERC/.../5.5. Reports on adverse event

ERC/.../5.6. Reports on site visit

ERC/.../5.7. Protocol deviation/violation

ERC/.../5.8. Other communications related to approved protocols

ERC/.../6. Correspondents

ERC/.../7. Any other business

Close and date of next meeting

Kindly be present for this meeting.

Yours sincerely,

.....
Secretary/Ethics Review Committee
Date:

Annexure 12/ SOP14/ V3: Minutes of the meeting**Minutes of theth 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****Announcement****Conflict of interest**

The following members of the ERC declared Conflict of interest

1. – PI/Co-investigator/Supervisor/Consultant/Data collector of the Research Project titled “.....” submitted by(name of PI)

ERC/.../... Matters arising from the Minutes

ERC.../.../... Research proposal titled
 “.....” submitted by –
 Reference No.....

Details including version numbers and dates (The reply is awaiting from the Principal Investigator/).

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

Exempted from ethics review

ERC.../.../.. Research Proposal titled
 “.....” submitted by
 – Reference

At the ...the subcommittee meeting held on it was decided to exempted from ethics review

Expedited review

ERC.../.../.. Research Proposal titled “.....”
 submitted by – Reference

At the ...the subcommittee meeting held on...., it was decided to expedite the review

The reviewer is:

1. Name, designation and affiliation

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:

Full board review

Research Proposal titled “.....”
 submitted by – Reference

The reviewer is:

Name, designation and affiliation

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 clarifications and revised protocol could undergo expedited review by chairperson and secretary.

ERC/.../. Undergraduate research proposal

ERC/.../. Follow up

ERC/.../. Amendments

ERC/.../. Request for extension of ethical clearance

ERC/.../. Progress reports

The Chairperson informed that the Progress Reports have been received from the following:

1.(Name of PI and Reference Number)
Title “.....’

It was discussed in detail and decided to approve the progress report

ERC/.../. Completion reports

The Chairperson informed that the completion Reports have been received from the following:

1.(Name of PI and Reference Number)
Title “.....’

It was discussed in detail and decided to approve the completion report

ERC/.../. Reports on adverse event

ERC/.../. Reports on site visit

ERC/.../. Protocol deviation/violation

ERC/.../. Other communications related to approved protocols

ERC/.../. Any Other Business - Nil

Secretary/Ethics Review Committee

Date:

Annexure 13/ SOP14/ V3: Extracts of minutes

**Minutes of theth 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 theth 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 proposal titled “.....” submitted by
..... (name of the PI) – Reference No.....

Decision.....

ERC.....

ERC....

ERC/84/3 New proposals submitted for ethical clearance

ERC..... Research Proposal titled “.....’ by
(Name of PI – Reference No.....

Decision.....

ERC/..../.... Follow up**ERC/..../.... General correspondents****ERC/..../.... Any Other Business**

Secretary/Ethics Review Committee

Date

Annexure 14/ SOP17/ V3: 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 reviewed by the ERC at it's..... meeting held on and requires revision with minor corrections/resubmission with major correctionsof version of the protocol. The ERC has made following observations and recommendations.

1.
2.

Kindly submit your clarifications and revised protocol as early as possible (on or before). If you fail to submit the clarifications within 3 months from the application will lapse. In such case if you want to get the ethical clearance for the same project from our ERC, a new application must be submitted to the ERC.

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

Annexure 15/ SOP17/ V3: 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 has decided to exempt theVersion
..... of study titled “.....” from ethics reviewwith following reasons.

1.....

2.....

The exemption is pertaining to the submitted 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/ V3: 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 project)

(Reference number)

(Co-investigators)

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

1. If the study extends beyond one year, the ethical clearance has to be extended/ renewed at the end of one year.
2. Progress report must be submitted at least every 6 months (refer SOP 17/V3).
3. At the conclusion of the study completion report must be submitted (refer SOP 17/V3).
4. If needed, request for extension/ renewal of ethical clearance must be submitted at the end of one year along with progress report.
5. If the study ends within one year a completion report of the project must be submitted to the ERC.
6. Any amendments in the protocol should not be carried out without prior approval from the ERC (refer SOP 15/V3).
7. Following must be submitted when applicable
 - a. Report on serious adverse events (refer SOP 18/V3)
 - b. Protocol violation report (refer SOP 20/V3)
 - c. Suspension/ termination of the project (refer SOP 21/V3)

Chairperson/vice-Chairperson
Ethics review committee

Secretary/assistant secretary
Ethics review committee

Annexure 17/ SOP17/ V3: 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 has reviewed the application and has decided to disapprove the proposal for following reasons;

- 1.....
- 2.....

If you have any further clarifications/ queries, please write appeal 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/ V3: 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 project)

(Application number)

(Co-investigators)

The ERC at its meeting held on has decided to grant approval for the amendment of the 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/ V3: Progress report

**Progress report form
Ethics review Committee
Faculty of Medicine, University of Jaffna**

ReferenceNumber:

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:

Protocol violation/ deviation:

Any deviations from the Ganttchart:

Any ethical issues encountered and action taken:

A summary of any relevant recent literature, interim findings, and amendments or modificationsto the research since the last Committee review (not more than 500 words):

Publications/ presentations related to the study:

Signature of the PI:

Date:

Annexure 20/SOP18/ V3: Completion report

**Completion report form
Ethics review Committee
Faculty of Medicine, University of Jaffna**

Reference Number:

Protocol Title:

Principal Investigator:

Telephone: E mail address:

Sponsor's name:

Address:

Telephone: E mail address:

Study site(s):

Total number of study participants:

Number of study arms:

Objective(s):

Study materials and method:

Study dose(s):

Duration of the study:Months/Years

Date of start:

Date of completion

Treatment form:

Adverse events:

Results and conclusions:

Protocol violation/ deviation

Any ethical issues encountered and action taken

A summary of entire findings, recommendation and limitation to the research (not more than 1000 words):

Publications, if any

Signature of PI:

Date:

Annexure 21/ SOP19/ V3: Adverse event reporting form**ADVERSE EVENT REPORTING FORM****Reference Number:****Protocol Title:****Principal Investigator:****Sponsor's name:****Study site:****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 | |
| Result in hospitalisation | | Birth defect | |
| Prolongation of Hospitalisation is expected | | Others (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 event 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/ V3: Site monitoring check list

**Checklist for site monitoring visit
Ethics Review Committee
Faculty of Medicine, University of Jaffna**

Application Number:

Study Title:

Date of visit:

Reason for the visit:

Name of the 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 status in the proposal? yes No

Comments:

Are informed consent obtained appropriately and filed? yes No

Comments:

Any adverse event found? yes No

Comments:

Any protocol non-compliance/violation? yes No

Comments:

Are all case records forms up to date? yes No

Comments:

Are storage of data and investigating products kept under lock and key? yes No

Comments:

Participant protection: Good Fair Poor

Comments:

Details of action or results of the visit:

Duration of visit:.....hours. Starting from:

Names and signature of the ERC members

1.

2.

3.

Date: