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Purpose of this SOP is to describe the processes of developing, implementing, reviewing and amending the SOP of the Ethics Review committee (ERC)

The SOP provides clear and unambiguous instructions to conduct the activities of the ERC. It is the responsibility of the ERC to develop/ review the SOP for its activities. It is usually done by SOP subcommittee appointed by the ERC.

**SOP 1.1. Purpose of SOP**

The purpose of SOP is to;

- provide clear and unambiguous instructions to conduct the activities of the ERC.
- give instructions to the members and reviewers regarding operational procedures of the ERC.
- guide the researchers in obtaining ethical clearance.

**SOP 1.2. Development/ review of SOP**

The ERC appoints a team of members to develop and review the SOP. The subcommittee for SOP drafts and revises the SOP. The ERC reviews and approves the SOP. The secretariat of the ERC coordinates the activities of the subcommittee. Once the ERC approves the SOP it will be forwarded to the Faculty Board of the Faculty of Medicine and then to the Senate of University of Jaffna for their approval. The secretariat maintains the file of current and the previous SOPs.
SOP 1.3. Implementation of SOP

Once the SOP is approved by the Faculty Board of Faculty of Medicine and the Senate of University of Jaffna, it will be implemented from the effective date. The SOP will be distributed to all the ERC members and will be made available for researchers and public. When the new version is distributed, the old version will be retrieved from the members. One copy of the old version will be archived. All the activities of the ERC will be conducted according to the instructions of the SOP.

SOP 1.4. Revision and amendment of SOP

The SOP is reviewed every 2 years and changes made in the SOP in between revision will be amended with the approval of Faculty Board of Faculty of Medicine and Senate of University of Jaffna. These procedures are described in SOP 10.
Purpose of this SOP is to describe the responsibilities and composition of the ERC and the Secretariat

Ethics review committee is an independent subcommittee of the Faculty Board of the Faculty of Medicine, approved by the Senate of University of Jaffna to have the authority to provide ethical guidance and advice to researchers and to grant ethical clearance for research projects that to be conducted by staff and students of University of Jaffna or researches to be conducted in Northern Province of Sri Lanka. The ERC of the Faculty of Medicine of University of Jaffna will review researchers involving human participants as well as animal subjects.

**SOP 2.1. Responsibilities of the ERC**

The ERC functions with the objectives of

1. protecting the interests, rights, welfare, dignity, health and safety of human participants and animal subjects used for researches.
2. facilitating ethical considerations to research through efficient and effective review processes.
3. facilitating excellence in health research and innovative practices for the wellbeing of the society by maintaining the ethical standards of human and animal researches.
4. reviewing of research and granting ethical clearance according to National and International guidelines for ethics review committees.
Responsibilities of the ERC are;

1. ensuring the welfare of human participants and experimental animals.
2. reviewing and giving ethical clearance/recommending modifications to the research projects submitted to it.
3. disapproving/suspending/withdrawing ethical clearance for researches submitted to this ERC which are scientifically or ethically unacceptable.
4. monitoring and receiving progress and completion reports of research projects that are approved by the ERC.
5. maintaining the records of minutes of the meeting and archiving the research project proposals submitted to the ERC.
6. conducting regular workshops on ethics review for the members of the ERC, reviewers and researchers.
7. maintaining the proceedings and documents confidential.

**SOP 2.2. Accountability of the ERC**

The ERC is accountable to the Faculty Board of Faculty of Medicine and the Senate of University of Jaffna. Extracts of the confirmed minutes of the ERC meeting are sent to the Faculty Board. The ERC provides annual report on the activities of the ERC at the end of each calendar year to the Faculty Board. The ERC maintains an account book and provides an annual financial report to the Faculty Board and the Internal Audit of University of Jaffna.

**SOP 2.3. Composition of the ERC**

The composition of the ERC is in accordance with the World Health Organisation (WHO) guidelines. The committee should have minimum of 10 members. The members of the ERC must be from various backgrounds to promote more comprehensive review of research projects. The composition is as follows;

- 2-3 persons with expertise in basic medical sciences
- 2-3 clinicians
- At least one (01) person with expertise in the following fields;
• Public health research
• Biostatistics
• Ethics of medical research
• Law
• Philosophy/Social Science
• Biology
• Veterinary science
• Lay person conversant with social values

Members are appointed by the Faculty Board and the appointment process is described in SOP 3.1.

**SOP 2.4. The ERC office**

The ERC should have a dedicated secretariat. The office must be adequately equipped to ensure efficient functioning. Access to confidential documents and digital data will be restricted to the ERC Chairperson, member Secretary and members and persons authorised by the ERC. Administrative secretary of the ERC will access the confidential documents for working on them in the presence of an authorised member.

**SOP 2.4.1. Office bearers**

The Chairperson and the member secretary are elected from the members of the ERC every year.

**Chairperson**

The Chairperson must be a person with the capacity to handle the matters of the ERC efficiently and impartially. Any member of the ERC can be elected as the Chairperson.

**Member Secretary**

Member secretary (one or two) must be a senior academic staff of Faculty of Medicine, University of Jaffna with the capability of coordinating and managing
the ERC activities. Member secretary will be responsible for scheduling the ERC meeting and ensuring proper functioning and record keeping including financial activities.

**SOP 2.4.2. Secretariat of the ERC**

The secretariat comprises of member and administrative secretaries. Functions of secretariat are;

1. Receiving applications and follow up.
2. Maintaining registry of research projects.
3. Organising and conducting the ERC meetings and workshops.
4. Preparing agenda and minutes of the ERC meetings.
5. Circulating the minutes and other documents to the ERC members.
6. Communicating with the ERC members, Principal Investigator (PI) and others.
7. Documentation and archiving.
8. Keeping financial records.
9. Preparing annual and financial reports of the ERC.

Appointment and working norms of administrative secretary shall be as per the regulations of University of Jaffna for Computer Application Assistant.

**SOP 2.5: External Reviewers**

The ERC will have a pool of external reviewers comprising experts from various disciplines to facilitate effective review of research projects. The external reviewers are appointed by the ERC and new reviewers are added whenever needed. The external reviewers have to sign a confidentiality and conflict of interest agreement (AX 1/ SOP 2/ V 1).

**SOP 2.6: Independent Consultants**

The ERC may invite independent consultants for the ERC meeting to obtain expertise opinion on a particular research protocol. They will not have voting
right. The independent consultant must sign a confidentiality and conflict of interest agreement (AX 2– SOP 6/ V 1) before attending the meeting.

**SOP 2.8. Subcommittee of the ERC**

The ERC may appoint subcommittees to carry out specified tasks. Members of subcommittee must be from the members of the ERC.
CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT FOR EXTERNAL REVIEWERS OF THE ERC

I, ..................................................... the undersigned external reviewer of the ERC of the Faculty of Medicine of University of Jaffna agree NOT to disclose or utilize directly or indirectly any confidential or proprietary information of the project protocols reviewed by me.

I also assure that whenever I have a conflict of interest I shall inform the Chairperson before reviewing such project proposals.

............................................................... Date:
Signature of the External Reviewer

Name & designation of the external reviewer:
Purpose of this SOP is to describe the procedures, terms and conditions for the appointment of members to the ERC

**SOP 3.1. Appointment of members**

Members are appointed by the Faculty Board. The members will be selected according to the requirement of composition of the ERC which is described in SOP 2. The selection of members is based on their personal capacities, qualifications, knowledge and experience in scientific research and research ethics and expertise in their fields.

Members are expected to have the interest in serving the ERC with time, effort, commitment and integrity.

The Faculty Board will obtain the written consent for willingness to be an ERC member from each member.

**SOP 3.2. Terms of appointment**

1. The term of an ERC member is three years. At the time of establishment of the ERC one third of the members are appointed for three years, another one third of the members will be appointed for two years and the other one third of the members will be appointed for one year. Thereafter to maintain the continuity every year one third of the members will be replaced and appointed for three years. They can be reappointed at the end of their term.

2. There is no limit in the number of times for reappointment of a member. The ERC may nominate the names of the members for reappointment or
new appointment to the Faculty Board. The appointment of members will be made by the Faculty Board.

3. If a member fails to attend three consecutive meetings of the ERC without excuse the membership lapses. The 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 term by the Faculty board.

4. A member may resign from the ERC at any time by giving one month advance notice in writing to the Chairperson. It will be discussed at the ERC and if accepted, another person may be recommended. This notice will be placed at the Faculty Board for approval and to fill the vacancy.

5. A member may seek leave of absence from the ERC up to 6 months and those members can suggest the replacement and which will be approved by the ERC and the Faculty Board, if appropriate.

6. On appointment each member will be provided with;
   a. Terms of Referenced (TOR) of the ERC
   b. SOP of the ERC
   c. Latest guidelines for Ethics Review Committees
   d. Contact details of the ERC office and other members
   e. Other regulatory documents used by the ERC

**SOP 3.3. Conditions of appointment**

1. Each member should give a letter of consent for membership before formal appointment.

2. At the time of appointment members should provide their curriculum vitae and sign confidentiality and conflict of interest agreement undertaking;
   a. that all matters of which he/she becomes aware during the course of his/her work on the ERC shall be kept confidential.
   b. that any conflicts of interest which exist or may arise during his/her tenure in the ERC shall be declared at the earliest opportunity.
c. that he/she has not been subjected to any criminal conviction or disciplinary action which may prejudice his/her standing as a ERC member.

3. Each member must undergo training in ethics and Good Clinical Practice (GCP) and the certificates must be submitted to the ERC.

4. Members must agree to their names, designations and affiliations made public by the ERC.

5. Members are not offered remuneration. However, members shall be reimbursed for expenses incurred pertaining to the ERC activities.

SOP 3.4. Responsibilities of ERC members

1. Protection of the safety and rights of research participants and experimental animals.

2. Perform duties assigned by the ERC.

3. Regular attendance of the ERC meeting and workshops.

4. Review of research projects and participation in decision making.

5. Maintaining confidentiality.

6. Continuing education of activities in biomedical researches and research ethics.

SOP 3.5. Disqualification procedure of member

A member will be disqualified in the following circumstances:

- Disclosure of confidential information
- Utilizing the proprietary information
- Fails to declare conflict of interest
- Evidence for personal or professional misconduct
CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT
FOR MEMBERS OF THE ERC

I, ………………………………………… the undersigned member of the ERC of Faculty of Medicine of University of Jaffna agrees not to disclose or utilize directly or indirectly any confidential or proprietary information belonging to a third party outside the committee mandate.

I also assure that whenever I have a conflict of interest I shall inform the Chairperson promptly and will not participate in the decision making of the matter concerned.

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 Dean/ Faculty of Medicine
Purpose of this SOP is to describe and define the functions of the ERC.

Primary function of the ERC of the Faculty of Medicine of University of Jaffna is to protect the welfare, rights, dignity and the safety of the research participants and experimental animals and to provide an updated ethical frame work and guidance to the researchers in order to promote the standards of researches.

**SOP 4.1. Review of research projects and granting ethical clearance**

The ethics review committee will review the research projects submitted to the ERC by the staff and students of University of Jaffna and that are conducted in Northern Province. The detail description of the submission and review process are given in SOP 5.1 and SOP 5.2 respectively.

Ethics review committee may approve/ disapprove ethical clearance or provide recommendations to the research projects submitted to the ERC depending on issues raised by the reviewers.

**SOP 4.2. Providing advice to researchers**

One of the objectives of the ERC is to provide the ethical framework and advice for the researchers who seek the help from the ERC in developing research protocols and conducting researches. The ERC also provide support to the researchers for ongoing studies on ethical issues.
SOP 4.3. Follow up and monitoring of research projects
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 and/ or completion report. The details of follow up and monitoring procedures are described in SOP 4.5.

SOP 4.4. Prescribing principles and standards for research project
The ERC will provide an ethical frame work to promote the standards of biomedical researches. Based on the national and international guidelines, the ERC has drawn standard formats for preparing the research protocols for researchers who wish to submit to the ERC for ethical clearance. This format is available at the faculty website.

SOP 4.5. Conducting workshops and orientation programmes
1. The ERC conducts an orientation programme for the new members in research ethics and ERC function.
2. The ERC will conduct workshop from time to time to train/ update the ERC members and the researchers of University of Jaffna.
3. The ERC may organize workshop on research ethics for the researchers of the region.
4. Members of the ERC may involve in workshops and training programmes on research ethics organised by other institutions.

SOP 4.6. Conducting regular ERC meeting
The ERC meets every month to discuss the research projects submitted to the ERC and other activities. Details of conduct of the ERC meetings are described in SOP 5.

The subcommittees of the ERC will meet as required to a defined task or to carry out a function on behalf of the ERC. Minutes of subcommittee meeting will be submitted at the subsequence meeting of the ERC.
SOP 4.7. Emergency meeting
The Chairperson of the ERC may direct the 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 reported for an approved project. Such meetings can be conducted in between regular ERC meetings with 3 working days’ notice to the members. The ERC will discuss only that matter.

SOP 4.8. Communications
The Secretariat of the ERC does the following communications on behalf of the ERC:

1. Circulates the agenda, minutes and other relevant documents among the ERC members before each meeting.
2. Sends the protocols and other relevant documents along with review forms to the reviewers.
3. Receives the reviewers’ evaluation reports.
4. Communicates the decision of the ERC to PI, as described in SOP 5.4.
5. In addition to the routine communications it corresponds with individuals / institutions/ regulatory authorities if necessary.

SOP 4.9. Documentation and archiving
It is the responsibility of the member secretary of the ERC to document the ERC activities. Access to the confidential documents is restricted to authorised members of the ERC. Other members of the ERC, regulatory authorities or PI (only the documents related to their projects) could access the relevant documents upon approval of a written request to the ERC.

The ERC maintains registries for the submitted protocols and correspondences and keeps the records of ERC related and project related documents. The procedures for documentation and archiving are described in SOP 6.
Purpose of this SOP is to describe the procedures for submission, review, decision making, communication of decisions of the ERC and follow up of the Research Projects

The ERC secretariat will receive, record and forward applications to the subcommittee for the appointment of primary reviewers and, circulate them for review by primary reviewers and members of the ERC. The ERC will make the decision on each project following review. The secretariat will communicate the decision to the applicants and receive progress and/ or completion reports from the applicants and archive the research projects.

**SOP 5.1. Submission**

The protocol submissions include submission of new research project, resubmission of revised or corrected protocol, and submission of project amendments, progress and / or completion or protocol termination reports.

**SOP 5.1.1. Submission of new research project**

New applications to the ERC must be submitted in appropriate format. Applications must be duly filled and signed and submitted along with all the documents required by the ERC. Application form and guidance for applicants in the preparation of application to the ERC are available at [http://www.jfn.ac.lk/med](http://www.jfn.ac.lk/med). Three hard copies of the duly filled and signed application form, protocol and other documents required by the ERC and soft copies of application and the protocol and the supporting document in a CD have
to be submitted at the secretariat. Initial protocol must be indicated in the pages (water marked/ footer, header, etc.) as version 1.

An application fee will be charged for each new application except undergraduate research projects. The authorized copy of the completed paying in voucher for the appropriate payment (can be down loaded from the following link; jfn.ac.lk/med) should be handed over along with the application. Payment can be made by cash/money order/postal order (in favor of University of Jaffna) at the shroff 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.

Applications submitted before the stipulated date (3 weeks prior to the scheduled meeting) will be considered for review at the very next meeting.

On submission one copy of check list of content of the application will be given to the applicant along with the acknowledgment for new application to the applicant by the secretariat and another copy of the check list will be attached to the application for further processing. A reference number is assigned to each application which must be mentioned in all the future correspondents regarding the project.

Incomplete applications will not be accepted.

**SOP 5.1.2. Submission of undergraduate research projects**

Undergraduate research projects should be submitted through the department concerned and must be submitted under the responsibility of the Head of the Department or Unit.

**SOP 5.1.3. Submission of postgraduate student research projects**

Postgraduate student research proposals should be submitted under the responsibility of a qualified supervisor/ authorised person unless the researcher is exempted from working under a supervisor by the degree awarding institution with a covering letter indicating:

a. the degree to be obtained
b. the institution where the candidate is registered for postgraduate degree
c. a brief account on the procedure of approving the project at that institution
d. declaration about the exemption if applicable.

**SOP 5.1.4. Submission of collaborative research projects**

In the case of international collaborative researches following documents should be submitted with the application:

a. Evidences for prior written agreement between the local and foreign collaborator on the following:
   - Fate of data and samples/ specimens.
   - Ownership of the data and publication and intellectual property rights.
   - Nature of benefits and their distribution.

b. Ethical clearance certificate from the country of collaborator.

c. Transfer of biological or genetic materials should follow the standards drawn by this country and supporting documents should be submitted.

**SOP 5.1.5. Resubmission of revised research project**

Revised projects need to be submitted along with a covering letter addressed to the Chairperson / ERC which must have the information on the page numbers of corrected sections. Version of the protocol must be indicated in both hard and soft copies of the revised protocol.

**SOP 5.1.6. Submission of Amendments**

After obtaining the ethical clearance, if the researcher wants to make any amendments to the accepted protocol, following documents must be submitted to the secretariat.

- a covering letter addressed to the Chairperson / ERC explaining the reason for amendment.
- description of amendments.
• supporting documents if any.

SOP 5.1.7. Submission of progress reports and/ or completion reports / termination reports
The principal investigator (PI) must submit a completion report at the end of the project. If the project is extended beyond one year the PI must submit an annual report on the status of his/ her projects for which the ethical clearance is obtained from the ERC. In case of premature termination of a project the PI should inform it to the ERC with the reason for termination.

SOP 5.1.8. Submission of request for extension of Ethical Clearance
If the data/ sample collection could not be completed within the stipulated time, the PI may request the ERC to extend the ethical clearance. Following documents must be submitted to the secretariat

• Request letter indicating the reason for the need of extension of ethical clearance.
• Progress report
• Copy of the ethical clearance letter

SOP 5.2. Review procedures
The submitted applications, protocols, amendments or the reports will be processed by the secretariat for review by the ERC. The member secretary will verify all the submitted applications, amendments and the reports and schedule the subcommittee meeting comprising the Chairperson or nominee, secretary or nominee and a member. The subcommittee meeting will be held within a week of stipulated date. The subcommittee will carry out preliminary review and appoint primary reviewers for each application. The documents will be sent to the reviewers within 5-7 working days.
SOP 5.2.1. Review of new research project
Depending on the nature of the project the subcommittee will decide on the type of review and appoint the reviewers for each application.

SOP 5.2.1.1. Exemption from review
The subcommittee of the ERC, may exempt from ethics review audits, surveys and research with no risk to the participants provided that human participants involved will not be identified directly or indirectly.

SOP 5.2.1.2. Expedited review
The subcommittee of the ERC, will consider for expedited review of the projects under following circumstances;

a. projects with minimal risk and non-sensitive issues;
   i. Collection of secondary data.
   ii. Studies on the effectiveness of educational methods and curricula.
   iii. Projects evaluating the public benefits of existing programmes and impact of changes in programmes without intervention.

The subcommittee may decide on expedited review of research protocols between scheduled meetings and reviewed by either Chairperson or Secretary or another member. The Chairperson or secretary may seek advice from appropriate experts before reaching a decision if necessary. If ethical clearance is granted, it shall be considered for ratification at the subsequent ERC meeting.

SOP 5.2.1.3. Full board review
For each application minimum of 3 primary reviewers will be appointed by the subcommittee with their consent. It is preferable to have all 3 primary reviewers from the members of the ERC. If not possible 2 primary reviewers should be from the ERC members and the third primary reviewer could be from the pool of external reviewers. The ERC may also obtain expert opinion when needed.
The secretary shall circulate the applications received with the agenda of the meeting to all members of the ERC at least five (5) days prior to the next meeting. The reviewers’ comments will be discussed at the meeting to arrive at a decision.

**SOP 5.2.1.4. Review of undergraduate projects**

Undergraduate research projects are reviewed by a subcommittee comprising the Chairperson/ nominee and secretary/ nominee of the ERC and an expert from the department concerned. Decision of the subcommittee will be informed in writing to the Head of the relevant department and submitted to the next ERC meeting for formal approval.

**SOP 5.2.2. Review of revised research projects**

Depending on the decision of the ERC at the review, the clarifications or revised projects could undergo;

a. expedited review by Chairperson/ nominee and Secretary/ nominee in between the ERC meetings.

b. full board review.

In the case of expedited review, it shall be considered for ratification at the next the ERC meeting.

**SOP 5.2.3. Review of amendments**

The subcommittee of the ERC depending on the nature of the amendments will decide on the type of review, either expedited or full board review. Following will be considered as minor amendments and could be qualified for expedited review;

a. inclusion or exclusion of investigators.

b. changes in study setting.

c. sampling and analysis.

d. changes in non-confidential information.
SOP 5.3. Decision making
Any member of the ERC who has any interest, financial or otherwise, in a protocol or other related matter(s) considered by the ERC, should declare such interest and shall not participate in the decision making.
A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum for the meeting of the ERC is at least five (5) members. The ERC will endeavor to reach a decision concerning the ethical acceptability of a protocol by consensus. Where a decision cannot be reached by consensus, the decision will be taken by a majority of two-thirds of the members present. The ERC may invite the PI to attend the particular meeting to discuss ethical issues of the project before coming to a decision. The PI has to sign a confidentiality agreement before attending the meeting which is described in SOP 6.
The decision of the ERC can be;
- exempted from ethics review.
- approval for ethical clearance.
- provisional ethical clearance subject to clarification, modifications or further information.
- request for clarifications, modifications or further information.
- re-review of revised project.
- rejection.

SOP 5.3.1. Exemption from ethical review
If the subcommittee of the ERC, consisting of at least the Chairperson (or nominee), Secretary (or nominee) and another ERC member decides that if the project fulfill the criteria for the exemption from ethics review mentioned in SOP 5.2.1.1, it could be exempted from ethics review which will be ratified at the next meeting.
SOP 5.3.2. Ethical clearance
The ERC approve projects that fulfill all the requirements of the ERC or when the clarifications, modifications or further information are satisfactorily resolved. The ethical clearance is given for a period of one year which could be extended/renewed. Extension or renewal would be considered only on receiving the progress report and on request by the PI.

SOP 5.3.3. Provisional ethical clearance
If there are only minor clarifications or modifications required, the ERC could give provisional ethical clearance which gives approval to start the data collection. But the formal ethical clearance will be given only after the clarifications or modifications are satisfactorily resolved within the stipulated period.

SOP 5.3.4. Clarifications, modifications or further information
If the ERC needs clarifications, modifications or further information, it will be communicated to the principal investigator (PI) in writing. Response from the PI to ERC’s comments should be received within 3 months from the date of communication from the ERC. 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.

SOP 5.3.5. Rejection of a project
The ERC rejects projects with grievous ethical and/or scientific issues. The decision of the ERC will be communicated to the PI including the reason/s for rejection.

SOP 5.3.6. Re-review
If there are major corrections in the protocol, the clarification and revised protocol will be subjected to re-review by the same reviewers.
SOP 5.3.7. Extension of Ethical Clearance

For research projects extending beyond one year the ERC could consider extension of ethical clearance if the PI request for extension of ethical clearance as described in SOP 5.1.8. Each extension will be given for a period of one year.

SOP 5.3.8. Amendments to the protocols

The ERC could approve or disapprove or may request for further clarifications.

SOP 5.4: Communication of the ERC decision

The decision of the ERC on research projects will be informed to the PI in writing signed by Chairperson and secretary. Notification of the ERC decisions shall normally be sent within five (5) working days after the meeting.

SOP 5.4.1. Communication of exemption from ethical review

The decision of exemption from ethics review will be notified to the PI and the notification letter will contain the following:

- ERC reference number.
- Date of submission of the application.
- Date of the meeting at which the project was exempted from ethics review.
- Conditions, if any.

Template of notification of exemption from ethics review is attached as annexure AX 7 – SOP 5/ V 1.

SOP 5.4.2. Communication of Ethical clearance

The PI will be given an ethical clearance certificate which contains the following information;

- ERC reference number.
- Title and version of the project protocol.
- Date of submission of the application.
• Date of the meeting at which the ethical clearance is given.
• Conditions for ethical clearance, if any.
• Duration of ethical clearance.
• Frequency of progress report and date of submission of completion report.

Template of ethical clearance certificate is attached as annexure AX 8 – SOP 5/V 1.

**SOP 5.4.3. Communication of extension of ethical clearance**

If the ERC decides to extend the ethical clearance, which will be given in the following format;

• ERC reference number.
• Title and version of the project protocol.
• Date of submission of the application.
• Date of the meeting at which the extension of ethical clearance is given.
• Conditions for extension of ethical clearance, if any.
• Duration of extension of ethical clearance.

**SOP 5.4.4. Communication of provisional ethical clearance**

If the ERC decides to give provisional ethical clearance, it will be notified to the PI in writing. The provisional approval letter will contain the following information;

• ERC reference number.
• Title and version of the project protocol.
• Date of submission of the application.
• Date of the meeting at which the provisional approval is given.
• Clarifications, modifications or further information requested.
• Deadline for responding to the request.

Note: If no response from PI for 3 months the application will lapse and the provisional ethical clearance will be withdrawn. If the ethical clearance is desired for the same project a fresh application has to be submitted.

Template of provisional approval letter is attached as annexure AX 8 – SOP 5/ V 1.

SOP 5.4.5. Communication of clarifications, modifications or further information

The request for clarifications, modifications or further information will be communicated to the PI with the following;

- ERC reference number.
- Title and version of the project protocol.
- Date of submission of the application.
- Date of the meeting at which the request for clarifications, modifications or further information is made.
- Clarifications, modifications or further information requested.
- If no response from PI for 3 months the application will lapse and if the ethical clearance is desired for the same project a fresh application has to be submitted.

The template for request for clarification, modification or further information is attached as Annexure AX 9 – SOP 5/ V 1.

SOP 5.4.6. Communication of rejection of a project

If the ERC rejects any project that is not ethically and / or scientifically acceptable, the decision will be notified to the PI with the following information;

- ERC reference number.
- Title and version of the project protocol.
• Date of submission of the application.
• Date of the meeting at which the decision of rejection of the project is made.
• Reason/s for rejection.

Template for notification of rejection of a project is annexed as Annexure AX 11 – SOP 5/ V1.

SOP 5.4.6. Communication of the decision on undergraduate research projects
The decision of the ERC on undergraduate projects will be communicated to the Head of the concerned Department.

SOP 5.3.7. Communication of decision on Amendments to the protocols
The ERC could will form the decision on the amendment to the PI in writing.

SOP 5.5. Follow up and monitoring of approved research projects
The ERC will follow up the research projects that are approved to ensure the adherence of researchers to the conditions of ethical clearance and to ensure the safety of the participants routinely by reviewing progress and completion reports. Extending or renewing of ethical clearance at the end of stipulated period will be done on receiving progress reports. The ERC will adopt additional mechanism to monitor whenever necessary. It is the responsibility of the ERC to take necessary steps when there is serious or unexpected adverse event.

SOP 5.5.1. Progress reports and completion reports
It is the PI’s responsibility to send progress reports to the ERC as requested. The follow-up intervals will be decided by the ERC considering the nature of the project, at least annually. Progress report is a prerequisite for requesting
extension or renewal of ethical clearance. The progress report should contain the following information;

- Title of the project.
- Reference number.
- Date of ethical clearance.
- Progress of the project to date.
- Compliance with the approved protocol.
- Compliance with the conditions of the ERC.

At the end of the project the PI should send the ERC a completion report which should include;

- Title of the project.
- Reference number.
- Date of ethical clearance.
- Date of completion.
- The outcome of the study.
- Compliance with the approved protocol.
- Compliance with the conditions of the ERC.

**SOP 5.5.2. Safety reports and serious adverse events**

The ERC will inform the PI in the ethical clearance certificate or provisional approval letter that any serious or unexpected adverse events occurred during the study must be promptly notified to the ERC

**Serious Adverse Event**

Following are considered as serious adverse events;

- Death
- Life threatening adverse events
- Hospitalization
- Disability
- Congenital abnormalities
Unexpected adverse events

Unexpected adverse events are the events 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.

Such adverse events will be reported to the ERC at the next meeting.

**SOP 5.5.2.1 Reporting Adverse Events to ERC**

Death or serious adverse events must be notified to the ERC immediately (within 5 days of the event). Other adverse events must be notified as soon as possible (not later than 7 days).

Notification of adverse event to the ERC must be submitted in appropriate format, which is available at [http://www.jfn.ac.lk/med](http://www.jfn.ac.lk/med). The adverse event reporting form is annexed as Annexure AX 14 – SOP 5/ V 1.

**SOP 5.5.2.2. Review of Adverse Events**

Member secretary of the ERC in consultation the Chairperson, would call for a special meeting. A subcommittee of the ERC consisting appropriate members and experts will be appointed at the meeting to review the Adverse Events.

**SOP 5.5.2.4. Decision and communication on Adverse Events**

Following decisions could be taken depending on the nature and seriousness of adverse event;

- permits continuation of the project if it is proved that the adverse event is not connected to the drugs used or intervention or study procedures undertaken.
- immediate request for additional information.
- immediate suspension of ethical approval.
- immediate termination of ethical approval.
• increased monitoring of the project.
• a request for an amendment to the protocol.

Decision of the ERC will be notified to the PI in writing.

**SOP 5.5.3. Suspension/ premature termination of researches**

Protocol may be suspended/ terminated before scheduled time at the recommendation of the ERC, Data safety monitoring committee, adverse event monitoring committee or sponsor or other authorised bodies during enrollment or follow up.

• If the ERC recommends termination of a study, the information will be sent to the PI in writing explaining the reasons for recommending termination. Copy of the letter must be sent to
  o Data safety monitoring committee.
  o Adverse event monitoring committee.
  o Sponsor.
  o Head of the institution/s where the research is carried out.
  o Others involved in the research if any.

• If other bodies recommend termination or suspension it should be notified to the ERC by the PI. On such circumstances the Chairperson calls for an emergency meeting and acknowledges and notifies the termination or suspension in writing.
<table>
<thead>
<tr>
<th>Reference number</th>
<th>J/ ERC/</th>
<th>Date received</th>
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</tr>
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</table>

Reviewer 1
Reviewer 2
Reviewer 3

**THE ERC decision**

**ERC Meeting**
Date: / / | Date informed: / / 

Part I – Project Information

1. Title of the project
2. Type of project
Non-degree
Postgraduate Degree (specify) .................................................
Undergraduate
Sponsored clinical trial
Others (specify) .................................................................

3. Investigators
3.1. Principal investigator
<table>
<thead>
<tr>
<th>Name</th>
<th>Qualification/s</th>
<th>Area of specialisation</th>
<th>Designation</th>
<th>Institution</th>
<th>Contact Address</th>
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3.2. Co-investigator / Supervisor (indicate the status)
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<th>Name</th>
<th>Qualification/s</th>
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Contact number
e-mail
Signature
**3.3. Co-investigator / Supervisor (indicate the status)**

**3.4.**

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<th>Name</th>
<th>Qualification/s</th>
<th>Area of specialisation</th>
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<th>Contact Address</th>
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<th>e-mail</th>
<th>Signature</th>
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</table>

**3.5. Co-investigator / Supervisor (indicate the status)**

**3.6.**

<table>
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<th>Name</th>
<th>Qualification/s</th>
<th>Area of specialisation</th>
<th>Designation</th>
<th>Institution</th>
<th>Contact Address</th>
<th>Contact number</th>
<th>e-mail</th>
<th>Signature</th>
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</table>

**Attach extra sheet if necessary.**

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

**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?

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Yes [ ]  No [ ]

If yes,

<table>
<thead>
<tr>
<th>Name of the committee</th>
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<tbody>
<tr>
<td>Decision *</td>
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<td>Date</td>
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* Attach documentary evidence.

7. Has this project been subjected to scientific review?

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Yes [ ]  No [ ]

If yes,

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<th>Name and address of the committee</th>
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<td>Decision *</td>
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* Attach the copy of communication of the above decision.

8. Funding

<table>
<thead>
<tr>
<th>Name and address of funding agent</th>
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<tr>
<td>Amount</td>
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9. Have you submitted any application to this ERC before? (attach extra sheets if necessary)

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Yes [ ]  No [ ]

If yes,

<table>
<thead>
<tr>
<th>Title</th>
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<tr>
<td>reference number of the project</td>
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<tr>
<td>Decision *</td>
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<tr>
<td>Date</td>
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</tbody>
</table>
Current status of the project

* Attach copy of communication of the above decision.

10. Collaborative research

10.1. 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:

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

(For further information refer the section 8.4 of the Terms of Reference)

10.2. List the collaborating institutions

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

10.3. 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
10.4. Why this project is carried out in Sri Lanka and not in the sponsoring country?


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


10.6. Are biological samples transferred abroad?

Yes ☐ No ☐

If yes, attach the material transfer agreement.

11. Clinical trial

11.1. Which phase of the trial is being conducted?

Phase I ☐
Phase II ☐
Phase III ☐
Phase IV ☐
Others (specify) ☐ ..............................................................................................

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

Yes ☐ No ☐

If yes*,

<table>
<thead>
<tr>
<th>Name of the registry</th>
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<tbody>
<tr>
<td>Registration number</td>
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</table>

* Attach the documentary evidence.

11.3. Is the drug/product registered in SL?

11.4. If no submit the approval from Drug Regulatory
11.5. Is it a multicenter trial?
Yes [] No []
If yes, list the other centers.

11.6. Are the participants paid?
Yes [] No []
If yes, amount of money per participant?

11.7. Are the investigators paid?
Yes [] No []
If yes, by whom?

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

<table>
<thead>
<tr>
<th>Name of member</th>
<th>Designation</th>
<th>Role</th>
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</table>

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

14. Conflict of interest (please declare).
15. Declare your objection to send this project for review to any particular reviewer/s if any.

<table>
<thead>
<tr>
<th>No.</th>
<th>Part II – Protocol Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Summary of the project</td>
</tr>
<tr>
<td>2</td>
<td>Introduction/ background</td>
</tr>
<tr>
<td>3</td>
<td>Justification</td>
</tr>
<tr>
<td>4</td>
<td>Review of literature</td>
</tr>
<tr>
<td>5</td>
<td>Objectives of the study</td>
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<tr>
<td>6</td>
<td>Methodology</td>
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<tr>
<td>7</td>
<td>Study design</td>
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<td>8</td>
<td>Place of study</td>
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<td>9</td>
<td>Duration of the study</td>
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<td>10</td>
<td>Study population</td>
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<td>11</td>
<td>Sample size and calculation of sample size</td>
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<td>12</td>
<td>Inclusion criteria</td>
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<tr>
<td>13</td>
<td>Exclusion criteria</td>
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<tr>
<td>14</td>
<td>Study instrument/s</td>
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<tr>
<td>15</td>
<td>Pilot study</td>
</tr>
<tr>
<td>16</td>
<td>Sampling/ recruitment procedure</td>
</tr>
<tr>
<td>17</td>
<td>Data collection</td>
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<tr>
<td>18</td>
<td>Data analysis</td>
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<tr>
<td></td>
<td>Maintenance and fate of data</td>
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<tr>
<td>19</td>
<td>Dissemination of results</td>
</tr>
</tbody>
</table>

**Ethical issues**

<table>
<thead>
<tr>
<th></th>
<th>Assessment of risks/ benefits</th>
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<tbody>
<tr>
<td>21</td>
<td>Procedure for obtaining consent</td>
</tr>
<tr>
<td>22</td>
<td>Informed consent form</td>
</tr>
<tr>
<td>23</td>
<td>Justification for including vulnerable population</td>
</tr>
<tr>
<td>24</td>
<td>Procedures to protect the rights of participants</td>
</tr>
<tr>
<td>25</td>
<td>Confidentiality</td>
</tr>
<tr>
<td>26</td>
<td>Safety monitoring</td>
</tr>
<tr>
<td>27</td>
<td>Provision of medical and psychological support to participants</td>
</tr>
</tbody>
</table>

**Biological Samples**

<table>
<thead>
<tr>
<th></th>
<th>Justification for using biological sample/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>28</td>
<td>Procedures for collection, storage and disposal of biological sample/s</td>
</tr>
<tr>
<td>29</td>
<td>Consent for collecting biological sample/s</td>
</tr>
</tbody>
</table>

**Collaborative research**

<table>
<thead>
<tr>
<th></th>
<th>Justification and benefits of collaboration with foreign investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Protection of the rights of local collaborator</td>
</tr>
<tr>
<td>32</td>
<td>Justification for transfer of data and /or biological/ genetic materials to the country of foreign collaborator</td>
</tr>
<tr>
<td>33</td>
<td>Fate of transferred data and biological/ genetic material</td>
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<td>No.</td>
<td>Document</td>
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<tr>
<td>34</td>
<td>Criteria for termination of participants from the trial</td>
</tr>
<tr>
<td>35</td>
<td>Criteria for termination of the trial</td>
</tr>
<tr>
<td>36</td>
<td>Adverse event monitoring, management and reporting</td>
</tr>
<tr>
<td>37</td>
<td>Justification for withholding/ withdrawing standard therapy</td>
</tr>
<tr>
<td>38</td>
<td>Provision for making the trial drug available after completion of the trial</td>
</tr>
</tbody>
</table>

**Research involving animals**

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<thead>
<tr>
<th>No.</th>
<th>Document</th>
<th>Check box</th>
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<tbody>
<tr>
<td>39</td>
<td>Justification for involving animals</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>Measures to minimize the suffering of animals</td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>Description of infrastructure and other facilities available to handle animals and to carry out animal experiments</td>
<td></td>
</tr>
</tbody>
</table>

* NA – Not applicable

**Part III – Application Checklist**

I declare that I have attached the following documents.

(Please tick the appropriate check box)

<table>
<thead>
<tr>
<th>No.</th>
<th>Document</th>
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<tbody>
<tr>
<td>1</td>
<td>Application form – 4 copies</td>
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<tr>
<td>2</td>
<td>Summary of the project – 4 copies</td>
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<tr>
<td>3</td>
<td>Research protocol – 4 copies</td>
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<tr>
<td>4</td>
<td>Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4 copies</td>
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<td>5</td>
<td>Questionnaire (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4 copies</td>
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<tr>
<td>6</td>
<td>Data record booklets/ event record diary/data record sheet or form (should be provided in English and local language of</td>
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participants i.e. Tamil / Sinhala/ both Tamil & Sinhala if self-administered by participants) – 4 copies

7 Approval from Drug Regulatory Authority (for clinical trials)

8 Insurance coverage (for clinical trials)

9 Ethical clearance from the country of foreign collaborator if applicable

10 Soft copies of all documents (CD)

11 Receipt for payment of application fee to the Finance Department of University of Jaffna

12 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.).

I understand that the application for ethics clearance will not be accepted unless all necessary documents are submitted and at least two months 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 Head of the Institution

**Document Receipt Checklist**  
*(Office copy)*  
*(Please tick the appropriate check box)*

<table>
<thead>
<tr>
<th>No.</th>
<th>Document</th>
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<tbody>
<tr>
<td>1</td>
<td>Application form –</td>
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<tr>
<td>2</td>
<td>Summary of the project – 4 copies</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Research protocol – 4 copies</td>
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<tr>
<td>4</td>
<td>Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 4 copies</td>
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<td>5</td>
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<td>6</td>
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<td>8</td>
<td>Insurance coverage (for clinical trials)</td>
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<tr>
<td>9</td>
<td>Ethical clearance from the country of foreign collaborator if applicable</td>
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<td>10</td>
<td>Soft copies of all documents (CD)</td>
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<tr>
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<tr>
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</table>
Document Receipt Checklist
(Applicant’s copy)
(This document will be filled and handed over to the applicant by the staff accepting the application.)

<table>
<thead>
<tr>
<th>Reference number</th>
<th>J/ERC/</th>
<th>Date received</th>
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</table>

Title of the project

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

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<td>Description</td>
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</table>

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

………………………………………………….. Date:  
Receiver’s signature  
(ERC secretariat)
GUIDE TO APPLICANTS

Ethics Review Committee
Faculty of Medicine of University of Jaffna

1. Research projects involving humans or animals to be conducted in the region could be submitted for ethical clearance.

2. Ethics review application form can be downloaded from the following link;

3. With completed application form four hard copies of project protocol, a summary of the protocol and all relevant documents along with soft copy of all the documents in a CD should be submitted to the designated officer at the Office of the Dean, Faculty of Medicine, 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 authorized copy of the completed paying in voucher for the appropriate payment (can be downloaded from the following http://www.jfn.ac.lk/med) should be handed over along with the application. Payment can be made by cash/money order/postal order/cheque (in favor of University of Jaffna) at the shroff 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.

6. Any conflict of interest between the researchers and the members of the
ERC should be declared.

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 a senior
lecturer in a University, exempted from working under a supervisor)
with a covering letter indicating:
   a. the degree to be obtained
   b. the institution where the candidate is registered
   c. a brief account on the procedure of approving the project at that
   institution

9. Applications for research with foreign collaborators: please read
instructions in the application form and also the section of the TOR and
SOP on collaborative research.

10. Completed applications submitted before the end of the calendar month
will be considered at the next ERC meeting and the decision of the ERC
will be communicated to the PI/ Head. This process will take minimum
of 4 weeks.

11. The ERC will reject 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
effectuated 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 as requested 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 ‘Terms of Reference’ at the following link: http://www.jfn.ac.lk/med

16. If you need any further clarifications, please call 021 2222073.

17. If you want to make any complaints about the ERC, please write to the Chairperson, ERC, Faculty of Medicine, University of Jaffna. If you are still not satisfied, write to the Dean, Faculty of Medicine/the Vice Chancellor, University of Jaffna.

18. Details of application fee for proposals submitted for ethical clearance:
   - personal research
     Grants less than 300000/=) Rs.1500.00
     Grants more than 300000/=) Rs. 3000.00
   - Research with foreign collaboration
     Sri Lankan PI Rs. 5000.00
     Non-Sri Lankan PI Rs. 50000.00
     Sponsored clinical trials- Rs. 200000.00
   - Undergraduate projects- 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
(Title of the project)
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 and potential hazards and discomforts;
Participation in this study may benefit you and/or others by (mention all the actual and potential benefits).
(Any potential or actual risks, hazards and discomforts should be clearly mentioned).

5. 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).

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

7. 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.

8. Confidentiality
The information collected will be kept confidentially. Personal details and any information that identify you will not be disclosed or published.
9. Clinical trial

Following need to be clearly explained:

Phase of the trial and its explanation.

Reason for development of new drug/ treatment and manufacture information

Explanation on known experience with the new drug.

Explanation on known and potential adverse effects of this and other drugs used in the trial.

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.

10. 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.
Part II – Certificate of Consent

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 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.

OR

I do not wish to take part in the research.

Print name of child ___________________

Signature of child: ____________________

Date:________________

**Format for certificate of consent from parent or guardian**

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/ guardian

Name of the surrogate decision maker:

Relationship to the Participant:
Format for certificate of 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:
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: ...........................................................
   ...........................................................................................

   a) Application fee ...................... ............
   b) ......................... ...................... ............
   c) ......................... ...................... ............

   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 University of Jaffna Account No.: 162-1-001-8-0000902.

Date: .................................................................
Shroff
TEMPLATE FOR ACKNOWLEDGING NEW APPLICATION

Dear ……………………,

(Title of the project)

Thank you for applying for ethical clearance from our ERC. The reference number of your application is ………………………………………………………………

Please quote this number in all your future communications to the ERC regarding this project. The process of review would take minimum of two months from the date of submission.

Thank you

Secretary
Ethics Review Committee
## Ethics Review Form

**Office use only**

<table>
<thead>
<tr>
<th>Reference number</th>
<th>J / ER C/ 12 /</th>
<th>Date received / / /</th>
</tr>
</thead>
</table>

### Title of the Project

#### Principal Investigator:

#### Institute:  

#### Contact No:

### Duration of the Study

#### Status

New  [ ] Revised  [ ] Amended  [ ]

### Type of the Study

- [ ] Observational
- [ ] Interventional
- [ ] Document based
- [ ] Others (specify)  

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<th>Yes</th>
<th>No</th>
<th>NA</th>
<th>Comments</th>
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<tr>
<td>1.</td>
<td>All the necessary documents are provided.</td>
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<td></td>
<td>Evidence for appropriate approval/s from relevant authorities is/ are provided.</td>
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<td>2.</td>
<td>Background appropriate</td>
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<td>3.</td>
<td>Justification is sufficient.</td>
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<td>4.</td>
<td>Objectives are clear.</td>
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<td>5.</td>
<td>Review of literature is appropriate.</td>
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<td>6.</td>
<td>Investigator/s has/have scientific, clinical or other relevant qualification/s that is/are appropriate for the study.</td>
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<td>6.</td>
<td>Study design is appropriate.</td>
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<td>7.</td>
<td>Involvement of human participants is necessary for this study.</td>
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<td>8.</td>
<td>Study population is appropriate for this study.</td>
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<td>9.</td>
<td>Inclusion criteria are appropriate.</td>
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<td>10.</td>
<td>Exclusion criteria are appropriate.</td>
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<td>11.</td>
<td>Sample size is appropriate.</td>
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<td>12.</td>
<td>Statistics used is appropriate.</td>
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<td>13.</td>
<td>Recruitment of participants is appropriate.</td>
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<td>14.</td>
<td>Voluntary participation is ensured.</td>
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<td>15.</td>
<td>Participants have the right to withdraw unconditionally at any time of the study without penalty and/or loss of benefit.</td>
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<td>16.</td>
<td>Participants are allowed to ask questions and register complaints.</td>
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<td>17.</td>
<td>Procedure for obtaining consent is appropriate.</td>
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<td>18.</td>
<td>Contents of information sheet and consent form are adequate and clear.</td>
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<td>19.</td>
<td>Translations of all forms are consistent.</td>
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<td>20.</td>
<td>Risk-benefit assessment is acceptable.</td>
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<td>21.</td>
<td>Confidentiality is ensured.</td>
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<td>22.</td>
<td>Privacy of the participants is protected.</td>
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<td>23.</td>
<td>Provision for compensation is appropriate.</td>
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<td>24.</td>
<td>No inducement for participants.</td>
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<td>25.</td>
<td>Provision of adequate medical and psychological support.</td>
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<td>26.</td>
<td>Facilities and infrastructure of the site are appropriate.</td>
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<td>27.</td>
<td>Analysis is appropriate.</td>
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<td>28.</td>
<td>Dissemination and fate of data are mentioned.</td>
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<td>29.</td>
<td>Source of funding is appropriate</td>
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<tr>
<td>Researches involving biological samples</td>
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<td>30. Justification for collecting biological samples</td>
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<td>31. Standards procedures are adopted in sample collection</td>
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<td>32. Procedures for disposal of sample are appropriate</td>
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<td>33. Consent procedure for storage and future usage of sample is described</td>
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<td>34. Justification for transfer of biological materials is adequate</td>
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<tr>
<td>35. Procedure for transfer of biological materials is appropriate</td>
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<th>Vulnerable population</th>
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<tr>
<td>36. Adequate justification is given for studying the vulnerable population.</td>
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<tr>
<td>37. Procedures for obtaining consent for vulnerable population are appropriate.</td>
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<tr>
<td>38. Measures to protect the rights and prevent exploitation of vulnerable population are adequate.</td>
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<tr>
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<tr>
<td>39. Registered with clinical trial registry.</td>
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<tr>
<td>40. Clearance from Drug Regulatory Authority is attached.</td>
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<tr>
<td>41. Evidences for safe use of the drug/s in human are provided.</td>
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59. Transfer of such materials follows the standards drawn by this country.

**Researches involving experimental animals**

60. Involvement of animals in the study is justified.

61. Selection of species is appropriate

62. Number of animals used in the study is appropriate.

63. The site has the infrastructure and facilities to handle and carry out the animal experiments.

64. Procedures for obtaining and transporting animals are appropriate.

65. Adequate measures are taken to minimize the suffering of the animals.

66. Fate and procedures for disposal of animals are appropriate.

---

**Additional comments:**

..........................................................................................................................................................  
..........................................................................................................................................................  
..........................................................................................................................................................  
..........................................................................................................................................................  
..........................................................................................................................................................  
..........................................................................................................................................................  
..........................................................................................................................................................  
..........................................................................................................................................................  
..........................................................................................................................................................  
..........................................................................................................................................................
Accept □
Accept with corrections □
Re-review after correction □
Reject □

........................................... Date:

Signature

Name of the reviewer:
| Ethics Review Committee  
| Faculty of Medicine  
| University of Jaffna  
| **SOP Code:** AX 7 – SOP 5/ V 2  
| **Annexure:**  
| Template for notification of exempted from ethics review  
| **Effective date:**  
| 01.04.2016  
| Page: 67 |

Dear ……………………,

*(Title and the reference number of the project)*

The ERC at its ……… meeting held on ……………….. has decided to exempt the above study from ethics review.

Chairperson                  Secretary  
Ethics review committee      Ethics review committee
Reference number of the project

……………………

Dear ………………..,

*(Title and the date of submission of the project)*

The ERC at its ……… 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;

……………………………………………………………………………………

……………………………………………………………………………………

……………………………………………………………………………………

Chairperson
Ethics review committee

Secretary
Ethics review committee
Reference number of the project

Dear ………………………,

(Title of the project)

The ERC at its ……… meeting held on ………………. has decided to grant provisional ethical clearance for the …….. Version of the above project for a period of three months from ……………. Considering the following;

............................................................................................................................
............................................................................................................................
............................................................................................................................

Kindly submit your clarifications and revised protocol on or before …………… to obtain formal ethical clearance. If you fail to submit the clarifications within 3 months, the provisional ethical clearance 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
Ethics review committee

Secretary
Ethics review committee
Reference number of the project

……………………

……………………

……………………

Dear ……………………,

(Title of the project)

The ERC at its …….. meeting held on ……………….. has reviewed the above project and decided to request you to fulfill the following;

……………………………………………………………………………………

……………………………………………………………………………………

……………………………………………………………………………………

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
Ethics review committee

Secretary
Ethics review committee
Reference number

Dear ……………………

(Title of the project)

The ERC at its ……… meeting held on ……………….. has reviewed the above project and has decided to not grant ethical clearance for following reasons;

……………………………………………………………………………..

……………………………………………………………………………..

……………………………………………………………………………..

Chairperson
Ethics review committee

Secretary
Ethics review committee
<table>
<thead>
<tr>
<th>Ethics Review Committee</th>
<th>SOP Code: AX 12 – SOP 5/ V 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty of Medicine</td>
<td>Effective date: 01.04.2016</td>
</tr>
<tr>
<td>University of Jaffna</td>
<td>Page: 72</td>
</tr>
<tr>
<td>Annexure:</td>
<td></td>
</tr>
<tr>
<td>Template for approval</td>
<td></td>
</tr>
<tr>
<td>of amendments</td>
<td></td>
</tr>
</tbody>
</table>

Reference number

Dear ......................,

*(Title of the project)*

The ERC at its ........ meeting held on .............. has reviewed the amendments of the above project and has approved the amended version ........ of the above project with following conditions;

- ....................................................................................
- ....................................................................................
- ....................................................................................

Chairperson
Ethics review committee

Secretary
Ethics review committee
Annexure:
Template for reminder to PI

Reference number

Dear ……………………,

(Title of the project)

This is to remind you that progress / completion report of the above project need to be submitted on or before…………..

Secretary
Ethics review committee
ADVERSE EVENT REPORTING FORM

1. Patient details

<table>
<thead>
<tr>
<th>Record No.</th>
<th>Name &amp; address</th>
<th>Age</th>
<th>Weight</th>
<th>Ethnicity</th>
<th>Gender</th>
</tr>
</thead>
</table>

If pregnant POA: ……………………………………………

2. Suspected adverse drug reaction

<table>
<thead>
<tr>
<th>Date of onset:</th>
<th>Date of recovery:</th>
</tr>
</thead>
</table>

Description of the event:

Outcome (tick the appropriate box)

<table>
<thead>
<tr>
<th>Recovered</th>
<th>Recovering</th>
<th>Continuing</th>
<th>Hospitalised</th>
<th>Fatal</th>
</tr>
</thead>
</table>

Laboratory reports

Seriousness (tick the appropriate box)

<table>
<thead>
<tr>
<th>Life threatening</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result in hospitalisation</td>
<td>Birth defect</td>
</tr>
<tr>
<td>Prolongation of Hospitalisation</td>
<td>Others (specify)</td>
</tr>
<tr>
<td>Permanent disability</td>
<td></td>
</tr>
<tr>
<td>Impairment or damage to organs</td>
<td></td>
</tr>
</tbody>
</table>
Relevant Medical History

3. Suspected drug

<table>
<thead>
<tr>
<th>Generic Name:</th>
<th>Trade Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Batch No.:</th>
<th>Expiry Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date started:</td>
<td>Date stopped:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosage form</th>
<th>Route</th>
<th>Dose</th>
<th>Frequency</th>
<th>Reason for Using</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other Drugs used

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosage form</th>
<th>Route</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Reason for Using</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Adverse event on discontinuation of the drug/ reduction of dose (tick the appropriate box)

Drug stopped | Dose reduced (indicate the reduced dose)

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:
Signature:
Date of reporting:
Purpose of this SOP is to describe the conduct of business, decision making and communication of the ERC.

It is the responsibility of the secretariat to organise the meeting. Administrative secretary, under the instructions of member secretary, prepare the agenda and the minutes of ERC meeting. Routine ERC meetings are conducted monthly. Secretariat is also responsible for receiving and delivering commutations of the ERC meetings.

**SOP 6.1: Agenda of the meeting**

Agenda for the each meeting will be prepared by the secretariat under the instructions of member secretary. Contents of the agenda include;

- confirmation of previous meeting minutes.
- matters arising from the minutes.
  - Title of each item is included in the agenda.
- new proposal submitted for ethical clearance.
- any other business.

Template for the agenda of the meeting is attached as Annexure AX 2 – SOP 6/ V 1.

Agenda and the minutes are checked and signed by the member secretary and circulated to the members 5 days prior to the meeting.

**SOP 6.2: Conducting ERC meeting**

The ERC meets monthly, usually on a fixed day that is convenient to all members. Members attend the meeting in person and those who are unable to attend the
meeting must inform their excuses to the secretary prior to the meeting which will be recorded in the minutes.

Any member of the ERC who has any interest, financial or otherwise, in a protocol or other related matter(s) considered by the ERC, should declare such interest as soon as practicable. The member will not participate in the discussions and will not involve in the decision making with respect to that matter. All declarations of conflict of interest and abstinence of the member concerned will be recorded.

Guest attendees may be invited to the meeting to discuss the protocol or for expert opinion. Such attendees must sign a confidentiality agreement before attending the meeting. Guest attendees will not involve in decision making. The confidentiality agreement is attached as Annexure AX 2 – SOP 6/ V 1. Usually they are present during the discussion of the particular item/s concerned.

**SOP 6.3: Quorum requirements**

A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum for the meeting of the ERC is at least five (5) members (at least one member with primary area of expertise is in a non-scientific area) to arrive at a decision.

If a meeting does not have a quorum, decisions cannot be made and which will be made at the next scheduled meeting. In circumstances where decisions has to be made before the next meeting the chairperson will decide either

- To make the decision and ratifications at the next meeting.
- To cancel the meeting and call for an emergency meeting within 05 working days.

**SOP 6.4: Decision making**

The ERC will endeavor to reach a decision concerning the ethical acceptability of a protocol by consensus. Where a decision cannot be reached, the decision will be taken by a majority of two-thirds of the members present.
SOP 6.5: Correspondence

Decisions of the ERC on protocols and other communications are prepared by the secretariat under the supervision of member secretary. Notifications to PI and ethical clearance certificates are signed by both the Chairperson and the member secretary. Other correspondences are signed by either the chairperson or the member secretary. Correspondences are usually dispatched from the secretariat within 5 working days following the meeting.
Office of the Dean  
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 ………….. (Thursday) at 2.00 pm in the Board Room of the Faculty of Medicine.  

**Agenda of ……..meeting of the ERC**  
ERC…. .1. Confirmation of the Minutes of the …………..meeting held on ………….. (annexed).  
ERC…. .2. Matters arising from the Minutes.  
ERC………  
ERC………  
ERC………  
ERC…. .3. New research proposals submitted for ethical clearance.  
ERC…..3.1.  
ERC…..3.2.  

ERC…. .4. Any Other Business  
Kindly be present for this meeting.  

Yours sincerely,  

Secretary/Ethics Review Committee
CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT
FOR GUEST ATTENDEE/ OBSERVER

I, .................................................., the undersigned guest attendee/ observer for the ERC meeting of Faculty of Medicine of University of Jaffna held on ................., agree not to disclose or utilize directly or indirectly any confidential or proprietary information of the project protocols reviewed by me.

I also assure that whenever I have a conflict of interest I shall inform the Chairperson as soon as practicable.

.......................................................... Date:
Signature of the guest attendee / observer

Name & designation of the guest attendee / observer:
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 for ethical clearance.

Record keeping, documentation and archiving will be done by the secretariat under the guidance of member secretary. All the documents and communications received by the ERC will be entered in a register by the secretariat and all those are delivered by the ERC will be entered in delivery book. Electronic versions of the confidential documents will be protected with password and only accessible by the chairperson and member secretary of the ERC. Any member, PI or other authorities may be allowed to access a confidential document on written request to the Chairperson on the approval of the ERC. All the confidential documents that are no longer required will be disposed in a secured procedure using shredder by the chairperson or member secretary. The administrative secretary deals with the confidential documents only in the presence of authorised ERC member.

SOP: 7.1: ERC-related documents

Documents and records that are related to the activities of the ERC are maintained by the secretariat. These documents and records are categorized as

- Documents that are accessible to the researchers and public;
  - TOR and SOP of the ERC
  - Regulatory documents used by the ERC
- Documents with limited access;
  - Annual reports of the ERC.
Agenda of the meetings.
Extracts of minutes to the Faculty board.
Financial record.

These documents are accessible to the members of the ERC and authorised officials of the University.

- Confidential documents
  - Personal files of the ERC members.
  - Minutes of the meeting.

**SOP 7.1.1: TOR and SOP**
The SOP and TOR are documented both in hard and soft copies at the secretariat and are freely accessible to the researchers and public. These documents are also available online at the Faculty Website.

**SOP 7.1.2: Annual reports of ERC**
At the end of each calendar year the ERC submit an annual report which contains following information;

- Titles of the projects reviewed and their current status.
- Nominations and appointments.
- Workshops and training programmes conducted and attended.
- Revisions and amendments to TOR and SOP.
- Summary of income and expenditure for the year.

**SOP 7.1.3: Personal files of the ERC members**
The secretariat will maintain personal file for each member of the ERC. Following documents are filed in the personal files of the members;

- Curriculum Vitae of the member.
- Appointment letter as member of the ERC.
- Confidentiality and conflict of interest agreement
- Certificates for attending or conducting workshops and training programmes related to ERC.
- Other correspondence to and from the member.

Personal files of the members are highly confidential documents and access is restricted to the chairperson and the secretaries of the ERC.

**SOP 7.1.4: Agenda of the ERC meetings**
Preparing of agenda is described in SOP 5.1. the agenda of the meeting will be filed separately by the secretariat. Agenda is not freely available for researchers and public.

**SOP 7.1.5: Minutes of the ERC meetings**
Minutes of the ERC meeting will be prepared by the secretariat under the instructions of member secretary. The minutes will be signed by the member secretary and will be circulated among the members with the agenda of the next meeting. The confirmed minutes signed by the member secretary will be filed. Minutes of the meetings of the ERC are highly confidential and electronic versions of the minutes are password protected. Only the extracts of confirmed minutes will be sent to the Faculty Board.

**SOP 7.1.6: Extract of minutes sent to faculty board**
Extracts of confirmed minutes will be prepared and signed by the member secretary and sent to the faculty board. A copy of it is filed and kept in the ERC office. Extract of minutes is not freely available for researchers and public.

**SOP 7.1.7: Financial records**
All the income and expenditures of the ERC must be recorded and balanced in a financial record book by the secretariat. Summary of the financial status of the ERC will be reported in the annual report of the ERC. Extract of minutes is not freely available for researches and public. Financial record is not freely available for researchers and public.
SOP 7.1.8: Regulatory documents used by the ERC
The regulatory documents that are used in the development and implementation of the ERC guidelines, TOR and SOP are available at the office of the ERC. Electronic versions also may be available. These regulatory documents are freely available for researchers and public.

SOP 7.2: Project-related documents
Projects related documents include
- Registry of projects submitted.
- Application, project protocol and other supportive documents.
- Notification of the ERC decisions.
- Response of PI to the ERC comments.
- Ethical clearance certificate.
- Progress and completion reports.
- Any other documents or communications related to the projects.
These are highly confidential documents and access is limited to the chairperson and member secretary of the ERC and the electronic versions are password protected.

SOP 7.2.1: Registry of research projects submitted to the ERC
All the applications submitted to the ERC will be recorded in a registry. The information that have to be entered in the registry include
- Reference number
- Title of the project
- Date of submission
- Decision of the ERC
- Date of the ERC meeting at which the decision is made.
SOP 7.2.2: Archiving of documents of submitted research projects

Each project proposal submitted to the ERC will be maintained in separate files. Each file contains

- Application form
- Office copy of the check list.
- Copy of paying in voucher
- Protocol and related documents.
- Communications to reviewers
- Reviewers’ comments.
- Notification of the decision to the PI.
- Response from the PI.
- Revised version/s of the protocol
- Ethical clearance certificate
- Progress and completion reports.
- Any other communications or documents related to the project

The project files will be active till completion or termination reports or the ERC decides to reject project or close the file. Once the file is closed, it will be archived and will be maintained at the office of the ERC for 5 years from the date of final decision of the ERC. After that it will be destroyed in a secured manner.

SOP 7.3. Other correspondence

Other correspondence to and from the ERC will be categorized and maintained by the secretariat. Confidentiality of the document will be decided by the ERC depending on the nature of such documents.
The purpose of this SOP is to describe procedures for handling conflict of interest.

One of the conditions of the ERC to the members, external reviewers and the guest attendee / observer to declare the conflict of interest if any and have to sign a confidentiality and conflict of interest agreement. Procedures for the above are described in the sections SOP 1.6, SOP 2.3 and SOP 5.4.

In such circumstances person who declares conflict of interest will not be allowed to participate in the review and decision making on the concerned project.
Purpose of this SOP is to describe the procedures for handling the complaints.

Complaints can be about

- the ERC’s operating procedures.
- decision of the ERC.
- conduct of projects approved by the ERC.

Such complaints will be received by secretariat and the Chairperson depending on the nature and seriousness of the complaint will decide whether to call for an emergency meeting or to discuss at the next scheduled meeting.

**SOP 9.1: Complaints concerning ERC review process**

Any concern or complaint about the ERC’s review process should be directed to the attention of the Chairperson of the ERC, detailing it in writing. The Chairperson will investigate the complaint and its validity and make a recommendation to the ERC on the appropriate course of action.

If the complainant is not satisfied with the outcome of the Chairperson’s investigation, then he/she can refer the complaint to the Dean/ the Vice chancellor.

**SOP 9.2: Complaints concerning ERC decision**

The Principal Investigator may submit a written request with an explanation for reconsideration of an ERC decision. The Chairperson and the ERC will refer documentation and supporting materials from the Principal Investigator to other members of the ERC for discussion at its next meeting. The ERC will review the
written documents. Considering all additional information, the ERC will render a
decision on whether to change its original position. Every attempt will be made
by the ERC, in consultation with the Principal Investigator, to reach a resolution.
A meeting between the principal investigator and the ERC will be arranged.
Appeal of an ERC decision in the event, if the matter cannot be resolved at the
meeting, an appeal may be made to the Dean/ the Vice-Chancellor.

**SOP 9.3: Complaints concerning conduct of research project approved by
the ERC**

Any concern or complaint about the conduct of a project should be directed to the
secretary of the ERC. When complaint is received the secretary shall notify the
Chairperson as soon as possible and at the subsequent meeting of the ERC a
subcommittee will be formed comprising minimum of three members to
investigate the complaint. The subcommittee of the ERC shall investigate the
complaint and make necessary recommendations on the appropriate course of
action and report at the subsequent meeting of the ERC.

If the complainant is not satisfied with the outcome of the subcommittee’s
investigation, then he/she can refer the complaint to the Dean/ the Vice
Chancellor.
The purpose of this SOP is to describe the procedures for approval of amendments and revision of TOR and SOP.

The TOR and SOP will be reviewed every 2 years. A subcommittee comprising the member secretary and four other members of the ERC will be formed for the review of TOR and SOP. The revised versions then will be reviewed and approved by the ERC. Approved new versions will be forwarded to the Faculty Board and Senate of University of Jaffna for their approval. With each revision new versions of the TOR and SOP will be implemented after obtaining the approval of the Faculty Board and University Senate. If there is a situations where some changes need to be made in TOR or SOP in between revision, those amendments must be approved by the Faculty Board and Senate before implementation.