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1. INTRODUCTION

Terms of Reference (TOR) is intended to draw the standards and guidance for the functioning of the Ethics review committee (ERC) of the Faculty of Medicine, University of Jaffna which was established to fulfill the ethical responsibilities of the University concerning research involving human participants and animals of the region. Its responsibility is to evaluate all ethical aspects of research protocols submitted to the committee.

Ethical clearance (EC) is essential for human and animal researches involving pharmaceuticals, medical devices, medical radiation and medical imaging, surgical procedures, biological samples, medical records, as well as epidemiological, social and psychological investigations.

2. OBJECTIVES OF THE ERC

The objectives are to:

2.1. protect the interests, rights, welfare, dignity, health and safety of human participants and animal subjects in research.

2.2. facilitate ethical considerations to research through efficient and effective review processes.

2.3. facilitate excellence in health research and innovative practices for the wellbeing of the society by maintaining the ethical standards of human and animal research. Review in accordance with the relevant guidelines of the Forum of Ethics Review Committees - Sri Lanka (FERCSL) and other relevant National and International guidelines.
3. FUNCTIONS OF THE ERC

3.1. Providing independent, competent and timely review of research projects with respect to their ethical acceptability and granting EC to the research projects that are scientifically and ethically valid.

3.2. Providing ethical advice for research projects.

3.3. Prescribing the relevant principles and standard procedures that govern research projects, including those involving tissue samples and/or personal records.

4. SCOPE OF RESPONSIBILITIES OF THE ERC

4.1. Ensuring that the welfare of the participants is not affected by the research activities.

4.2. Research protocols submitted to ERC shall be reviewed for ethical clearance prior to being conducted.

4.3. The ERC is responsible for granting ethical clearance or suggesting appropriate modification to an application.

4.4. The ERC can withdraw or suspend the ethical clearance given, with sufficient reasons if necessary.

4.5. Maintaining the minutes and documents relating to reviews, including decisions, dissents and rationale within the organization.

4.6. The ERC will maintain a continuous contact with the researchers involved in approved projects by obtaining regular progress reports on updates of their research and completion reports.

4.7. The ERC may provide support to the researchers for ongoing researches on ethical issues.
5. STATUS OF THE ERC

5.1. Ethics review committee is an independent subcommittee of the Faculty Board of Faculty of Medicine, approved by the Senate of the University of Jaffna to have the authority on behalf of the University of Jaffna to:

- give ethical clearance for the conduct of ethically acceptable research.
- suggest amendments to research.
- suspend the ethical clearance.
- withdraw the ethical clearance given.

6. ACCOUNTABILITY OF THE ERC

6.1. The ERC is accountable to the Board of Faculty of Medicine and the Senate of the University of Jaffna.

6.2. The extract of the minutes of each ERC meeting shall be forwarded to the Faculty Board.

6.3. The ERC shall provide an annual report to the Faculty Board at the end of each calendar year, which shall include information on membership, the number of protocols reviewed, status of protocols, a description of any complaints received and their outcome, and general issues raised.

6.4. The ERC may bring, from time to time to the attention of the Dean and the Faculty Board issues of significant concern.

6.5. The ERC’s Terms of Reference, Standard Operating Procedures and names and professions of the members shall be available for the public.
7. COMPOSITION OF THE ERC AND APPOINTMENT OF MEMBERS

7.1. Composition of the ERC

7.1.1. The composition of the ERC shall be in accordance with the relevant Guidelines of the Forum of Ethics Review Committee in Sri Lanka and the international guidelines:

- 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

7.1.2. Chairperson and a Secretary will be elected from among the members annually.

7.2. Terms of Appointment of Members to the ERC

7.2.1. Members shall be appointed by the Faculty Board for the period of three years. They can be reappointed at the end of the term. One third of the members will be appointed every year to maintain continuity. One third of the members to be replaced at the end of first and second years will be determined by the attendance at the meetings i.e. replacement would be considered for the member absent most.
7.2.2. Membership shall lapse if a member fails to attend three consecutive meetings of the ERC without excuse. The Chairperson shall notify the member in writing of such lapse of membership and steps shall be taken to fill the vacancy of such member.

7.2.3. Each member should give a letter of consent for membership and sign a confidentiality agreement undertaking;

- that all matters of which he/she becomes aware during the course of his/her work on the ERC shall be kept confidential;
- that any conflicts of interest which exist or may arise during his/her tenure on the ERC shall be declared;
- that he/she has not been subject to any criminal conviction or disciplinary action which may prejudice his/her standing as a ERC member.

7.2.4. A member may resign from the ERC at any time by giving three months advance notice in writing to the Chairperson. It will be discussed at the ERC level and another person can be suggested by the ERC. Later this notice will be placed at the Faculty Board for approval and filling the vacancy.

7.2.5. Members must agree to their names and professions being made publicly available.

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

7.2.7. Members 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 Faculty Board, if appropriate.

7.2.8. 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

7.3. Orientation of New Members to the ERC

7.3.1. New ERC members will be provided with adequate orientation.

7.4. Subcommittees

7.4.1. The ERC may appoint sub-committees from the members and / or external experts whenever necessary.

8. CONDUCT OF BUSINESS

8.1. Submissions, Notifications and Approvals

8.1.1. Guidelines shall be made available to the applicants in the preparation of their applications.

8.1.2. All applications for ethical clearance must be submitted to the relevant official of the ERC, by closing date, in writing in the format approved from time to time by the ERC and shall include such documentation as the ERC may specify.

8.1.3. The ERC may request the applicant to supply further information in relation to an application and/or request the applicant to be present at the meeting of the ERC at which the application shall be considered for the purpose of providing information and clarification from the ERC members.

8.1.4. The ERC shall consider every completed application which it receives on or before 1st of every month at its next available meeting. The secretary shall circulate the list of completed applications received with the agenda.
of the meeting to all members of the ERC at least five (5) days prior to the next meeting. Incomplete applications shall be returned to the applicants.

8.1.5. A subcommittee consisting the chairperson or nominee, secretary or nominee and another member of ERC will meet on the first working day following 1st of each month to appoint the reviewers. For applications received after 1st of the month will be reviewed at the ERC meeting of the following month. For each application minimum of 3 primary reviewers will be appointed by the subcommittee. It is preferable to have all 3 primary reviewers from the members of 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.

8.1.6. The reviewers’ comments will be discussed at the very next meeting to arrive at a decision.

8.1.7. The ERC may take into account the opinions or decisions of another ethics review committee in relation to a research protocol to arrive at a decision;

8.1.7.1. Decision of another ERC of a research protocol will be considered in approving or rejecting the protocol.

8.1.7.2. ERC may seek opinion from other ERCs if need arises.

8.1.7.3. To facilitate multi-center research the ERC may:

- communicate with any other ERC.
- accept a scientific/technical and/or ethical assessment of the research by another ERC.

8.1.8. The ERC shall promptly notify the applicant its decisions in writing. If the ERC has granted clearance, it shall inform the applicant in writing that the research may be commenced. Notification of ERC decisions shall normally be sent within five (5) working days.
8.1.9. Response from the principal investigator (PI) to ERC’s comments should be received within 3 months from the date of communication of ERC. If the PI does not respond within 3 months the application concerned will lapse. In such circumstance if the ethical clearance is desired for the same project a fresh application has to be submitted.

8.1.10. The PI should send progress reports at the end of each year if the project duration is more than one year and the completion report should be sent at the end of the completion of the project to ensure compliance of ethical issues.

8.2. Exemption from ethical review

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.

8.3. Expedited review

8.3.1. The ERC will consider for expedited review of the projects with minimal risk and non-sensitive issues such as collection of secondary data, Studies on the effectiveness of educational methods and curricula, projects evaluating the public benefits of existing programmes and impact of changes in programmes without intervention.

8.3.2. The ERC may establish a subcommittee, consisting of at least the Chairperson (or nominee), Secretary (or nominee) and another ERC member may undertake expedited review of research protocols between scheduled meetings at the discretion of the Chairperson. The subcommittee may seek advice from other ERC members, as appropriate, before reaching a decision. If ethical clearance is granted, it shall be considered for ratification at the next ERC meeting.
8.3.3. The subcommittee may consider other applications for expedited review that are considered to be of minimal risk to participants such as expected non serious adverse events, protocol reports, minor amendments and the like. The minutes of any such meetings shall be tabled for ratification at the next ERC meeting.

8.4. Undergraduate Researches

8.4.1. Applications must be submitted under the responsibility of a qualified supervisor.

8.4.2. Undergraduate research projects should come through the department concerned.

8.4.3. Such projects are reviewed by the subcommittee comprising the Chairperson and secretary of ERC and an expert from the department concerned.

8.4.4. Decision of the ERC will be communicated to the Head of the concerned Department.

8.4.5. Once the ethical clearance is given the department concerned will be responsible for the conduct and monitoring of the project.

8.5. Postgraduate Student Researches

8.5.1. Postgraduate student proposals 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
8.6. **Collaborative Researches**

8.6.1. In the case of international collaborative researches following documents should be submitted with the application;

8.6.1.1. Evidences for prior 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.

8.6.1.2. Ethical clearance certificate from the country of collaborator.

8.6.2. Transfer of biological or genetic materials should follow the standards drawn by this country.

8.6.3. The ownership of the data and right of publication should lie with the researcher who collects the data. In the case of multicenter research data must be pooled for publication, but, researchers from Sri Lanka should be allowed to publish data collected by them that of relevance to this country.

8.7. **Ethical clearance**

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.

8.8. **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.
8.9. Meetings of ERC

8.9.1. 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 ERC is at least five (5) members to arrive at a decision (at least one member with primary area of expertise is in a non-scientific area).

8.9.2. The ERC shall be free to consult any outside expert to provide advice and assistance in the review of any research protocol submitted to it subject to the person(s) having no conflict of interest.

8.9.3. ERC meets on a regular basis, which is normally at monthly intervals.

8.9.4. Meeting dates and agenda will be circulated to members.

8.9.5. 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 the matter. All declarations of interest and abstinence of the member concerned will be recorded.

8.9.6. 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.

8.10. Records

8.10.1. The secretary and a designated official of the ERC shall prepare and maintain written records of the ERC’s activities, including agendas and minutes of all meetings of the ERC.

8.10.2. The secretary and/or a designated official of the ERC shall prepare and maintain a file for each application received including a copy of the
application, and any relevant correspondence including that between the applicant and the ERC.

8.10.3. Files shall be kept securely and confidentially.

8.10.4. Records shall be held for sufficient time to allow future reference. The minimum period for retention is at least five years from the date of completion of a project but for specific types of research, such as clinical trials, 15 years shall apply. Files which are no longer required for retention shall be electronically archived.

8.10.5. The ERC shall maintain a register of all the applications received and reviewed in accordance with the Guidelines of the Forum of Ethics Review Committees-Sri Lanka and other relevant national and international guidelines.

9. POST-APPROVAL RESPONSIBILITIES OF THE ERC

9.1. The ERC will, as a condition of approval of each project, require that investigators immediately report any significant changes which might warrant review of ethical approval of the project, including:

- proposed changes in the research protocol or conduct.
- unforeseen events that might affect continued ethical acceptability of the project.

10. COMPLAINTS

10.1. Complaints concerning ERC’s Operating Procedures

10.1.1. 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.
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. The Chairperson will provide to the Dean/the Vice chancellor or his/her nominee all relevant information about the complaint/concern and the course of action. The Dean/ the Vice Chancellor or his/her nominee will determine whether there is to be a further investigation into the complaint. If it is decided that there is to be any further investigation, then the Dean/ the Vice Chancellor or his/her nominee will convene a suitable panel to review the complaint, ensuring that both the complainant and the ERC are afforded the opportunity to make submissions.

10.1.2. In conducting its review, the panel shall be concerned with ascertaining whether the ERC acted in accordance with TOR and then the National guidelines.

10.1.3. Community complaint from third party or subject can be submitted to chairperson of ERC or to the Dean/ the Vice Chancellor.

10.2. Complaints concerning the Conduct of a Project Approved by the ERC

10.2.1. 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 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.

10.3. Complaints concerning the ERC’s Decision

10.3.1. The Principal Investigator may submit a written request with an explanation for reconsideration of an ERC decision not granting ethical clearance. The Chairperson and 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 and, if necessary, an informal meeting of the ERC and the Principal Investigator will be held. 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.

10.3.2. A person with a complaint about the ERC’s rejection of his/her application should bring the complaint to the attention of the Chairperson of the ERC, detailing the grounds of the complaint. Complaints may also be made to the Vice Chancellor. The Chairperson shall notify the Vice Chancellor of the complaint as soon as possible. The Vice Chancellor shall notify the Chairperson of any complaints received by him/ her as soon as possible. The Chairperson shall investigate the complaint and its validity, and recommend to the ERC on the appropriate course of action at its next meeting. At the Chairperson’s discretion, the complainant may be invited to attend the next ERC meeting, or the complainant may request the
opportunity to attend. The complainant shall be informed of the ERC’s response in writing, normally within seven (7) working days of the ERC meeting. If the complainant is not satisfied with the action taken by the ERC, then he / she can refer the complaint to the Vice Chancellor or request the Chairperson to do so. The Chairperson shall provide to the Vice Chancellor all relevant information about the complaint. The Vice Chancellor shall determine whether there is to be a further investigation of the complaint. If it is decided that there is a valid case for investigation, then the Vice Chancellor shall convene a suitable panel to review the complaint, ensuring that both the complainant and the ERC are afforded the opportunity to make submissions. The outcomes of this process may include:

- The complaint/concern is dismissed.
- The complaint/concern is referred back to the ERC for consideration, bearing in mind the findings of the panel.
- The application may be referred for external review by an independent ERC if the Vice Chancellor concludes that due process has not been followed by the ERC in reaching its decision.

10.3.3. Should the ERC be requested to review its decision, then the outcome of this review by the ERC shall be final. In accordance with section 5, the panel or the Vice Chancellor cannot substitute its approval for the approval of the ERC.
11. REVIEW / AMENDMENT OF TERMS OF REFERENCE OF ERC

11.1. The ERC shall review the Terms of Reference once in 2 years and propose changes to the Faculty Board for approval if appropriate.

11.2. Members of the ERC may from time to time propose changes to the Terms of Reference for review by the ERC. If considered acceptable, such changes shall be forwarded to the Faculty Board for approval if appropriate.