

## **Ethics review policy of the Open University of Sri Lanka**

### **1. Policy statement/ Preamble**

The ERC OUSL was established to ensure the highest ethical standards in the conduct of research by staff and students of the University. The purpose, objectives, scope, composition and Terms of Reference) of the ERC are outlined below.

The primary objective of the ERC- OUSL is to protect the welfare, rights, dignity and safety of human and non-human participants used in research. The Open University of Sri Lanka firmly believe research that override the health, well-being, and care of research participants should never be permitted. This also takes into consideration the principle of justice. Justice which requires that the benefits of research be distributed fairly among all groups in society, taking into account age, gender, economic status, culture and ethnic considerations. ERC- OUSL shall provide independent, competent and timely review of the ethics of proposed studies.

In their composition, procedures, and decision-making, ERC- OUSL needs to ensure independence from externally imposed conditions to the best of its ability.

### **2. Purpose**

To describe the overall function and scope of responsibilities of the ERC- OUSL to safeguard the dignity, rights, safety, and well-being of all actual or potential research participants.

### **3. Objectives**

- To maintain ethical standards of best practices in the conduct of research by protecting the welfare, dignity and rights of all research participants and researchers
- To ensure that animals which are used in research are treated humanely
- To create awareness of ethical issues arising from research and develop relevant guidelines and procedures
- To contribute to the highest standards in the conduct of research
- To develop relevant guidelines and procedures that will contribute to the highest standards of research
- To enlighten the scientific community on the need to adhere to proposed ethical framework

### **4. Scope**

The ERC- OUSL will be mandated to review any research study that involves humans and non-human subjects, biological samples and data for their ethical acceptability in a timely and transparent manner.

## **5. Composition of the ERC- OUSL**

The ERC- OUSL will comprise 18 members representing the following categories:

- a) The Chairperson of ERC – OUSL will be Director /Research
- b) Nine (9) members who are Senior Professors/ Professors from each Faculty as follows: 2 from the Faculty of Health Sciences, 2 from the Faculty of Humanities and Social Sciences, 1 from the Faculty of Natural sciences, 1 from the Faculty of Education and 1 from the Faculty of Engineering Technology, 1 from the Faculty of Management and 1 from Post Graduate Institute of English (In case no Senior Professor/ Professor is available in a Faculty, a Senior Lecturer shall be nominated).
- c) Six (6) members from external institutions representing the following disciplines,
  - i) Medical Sciences, ii) Natural Sciences, iii) Law, iv) Allied Health Sciences, v) Social Sciences vi) Information Technology
- d) A member with expertise in statistics
- e) Legal Officer of OUSL
- f) A lay member

## **6. Appointment and Responsibilities of members**

### **Appointment**

All members (including b, c, d and e above) are to be nominated by the relevant Faculties and appointed by the Senate of the OUSL. Each member shall be appointed for a period of three years with provision for re-appointment, and renewable at the discretion of the Faculty Board for not more than two consecutive terms. The committee shall elect its Secretary from amongst its members. The ERC- OUSL shall have provision to seek expert advice outside the membership, if needed.

The letters of appointment shall be issued by the Vice- Chancellor.

The letter of appointment shall include the date of appointment, length of tenure, responsibilities/ Terms of References.

Members shall agree to their name and profession being made available to the public, (e.g., on the ERC- OUSL website).

Upon appointment, members shall be provided with the Terms of Reference of the ERC- OUSL, an up-to-date list of names of members and their contact information and any other relevant information about the processes and procedures of ERC- OUSL and proposals.

Appointments shall allow for continuity, the development of expertise within the ERC- OUSL, and the regular input of fresh ideas and approaches. All members are encouraged to attend education and training sessions.

## **7. Conflicts of interests**

Members shall be required to sign a confidential agreement and a declaration of Conflicts of Interest stating inter alia, 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.

## **8. Attendance and Remuneration**

Members will be expected to participate in regular meetings and other relevant specialised working groups as required.

The Chairperson shall participate at these meetings when required.

Members may seek a leave of absence from the ERC for a period not exceeding six months.

Membership will lapse if a member fails to attend three consecutive meetings of the ERC or fails to attend at least 2/3rds of scheduled ERC meetings each year without reasonable excuse/apology. A member may resign from the ERC at any time upon giving one month notice in writing.

In the event that membership has lapsed, the Chairperson shall notify the member of such lapse of membership in writing. Steps shall be taken to fill such vacancy having duly informed the Vice-Chancellor.

External members shall be paid an honorarium and travelling expenses.

## **9. Terms of Reference / Responsibility**

It is the responsibility of the members of ERC- OUSL to read, understand, and respect the rules set by ERC- OUSL.

### **Detailed functions**

#### **Overall function**

The ERC- OUSL is responsible for carrying out the review of proposed research before the commencement of the research. The ERC is responsible for acting in the full interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers.

The functions of the ERC are:

- i) To consider written applications and provide independent, competent and timely review and monitoring of the ethics of research projects involving human and non-human subjects, biological samples and data.
- ii) To be available to researchers for consultation on ethical issues

- iii) To develop guidelines and Standard Operating Procedures (SOPs) for ethics review and ethical conduct of research, as per the national/ international guidelines.
- iv) To work out the principles and procedures that govern research projects involving biological, clinical, psychological or social processes in human beings.
- v) To report at least once in three months to the Senate of its proceedings.
- vi) To conduct and promote education and training in research ethics for both staff and students in collaboration with SDC
- vii) To train committee members to ensure the quality and consistency of ethics review

10. The terms “human subjects” and “non – human subjects” relate to those who are among the living as well as those who are dead included in a study. ERC-OUSL should be receptive to diverse methods to be employed in studies and shall not be limited to the methods listed below:

- i. Surveys, interviews, focus groups or ethnographic observations.
- ii. Review of medical records where there is access to personal information.  
Interventional studies including psychological, physiological or medical treatment/testing
- lii. Collection of data from registries, repositories or databases where personal health/ medical information are stored and/or
- iv. Use of biological specimens (tissues, biopsies, organs, blood, urine, saliva, faeces).

## **11. References**

Standard Operating Procedure of the Ethical Review Committee of the Faculty of Medicine, University of Peradeniya, Sri Lanka.