Lahore University of Management Sciences

Institutional Review Board

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Document Change Record

Author	Version Number	Change Reference	Signature	Date
OR	00		Dr. Shafay Shamail	
OR	01	Change of Department Name	Dr. Saad Azmat	March 11, 2020

Approvals

Name	Designations	Signature	Date
URC	Convener, URC	Dr. Amir Faisal	September 24, 2018
URC	Convener, URC	Mr. Uzair Kayani	June 20, 2020

1. Purpose of Policy

The purpose of this policy is to provide a comprehensive standard of protection and humane care for human subjects and animals used in research respectively. Moreover, it also deals with the research and academic activities involving biosafety issues.

2. Scope of Policy

LUMS Institutional Review Board (IRB) is responsible for overseeing all research activities that involve the use of human subjects and animals or issues related to biosafety. This policy is applicable to any member of the LUMS community carrying out research or an external researcher carrying out research at LUMS or on subjects recruited from LUMS.

3. Definitions

Human Subjects

Human subjects are defined as living individuals about whom a researcher conducting research obtains:

1. Data through intervention or interaction with the individual; or
2. Identifiable private information i.e. information about behaviour that occurs in a context in which a subject would reasonably expect that no observation would take place and which has been provided for specific purposes by a subject and which the subject can reasonably expect will not be made public (for example a medical record).

4. Policy Statement

4.1 Responsibilities of the IRB

4.1.1 Research Involving Human Subjects

LUMS agrees with the philosophies laid out in Helsinki Declaration, Nuremberg Code and Belmont Report for all research activities that include human subjects. The rights and welfare of humans must be safeguarded at all times, regardless of their age, gender, sect, religious affiliation and socio-economic and disease status.

The IRB conducts the initial review, approval and the continuing review of research involving the participation of human subjects. All reviews are conducted for the purpose of protecting the rights and welfare of human subjects involved in the research and to assist the Principal Investigator (PI) and the University in their mutual obligation to comply with all government regulations and LUMS policies with respect to these subjects.

4.1.2 Research Involving Animals

Research studies involving purchase or use of animals require approval from IRB to ascertain that they are handled, treated, kept and euthanized in as humane a manner as possible. All such activities shall be undertaken only after review and approval by the IRB and must comply with all related government regulations and LUMS policies.

4.1.3 Issues Related to Biosafety

IRB is responsible for all biosafety aspects of University teaching and research programs. The specific responsibilities of IRB in this regard are as follows:

1. Conducting short training course(s) intended to educate research workers about conditions, requirements and restrictions which must be followed for safe handling of biohazardous materials. In this regard, IRB appoints or designates a Biosafety Officer who is responsible for:

1.1. Training individuals in procuring, handling, using and disposing of radioactive substances, and potentially biohazardous chemicals and biological;

1.2. Taking appropriate and timely action and recommending procedures in the event of an accident (e.g. accidental spill, contamination etc.) or theft of harmful substances;

1.3. Reporting to the IRB any irregularities, violations, accidents and illnesses caused by mishandling of human subjects, animals and biohazardous materials; and

1.4. Offering periodic training, education, advice and guidance to investigators who intend to embark on studies involving the use of human subjects, animals or potentially harmful substances.

2. Authorization of the designated Biosafety Officer from IRB is required before an individual is allowed to handle biohazardous substances;
3. Provision of guidelines on to how and where biohazardous materials are to be stored and disposed in the laboratory and university premises;
4. Review of applications that involve use and disposal of radioactive chemical or biohazardous substances on LUMS premises; and
5. Periodical review of exposures of individuals to biohazardous substances and records of purchase, transfer or disposal of biological materials.

4.1.4 Other Responsibilities

Other responsibilities of the IRB include:

1. To liaise between the sponsor or regulatory body and the University in the matters outlined above;
2. To recommend and initiate remedial actions through LUMS policy on research misconduct when policies and procedures relevant to IRB are not adhered to by a PI or one or more members of research team. However, if necessary, IRB may terminate a project on its own accord; and
3. To be involved in the planning or renovation of buildings in which laboratories will be housed to recommend inclusion of designated areas in which radioactive and biohazardous materials or

animals will be stored and kept, used and disposed. In this regard, IRB may make recommendations about key issues such as ventilation and exhaust systems, surface finishes in laboratories and cabinet selection for housing animals, and storing radioactive, flammable and hazardous materials.

4.2 Application Submission and Processing

Prior to embarking on a project, PIs of all studies involving the use of human subjects, animals or issues related to biosafety must submit their applications to IRB through the Office of Research (OR). IRB serves autonomously and functions independently without being influenced by external forces and has the rights to approve or reject a proposal or suspend or terminate approval of an ongoing research. No individual at LUMS or peripherally affiliated with the institution may approve research that has been rejected by IRB.

If the research methodology involves data collection from the human subjects, the draft questionnaire must also be enclosed with the application along with any information that PI might deem pertinent to the proposed research. If the research study involves any collaborators, an IRB ethics approval from the collaborator's organization must also be submitted along with the application form.

Applications are accepted on a rolling basis and decisions are communicated to PI within four weeks after submission. Applications requiring expeditious review may be processed within one week after receipt.

IRB Convener decides the mechanism for processing of an IRB application which may be one of the following:

1. Application is reviewed by the IRB Convener;
2. Application is reviewed expeditiously through a short board of IRB to cater for any time constraints; or
3. Application is reviewed by full board of IRB.

If needed, an application may be circulated electronically to all IRB members. IRB may also ask the PI to present or clarify certain aspects of the proposal during its review.

Following decisions may be taken in respect of an IRB application:

1. Application may be declared exempt from review by the IRB convener;
2. Application may be approved along with any conditions imposed by IRB;
3. Application requiring further clarification or more details is returned with comments and PI is expected to submit a revised application within four weeks. This process continues for as long as necessary until the IRB is satisfied with the protocol; or
4. Application may be rejected.

Decision to approve or reject a submission is based on majority vote and may be time bound. Decisions on submissions are conveyed by the IRB Convener to OR.

Furthermore, to ascertain that the procedure(s) proposed in the approved application are adhered to by the PI, IRB may exercise surveillance as it deems appropriate at any time after granting approval.

4.3 Consent of the Participants and Respondents

If the research methodology involves data collection from the human subjects, a consent form must be signed by all the participants and respondents of the research study. If some or all respondents of the study are uneducated, an Urdu translation of consent form is required and should be signed by the participants. If some or all respondents are under the age of eighteen, the consent form must also be signed by the parents or guardian of the participant.

4.4 Modification or Termination of Research

All PIs are expected to strongly adhere to the IRB approved protocols involving use of human subjects or animals. After an application has been approved, no part of the study design or procedure may be modified without the written permission of the IRB. PIs wanting to introduce changes in one or more protocols that were previously approved may do so by filling out and submitting the IRB modification form along with the details of modification e.g. revised questionnaire.

Upon termination of a research activity involving human or animal subjects or issues related to biosafety, a PI must submit IRB termination form and copies of consent forms along with other required documents to the OR indicating closure of research activity.

4.4.1 Modification of Research Procedure

Sr. No.	Responsibility	Procedure / Activity	Output
1	PI	PI forwards IRB modification form along with any revised documents to the Relevant Personnel (OR).	IRB modification form
2	Relevant Personnel (OR)	Relevant Personnel (OR) forwards the IRB modification form for IRB approval to IRB Convener.	IRB modification form
3	IRB Convener	IRB Convener proceeds with the approval of the proposed modification as per applicable LUMS policies and conveys the decision to the Relevant Personnel (OR).	Email/letter containing IRB's decision
4	Relevant Personnel (OR)	Relevant Personnel (OR) conveys the decision of IRB to the concerned PI through email.	Email containing IRB's decision

4.5 Financial and Administrative Support

IRB is administratively and financially supported by the OR. OR is responsible for safekeeping of contemporary and historical records of all applications received. It also maintains records of IRB meeting minutes, actions taken, protocols reviewed and other documents related to IRB activities.

5. Waiver of Policy

In exceptional cases, and on a showing of good cause, the Vice Chancellor or his designated authority may waive a policy or procedural requirement. A waiver must be granted in writing and be specific to each case. The written request for a waiver should be timely communicated to the Office of Research (OR). Repeated waivers of any requirement shall prompt a policy review of that requirement under the LUMS governance structure. To show good cause, the written waiver shall provide reasonable justifications that:

1. The requirement being waived is impossible or impracticable;
2. The waiver does not violate any applicable law; and
3. The waiver is fair, in the best interest of the University, and narrowly tailored to address an exceptional case.

6. Special Circumstances/Exceptions

No special circumstances are identified in this policy. Each identified case of misconduct will be reviewed on its own merit.

7. Roles and Responsibilities of Policy Implementation

The major responsibilities that each party has in connection with this policy are as follows:

PI is responsible for:

1. Submission of IRB related forms to OR;
2. Compliance with all conditions and reporting or training requirements imposed by the IRB; and
3. Ensuring that human subjects or animals involved in all undertaken research activities receive proper treatment.

OR is responsible for:

1. Coordinating the overall process for IRB approval;
2. Announcing IRB decision to concerned PI; and
3. Providing financial and administrative support to IRB.

IRB is responsible for:

1. Initial review, approval and the continuing review of research and academic activities under its purview;
2. Liaison between the sponsor or regulatory body and the University in the matters outlined above; and
3. Recommending and initiating remedial actions against violators of this policy.

8. Title of Position with Maintenance Responsibility

OR will be responsible for maintenance of the policy including its periodic review and approval of any subsequent modifications to the said policy.

9. Consequence(s) of Non-Compliance with Policy

Each instance of non-compliance will be referred to University Research Council (URC) for review, which will finalize its recommendations for the action to be taken by VC. In all cases, the decision of VC will be final.

10. Related Documents / Policies

1. OSP-308-02 – IRB – Application Guidelines;
2. OSP-308-03 – IRB – New Application Form;
3. OSP-308-04 – IRB – Consent Form;
4. OSP-308-05 – IRB – Modification Form; and
5. OSP-308-06 – IRB – Termination Request Form.

11. Related Laws

It is mandatory to abide by all laws and regulations as applicable in Pakistan. In certain circumstances, sponsors may require compliance with certain laws and their own statutory regulations as well.

12. Distribution & Physical Security

Access to these Policies & Procedures on the intranet portal shall be restricted and access shall be provided by Director of OR through following LUMS Access Management Process. For further information, refer Access Management Policies & Procedures. However, in case a hard copy is required, printing rights shall be granted to the respective stakeholder as part of standard Access Management Process. System shall track the number of hard copies printed against each Login ID and shall maintain log as well.

Where there is a change in responsibility of an employee, the copy / access that the employee has of policy document should be handed over to the new employee and this action shall be documented in the previous employee's handing over notes. When an employee leaves the employment of LUMS, then the copy of/access to policy document should be returned to/ revoked by the Head of Department / IT Department prior to his departure.

13. Contacts

Contact	Designation	Phone
Office of Research (OR)	Director	8336, 8207, 8042