

LIAQUAT UNIVERSITY OF MEDICAL & HEALTH SCIENCES -

Ethics Review Committee

Terms of Reference

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Ethics Review Committee -Terms of Reference

1. TITLE

Liaquat University of Medical & Health Sciences Ethics review Committee (ERC)

2. RESPONSIBILITIES OF THE COMMITTEE

2.1 The Ethics research Committee (ERC) has responsibility to consider the ethical implications of proposed human research studies conducted at the University, or by staff or students at any site and determine whether or not they are acceptable on ethical grounds.

2.2 TheERC shall:

- Review and approve (with or without modification) or withhold approval, proposals for research on human subjects tissue, products, foetus or genetic material from human subjects, whether dead or alive by the University's faculty members, students or visiting scholars, on the basis of ethical considerations.
- Advocate, encourage and monitor "best practice" ethical standards in research; protect subjects of research from unnecessary harm; preserve the rights of the subjects and provide reassurance, where required, to the public that this is being done.
- Undertake a regular review of the ongoing research for any unethical practices.
- Record in database, information pertaining to all research proposals including name, address and qualifications of the Principal Investigator(s), the financial sponsor, title of the project, research methodology and the research objectives.

3. ERC MANDATE

All research taking place at LUMHS or by its staff or students at any site, which involves human subjects, tissue, products, foetus or genetic material from human subjects, whether dead or alive, will need approval by the ERC before the research can commence.

3. WORKING OF ERC

3.1 **Administrative Structure:**

Chairman, who heads the committee and calls the meetings,

Co-Chair, who Chairs the meetings and acts in the capacity of the Chair in his/her absence,

Coordinator, assigns primary reviewers in consultation with the Chair/Co-Chair and receives and reviews all the protocols, maintains the record in his safe custody, and maintains follow-up as and when necessary,

Secretary, who will be a full member and will be responsible for taking the minutes which will be sent to the Coordinator for his/her input within 48 hours of the meeting in order to ensure accuracy and efficiency.

3.2 **Record keeping/archiving:** The Secretary together with the Coordinator will be responsi-

ble for the record keeping. The Coordinator will be responsible for safe archiving of the records.

- 3.3 Reporting Relationship:** The Chair/Co-Chair, together with the Coordinator will report directly to the Vice Chancellor of LUMHS on a periodic basis.

4. MEMBERSHIP

- 4.1 Mechanism of Appointment of Chair:** By nomination by the Vice Chancellor LUMHS for the first time and then by consensus of the ERC members.
- 4.2 Mechanism of Appointment of the Co-Chair:** By nomination of the Chair ERC for the first time and then by consensus of the ERC members.
- 4.3 Tenure of Chairman/Co-Chair:** 3 years, but both to retire separately to ensure continuity.
- 4.4 Number of ERC members:** 12 to 14. One University academic staff member from each faculty with knowledge of, and current experience in research involving one or more of the disciplines covered.
- 4.5 Mechanism of Appointment of Members:** New members will be appointed by the Chair/Co-Chair and existing ERC members.
- 4.6 Tenure of Membership:** 2 years with only half of the members retiring after the first cycle of one year. Members will draw straws to see who retires.
- 4.7 Mechanism of Appointment of the Coordinator:** By nomination by the Vice Chancellor LUMHS for the first time and then by nomination by the Chair/Co-Chair and members.
- 4.8 Tenure of the Coordinator:** 3 years in order to ensure continuity.
- 4.9 Reappointment for Members/Chair/Co-Chair:** Chair/Co-Chair/Coordinator and members have no limit for re-appointment.
- 4.10 Lay Members:** At least one lay member (non-medical person of good standing)
- 4.11 Revocation of Membership:** If a member is absent for three (3) consecutive meetings without assigning a reason, despite being informed of the meeting, he/she will have her membership revoked.
- 4.12 Gender Balance:** Efforts should be made to maintain gender balance; At least one woman should be member of the ERC at any one time.

5. MEETINGS

- 5.1 Responsibility:** The secretary, in consultation with the Coordinator.
- 5.2 Quorum:** The quorum for a meeting of the Committee is:
- Where there is an odd number of members, a majority of members; or
 - Where there is an even number of members, the half of members plus one.

- 5.3 **Frequency of Meetings:** Thrice in a year.
- 5.4 **Minutes of the Meeting:** Responsibility of the Secretary
- 5.5 **Archiving:** The Coordinator will be responsible for archiving of the proceedings in his/her safe keeping.

6. MECHANISM OF REVIEW

- 6.1 **Regular Protocols**
 - 6.1.1 **Mechanism of submission of Protocols:** Protocols will be submitted to the Coordinator who is responsible to assign reviewers, in consultation with the Chair/Co-chair.
 - 6.1.2 **Mechanism of preliminary review:** Two primary reviewers for each protocol.
 - 6.1.3 **Presentation to full committee:** The two reviewers will present their respective opinions independently and without prior mutual consultation to the ERC members.
- 6.2 **Zero Risk Protocols:**
 - 6.2.1 **Review:** Review by Chair/Co-Chair (or person designated) and the Coordinator.
 - 6.2.2 **Ratification:** Such approvals/review to be submitted to regular meetings for ratification.
- 6.3 **PI's Involvement in Meetings:** As and when needed, PI can be invited to the meeting.
- 6.4 **Maximum Duration for a review:** Within 2 meetings with efforts to include in the next meeting.
- 6.5 **Decision Making Process:** Consensus, with open discussion. In case of deadlock, Chair/Co-Chair's opinion will be binding.
- 6.6 **Declaration of Interest:** Committee member must inform the Chair if they have a financial or personal interest in a research proposal. The Chair will decide whether the interest disqualifies the member from discussion. Members have to step out of the room if their own or of their candidate/student's proposal is under review/discussion.
- 6.7 **Specialist Advice:** The Chair/Co-Chair may invite an individual to attend a particular meeting/s to give specialist advice to the committee. Such individuals should not participate in the final decision of the Committee.
- 6.8 **Chair:** If the Chair or deputy Chair is not present at the meeting, the Committee may elect one of the members present to act as a Chair.
- 6.9 **Appeal Process:** Reviewers will be allowed to appeal to the ERC for any reviews deemed unfavourable by them.

- 6.9 Duration of Approval of a Project:** One year, at the end of which the PI should submit a progress report following which the approval may be extended if required.
- 6.10 Cancellation of Approval:** The ERC will have the authority to cancel approval if a progress report is not submitted even after it is sought. The approval may also be withdrawn if new risks/side effects are revealed. The approval may also be withdrawn if the ERC comes to know of misconduct by the PI, breaching contract of trust between the PI and the ERC. In such circumstances, the ERC will have the right to inform the funding agency of the withdrawal of approval.
- 6.11 Mechanism of Informing PI:** The PI will be informed through an official letter sent by the Chair.

7. POWERS OF THE COMMITTEE

- 7.1** The Committee may:
- Revoke approval if dissatisfied with the conduct of the research or of the researcher
 - Reject the research proposal in whole or in part
 - Defer consideration of a research proposal to a subsequent meeting if substantial modification is required or where significant additional information is needed.
 - Authorize the research to proceed without requiring any amendment.
 - Require clarification or modification of parts of the research submission. The Chair will normally be granted authority to approve the amendments without requiring further deliberations by the full Committee

8. RESPONSIBILITIES OF THE APPLICANT SUBSEQUENT TO APPROVAL

- 8.1** The applicant is responsible for:
- Reporting any adverse incident during the course of a study to the Committee, even if the incident is not directly related to the study (e.g. a complaint by a subject etc)
 - Notifying the Committee of any change in protocol and obtaining further ethical approval as appropriate.

9. CONFIDENTIALITY:

Proceedings of the meetings, the minutes and the archives are considered highly confidential and shall be maintained as such.

10. INDEMNITY:

All decisions of the ERC will have complete support of the University.

