ZIAUDDIN UNIVERSITY

Policy on Institutional Review Board (IRB)

Policy Title:	Ziauddin University Ethical Review Policy
Policy No:	Zu/Admin/Policy/ERC/01
Approved By:	Academic Council
Approval Date:	December 2024
Department	ORIC

Policy Statement

Ziauddin University is committed to maintaining the highest standards of ethical review for all research involving human and animal subjects. This policy establishes the guidelines, structures, and processes for the Institutional Review Board (IRB) and its subcommittees, ensuring compliance with national and international ethical standards while fostering a robust research environment.

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1. Purpose and Scope

1.1 To ensure all research proposals undergo rigorous ethical review.

1.2 To enhance transparency, efficiency, and consistency in the review process.

1.3 To support the growing research activities across Ziauddin University campuses.

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2. Applicable to:

1.4 Faculty-led research.

2,2 Undergraduate and postgraduate student projects.

2.3 Clinical trials and grant-funded studies.

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3. POLICY

3.1 Structure of Ethical Oversight

3.1.1 The IRB shall serve as the central body overseeing all research ethics at Ziauddin University.

3.1.2 Four ERCs shall operate under the IRB, each specializing in the following areas:

- ERC 1: Health and Nursing Sciences
- ERC 2: Allied Health and Pharmaceutical Sciences
- ERC 3: Engineering and Technology
- ERC 4: Social Sciences

3.1.3 Each ERC shall consist of 10 members, including faculty representatives, external experts, and a general member to ensure diversity and objectivity.

3.1.4 The Animal Care and Use Ethics Committee (ACUEC) will oversee research involving animals, ensuring compliance with welfare standards.

3.1.5 Regular evaluations and audits of ERC and IRB activities will ensure accountability and continuous improvement.

3.2 Types of Reviews

3.2.1 **Waiver Review (2 Days):** For low-risk projects with minimal ethical concerns.

3.2.2 **Expedited Review (1 Week):** For medium-risk studies requiring moderate scrutiny.

3.2.3 **Full Review (2 Weeks):** For high-risk studies, including clinical trials and complex research projects.

3.2.4 **Appeals Review:** For reconsidering decisions on previously rejected proposals.

3.3 Proposal Submission and Tracking

3.3.1 All proposals must be submitted via a centralized online portal managed by the IRB.

3.3.2 Submissions must include complete documentation, including informed consent forms, questionnaires, and detailed protocols.

3.3.3 Researchers can track their proposal's progress and receive updates through the portal.

3.3.4 Assistance and support for using the submission portal will be available through designated coordinators.

3.4 Ethical Review Criteria

3.4.1 Proposals will be evaluated based on:

- Risk-benefit analysis
- Participant protection and confidentiality
- Adherence to ethical standards
- Scientific validity and relevance

3.4.2 Specialized ERC panels will review proposals to ensure discipline-specific expertise is applied.

3.4.3 Additional considerations include cultural sensitivities, community engagement, and compliance with regulatory frameworks.

3.5 Responsibilities of IRB and ERCs

3.5.1 IRB:

- Coordinate and monitor ERC activities.
- Maintain oversight of ethical review processes across campuses.
- Provide training and capacity building for ERC members.
- Develop and implement policies to address emerging ethical challenges.

3.5.2 ERCs:

- Conduct detailed reviews of submitted proposals.
- Ensure compliance with SOPs and ethical standards.
- Report decisions and recommendations to the IRB.
- Maintain records of all reviewed proposals for audit purposes.

3.6 Standard Operating Procedures

3.6.1 Comprehensive SOPs will guide the following:

- Proposal submission, review, and decision-making processes.
- Monitoring and compliance for ongoing studies.
- Participant protection, including informed consent and confidentiality.
- SOPs will be periodically reviewed and updated to reflect emerging ethical issues and regulatory requirements.

3.6.2 SOPs will include a detailed escalation process for addressing non-compliance or ethical violations.

3.7 Training and Capacity Building

3.7.1 Regular workshops and seminars will be conducted to:

3.7.2 Update ERC members on national and international ethical guidelines.

3.7.3 Enhance the understanding of emerging ethical challenges.

3.7.4 Build capacity for efficient and effective reviews.

3.7.5 Training programs will be tailored to address the specific needs of ERC members, researchers, and administrative staff.

3.8 Monitoring and Reporting

3.8.1 Ongoing studies will be monitored through periodic progress reports submitted to the relevant ERC.

3.8.2 Annual reports summarizing IRB and ERC activities will be submitted to university leadership.

3.8.3 A feedback mechanism will be established to incorporate stakeholder input into the review process.

3.9 Appeals and Grievances

3.9.1 Researchers may appeal IRB/ERC decisions following the outlined procedures in the SOPs.

3.9.2 Complaints and grievances will be addressed promptly to ensure transparency and fairness.

3.9.3 An independent appeals committee will be constituted to handle unresolved disputes.

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4. STORAGE AND DOCUMENTATION

4.1 All records, including proposal submissions, meeting minutes, and correspondence, will be securely stored for a minimum of 5 years.

4.2 Access to records will be restricted to authorized personnel to maintain confidentiality.

4.3 Digital archives will include secure backups to prevent data loss.

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5. FINAL DISPOSAL

5.1 Approved research proposals will be archived electronically and physically.

5.2 Withdrawn or rejected proposals will be documented and securely disposed of after the retention period.

5.3 Disposal of records will adhere to data protection and confidentiality policies.
