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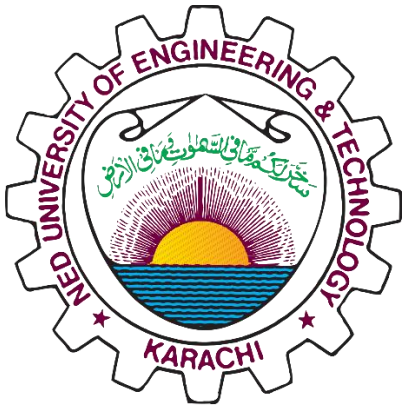

Research Ethics Policy

NED UNIVERSITY OF ENGINEERING AND TECHNOLOGY

Research Ethics Policy

NED University of Engineering and Technology

1. Preamble:

Research is essential for gathering new knowledge and for the advancement of science. It obviously involves engagement with fellow experts, ordinary human beings, involvement with private data and opinions, and sometimes animals, among many other things. Research ethics aims to ensure protection of research participants in every aspect, thereby enhancing the quality and morality of research.

2. Purpose:

The purpose of this document is to provide guidance to researchers working at NED University of Engineering and Technology, regarding the research ethics compliance, processes and procedures; with an aim to safeguard the dignity, rights, safety and wellbeing of all research participants and ensure that animals, if used for research, are treated humanely.

3. Principles:

While several international guidelines on research ethics have been developed, the key is that ethics is governed by certain key principles, which need to be consciously applied:

3.1 Volunteer participation of research participants should be ensured, free from undue influence or any coercion, and their dignity, rights, dignity and autonomy (when possible) should be respected and protected appropriately.

3.2 Research should provide value and must be sufficiently meaningful that outweighs any harm and risk. Maximum benefit of the research should be aimed by Researchers, while at the same time potential risk of harm to participants and researchers must be minimized. Potential risk and harm of all types must be robustly mitigated through appropriate precautions.

3.3 Appropriate information about methods, purpose and research intention should be provided to the Research personnel and participants – specifically about the role of their participation in the research, and what benefits and risks are involved (if any).

3.4 Preferences such as anonymity of individuals or groups as research must be respected, especially those concerning the confidential nature of information and all types of personal data must be respected.

3.5 Implementation of recognized standard of integrity must be ensured, while designing research, and must be rigorously reviewed. Quality and transparency should be reflected in research design.

3.6 All conflicts of interest or partiality must be explicitly spelled out, and the independence of research should be clear from the proposals.

4. Alignment with National and International Guidelines:

This document has been prepared in accordance with the following national and international guidelines and regulations for researches involving human subjects (primary or secondary), health and other private data, biobanks and biomaterials:

4.1 Personal Data Protection Bill 2018 – Draft, Ministry of IT

4.2 ESRC Framework for research ethics

4.3 World Health Organization: A Practical Guide for Health Researchers

4.4 World Health Organization: Standards and operational guidance for ethics review of health-related research with human participants

4.5 The Council for International Organizations of Medical Sciences (CIOMS): International ethical guidelines for health-related research involving humans

4.6 The World Medical Association (WMA): The Declaration of Helsinki- Ethical Principles for Medical Research Involving Human Subjects

4.7 World Medical Association (WMA): The Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks

5. Ethical Review Committee

5.1 An essential component of research ethics guidelines is the need for a research to be subject to prior review by a competent Ethics Review Committee or Research Ethics Committee (ERC). Independent ethical review is vital to ensure that participant safety is at the center of the research. The review by an ethics committee is one of a series of safeguards intended to protect the people taking part in the research.

5.2 Any research project being conducted by NED University employee and/or postgraduate students should be submitted to the NED University ERC for ethical review if it involves human participants (including secondary analysis of data gathered from humans) or other possible ethical risk factors, and is not being reviewed externally.

5.3 It is the responsibility of the Chairpersons of the teaching departments to review and approve applications involving undergraduate and taught postgraduate students undertaking research projects that involve human participants or other possible ethical considerations.

5.4 The aim of the ERC is to ensure that ethical considerations and issues are appropriately addressed in the conduct of research. The committee seeks to encourage and support ethically conduction of research at NED. Specific roles of the ERC are:

5.4.1 The ERC should ensure the full review and evaluation of all ethical aspects of the research proposals it receives before they are carried out to make sure they follow ethical principles.

5.4.2 The ERC should provide independent, competent and timely review of the ethics of the proposed studies

5.4.3 To review the ethics of research involving human subjects including tissue and data; and animals used in research in a biomedical setting.

5.5 Ethical Review Committee (ERC) at NED University is comprised of the following members:

Pro-Vice Chancellor	Convener
Dean, Faculty of Civil and Petroleum Engineering	Member
Dean, Faculty of Mechanical and Manufacturing Engineering	Member
Dean, Faculty of Electrical and Computer Engineering	Member
Dean, Faculty of Chemical and Process Engineering	Member
Dean, Faculty of Information Sciences and Humanities	Member
Dean, Faculty of Architecture and Management Sciences	Member
Chief Editor, NED University Journal of Research	Member
Chairperson Department of Biomedical Engineering	Member
One internal female faculty member working at least as Associate Professor, as Vice-Chancellor's nominee	Member
One external member from a Medical University	Member
Secretary ASRB	Member/Secretary

5.6 The quorum of the meeting shall be one-half, fraction being counted as one.

5.7 The committee shall meet as per the need of reviews.

5.8 All research projects involving human subjects, whether as individuals or communities, including the use of fetal material, embryos and tissues from the recently dead, undertaken or

supported faculty, staff or students, wherever conducted, shall be reviewed by the ERC before a study can begin.

5.9 The Committee shall review ethical considerations for submitted applications based on the ethical guidelines, ensuring the principles defined in this document are adequately and appropriately met. Specifically, the ERC will rest its decision based on the following:

5.9.1 Respect for an individual's capacity to make reasoned decisions, and protection of those whose capacity is impaired or who are in some way dependent or vulnerable.

5.9.2 The risks of the proposed research in respect of expected benefits, the research design and competence of the investigators having been assessed.

5.9.3 A proposal must state the purpose of the research; the reasons for using humans as the subjects; the nature and degree of all known risks to the subjects; and the means for ensuring that the subjects' consent will be adequately informed and voluntary.

5.9.4 The subjects of research should be clearly aware of the nature of the research and their position in respect of it.

5.9.5 Consent must be valid. The participants must be sufficiently informed and have adequate time to decide without pressure. Consent must be obtained from the subjects, preferably written.

5.9.6 Subjects must be able to easily withdraw from a research protocol without giving reasons and without incurring any penalty or alteration in their relationship with providers of services.

5.9.7 Specify procedures, including periodic appraisal of the progress of approved projects, for ensuring that subjects of research are protected from harm, their confidentiality is maintained, and their rights are respected.

5.9.8 The tasks of the ERC shall be executed free of bias and influence. The ERC has the authority to request research protocol modifications, enforce and monitor all informed consent or participants/animal rights issues and to suspend or stop any research that doesn’t conform to the protocol approved by the ERC.

5.9.9 The ERC shall also be involved in the on-going monitoring of conduct of research projects that are approved by it, in case necessary.

5.9.10 The ERC is responsible for acting in the interests of potential research participants and the concerned communities, taking into account the interests and needs of the researchers.

5.9.11 ERC may call for the proposal to be externally reviewed.

5.9.12 All proposals needing approvals from ASRB, shall have their ERC decisions prior to being submitted to ASRB (if applicable).

5.9.13 Working papers shall be circulated at least seven working days before the meeting and the minutes shall be issued within seven working days.

5.9.14 If no observations on minutes are received within three days, Secretary ASRB shall communicate ERC decision to the applicant, copy of which shall be sent to Registrar for record.

5.9.15 Appeals to the ERC, can be made to the Vice-Chancellor, within two weeks of the ERC decision. The Vice-Chancellor may take expert opinion as per his/her discretion. The decision of the Vice-Chancellor shall be final.

6. Documents Submission Guidelines:

6.1 All documents required for a thorough and complete review of the proposed research project should be submitted by the applicant on prescribed Application format to Secretary ASRB. As per applicability, this include, but not limited to:

6.1.1 Complete application form

6.1.2 Project Proposal

6.1.3 The data management and ethics protocol for the proposed research project, clearly identified and dated, together with supporting documents and annexes:

a) A project summary or synopsis in non-technical language

b) A description (which may be included in the protocol) of the ethical considerations involved in the proposed research

c) Background information on previous research in the same area of work that justifies and/or supports the proposal

d) When the research involves an experimental product (such as a pharmaceutical or medical device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator's brochure, published data, a summary of the product's characteristics)

e) All forms, documents, advertisements to be used in recruitment of potential participants.

f) Informed consent form(s) (with date and version number) in languages understood and at a reading level appropriate for the potential research participants and when required, in other languages

g) A description of the process that will be used to obtain and document informed consent

h) A description of measures that will be taken to ensure the protection of participants' privacy and the confidentiality of data

i) Electronic data acquisition and management plan

j) A statement describing any remuneration or other goods or services to be provided to study participants, including in-kind provisions.

6.1.4 Current curricula vitae of the principle investigator from NED.

6.1.5 Disclosure of all previous decisions (including those leading to a negative decision or modified proposal) by other ERCs or regulatory authorities for the proposed study, whether in the same location or elsewhere, and indication of the reasons for previous negative decisions and modification(s) to the proposal made on that account

6.1.6 A signed statement that the researcher(s) agree to comply with ethical principles during the course of research

6.1.7 For questions about the application format, logistics of the application process, ethical issues and application content, please contact Secretary ASRB at asrb@neduet.edu.pk

7. Definitions:

1) The term "research" refers to activities designed to develop or contribute to generalizable health knowledge within the more classic realm of research with humans, such as observational research, clinical trials, biobanking and epidemiological studies.
2) The terms "human beings", "research participants", and "human subjects" are used interchangeably
3) A Health Database is a system for collecting, organizing and storing health information.
4) A Biobank is a collection of biological material and associated data.
5) Biological material refers to a sample obtained from an individual human being, living or deceased, which can provide biological information, including genetic information, about that individual.