

Vision, Mission and Mandate

Vision

A world class University in socio-economic and technological Advancements.

Mission

To generate, disseminate and apply knowledge, while, sustaining excellence in teaching, learning and research.

Philosophy Statement

Creative, dynamic and responsive

The Pre-amble

Research dealing with human subjects as well as those related to Environmental and scientific conduct is guided by international rules and regulations the most important being the World Medical Association Declaration of Helsinki. The declaration quotes numerous other documents that deal with ethical handling of human subjects. World Health Organization (WHO) recommends the formation of Ethical Review Committees (ERCs) at Regional, National and Institutional level and has provided guidelines for ERCs.

It is in this context that Pwani University (PU) constituted the ERC in order to provide guidance to Pwani University Ethical Review Committee to review and clear biomedical Research proposals.

PWANI UNIVERSITY ETHICS REVIEW COMMITTEE OPERATIONAL GUIDELINES

Review Process

- (i) Submitted proposals will be received by the secretary of the ERC.
- (ii) The ERC will acknowledge receipt of submitted proposal to the applicants or research bodies.
- (iii) Each proposal will be assigned two reviewers whose recommendations will be discussed in an ERC general meeting.
- (iv) The reviewed proposals will be documented in a database of records (soft and hard copies).
- (v) The general meeting will procedurally adopt the recommendations and approve. The ERC decisions will be under seal and authenticated by the Chairperson, Secretary and lay member appending their signatures.
- (vi) The reviewed proposals shall be sent back with ERC recommendations to the applicants or research bodies within 21 days.

The decisions of the ERC will not be made public, but communicated to the applicant through a letter of decision accompanied by a Certificate of Approval upon acceptance by the applicant, the conditions of approval given by the ERC.



PWANI UNIVERSITY, Ethics Review Committee, PU-ERC

**The Chairman,
Ethics Review Committee,
Pwani University**
P.O. BOX 195 -80108
KILIFI – KENYA
Tel: +254-41-7525102/3/4
Fax: +254-41-7522128
Email: Chairman.erc@pu.ac.ke
Email: Secretary.erc@pu.ac.ke

ROLES OF PU-ERC

- Review and clear proposed research before its commencement
- Provide independent, competent and timely review of the ethics of proposed studies.
- Review prospective and continuing research protocols
- Take into consideration the principle of justice.
- Review adequacy of Informed consent document
- Regular evaluation of ethics of ongoing studies that received positive decision.
- Evaluate reports for unanticipated problems, non compliance and other information, that might affect approval of the protocol or subject's willingness to continue to participate.
- Act in the interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers and having due regard for the requirements of the relevant regulatory agencies and applicable laws

SUBMITTING APPLICATION

Application for proposed ethics review for biomedical research must be submitted by a qualified research team responsible for the ethical and scientific conduct of the research.

Application requirements

- Names and addresses of the ERC secretariat to whom application material is to be submitted.
- Appropriate documentation (Research Proposal, Researchers CVs and/or questionnaires, informed consent)
- The language in which document will be submitted will be English

- Application fee shall be determined by PU-ERC from time to time (refer to Table below).

Elements of Review

Plagiarism and scientific misconduct
Use and misuse of data
Management of privileged information
Scientific design and conduct of the Study
Recruitment of research participant
Care and protection of research participant
Informed Consent Process
Protection of research participant's confidentiality
Community considerations

Approval Conditions

Approval shall be given for a specified period – If project takes longer than specified period, then a request for an extension of the ethics clearance shall be sought

Approval shall be given on conditions that any alterations proposed to the approved protocol are submitted to the committee for approval prior to alterations being effected

Approval shall be given on condition, that a copy of research project final report will be submitted to ERC for its information

Approval shall be given subject to researchers notifying the ERC if and when the project is curtailed, terminated or completed.

Approval shall be given for therapeutic trials subject to the Principal Investigator (PI) notifying ERC within 7 days (A week) of any adverse events or occurrence that takes place during that trial.

Research may be audited by PU – ERC during research period to ensure compliance with guidelines

Application

The Investigator responsible to the ethical and scientific conduct of the research should submit a **typed application** for the review of the ethics of the proposed research to the following address;

**The Chairman,
Ethics Review Committee
Room 367, Administration Block
Pwani University
P.O. Box 195 -80108, Kilifi, Kenya
Email: chairman.erc@pu.ac.ke
Tell: 041-7525102/3/4 Ext 367
Website: www.pu.ac.ke**

PU-ERC Secretariat

The PU –ERC secretariat shall receive and process the application forms. The forms and guidelines for submission of proposals can be downloaded from the PU website.

PU-ERC reviewing fees (Subject to change)

Category	Amount
Undergraduate projects	Kshs. 1,000.00
Masters Projects (PU)	Kshs. 2,000.00
External Masters Projects	Kshs. 3,000.00
PhD Projects (PU)	Kshs. 3000.00
External PhD Projects	Kshs. 5,000.00
PU Staff Private Projects	Kshs. 3,000.00
External Projects	USD 500 or 0.1% of the project budget whichever is higher

The PU-ERC performs ethics review of all proposals submitted to the committee from researchers worldwide. All submitted proposals shall be reviewed within the stipulated time frame in accordance with the established review procedure.