



PWANI UNIVERSITY (PU)

ETHICS REVIEW COMMITTEE (ERC)

ERC – PU Proposal Review Process

October, 2015

Introduction

The PU-ERC is mandated to perform ethics review of all proposals submitted to the Pwani University, School of Graduate Studies, as well as all proposals to be submitted for internal funding by PU Research and Innovation Committee, to external donors, such as the National Commission for Science, Technology and Innovation (NACOSTI). All submitted proposals shall be reviewed within the stipulated time frame in accordance with the established review procedure.

Meetings

1. The ERC will conduct regular meetings on scheduled dates that will be announced in advance.
2. ERC members shall be given enough time to review the relevant documents;
3. Meetings should have minutes and there should be an approval procedure for the minutes;
4. The applicant, sponsor, and/or principal investigator may be invited to present the proposal or elaborate on specific issues;
5. Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements.

Review Process

1. Submitted proposals will be received by the secretary of the ERC.
2. The ERC will acknowledge receipt of submitted proposal to the applicants or research bodies.
3. Each proposal will be assigned two reviewers whose recommendations will be discussed in an ERC general meeting.
4. The reviewed proposals will be documented in a database of records (soft and hard copies).
5. 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.
6. The reviewed proposals shall be sent back with ERC recommendations to the applicants or research bodies within the stipulated time frame.
7. The decisions of the ERC will not be made public

CHECK LIST FOR REVIEWING PROPOSALS

The emphasis in ethical review is indicated in the checklist below.

	Review Item	Comment (evaluation of status of review item)	Remarks
1	Plagiarism and scientific misconduct		
2	Use and misuse of data		
3	Management of privileged information		
4	Scientific design and conduct of the Study		
5	Recruitment of research participant		
6	Care and protection of research participant		
7	Informed Consent Process		
8	Protection of research participant's confidentiality		
9	Community considerations		
10	Any other issue of concern		

Date of review -----

General comments: -----

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DECISION*:	COMMENTS
1. ACCEPTED	
2. ACCEPTED WITH REVISION	
3. REJECTED	

**The decision of the ERC-PUC is subject to the information available at the time of approval. The ERC reserves the right to review its decision on the grounds of discovery of new and important information which was not within its knowledge at the time of approval or on account of mistake or error apparent on the face of the record or for any other sufficient reason.*

Seal:

Chairperson: Signature _____ Date: _____

Secretary: Signature _____ Date: _____

Lay member: Signature _____ Date: _____

Decision making process

1. A member should withdraw from the meeting if a conflict of interest arises; the conflict of interest should be indicated to the chairperson prior to the review of be indicated to the chairperson prior to the review of the application and recorded in the minutes;
2. A decision may only be taken when sufficient time has been allowed for review and discussion of an application
3. Decisions should only be made at meetings with a quorum ;
4. The documents required for a full review of the application should be complete .Only members who participate in the review should participate in the decision;
5. There should be a predefined method for arriving at a decision (e.g. by consensus, by vote); it is recommended that decisions be arrived at through consensus, where possible; when a consensus appears unlikely, it is recommended that ERC vote;
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified;
7. A negative decision on an application should be supported by clearly stated reasons.
8. A decision should be communicated in writing to the applicant according to SOPs, preferably within two weeks’ time of the meeting at which the decision was made. The communication of the decision should include, but is not limited to, the following;
 - i. The exact title of the research proposal reviewed;
 - ii. The name and title of the applicant;
 - iii. The name of the site(s);

- iv. The date and place of the decision;
- v. The name of the ERC taking the decision;
- vi. A clear statement of the decision reached;
- vii. Any advice by the ERC;
- viii. In the case of conditional decision, any requirements by the ERC, including suggestions for revision and the procedure for having the application re-reviewed;
- ix. In the case of a positive decision, a statement of the responsibilities of the applicant; for example, confirmation of the acceptance of any requirements imposed by the ERC; submission of progress report(s); the need to notify the ERC in cases of protocol amendments ,
- 1. The need to report serious and unexpected adverse events related to the conduct of the study; the need to report unforeseen circumstances, the termination of the study, or significant decisions by other ERCs.