



ETHICS REVIEW COMMITTEE

STANDARD OPERATING PROCEDURES

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PART I

PREAMBLE

1.0 Introduction

Pwani University (PU) is situated in Kilifi resort city in the Coast province of Kenya. Research being a core mandate of the University, the University has a fully operational Research and Innovation Committee Chaired by the DVC Research and Extension. Pwani University Ethics Review Committee (PU-ERC) is an Institutional Ethics Review Committee operates under National Commission of Science, Technology and Innovation (NACOSTI) and is charged with promoting, reviewing and regulating research within PU and Coast region at large.

1.1 Research Vision

To create a centre of excellence in research, technological development and socio-economic advancement

1.2 Research Mission

To generate, disseminate and apply research knowledge

1.3 Research Mandate

The PU research mandate is derived from the University Charter 2013 which stipulates, in article 7(1A and 1B) that among the Institution's objectives and functions PU will be "..... to provide direct, or in collaboration with other Institutions of higher learning, facilities for University education and research including technological, scientific and professional education; conduct research and create knowledge".

1.4 Membership of and Appointment to the ERC

1. The Vice Chancellor is responsible for the appointment of ERC members.
2. Members are selected based on their interests, ethical and/or scientific knowledge and expertise, and on their commitment and willingness to volunteer the necessary time and efforts for the Committee's work.
3. Appointments will reflect equal gender distribution.
4. Appointments will reflect relevant and diverse professional representation.
5. The Vice Chancellor will write an appointment letter to each member.
6. Membership will come into effect upon receiving the letter of appointment.
7. Members will normally be appointed for a minimum period of three (3) years
8. A member may be re-appointed for up to a maximum of three (3) terms (nine years).
9. A member has the option of stepping down upon by submitting a notification to the Vice Chancellor one month in advance.
10. Members will be facilitated by the appointing authority to carry out their mandate.

PART II

FUNCTIONS AND DELEGATED AUTHORITY

2.0 Terms of Reference of the ERC

1. Review, monitor and ensure that ethical standards are maintained in research at PU.
2. Ensure that all research at PU takes into consideration the need for bioethical and environmental sustainability.
3. Ensure that all research at PU which involves human subjects adheres to ethical standards. The Committee shall therefore:
 - a. Register and liaise with the National Commission for Science, Technology and Innovation (NACOSTI).
 - b. Review prospective research proposals involving human subjects, including assessing risks and benefits.
 - c. Review the adequacy of the informed consent document in relation to the risk and benefits involved.
 - d. Monitor research processes to ensure adherence to approved research protocol.
 - e. Ensure that research subjects are free from psycho-social harm of any kind.
4. Promote an atmosphere of trust, honesty and collaboration among researchers.
5. Establish misconduct in research and determine whether allegations form a basis for further investigation.

2.1 Functions of the ERC

1. Safeguard the dignity, rights, safety and well being of all actual or potential research participants and/or communities.
2. Review proposals submitted by researchers from PU that involve participation of humans/animals or affecting humans/animals directly or indirectly.

3. Act in the full interest of actual or potential research participants and concerned communities taking into account the interests and needs of the researchers and having due regard for the requirements of relevant regulatory agencies and applicable laws.
4. Ensure that only qualified investigators are allowed to conduct proposed studies. (These should be qualified by training and/or expertise).
5. Provide ethical oversight through passive and active monitoring of approved projects.
6. Suspend, withdraw the approval of or stop research projects that the Committee had approved but are noted to be harming participants to an extent that makes the risk/benefit ratio ethically unacceptable.
7. Ensure that research results have potential benefit to the participating individuals/communities and are disseminated to policy makers for their translation into policies and/or interventions.
8. Review research proposals, including any amendments to the proposals.
9. Give ethical support and advice to researchers, policy makers and other stakeholders.
10. Conduct outreach activities aimed at sensitizing communities on the importance of research.

2.2 The Chairperson

1. The Chairperson will be a full-time employee of the institution where the ERC is based.
2. The Chairperson will sign official documents of the ERC.
3. The Chairperson will assign support staff to the Secretariat.

2.3 Secretariat

1. The secretariat should be made up of full-time employees of the institution where the ERC is based.
2. The Secretary may have support staff, that is not members of the ERC but help with clerical work as assigned by the Chairperson.
3. Secretariat support staff should keep all information that they are exposed to in the ERC office private and confidential.
4. The Secretary will receive all applications to the ERC.
5. All decisions and communication from the ERC to applicants will be conveyed by the Secretary.

2.4 Documentation

1. All communication by the ERC should be filed and archived in the ERC office. Documents that should be filed and archived include but are not limited to:
 - a. Written SOPs of the ERC
 - b. Updated list of ERC Members.
 - c. CVs of Members
 - d. Agenda of ERC meetings.
 - e. Minutes of ERC meetings with names of Members present, date of meeting, decisions made, and any other details.
 - f. A copy of each and every material submitted by an applicant.
 - g. Correspondence between ERC Members and applicants or concerned parties regarding application, decision and follow up.
 - h. A copy of the decision and one of any advice or requirements sent to an applicant.
 - i. Progress reports received from researchers as per ERC requirements.
 - j. Serious Adverse Events reports submitted by researchers.
 - k. Final reports from researchers.
 - l. Oversight visit reports by ERC Members.
2. Documents should be archived for a minimum period of three years following the completion of a study.

2.5 Physical Location and Security

1. The ERC will have a dedicated office located at PU.
2. ERC documents will be kept securely in the ERC strong-room and accessed by authorized ERC secretariat members only.

PART III

MEETINGS OF THE ERC

3.0 Scheduled Full Meetings

1. The ERC Secretary should send an agenda, minutes of the previous meeting, notice about the date, venue and time of the next scheduled meeting and other relevant documents to all ERC members at least 7 working days before the meeting
2. Quorum must be greater than half of the total number of ERC Members (half of the total number of ERC members (N) plus one ($N/2 + 1$)).
3. Quorum should include members with the relevant expertise to effectively review the business of the day.
4. An application should be submitted to the ERC Secretary at least three (3) weeks before the meeting that the applicant(s) wants to consider the application.

3.1 Extraordinary Meetings

1. Any such meeting should be held if there is an urgent issue or issues that do not qualify for expedited review and require a full meeting.
2. The Secretary should circulate notice indicating the date, venue, time and agenda of the meeting at least 48 hours before the day of the meeting.
3. The Secretary should avail relevant documents to all the Members at least 24 hours before the day of the meeting.
4. Quorum must be present.

PART IV

APPLICATION PROCEDURES

4.0 Submission of Application Packages to the ERC

1. The applicant must be the Principal Investigator (PI) or co-PI of the proposed research project.
2. The Proposal Application Form should be completed, signed, and dated by the PI/co-PI or his/her designee.
3. Signed cover letter from the PI or co-PI and the Head of the Institution (which should include physical address, fax number, telephone number, mobile number and email address) must be submitted.
4. The applicant should submit hard and electronic copies of the full research proposal (number of copies to be determined by the ERC).
5. All materials to be used in ‘advertising’ the research project (e.g. campaign materials and brochures) should be submitted for ethical review.
6. Updated CVs of the PI and/or co-PI should be submitted.
7. Where the proposal is for an intervention study:
 - a. For clinical trials Insurance certificate covering damages on participants and errors in the Proposal implementation should be submitted.
 - b. A letter showing commitment to make the products readily available to the study community should be submitted to the ERC
8. Material Transfer Agreement (MTA) if applicable.
9. Data Sharing Agreement (DSA) if applicable.

4.1 Contents of Application Packages

1. The full proposal which should contain relevant sections from among the following: background/introduction; rationale; objectives (general and specific); clear-end points; methodology; recruitment strategy; laboratory investigations to be done; plans for

analysis and publication; personnel budget and justification; timeframe of the project; dissemination plan; community sensitization.

2. The informed consent form and information leaflet, in both the official and when necessary the translation into the local vernacular language. Back translation into official language may be requested by the ERC.
3. Data collection tools such as questionnaires, interviews/discussion guides, checklists and case record forms.
4. All materials to be used (including advertisements) for the recruitment of actual research participants.
5. Where the proposed study is a clinical trial, the investigator's brochure which provides adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience of the study product to date (e.g. recent investigator's brochure, published data, summary of the product's characteristics etc).

4.2 Amendments to Research Proposal

1. Any intended modifications/changes or revisions from the approved proposal and/consent forms should be submitted to the ERC as Proposal Amendments for review before they can be implemented.
2. Investigators should use the relevant amendment form and submit the amended proposal with track changes and a covering letter which briefly explains and justifies the changes.
3. Proposal amendments should be reviewed by the full ERC unless it is urgent and it qualifies to undergo expedited review as per the ERC conditions and requirements specified in the relevant SoP.
4. The ERC should assess if the intended proposal amendments are scientifically and ethically justifiable and whether they compromise the safety and welfare of the participants and communities.
5. Change of investigators, that is addition or removal of some PI, co-PI or other researchers originally included in the proposal is an amendment that must be reviewed and approved by the ERC. In case of addition of a new PI/co-PI or other researchers, their full CV or should also be submitted.
6. Implications of any proposed amendment on the timeframe and budget of the research project should be scrutinized.

4.3 Principal Investigator (PI) and Participating Investigators

In most cases, research is conducted by a principal investigator who has entered an agreement with a sponsor. She/he is the person responsible for the conduct of research at the trial site/s. A clinical trial can however be conducted with or without a sponsor. If a sponsor is involved in the research, the implementation must be designed, conducted and reported in collaboration with both the sponsor and the principal investigator. If there is no sponsor, the principal investigator must clearly state in the proposal who takes on the role of the sponsor in the initiation, management and / or funding of the research.

4.3.1 Principal Investigator (PI)

1. Must be based in Kenya
2. Will ensure that approval(s) from the relevant approved local ethics committee have read and accepted the relevant information package developed by the sponsor for the research
3. Will have good knowledge of the project, related documents and the regulatory requirements of the regulatory authority(ies) and other relevant legislation
4. Will have read, understood and agreed to work according to the project
5. Will undertake to use the investigational and comparator product(s) only for the purposes of the study as described in the project
6. Will take responsibility for accountability of the investigational product(s)
7. Will document clearly the sequence of events to be followed in the conduct of the research, including time-frames, roles and responsibilities
8. Will ensure the availability of all necessary facilities, equipment, and finance to conduct the research
9. Will develop proper mechanisms to ethically obtain informed consent of participants
10. Will accept the involvement of monitors to review and verify the quality control procedures and conduct data verification
11. Will accept the possibility of audit and/or inspection by an independent auditor appointed by the sponsor, regulatory authority or ethics committee
12. Will obtain the right to publish; it is unethical for the sponsor to reserve to right to publish
13. Will generate the information package for the participant, and where applicable with the sponsor
14. Will ensure proper safety reporting procedures

PART V

DECISION-MAKING

5.0 Procedure

1. The committee will arrive at a decision only if the quorum requirements are satisfied.
2. Any member with conflict of interest regarding a particular proposal will not participate in the review of the proposal nor the subsequent decision making process. He or she member must excuse himself/herself from the meeting.
3. Non-members such as project PIs and independent experts may be consulted as part of the review process.
4. A decision should only be taken after there has been sufficient time to allow for review and discussion of an application in the absence of non-members of the Committee.
5. Only ERC Members who participated in the review process and deliberations will participate in the decision-making process.
6. ERC committee decisions shall be either unanimous when all members are in agreement or by consensus when there is voting and the position voted for by the majority becomes the ERC decision. In case there is a tie, other members who were absent should be consulted; otherwise, independent expert opinion should be sought.
7. For any decision made by the ERC, clear reasons and justifications should be given and should be documented in the minutes and in the communication to the applicant.

5.1 Types of Decisions Relating to Applications

1. Approval
2. Provisional approval in case of expedited review
3. Conditional approval for proposal with minor changes required which can be verified by secretariat without submitting to full ERC meeting
4. Major changes necessitating resubmission of the application to full ERC meeting or to appointed members of the ERC
5. Deferment, pending a decision at a later date
6. Disapproval

5.2 Communication of Decisions

1. Decisions regarding submitted Proposals should be officially communicated, in writing, to the applicant within 10 working days of the meeting that made the decisions.
2. Communication of the ERC decision shall include but not limited to the following: name, title and address of the applicant; title of the proposal reviewed; name of the site(s) or study area; names and identification numbers (versions numbers/dates) of the reviewed documents; statement of the decision reached by the ERC; name of ERC taking the decision: a letter head of the ERC suffices date of the decision and signature of the Chairperson. In the case of a conditional decision, any requirements by ERC, including suggestion for revisions should be clearly explained in writing to the applicant. In the case of a positive decision, a statement of responsibilities of the applicant and any requirements as stipulated in the decision by the ERC; the validity period of the approval; the final approval certificate/letter shall be countersigned by the administrator and chairperson/Vice chairperson

5.3 Appeals and Appeal Decisions

1. Any decision of the ERC may be appealed to the ERC secretariat which shall hear such appeal within fourteen (14) days of notification of the appeal, unless requested in writing by the Appellant to delay such hearing or unless the Chair of the Appeals Panel determines that a hearing should not be held and denies the appeal.
2. The Appeals Panel shall render a written decision within fourteen (14) days following the conclusion of a hearing and shall deliver a copy of same to the Appellant, to the secretariat and to any other parties granted status in the matter.

PART VI

REVIEW

6.0 Initial review

1. Research proposals by investigators who are PU employees must undergo initial review by the Committee to gain approval prior to the study commencing.
2. Research proposals by investigators who are not PU employees but where the proposed research is to be conducted in the Institution must undergo initial review by the Committee to gain approval prior to the study commencing.
3. Initial review of health research proposals should be done by the full ERC unless it qualifies for expedited review and there is acceptable justification for the expedited review as per the relevant SOPs of the ERC.
4. A full proposal as per the ERC requirements should be submitted.
5. The ERC shall assess the social need and/or value of the proposed research.
6. The ERC shall assess the scientific merit and validity of the proposed research.
7. Where human participants are to be recruited, the inclusion and exclusion criteria will be assessed by the ERC for ethical and scientific appropriateness.
8. The ERC shall assess the informed consent process to ensure that all pertinent aspects are covered.
9. Adequate privacy and voluntariness of participants.
10. Satisfactory procedure to preserve the confidentiality.
11. The ERC shall determine the appropriateness of the informed consent process for the category of people to be enrolled in the study. This will include: provision for community consent, individual consent, proxy consent and assent; duration of contact with potential participants to seek consent; non-technicality of the consent form and its completeness; that the language in the informed consent documents is in lay terms provisions for vulnerable populations; provision for consenting illiterate potential participants; process to eliminate undue inducement; provision to continue providing study information to participants throughout the study period; and process of ensuring confidentiality.

12. The ERC shall also examine the information sheet and informed consent form for the following: purposes of the research; foreseeable risks; potential benefits; confidentiality; voluntariness; local contact information (PI and ERC contacts should be included); signature options (to include a witness in the case an illiterate participant); compensation; and brief questions to assess comprehension.
13. Potential risks already stated in the proposal and any other that may have been omitted but are deemed likely to occur should be assessed in light of potential benefits.
14. Criteria for withdrawal or discontinuation of participants should be assessed to ensure fairness and safety of participants.
15. Where a placebo is to be used, there must be scientifically and ethically acceptable evidence-based justification that must be clearly explained in the proposal.
16. The recruitment process should be suitable for the targeted prospective participants and their communities in terms of cultural, traditional, religious or socioeconomic factors.
17. Health research should be conducted on or with vulnerable groups such as orphaned children, pregnant women, children, prisoners and mentally ill people only if the research questions cannot be answered when non-vulnerable groups are used.
18. Relevant mechanism(s) of monitoring and auditing the conduct of the research must be clearly spelt out in the proposal.
19. In the case of clinical trials, Data Safety and Monitoring Board (DSMB) should be set up and should provide names and contacts of members, one of whom should be a national of at least one of the host countries (to be discussed by the entire group, local DSMB members) to the ERC.
20. In the case of clinical trials there should be documentary evidence of insurance policy to cover trial participants
21. Where the research project involves more than one institution and samples are to be shipped from one institution to another, a signed Material Transfer Agreement between the sample or data provider and the recipient must be submitted to the ERC.

6.1 Expedited Review

1. Expedited review is when the process of review is speeded up so that an application does not wait for the normal scheduled full committee meetings
2. Expedited review should be requested and justified by the investigator through a written application to the ERC.

3. For an application to qualify for expedited review, the proposed research should have minimal potential risks.
4. Minimal potential risks refers to risks which are not likely to cause serious or long lasting physical, psychological or socioeconomic harm.
5. Special attention should be given to research projects involving vulnerable populations (the issue of vulnerability to be emphasized under initial review procedures).
6. Research projects involving invasive procedures should not qualify for expedited review.
7. Research projects investigating sensitive social issues should not qualify for expedited review (Homosexuality, Commercial Sex Workers, drug abuse, child abuse, gender violence, Female Genital Mutilation, etc)
8. Research projects investigating issues that may potentially have serious negative impact at community, ethnic group or population level should not qualify for expedited review
9. Amendments from research projects with minimal potential risk to participants and community may qualify for expedited review.
10. Upon receiving an application for expedited review, the Chairperson makes the initial assessment to determine if it qualifies for expedited review. Where it qualifies for expedited review, ERC Member(s) whose area of expertise and experience is in the same field as the proposed research project and are available should be assigned to review the proposal.
11. Where the review involves a project amendment, the selected members to review the project should preferably be members who reviewed the previous version of the proposal.
12. A summary of the proposals reviewed through the expedited process should be submitted to Members of the full ERC, before a full board meeting.
13. A decision arising from an expedited review will be provisional pending confirmation from the full board meeting. Such decision should be communicated to the investigator in writing. In case of a provisional approval, the investigator may proceed with the study.
14. Expedited review shall not take longer than two (2) weeks to review.
15. The expedited review comments and approval or disapproval of the application should be tabled as part of the agenda for the next full ERC meeting.
16. In the event that a proposal did not attain approval from an expedited review, the proposal should be submitted for a full ERC review.
17. The full ERC meeting has the power to confirm, modify or reverse a decision emanating from the expedited review. If the decision of the full ERC committee is contrary to the

decision emanating from the expedited review, detailed reasons and explanations should be recorded in minutes.

18. The applicant has to be informed about any modifications that the full ERC committee may have recommended and the ethical justification for such a decision

6.2 Continuing Review

1. This review is for approved research projects that are due for renewal of ethical approval.
2. After initial ethical approval, projects are to be reviewed annually or as required by the ERC.
3. Continuing review is based on progress reports submitted by the PI of the projects.
4. Continuing review is meant to provide a mechanism of passive monitoring of the research projects so as to pick up any ethical issues that may need to be addressed to protect the welfare of participants and the integrity of the data generated.

PART VII

MONITORING

7.0 Passive Monitoring

1. The ERC receives information about research projects that it approved and uses the information to assess if the projects are progressing well from a scientific and ethical point of view
2. Investigators and/or sponsors are obliged to report in writing any serious adverse events (SAEs) to the ERC within 24 hours. The official Institutional ERC SAE report template (Appendix Y) should be used.
3. Adverse Events should be recorded by the investigators and reported to the ERC as and when progress reports are due.
4. PIs should submit progress reports at intervals stipulated by the ERC as a condition for renewal of approval. Such progress reports enable the ERC to assess if the research project is progressing as per the approved protocol and if there are no issues that may need to be addressed.
5. Material Transfer Agreement which states quantities, types and specific purpose of any samples to be moved from the institution where they are collected to another recipient institution within the same country or in another country should be signed by the provider and the recipient.
6. Reports from other relevant stakeholders such as Regulatory Authorities and Data Safety and Monitoring Boards (DSMB) that may be shared with the ERC help to assess the way approved research projects are conducted.
7. Information in the public domain such as publications in journals or reports in newspapers could draw attention to some research activities that were not ethical in one way or another. For instance, a publication may reveal that researchers used samples for other purposes that were not covered by the ethical approval granted in the first place. In this regards, Investigators should be obliged to submit copies of publications emanating from the approved protocol to the ERC.

8. Final reports which are supposed to be submitted when a research project has been completed help the ERC to determine if the whole project was conducted as per the approved protocol.

7.1 Active Monitoring

1. The ERC members should physically visit the research projects in the field in order to assess if the projects are being conducted as per the approved protocols.
2. The ideal is that each and every approved study should be actively monitored to ensure adherence of health research ethics.
3. In the event that there is a study being implemented without ethical approval, urgent site visit should be carried out and appropriate action taken.
4. ERC members should use the ERC Oversight tool (Appendix Z) in order to ensure that appropriate issues are assessed during the visit.
5. The number of ERC members to undertake the oversight visit should depend on the workload of the inspection activities that will be done. In order to maximize objectivity in the oversight exercise, at least 3 members of the ERC with relevant diverse expertise and drawn from different institutions should make up the oversight team. An oversight team may preferably include a community representative from the ERC where possible
6. Types of oversight visits: ERC –initiated announced oversight visits: the ERC informs the PI of the project to be visited in advance of the date of the visit; ERC-initiated unannounced oversight visits: the ERC does not inform the PI of the project in advance of the date of the visit
7. Reasons for additional oversight visits. ERC oversight visits in response to reports made directly to the ERC or circulating in the community: Increased frequency of serious adverse events reports; failure to submit progress reports or final report; reports of suspected research misconduct; researchers who extend their research beyond the approved time; frame without formal notification and approval by the ERC; researchers that are suspected to have changed their objectives and design of the study without prior approval; any other reason that the committee feels warrants further follow-up

7.2 Complaints Handling Procedures

The ERC may receive reports of cases of misconduct via investigators, community members, research participants, or through its oversight activities. Upon receiving such reports indicating that there are cases of misconduct, the ERC should confirm the validity of the alleged misconduct before deciding on an appropriate action to take. The actions that the ERC may take after confirming the misconduct include: a letter of warning written to the PI with instructions for the misconduct to be stopped and/or rectified; the head of the institution, partners and sponsor should be copied; corrective or educational measures; frequent monitoring of research activities; recommend frequent reporting by the researcher of his/her research activities; the ERC may black-list the researchers for a period determined by the ERC; during that period the ERC should not approve any research proposal submitted by the blacklisted researchers. The list should be copied to the relevant authorities; in the event that serious harm was caused to participants as a result of the misconduct, compensation for the harm caused should be demanded from the researchers. The compensation package should be determined by qualified and relevant authorities; Recommend restrictions on research practice; suspension of approval of the investigator's study as well as any other affected studies under the responsibility of the investigator; termination of the research project which should be considered as a last resort; legal action in the case of criminal misconduct.

PART VIII

LINKAGES

8.0 Linkages with ERCs

PU-ERC has one of its prime objectives geared towards linking with other relevant bodies with similar mandates.

Currently, PU has memoranda of understanding with the following organisations

1. Kenya Medical Research Institute (KEMRI), Kilifi
2. Kenya Agricultural and Livestock Research Organization (KALRO), Mtwapa
3. Ministry of Health, Coast General Provincial Hospital (CGPH), Mombasa
4. Kenya Coconut Development Authority (KCDA), Mombasa
5. University of Dortmund, Dortmund, Germany

Ethics Review Committee

Current Members' List

	Name	Category	Expertise	Gender
1	Dr. Thomas Rewe	Chairman	PhD, Agricultural Sciences*	M
2	Dr. Catherine Mwangi	Member	PhD, Literature in English	F
3	Dr. Argwings Otieno	Member	PhD, Language Education	M
4	Dr. Benard Okeyo	Member	PhD, Environmental sciences	M
5	Dr. Hassan Mwakimako	Member	PhD, Religious Studies	M
6	Dr. David Mburu	Member	PhD, Behavioural and Chemical Zoology	M
7	Mr. James B. Ndiso	Secretary	PhD Student - Agronomy	M
8	Mr. Patrobus Chai	Lay Member	Farming, (Dairy Production)	M
9	Mrs. Janet M. Kahindi	Health	Clinical Medicine	F
10	Mr. Chris W. Khaemba	Lawyer	LLB, PGD Law	M
11	Dr. Peris Amwayi	Member	Biochemistry	F
12	Dr. Rahama Udu	Member	Biochemistry	F
13	Mr. Martin Mwaisakenyi	KEMRI Kilifi	Medical Practitioner **	M

* On study leave until August 2015

** Left for Studies pending replacement

Date: 30th October 2014

Signature: 

Ndiso, J.B. Ag. Chairman, PUC- ERC