

Kwame Nkrumah University of Science and Technology, Kumasi

Animal Research Ethics Committee (AREC)

STANDARD OPERATING PROCEDURES



ANIMAL RESEARCH ETHICS COMMITTEE (AREC) **STANDARD OPERATING PROCEDURES**



KWAME NKURUMAH UNIVERSITY OF SCIENCE
AND TECHNOLOGY, KUMASI-GHANA
**QUALITY ASSURANCE AND
PLANNING UNIT**

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FORWARD

The Kwame Nkrumah University of Science and Technology, Kumasi has a mission to advance knowledge in science and technology through creating an environment for undertaking relevant research, quality teaching, entrepreneurship training and community engagement to improve the quality of life. In order to achieve this mission, there is the need to have Standard Operating Procedures for conducting research with animal subjects.

This policy seeks, among others, to provide the needed guidelines to ensure that the University adheres to ethical standards in research.

The University is grateful to all those who ensured the initiation, development and approval of this Policy.

PROFESSOR K. OBIRI-DANSO

VICE-CHANCELLOR

ACKNOWLEDGEMENT

As part of the strategic planning mandate of the Quality Assurance and Planning Unit (QAPU), university policies are initiated and proposed for approval by the Academic Board. The Unit therefore, initiated the Standard Operating Procedures (SPO) for Animal research which was approved by the Academic Board.

The QAPU is grateful to the Prof. Peter Donkor's committee for drafting this Ethical Review Policy and the appropriate SOPs and also the members of various committees that reviewed it. We are equally indebted to the staff of QAPU who facilitated the entire process.

Lastly, we wish to appreciate the contribution of all staff of this University who contributed in several ways in the development and approval of this Policy.

PROF. CHRISTIAN AGYARE

HEAD, QAPU

AUGUST, 2018

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1.0 INTRODUCTION

Pursuant to Section 303 of the Criminal Code, 1960 (Act 29) and the Wild Animals Preservation Act, 1961 (ACT 43) of the Republic of Ghana, the Animals Research Ethics Committee (AREC) shall regulate the handling and treatment of animals for research and other related activities in KNUST. The University shall hold colonies of rats, mice, pigeons, guinea pigs, rabbits, domestic animals, Xenopus and other amphibians, and fish etc. for the purpose of research, testing and teaching.

- i. The AREC encourages and supports the scholarly endeavours of students and research scientists.
- ii. AREC is aware that the pursuit of scholarly work and research may involve the use of animals.
- iii. Consequently, AREC shall review all research proposals involving the use of animals to ensure that:
 - a) The rights and welfare of animals used in research studies are protected;
 - b) The associated risks are considered and minimized;
 - c) The potential for benefit is identified and maximized;
 - d) Research is conducted in an ethical manner and in compliance with established standards; and
 - e) Those individuals seeking to conduct such research obtain ethical clearance from AREC before commencing the research.
- iv. The AREC is authorized to review, approve, require modifications in, or disapprove research activities conducted by researchers using animals.
- v. The AREC shall evaluate the science and ethics of the relevant proposed studies.

2.0 AIMS AND OBJECTIVES

The main aim of the AREC is to uphold all national and international guidelines for protecting the rights and welfare of animals for teaching and research.

The objective of this code of ethics is to ensure that members of the KNUST treat all animals in their control with due care and consideration for the animals' welfare, and to use them in research and teaching in such a way as to cause them minimal stress and suffering.

To achieve this goal, the AREC shall engage in the following:

- (i) Offer advice to investigators in designing their research projects in a manner to minimize potential harm to animals;
- (ii) Review all planned research involving animals prior to initiation of the research;
- (iii) Approve research that meets established criteria for protection of animals;
- (iv) Monitor approved research to ascertain that animals are adequately protected; and
- (v) Assist the entire university body and its researchers on ethical and procedural issues relating to the use of animals.

3.0 SCOPE

This Standard Operating Procedures (SOP) is designed to comply with all the requirements of Section 303 of the Criminal Code, 1960 (Act 29) and the Wild Animals Preservation Act, 1961 (ACT 43) so that animal species specified in these documents may only be used in research, testing and teaching by any member of KNUST once an application is approved by the AREC.

The scope of this SOP includes work carried out on the premises of the KNUST or in the field. Again, manipulations requiring approval include using animals that are not part of the normal care of laboratory animals and those that might affect the behaviour or health of domestic and wild animals. Approvals for work given by the AREC do not override other requirements, such as permissions required by the Wild Animals Conservation Act (ACT 43) for work on protected species.

Members of the KNUST for the purposes of the Code of Ethical Conduct include, any teacher, researcher, technician or employee of the University, whether paid or unpaid and/or any student enrolled at the Kwame Nkrumah University of Science and Technology (KNUST). It also includes any visitors and collaborators from other national or international institutions working with and/or using KNUST facilities for research or teaching.

4.0 INSTITUTIONAL AUTHORITY

The AREC derives its authority from the University and the laws of Ghana. The authority of the AREC includes the following:

- (i) Review all research proposals involving animals;
- (ii) Request from investigators revision in research proposals as a condition for initial or continual approval;
- (iii) Approve the initiation of a new research project;
- (iv) Monitor the activities in approved projects, in any way deemed necessary, including yearly scheduled continuing review and verification of compliance with approved research protocols;
- (v) Initiate periodic audits on approved projects as required;
- (vi) Ensure prompt reporting of any adverse events occurring in approved projects, or in other related projects; and
- (vii) Suspend or terminate a previously approved project.

5.0 ETHICAL PRINCIPLES

Procedures and policies will be put in place to ensure that animal facilities and practices are in accordance with good practice and scientific knowledge, such as that provided in the *Guide for the Care and Use of Laboratory Animals* by the National Research Council of the United States of America and National Institutes of Health. These include:

- (i) Justification for the research
 - a. Necessary and beneficial
 - b. The use of animals
- (ii) Proper maintenance of animals including
 - a. provision of food and water
 - b. humane containment
 - c. adequate facilities for rest and sleep
 - d. appropriate, opportunities to socialise with others of their species.
- (iii) Training for those responsible for routine care of the animals in the following:
 - a. husbandry
 - b. methods of restraint
 - c. recognising signs of ill health
 - d. maintaining sanitary conditions.
- (iv) Research testing, manipulations and teaching should be carefully planned to be of an appropriate design and performed on the minimum number of animals required to obtain scientifically valid results or meet teaching objectives.

The AREC is committed to the concept of the 3 Rs; i.e. Reduction, Replacement and Refinement.

- (v) Pain and anaesthesia: In every case the researcher will take all practical steps to minimise stress and pain to the animal. Manipulations must be carried out by trained individuals or under the supervision of trained individuals. All anaesthetic practices shall conform to normal veterinary standards. Where recovery from anaesthesia is necessary, appropriate post-operative measures shall be taken to minimise pain and discomfort in the animals. In cases where an animal is evidently in severe pain or where recovery from anaesthesia is not intended, it will be euthanized by trained individuals. Where appropriate, researchers must receive training in the use of anaesthetics and the administration of pain relief prior to the start of experiments. Furthermore, dietary manipulations must not involve significant suffering to the animal concerned.
- (vi) In all cases, animals shall not be allowed to die. When any animal becomes moribund, it shall be euthanized by trained individuals.
- (vii) Healthy animals should be returned to their natural habitat wherever practicable.

6.0 TERMS OF REFERENCE FOR THE COMMITTEE

- (i) No research or teaching, on or off campus, using live animals may be carried out by any staff or student member of the KNUST, unless an application for such use has been approved by the AREC.
- (ii) The composition and terms of appointment of the AREC is set out in Part 7 of these Standard Operating Procedures (SOP). Members are appointed for a five-year period and reappointments are permissible by nomination through the procedures set out in Part 7 of this SOP.
- (iii) The AREC will meet at least four times each year, but more frequently as needed or when a member requests a meeting to discuss any issue of concern.
 - a. Members will be notified in writing or by electronic means when a meeting is to be called.
 - b. Members will be given a minimum period of notice of one week before a meeting is held.
 - c. Meetings may be requested within 24 hours to deal with emergencies.
 - d. A quorum will be 50 percent of members and must include at least one of the following: Veterinarian/ Animal Scientist, Animal Welfare Association member or a Lay member.

7.0 MEMBERSHIP OF THE AREC

A) Composition

The AREC shall be multidisciplinary and multi-sectoral in composition, including persons with relevant but diverse scientific expertise, balanced age and gender distribution, who have the qualifications and experience to review and evaluate scientific and medical ethics aspects of research protocol. The Committee shall be composed of:

Chairperson:	Appointed by the Vice Chancellor
Deputy Chairperson:	Appointed by the Committee
Member:	Legal Representative
Member:	Animal Scientist
Member:	Social Scientist
Member:	Veterinarian
Member:	Biomedical Scientist
Member:	Representative from an animal rights advocacy group
Lay member:	Representative from the general public
Secretary:	Appointed by the Committee (Assistant Registrar level or higher) and will be the Administrator at the Secretariat

B) Terms/Conditions of Appointment

The Vice Chancellor shall be the appointing authority of members of the Committee. Members shall be appointed based on their expertise, commitment and willingness to serve. All members shall sign and abide by a confidentiality agreement.

- The AREC shall have at least a five-member quorum;
- Efforts shall be made to ensure gender equity;
- Committee Members shall be required to submit their curriculum vitae to the Administrator after nomination; and
- The AREC shall request for a replacement of any member under the following circumstances:
 - (i) Protracted ill health of a member, which does not permit him/her to participate in the deliberations of the AREC
 - (ii) Persistent absenteeism of a member without reasonable cause for six consecutive meetings
 - (iii) Misconduct or conviction by a court of competent jurisdiction
 - (iv) Resignation of a member
 - (v) Death of a Member

C) Responsibilities

The responsibilities of the AREC shall be to:

- Ensure that research activities at KNUST are carried out in compliance with the KNUST's Ethics Policy as well as national and international regulations.
- Review research proposals involving animals.
- Conduct an assessment of the risks and benefits of the proposed research.
- Approve all research protocols before research is commenced.

- Reject or suspend any research protocol that does not follow the AREC guidelines.
- Ensure the protection of the rights and wellbeing of animals for research.
- Ensure the security of research protocols and related materials.

D) Tenure of Committee Members

- The voting members shall serve a minimum of five (5) years renewable for another term only.
- The maximum term of office shall be ten years.
- In the case where all members of the Committee are completing their term of office at the same time at the end of the first or second five-year term, the Chairman, the Vice Chairman and the Veterinarian shall be retained to ensure institutional memory. These retained members are allowed to serve for an additional five-year term. The retention of these specific members for an additional term will only be required after the first or second five-year term after the establishment of the Committee. Subsequently, every member serves for the maximum term of ten (10) years only.
- The tenure of a permanently employed Secretary/Administrator is not limited provided they are still in employment.

E) Honorarium to Committee Members

Honorarium shall be paid to members to compensate them for services rendered.

The amount shall be determined by the Vice Chancellor.

F) Confidentiality and Protocol

Committee members must sign and abide by a confidential agreement regarding meeting deliberations, applications, information on research participants, and related matters.

G) Declaration of Conflict of interest

Members of the Committee shall declare conflict of interest at each meeting.

H) Co-opted Reviewers

- The Committee, at its discretion, may invite scientists or non-scientists from within or outside KNUST who are not members, but have the expertise to function as reviewers.
- These co-opted reviewers shall have access to all documents submitted to the Committee relevant to the specific proposal under review
- They may participate at the deliberations and make recommendations on the proposal
- They shall not vote during committee meetings
- They will also have to sign confidentiality forms

8.0 ADMINISTRATION AND FUNCTIONS

The AREC shall be managed in the following manner to ensure efficiency and effectiveness.

a) **The Secretariat**

- The AREC shall have a permanent secretariat at KNUST to be manned by the AREC Administrator.
- KNUST shall provide the necessary funding for the operations of the AREC.
- The Secretariat shall take charge of all documentation, records and archives related to applications as well as the management and administration of the AREC.
- The Secretariat shall maintain a database of all AREC related documents including minutes of Committee meetings, cvs of committee members and investigator(s), periodic and final reports.
- The Secretariat shall ensure that the Committee maintains up to date registrations with relevant bodies
- The Secretariat shall advise Investigators on the preparation and submission of protocols for review.

b) **The Officers**

The permanent officers of the secretariat shall comprise an Administrator and an Administrative Assistant

c) **The Responsibilities of the Administrator**

The Administrator shall observe the following:

- Be responsible for keeping the documents, records and archives of the Committee.
- Screen each application to ensure adherence to administrative requirements.
- Arrange training and educational programmes for Committee members and the greater scientific community.
- Support the Committee in all its activities.
- Design and disseminate formats for AREC application documents, including research protocols, agreements, and periodic and final reports.
- Prepare and submit annual AREC operational budgets and plan to the KNUST management in consultation with the Committee.
- Accept, verify and distribute all submitted items to members.
- Create and distribute meeting agenda, and arrange meeting logistics.
- Attend Committee meetings, take minutes during the meetings, and verify and distribute minutes in a timely manner.
- Correspond with all submitting researchers at all times throughout the submission and review process.
- Advise submitting investigators on the preparation and submission of protocols for review according to the Standard Operating Procedures (sop)
- Continually study and update researchers about the Committee's operational regulations.
- Participate in continuing education
- Participate in any investigations and/or audits of the Committee.

d) Responsibilities of the Chairperson

The chairperson, shall among others, have the following task

- Facilitate the provision of training and educational programmes to Committee members and the greater scientific community at KNUST. The training shall include, but not limited to, the basic principles of animal protection, current literature, regulations and guidelines affecting the Committee and KNUST.
- Check and accept revisions made as per the Committee's recommendations.
- Determine submissions that are exempt from review, and notify the AREC and the submitting investigator of such exemptions.
- Perform expedited review of applications that meet the criteria
- Assign responsibilities and duties to the Vice Chairperson or to other members.
- Supervise the Administrator.
- Be available for and attend any outside investigations by the Committee.

e) Responsibilities of the Vice-Chairperson

- In the absence of the Chairperson, the Vice-Chairperson shall perform the responsibilities of the Chairperson.

f) Responsibilities of the Committee Members

- Review research protocols to safeguard the rights and well-being of animals for research.
- Undertake duties assigned to them by the Chairperson/ Vice Chairperson.

- Keep Committee documents given to them in a secure, private and confidential manner.
- Attend meetings regularly and participate actively during deliberations.

g) Responsibilities of Investigators

- Develop research protocol(s) in line with prescribed guidelines.
- Document and report on any changes related to research animals (death, sickness, injury, or replacement) to the Committee.
- Conduct research in a manner that imposes minimal risks to animals.
- Notify the Committee of major changes to an approved protocol.
- Inform the Committee of the completion of a project.

9.0 MEETINGS

A. Committee Meetings

- i) The Committee shall meet, at least, once every two months or more frequently as necessary.
- ii) The Committee shall have an agenda for each meeting. The agenda will include listing and providing identifiers for all applications.
- iii) The Administrator shall notify all Committee members of an upcoming meeting two weeks in advance by e-mail. The notification will include a meeting agenda, which shall outline all protocol and related research application submissions for consideration, and shall include all related materials, including copies of protocols, continuing and final reviews, safety reports, minutes, amendments and any other necessary documents.
- iv) In the case where the Administrator is unsuccessful in sending the materials to members, the Administrator shall at least notify the member(s) of the occurrence of the meeting, and shall arrange for alternative means of material distribution.
- v) The Administrator shall notify all members of any changes in meeting time, date or agenda as soon as possible.
- vi) Members shall attend all meetings.
- vii) Any member who is unable to attend a meeting must provide at least twenty-four (24) hours' notice prior to the meeting to the Chairperson via email or telephone.
- viii) Major decisions and voting cannot take place unless there is a quorum.

- ix) A member with a conflict of interest on any application shall excuse himself or herself from voting on the application, and all discussion and decision making, verbal or written, in connection with the application or research.
- x) Where necessary, investigators may be invited to meetings to enable them describe their proposed study and to respond to any issues raised by members.
- xi) Generally, Committee meetings will not be open to the public
- xii) With the exception of applications eligible for expedited review, the Committee will determine the outcome of its review of applications at meetings, where a quorum has been established.
- xiii) All new protocols must be submitted for full board review and approval.

B. Procedures at the meeting

- i) A quorum must include an Animal Scientist/Veterinarian and the lay member.
- ii) The members attending the meeting shall discuss a protocol and either vote or by general consensus approve, disapprove, or defer any decision until revisions are implemented, additional information is provided, or further expert review is obtained.
- iii) Investigators may be invited to describe their proposed study and to answer any questions posed by members of the Committee where necessary.
- iv) If minor revisions to the submitted documents are required or a missing document of minor importance is to be obtained, the Committee may delegate the Chairperson to review and approve it when these lapses are corrected.

C. Submission of Report

- The Committee will submit an annual report to the Vice Chancellor through the Central Ethics Committee. This report will include the following:
 - A list of members;
 - The number of applications processed, approved and rejected;
 - Difficulties encountered; and
 - Any complaints or recommendations received.
- All information will be stored securely for a period of not less than 10 years. Access to this information will only be with the approval of the Chairperson.
- Procedures to deal fairly and promptly with complaints by applicants, Committee members, other members of KNUST and the general public are outlined in Appendix 2.
- A member of the Committee who is also an applicant is deemed to have a conflict of interest and must abstain from any discussion or vote on his/her application.
- Applicants seeking amendments to approved protocols are required to submit a completed Protocol Amendment Form, which will be subject to the same processes as new applications.
- The Vice Chancellor may institute an audit of the Committee at any time.

D. Minutes of Meetings

The Administrator shall prepare minutes of each meeting. The minutes will be in sufficient detail, and will include the following:

- Date and venue of the meeting.
- Attendance and absence.

- Decisions reached on each research project application reviewed.
- Reasons for requiring changes in a project, or disapproving, suspending or terminating a project.
- Summary of the discussion of disputed issues and their resolution, if possible.
- Date of next scheduled review of a project.

E. Communicating decisions to applicants

- Upon completion of the review of a research project application, the Administrator will prepare a notification letter to inform the applicant(s) or investigator(s) of the outcome of the review within five (5) working days.
- The outcome of the review shall include the date the decision was reached for approved projects, the date of the next scheduled continuation review (one year from the date of approval), and the reporting requirements for the investigator.
- For disapproved, suspended or terminated projects, the reasons for these decisions shall be communicated to the Investigator.
- Communication on applications will include the following:
 - The name, title and address of the applicant
 - The exact title of the proposal reviewed
 - The names and identification numbers (versions Numbers/dates) of the reviewed documents (if applicable)
 - A clear statement of the decision reached by the Committee
 - The date of the decision and signature of the Chairperson

- In case of a conditional decision, any requirements for revision
- In case of a positive decision, a statement of responsibilities of the applicant and any requirements stipulated by the Committee shall be stated.
- The validity period of the approval shall be stated.

10.0 PROCEDURES FOR REVIEW

A. Approval of Applications

The Committee will provide the prescribed forms needed for the application. On-going responsibilities of applicants will be clearly outlined on this form requiring their signature. These obligations include the keeping of detailed records of the species and numbers and sources of animals used, the approved manipulations to which they were exposed, and the animal's subsequent fate. This should indicate whether the animal died, was killed, released or retained. This information shall be part of the Committee's annual reports to the Vice Chancellor, and it is an obligation on the investigator to make this information available. In the application, all Principal Investigators must indicate that they have completed a course in Ethical Conduct of Research.

B. Types of Review

The Committee will review research protocols in one of the following: Exempt; Expedited or Full Committee Review.

Exemptions

The Chairperson of the Committee and some selected number of committee members may review the study. The protocol will be approved within two weeks of receipt/after deadline.

The procedural requirements of the SOPs for the use of Live Animals for Research, Testing and Teaching do not apply to the following:

- a) Research data to be obtained through the collection/ study of existing documented data and documented**

**records from animal breeding and allied stations/
institutions and Veterinary hospitals.**

- b) Research data obtained from animal behaviour studies.**
- c) Tissues obtained from a slaughterhouse, farm or at a routine post-mortem examination, where their use is incidental to the reason the animal died or was killed/ slaughtered.**
- d) Animals subject to diagnosis and treatment in the normal course of veterinary practice. This extends to situations where students examine animals or assist with treatments either at KNUST or in other veterinary practices as part of their course requirements, so long as they are under the supervision of a registered veterinary surgeon.**
- e) Animals being farmed under normal animal husbandry practices, so long as there are no additional manipulations.**
- f) KNUST staff who are co-applicants on applications considered by other ARECs. However, these staff are required to provide a copy of the signed approval by that committee to the KNUST AREC.**
- g) When a member of staff is on overseas leave, is attached to an overseas institution and participates in research, the responsibility for which clearly resides with the host institution. In this instance, the proposed work should be considered under the regulations pertaining to that country's laws on the use of animals in research, testing and teaching, provided that there is a mechanism in place. Notwithstanding this, the Committee requires the staff member to notify it of the type of research being undertaken and conditions pertaining to that research. If there is doubt in any particular situation, the matter should be discussed with the AREC.**

Expedited Review

This is used where there is no more than minimal risk. Additionally, the Committee could use the expedited review process when minor changes have been made to an already approved research project within the same year. For expedited review, the Committee Chair and a selected number of committee members may review the study. The protocol will be approved within two weeks.

Categories of studies that may receive expedited review include the following:

- i. Where the researcher participates in activities such as surveys, interviewing et cetera or by observing animal behaviour.**
- ii. Where the researcher will be using a data recording device which has been cleared or approved for marketing and is non-invasive and routinely employed in clinical practice.**

Full Review

The processes for conducting full review are reserved for the entire Committee and are used when there is potential risk to animals. The protocol will be approved within three weeks. Below are examples of research works subject to full review:

- i. Work that involves pregnant animals, foetuses or young animals.**
- ii. Research involving animals with life-threatening physical conditions, unhealthy or physically challenged**
- iii. Research that involves physically intrusive procedures.**
- iv. If the researcher has cause to believe, based on previous experience, that the research has potential risk to animals including significant levels of physical stress and/or psychological stress.**

- v. **Research that places protected animals at more than minimal risk.**

C. Procedure for Submitting Research Protocol

An Investigator, who intends to commence a research project involving animals, shall submit an application for review to the Committee. The application shall include:

- Completed Protocol Submission Forms.
 - 10 hard copies and soft copies of the research protocol.
 - A submission letter.
 - The Principal Investigator's cv.
 - Ethical training certification of the Principal Investigator
 - Any other relevant documentation.
- i. The Secretariat shall check the application to ensure that all the necessary documents are submitted. Each application shall then be assigned an individual (identification) number.
 - ii. The protocol shall be stamped and entered into a database.

11.0 PROCEDURE FOR COMPLAINTS

- a) Procedures and policies to ensure prompt and fair resolution of complaints are detailed in Appendix 2.
- b) Any member of the KNUST whose work is suspended on ethical grounds shall have the right to appeal to the Committee within 28 days from notification of the Committee's decision.

12.0 MONITORING AND COMPLIANCE

The Committee will ensure that adequate processes are set up and documented to monitor the activities of research and teaching personnel in relation to conditions of project approvals. Site visits by the Committee to animal facilities will be made at 6-month intervals. A veterinarian/Animal Scientist appointed by the Committee will also visit animal housing from time to time to confirm that all animal husbandry practices conform to recognised animal welfare standards and practices. The Committee will suspend the use of animals by a researcher if it is found that animal welfare is jeopardized or protocols are being conducted in breach of the approved procedures.

a) Corrective Action

- i. The Committee has the power to direct that any procedure, whether approved or not, be stopped or modified on ethical grounds. The Committee can also direct that animals be properly cared for and if appropriate, euthanized.
- ii. All staff of KNUST involved with a project have a responsibility to inform the Committee and take corrective action in any instance where animal welfare is a concern.
- iii. The Committee will investigate suspected or alleged non-compliance. If transgression is evident, the Chairperson will give formal written notification to the person involved and the Principal Investigator. The Chairperson, acting on behalf of the committee, may insist that work be stopped.
- iv. Disciplinary action for non-compliance will be in accordance with KNUST procedures, the Criminal code (Section 303) and the Wild Animals Preservation Act (Act 43), where appropriate.

- v. Where a conflict of opinion arises within the Committee that cannot be resolved by voting, the Chairperson shall cast the deciding vote.

b) Compliance/Non-Compliance

Non-compliance may include:

- Conducting research when the research protocol has not been approved;
- When a research protocol violates ethical standards as a result of deviation from the initially approved protocol;
- Failure to report to the Committee any harm caused to animals.

13.0 EDUCATIONAL ACTIVITIES OF THE COMMITTEE

- The Committee shall disseminate new information on ethical and safety issues involving animal research.
- The Committee shall educate researchers including those who have active research projects involving animals
- Resource persons who are experts in the subject matter may be invited to take part in these educational activities.

14.0 RECORD KEEPING

- All documents of the Committee shall be dated, filed and archived.
- Hard copies will be filed and archived for a minimum period of 10 years following the completion of a study.
- The following documents will be archived indefinitely:
 - The constitution, written standard operating procedures of the Committee, and regular reports.
 - Records of members of the Committee.
 - Published guidelines for submission established by the Committee.
 - Agenda of meetings.
 - Minutes of meetings.
 - Reports of internal audits of the AREC.
 - Correspondence by the Committee with applicants or concerned parties regarding application, decision and follow-up.
 - A copy of the decision and any advice or requirements sent to an applicant.
 - All written documentation received during the follow-up.
 - Notification of the completion, premature suspension, or premature termination of a study.
 - Final Reports of approved research
 - Electronic copies of Committee documents

- The Committee will maintain an archive of files for all research projects approved by the Committee.
- Such files will be retained for at least ten (10) years.
- Each project folder will include the following documents, as conventional hard copies:
 - Initial Review Application Form – FORM A
 - Study Protocol
 - Investigator’s Brochure (if applicable)
 - Investigator’s abridged cv
 - Insurance policy document (If applicable)
 - Certification documents from other agencies, as mandated by regulatory agencies
 - Committee Approval Certificate
 - Research Progress Report Form – FORM B (if applicable)
 - Research Final Report
 - Protocol Amendment Application
 - Statements on significant new findings
 - Correspondence between the Committee and investigators of the project
- The Committee shall maintain a computerized relational database to facilitate tracking of research projects involving animals submitted for review.
- Records on Committee members shall include the term and status of each member, Curriculum Vitae, appointment document and information about training received.
- Such information should be maintained and updated as necessary and should be retained for at least 3 years after completion of service.

- The Chairperson must review all Committee documents annually or whenever there is a change of Chairperson
- The documents are to be reviewed and signed, where appropriate
- Research investigators shall use the following standard forms when applying for ethics review:
 - Initial Submission Form (A)
 - Continuing Review Form (B)
 - Amendment Form (C)
 - Serious Adverse Event (SAE) Form (D)
 - Submission Cover letter (Template)
- The Committee at its own discretion may issue the following documents to investigators:
 - Ethical clearance
 - Approval letters
 - Notification letters
- Investigators may use the following document as guidance when writing their study protocol.
 - Guidance for Preparation of Study Protocol
- The Standard Operating Procedures (SOPs) shall guide the activities of Investigators and Committee Members in order to ensure ethical research.

15.0 GLOSSARY

Animal means any live member of the animal kingdom and thus comprises the following:

- i. A mammal;
- ii. A bird;
- iii. A reptile;
- iv. An amphibian;
- v. A fish (bony or cartilaginous);
- vi. Any octopus, squid, crab, lobster, or crayfish (including freshwater crayfish);
- vii. Any other member of the animal kingdom, which is declared from time to time to be an animal by the KNUST Institutional Review Board (AREC) and other relevant national bodies concerned with animal use.
- (a) Any mammalian foetus, or any avian or reptilian pre-hatched young, that is in its last half of its period of gestation or development;
- (b) Any marsupial pouch young; but
- (c) Does not include the following:
 - i A human being; or
 - ii Except as provided in paragraph (b) or paragraph (c) of this definition, any animal in the pre-natal, pre-hatched, larval, or other such developmental stage.

Manipulation

The term “manipulation”, in preamble to an animal, means interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately –

- (a) Subjecting it to a procedure, which is unusual or abnormal when compared with that to which animals of that type would be subjected under normal management or practice and which involves the following:**
 - i. Exposing the animal to any parasite, micro-organism, drug, chemical product, biological product, radiation, electrical stimulation or environmental condition: or
 - ii. Enforcing activity, restraint, nutrition or surgical intervention; or
- (b) Depriving the animal of usual care.**

The term “manipulation” does not include the following:

- i. Any therapy or prophylaxis necessary or desirable for the welfare of an animal; or
- ii. The hunting or killing of any animal in a wild state by a method that is not experimental.

Adverse Event/Serious Adverse Events

An adverse event is an outcome that is not described in the AREC approved protocol that has a negative effect on animal welfare and may result in a level of pain or distress that was not predicted during the planning of the project. This may include an adverse event that was not expected following a procedure or treatment (e.g. diarrhoea, vomiting, respiratory difficulty, collapse, abdominal swelling, rapid weight loss) and/or the death of an animal or group of animals that was not expected (e.g. during surgical procedures, during anaesthesia, following a procedure or treatment, during day to day husbandry). The event is serious and should be reported to the Committee.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Test article

Any drug, biological product for animal use, feed, additive, colour additive, electronic product that is subject to FDA and Standards Authority regulation.

16.0 APPENDICES

Appendix 1: AREC Operational Guidelines

Appendix 2: Complaints Procedures

Appendix 3: Forms and Templates

- **Initial Submission Forms for Research (R1)**
- **Initial Submission form for Teaching (1)**
- **Submission Cover Letter Template**
- **Continuing Review Form (B)**
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APPENDIX 1

Animal Ethics Committee (AREC) Operational Guidelines

Contents

- a. Submission and Review of Experimental Protocols**
- b. Document Control and Records**
- c. Surveillance**

1. Submissions and Review of Experimental Protocols

- a) Protocols are submitted to the AREC Secretary on the prescribed form (Form AI & AII).
- b) KNUST staff, or Post-graduate students in conjunction with their supervisors, may submit applications. Other applications outside the KNUST may also be considered.
- c) Copies of the submitted protocols are sent to AREC together with a cover sheet, which each AREC member fills in and signs after considering the application. The comments made by the committee on their application are forwarded to the applicant for a response.
- d) Any further information required of the applicant and received in response to comments made by one or more members of the AREC is sent to the committee for further consideration.
- e) All projects graded 2 or higher are automatically considered at a meeting called by the Chairperson. All projects graded 0 or 1 may be approved between meetings but are discussed retrospectively at the next meeting, unless a member of

the AREC requests a meeting before approval is granted. See classification of projects below.

- f) The Chairperson will sign off the protocol or refer the matter back to the AREC for further consideration.
- g) Applicants' answers to questions will be circulated to committee members.
- h) On request by any member of the committee, a meeting of the committee can be called.
- i) Applicants must be prepared to appear in person before the AREC to justify and explain their protocols.
- j) After approval, any amendments to protocols will require submission of the Application for Amendments form (Form B), to Approved Protocols. Amendment applications are circulated to all members of the AREC for feedback and approval. Amendments that are graded 2 or higher will require automatic consideration at a meeting called by the chairperson. Minor amendments and those graded 0 or 1 may be approved by the chairperson between meetings but discussed retrospectively at the next meeting.
- k) Animal use statistics are required annually and must be forwarded to the AREC Secretary by each protocol holder through their departmental office.
- l) AREC may co-opt additional non-voting members on a temporary basis when it requires that person's specialist knowledge.
- m) Applicants must submit a report to the AREC at the end of their project using the Final Report on Project form.

2. Document Control and Records

- a) All protocols are labelled by year and numbered consecutively as they are received. Each is then classified as "R" for Research or "T" for Teaching. E.g. 2007/04R is the 4th

application received in 2007 and involves Research rather than Teaching.

- b) The KNUST maintains a complete record of all protocols, exams, approvals, and amendments etc. for not less than 10 years.
- c) The AREC maintains a complete record of minutes, correspondence and reports.
- d) Matters relating to the AREC are confidential to the committee and members are to keep all documents in a secure place.
- e) No documentation except Animal Use Statistics is to be released unless approved by the KNUST after discussion with the Chairperson of the AREC.

3. Surveillance

- a) KNUST policy of responsibility for both Faculty and individual to ensure all work involving manipulation of animals conforms to the AREC code of ethics.
- b) All people carrying out manipulations on animals are required to notify the Animal Ethics Committee immediately of any untoward or unexpected reaction or deaths during experimental procedures.
- c) The AREC or its nominee has the authority to inspect animals, their accommodation, or experimental records at any time to be sure that procedures are being properly carried out.
- d) The AREC will visit all animal facilities (where approved research is being conducted) at KNUST every six months. The veterinarian/Animal Scientist appointed by the AREC can also independently visit and inspect animal facilities.

APPENDIX 2

Complaints Procedures

- a) Complaints received by AREC may involve concerns about: animal suffering and welfare, decisions made by AREC, or about personnel. Complaints against personnel may be directed towards researchers, teachers, students or members of the AREC, including the chairperson.
- b) Complaints are considered to be either Emergency or Non-emergency. Complaints considered an emergency are those in which animal welfare is jeopardized and the situation must be resolved immediately. Non-emergency complaints are all other complaints in which animal welfare is not immediately compromised.

Dealing with Complaints Categorized as Emergencies

- i. Complaints considered emergencies are defined as those in which animal welfare is jeopardized. This may be the result of inadequate care of the animal such that the animal no longer meets the criteria of BAR (bright, alert and responsive) in situations in which it would be expected, or when an animal is being subjected to protocols not approved by the AREC. In some cases, previously approved protocols may lead to unanticipated levels of suffering that may require a reassessment by the AREC.
- ii. All emergency complaints are to be directed to the Chairperson of the AREC (or to the Vice Chairperson in her/his absence).
- iii. The Chairperson (and one other member of the AREC) will then immediately investigate the complaint, which may

include an unannounced visit to the animal facility in question to make an assessment. If the situation is considered to have placed animal welfare in jeopardy, an immediate cessation to further work may be issued and only reinstated upon further consideration of the AREC.

- iv. The chairperson will report to the AREC the outcome of the emergency complaint for further action if warranted. Reinstatement of suspended protocols will occur upon consideration of the AREC. AREC may also consider whether Disciplinary measures are required. Such a process will follow the KNUST Policy on disciplinary Procedures.

Dealing with Complaints Categorised as Non-emergencies

- i. Complaints considered as non-emergencies are defined as those in which animal welfare is not jeopardized. This may include complaints against decisions made by AREC or personnel, including members of AREC. One likely example is the refusal of AREC to sanction an application and the applicant lodges a formal complaint.
- ii. All non-emergency complaints are to be directed to the Chairperson of AREC (or to the Vice Chairperson in his/her absence). A meeting of the AREC will then be arranged to address the formal complaint. The person filing the complaint may be asked to attend the meeting in part to address AREC and to discuss the source(s) of disagreement.
- iii. Complaints against the Chairperson will follow a normal University procedure, which is, lodging a formal complaint to the Vice Chancellor.
- iv. Procedures for dealing with complaints will follow the University procedure for addressing grievances.

APPENDIX 3

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

APPLICATION FOR USE OF ANIMALS IN RESEARCH – INITIAL SUBMISSION FORM (R1)

This form is required for all experimental work, capture, containment and obtrusive observational work on animals. The AREC is required to minimise the use of animals (to numbers required to obtain scientifically valid results or meet teaching objectives) as well as reduce, avoid, or ameliorate the pain, suffering, and death of animals used in Teaching and Research at the KNUST. This form must be written in language that is understandable to the entire Animal Ethics Committee, including the lay members of the committee.

“Animal”

(a) Means any live member of the animal kingdom of the following categories:

- i. A mammal;
- ii. A bird;
- iii. A reptile;
- iv. An amphibian;
- v. A fish (bony or cartilaginous);
- vi. Any octopus, squid, crab, lobster, or crayfish (including freshwater crayfish);
- vii. Any other member of the animal kingdom, which is declared from time to time to be an animal by the KNUST Institutional Review Board (AREC) and other relevant national bodies concerned with animal use.

- (b) Includes any mammalian foetus, or any avian or reptilian pre-hatched young, that is in its last half of its period of gestation or development;
- (c) Includes any marsupial pouch young; but
- (d) Does not include
 - (i) A human being; or
 - (ii) Except as provided in paragraph (b) or paragraph (c) of this definition, any animal in the pre-natal, pre-hatched, larval, or other such developmental stage.

Please send TEN copies of the completed form, signed by the Principal Investigator and the Head of Department, and any relevant documentation to the Secretary of the Animal Ethics Committee.

I (We) the undersigned have read and understood the Code of Ethical Conduct and the appendices under which the KNUST Animal Ethics Committee operates. All applicants must also successfully complete an examination on the use of Animals in Research, Testing, and Teaching. A study manual and copy of the examination are available by contacting the Secretary of the AREC directly.

If the application is approved I (We) agree to

- (i) *Resubmit to the Animal Research Ethics Committee for their approval, an application for Amendment of an Existing Protocol to the Approved Protocols (available from AREC secretary).*
- (ii) *Inform AREC immediately in writing if unanticipated problems arise that could be an offence under any law regulating animal use in Ghana.*
- (iii) *Furnish annual returns to AREC on the Animal Use Statistics form. These records are to be retained by the AREC Secretariat for ten years after the year to which they relate.*
- (iv) *Obtain approval from relevant national bodies if the work involves protected indigenous species*

- (v) *Complete a final report upon completion of the project using the Final Report on Project form available from the AREC secretary.*

Please note that in some circumstances applicants may be required to appear before the AREC to answer questions.

Signature of applicant(s):

Date:

Signature of the Chairperson of AREC:

Date:

Office use: Date received:

Date approved/declined:

1. Name(s) of applicant(s):

Type of Study/Degree Sought:

Contact address:

Phone:

Email:

Supervisor's Name(s):

Position(s):

Phone:

Email:

2. Title of project:

3. Purpose of the Research:

*Please provide a **LAY** summary of the proposed research using non-technical language (include a glossary of any technical terms that must be used). This purpose must be understandable to anyone, inside or outside the University. Proposals without an appropriate lay summary cannot be approved.*

4. Reasons for the Research

- a) What is the scientific reason(s) for this work?
- b) Will your project repeat similar work in the literature?
- c) How will the results be used (e.g. thesis, publication, teaching)?

5. Species and Number to be used:

Species	Number

- 6. **Provide a justification for the number of animals needed for your study (e.g., explain the number of treatment and control groups, how many animals are in each group, and how you arrived at these numbers; when appropriate use power analyses or statistical calculations to estimate sample sizes required).**
- 7. **Explain how you have attempted to reduce the number of animals, replace the use of animals with other methods, and refine your experiments to gain additional information in the planning of this work. This is the 3R's of animal ethics and each point needs to be carefully considered and addressed.**
- 8. **Describe the procedure(s) requiring approval from the Animal Ethics Committee. If more than one procedure is proposed, please list the procedures and describe each one.**
- 9. **For each of the procedures listed in part 8, indicate its likely severity according to the following scale (taking into account the effect of any anaesthetic, analgesic, euthanasia technique, or other strategy or practice that is applied or used, or any other step taken, to avoid or alleviate the stress or pain caused to the animal). Use the**

table to list each procedure and its grading (add more rows for additional procedures).

The grading scale is:

Grade	Description
0	No suffering (a manipulation that causes no stress or pain or virtually no stress or pain)
1	Little suffering (a manipulation that causes stress or pain, of a minor intensity for a short duration)
2	Moderate suffering (a manipulation that causes stress or pain, of a moderate intensity for a short duration, or of a minor intensity for a long duration)
3	Severe suffering (a manipulation that causes stress or pain, of a moderate intensity for a long duration, or of severe intensity for any duration)

Procedure	Severity grading

- 10. Describe why alternative methods (non-invasive, not involving the morbidity or mortality of an animal, etc.) are not available, or suitable
- 11. All studies should have an endpoint, or a series of conditions (e.g. time an animal is subjected to a treatment) under which the animal will no longer be subjected to a protocol and you consider the experiment completed. What are the endpoints of your study for each of the procedures listed in part 8?

- 12. Where are the animals to be held and the experiments performed?**
- 13. List the relevant qualifications and experience of applicants for carrying out all of the procedures listed in part 8:**
- 14. If applicable give details of anaesthetic procedure and post-operative care and/or method of euthanasia. Include information on choice of anaesthetic, dose rate, how anaesthetics will be administered, methods of maintaining sterility, monitoring of animal during and post anaesthesia and procedures for dealing with any potential complications.**
- 15. What will happen to the animals once the project has been completed?**
- 16. Expected start date of project:**

Completion date of project:

Applicants are reminded that any amendments to approved protocols (including extension to date of completion must be approved by the Animal Ethics Committee.

Approval:

Approved (Chairperson, Animal Ethics Committee) Date:

Any Special conditions applying:

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

APPLICATION FOR USE OF ANIMALS IN TEACHING – INITIAL SUBMISSION FORM (T₁)

This form is required for all experimental work, capture, containment and obtrusive observational work on animals that will be used in teaching. The Animal Ethics Committee (AREC) is required to minimise the use of animals (to numbers required to obtain scientifically valid results or meet teaching objectives) as well as reduce, avoid, or ameliorate the pain, suffering, and death of animals used in Teaching at the KNUST. This form must be written in a language that is understandable to the entire Animal Ethics Committee, including the lay members of the committee.

“Animal”

a) Means any live member of the animal kingdom that is –

- (i) A mammal; or
 - (ii) A bird; or
 - (iii) A reptile; or
 - (iv) An amphibian; or
 - (v) A fish (bony or cartilaginous); or
 - (vi) Any octopus, squid, crab, lobster, or crayfish (including freshwater crayfish); or
 - (vii) Any other member of the animal kingdom, which is declared from time to time to be an animal by the KNUST AREC and other relevant national bodies concerned with animal use.
- a) Includes any mammalian foetus, or any avian or reptilian pre-hatched young, that is in its last half of its period of gestation or development;
 - b) Includes any marsupial pouch young; but
 - c) Does not include
 - i. A human being; or

- ii. Except as provided in paragraph (b) or paragraph (c) of this definition, any animal in the pre-natal, pre-hatched, larval, or other such developmental stage.

Please send FIVE copies of the completed form, signed by the applicant and supervisor and the Head of Department, and any relevant documentation to the Secretary of the Animal Ethics Committee.

I (We) the undersigned have read and understood the Code of Ethical Conduct and the appendices under which the KNUST Animal Ethics Committee operates. All applicants must also successfully complete an on-line examination on the use of Animals in Research, Testing, and Teaching. A study manual and copy of the examination are available by contacting the Secretary of the AREC directly.

If the application is approved I (We) agree to undertake the following:

- (i) *Resubmit to the Animal Ethics Committee for their approval an application for Amendment of an Existing Protocol to Approved Protocols (available from AREC secretary).*
- (ii) *Inform the AREC immediately in writing if unanticipated problems eventuate that could be an offence under any law regulating animal use in Ghana.*
- (iii) *Furnish annual returns to AREC on the Animal Use Statistics form. These records are to be retained by the AREC Secretariat for ten years after the year to which they relate.*
- (iv) *Obtain approval from relevant national bodies if the work involves protected indigenous species*
- (v) *Complete a final report upon completion of the project using the Final Report on Project form available from the AREC's secretary.*

Please note that in some circumstances applicants may be required to appear before the AREC to answer questions.

Signature of applicant(s):

Date:

Signature of the Chairperson of AREC:

Date:

Office use: Date received:

Date approved/declined:

- 1. **Name(s) of applicant(s):**
Position(s):
Department:
Contact Address:
Phone:
Email:
- 2. **Course title and number:**
- 3. **Title of the exercise. Please attach a copy of the laboratory handout and/or instructions to students.**
- 4. **Species and Number to be used:**

Species	Number

- 5. **Provide a justification for the number of animals needed for your teaching exercise (e.g., explain the number of treatment and control groups, how many animals are in each group, and how you arrived at these numbers).**
- 6. **Explain how you have attempted to reduce the number of animals, replace the use of animals with other methods, and refine your use of animals during the planning of this teaching exercise. This is the 3R's of animal ethics and each point needs to be carefully considered and addressed.**
- 7. **Describe the procedure(s) requiring approval from the Animal Ethics Committee. If more than one procedure is proposed, please list the procedures and describe each one.**

8. For each of the procedures listed in part 7, indicate its likely severity according to the following scale (taking into account the effect of any anaesthetic, analgesic, euthanasia technique, or other strategy or practice that is applied or used, or any other step taken, to avoid or alleviate the stress or pain caused to the animal). Use the table to list each procedure and its grading (add more rows for additional procedures).

The grading scale is:

Grade	Description
0	No suffering (a manipulation that causes no stress or pain or virtually no stress or pain)
1	Little suffering (a manipulation that causes stress or pain, of a minor intensity for a short duration)
2	Moderate suffering (a manipulation that causes stress or pain, of a moderate intensity for a short duration, or of a minor intensity for a long duration)
3	Severe suffering (a manipulation that causes stress or pain, of a moderate intensity for a long duration, or of severe intensity for any duration)

Procedure	Severity grading

9. The educational value of this exercise.
10. Provide reasons why alternative methods (non-invasive, not involving the morbidity and mortality of an animal, etc.) are not available, or suitable

- 11. Where are the animals to be held and the experiments to be performed?**
- 12. Relevant qualifications and experience of teachers/ demonstrators:**
- 13. If applicable give details of anaesthetic procedure and post-operative care and/or method of euthanasia. Include information on choice of anaesthetic, dose rate, how anaesthetics will be administered, methods of maintaining sterility, monitoring of animal during and post anaesthesia and procedures for dealing with any potential complications.**
- 14. What will happen to the animals once the project has been completed?**

Approved (Chairperson, Animal Ethics Committee):

Date:

Special conditions applicable:

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

SUBMISSION COVER LETTER TEMPLATE

To:

**The Chairperson,
Animal Research Ethics Committee
KNUST**

Subject: Submission of Research Protocol Review and Approval.

Sir/Madam,

I write to submit my application for the project Titled "<>" to enable me to conduct the referenced research project at <>, if granted permission. I will be responsible for the co investigators for this project.

The total number of animals that is proposed for use in this research is "<>" over a period of "<>"

The study is sponsored by "<>"

Please find enclosed herein following documents for your review and approval.

I would be happy to offer any other information or clarification as may be required by you

Thank you.

Dr. "<>"

"<Designation>"

Dept. of "<>"

Mobile No. "<>"

Please provide required information

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

CONTINUING REVIEW FORM (B)

PROTOCOL TITLE:

.....

AREC: DATE OF INITIAL APPROVAL:

PRINCIPAL INVESTIGATOR:

DEPARTMENT:

CAMPUS ADDRESS: PHONE:

1. RECORD OF ANIMAL USE

Species

Total # Approved

Used to Date

.....

.....

2. NATURE OF THE PROTOCOL/STUDY. (Check [X] all applicable items.)

[] Survival (Chronic) Study [] Prolonged Restraint [] Inducement of a Disease State

[] Terminal (Acute) Study [] Neuromuscular Blockers [] Inducement of Behavioural Stress

[] Multiple Surgeries [] Antibody Production [] Blood/Tissue Collection

[] Transgenic Breeding

3. PROCEDURE SEVERITY GRADING [Indicate X]: [] 0 [] 1 [] 2 [] 3 [] 4

.....

4. PROTOCOL STATUS. Please indicate (X) the status of this project.

Request Protocol Continuance

A. Active – project on-going.

B. Currently inactive – project was initiated but is presently inactive.

C. Inactive – start date for anticipated but not yet initiated project is

.....

5. Request Protocol Termination

A. Inactive – project never initiated.

B. Currently inactive – project initiated but project has not/will not be completed.

C. Completed – no further activities with animals will be done.

6. FUNDING SOURCE: Specify the funding source.

7. PROJECT PERSONNEL.

[] Yes: Have there been any personnel/staff changes since the last approval was granted?

[] No: If yes, please complete the following sections (Additions/Deletions).

For additions, please submit a completed Personnel Qualification Statement with this Continuing Review Form

Additions: Name/Role/Responsibility for Project

.....

Deletions:

Name

.....

Effective Date

.....

8. PROGRESS REPORT. If the status of this project is 4.A. (active; project on-going) or 4.B. (project was initiated, but is presently inactive), provide a brief update on the progress made in achieving the specific aims of the protocol.

9. PROBLEMS/ADVERSE EVENTS. If the status of this project is 4.A. (active; project on going) or 4.B. (project was initiated, but is presently inactive), describe any unanticipated adverse events, morbidity or mortality, the

cause(s), if known, and how these problems were resolved. If NONE, this should be indicated.

10. **ALTERNATIVES TO ANIMAL USE.** Alternatives to the use of animals should be considered and used when possible. Since the last approval, have alternatives to the use of animals become available that could be substituted to achieve your specific project aims?
11. **ALTERNATIVES TO POTENTIALLY PAINFUL PROCEDURES.** (Address the following if your project involves procedure severity 2 or 3) Procedures that cause the least amount of pain or distress to the animals should be considered and used when possible. Since the last approval, have alternatives, which are potentially less painful or distressful become available that could be used to achieve your specific project aims?
12. **DUPLICATION.** Activities involving animals must not unnecessarily duplicate previous experiments. Provide written assurance that the activities of this project remain in compliance with the requirement that there must be no unnecessary duplication.

13. **FUTURE PLANS.**

☐ A. No changes are planned and the project will continue as previously approved

☐ B. Changes are planned. Provide a full description and justification for the proposed changes.

(A copy of the Amendment Form has been included for this purpose.)

[Please note that if the modifications are significant, you may be required to complete a new application. If you have questions or require assistance in making this determination, please contact the Secretariat.]

14. **CERTIFICATION OF THE PRINCIPAL INVESTIGATOR** Signature certifies that the Principal Investigator understands the requirements in this CEC and will continue to conduct the project in full compliance with the aforementioned requirements.

Signature of the Principal Investigator

Date

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

APPLICATION FOR AMENDMENT TO APPROVED PROTOCOLS (C)

This form is required for all proposed minor amendments to experimental work, capture, containment and obtrusive observational work on animals that has already been approved by the Animal Ethics Committee (AREC). New projects or substantial changes to previous applications must submit a full application. Applicants are reminded that AREC is required to minimise the use of animals as well as reduce, avoid, or ameliorate the pain, suffering, and death of animals used in Teaching and Research at the KNUST.

Please send a copy of the completed form to the Secretary of the Animal Ethics Committee.

Name(s) of applicant(s):

Department/Faculty/School/College:

Email:

Tel:

Number of application for which amendments is requested:

Title of application for which amendments requested:

Please describe changes requested to approved protocols:

- a) *Are additional animals to be used? If so, what is the number of additional animals to be manipulated, and what is the total number for the entire project (i.e. number previously approved plus the current number requested):*
- b) *Describe the proposed changes to previously approved manipulations or new manipulation requested. Please describe changes to proposed procedures including changes in equipment, duration of experiments, changes in diet, changes in surgical procedures, etc. Use as much space as required.*

- c) Describe the change in grading of suffering as a result of proposed change in manipulation. List each procedure for which you are requesting changes in the table below and give both the previous grading and new grading (add additional lines as needed):

The grading scale is:

Grade	Description
0	No suffering (a manipulation that causes no stress or pain or virtually no stress or pain)
1	Little suffering (a manipulation that causes stress or pain, of a minor intensity for a short duration)
2	Moderate suffering (a manipulation that causes stress or pain, of a moderate intensity for a short duration, or of a minor intensity for a long duration)
3	Severe suffering (a manipulation that causes stress or pain, of a moderate intensity for a long duration, or of severe intensity for any duration)

Procedure	Previous grading	New grading

- d) What is the justification for the changes proposed in Part b? Please provide justification for changes to number of animals to be used as well as the scientific reasons for the proposed changes in protocols described in Part b:

- e) Expected date of completion of amended project (please justify any changes from the original completion date):
-

Approval:

Amendments Approved (Chairperson, Animal Ethics Committee):

Date:

Any Special conditions applying:

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

SERIOUS ADVERSE EVENT FORM (D)

Protocol No:	Principal Investigator:
Project Title: _____	
Species:	
Date of incident:	Date of report:

1	Please summarize the circumstances surrounding the event, giving details of the symptoms exhibited by the animal and describing what action was taken.
Continuation	
2	If an unexpected death has occurred, has an autopsy been performed? If no, state why not. If yes, state by whom and provide a copy of the autopsy report.

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

FINAL REPORT ON PROJECT TO ANIMAL ETHICS COMMITTEE

This form is required upon completion of all approved applications from the Animal Ethics Committee (AREC) to work on animals. The purpose is to provide AREC with a record of your use of animals and what was achieved by your research project. We are very much interested in your findings and to learn what you have achieved.

Please send a copy of the completed form to the Secretary of the Animal Ethics Committee.

Name(s) of applicant(s):

Department/Faculty/School/College:

Email:

Tel:

Number of application:

Title of application:

What was the total number of animals used in your project?

Summarise (in lay terms) the main findings of your study and what you view as its contribution to your discipline:

What are the outputs that have resulted from this work (i.e., theses, publications, research seminars, conference presentations, etc.)?

Thank you for your cooperation.

QUALITY ASSURANCE AND PLANNING UNIT

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