

Kwame Nkrumah University of Science and Technology, Kumasi

Humanities and Social Sciences Research Ethics Committee (HuSSREC) STANDARD OPERATING PROCEDURES



HUMANITIES AND SOCIAL
SCIENCES RESEARCH
ETHICS COMMITTEE
(HuSSREC)
**STANDARD OPERATING
PROCEDURES**



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

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Quality Assurance and Planning Unit
Vice-Chancellor's Office
Kwame Nkrumah University of Science and Technology
KNUST, Kumasi
PMB UPO, Kumasi-Ghana

Tel: +233 322060319

Email: info.qapu@knust.edu.gh

Layout Design by
Frank Boadu, University Press, KNUST

Cover Design
Francis K. N. Nunoo, Department of Publishing Studies, KNUST

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 Humanities and Social Sciences Research Ethics Committee (HussREC) Standard Operating Procedures.

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 Humanities and Social Sciences 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

TABLE OF CONTENTS

1.0	INTRODUCTION	1
2.0	POLICY OBJECTIVES	2
3.0	SCOPE	3
4.0	MANDATE OF THE COMMITTEE	5
5.0	ETHICAL PRINCIPLES	6
5.1	JUSTIFICATION	6
5.2	Informed Consent	6
5.3	Voluntary Participation	9
5.4	Confidentiality	9
5.5	Avoidance of Harm	10
5.6	Good Research Practice	10
5.7	Research Governance and Ethics Policy	11
6.0	MEMBERSHIP OF HUSSREC	13
7.0	ADMINISTRATION AND FUNCTIONS	17
8.0	MEETINGS	21
9.0	PROCEDURES FOR REVIEW	26
10.0	PROCEDURES FOR COMPLAINTS	32
11.0	MONITORING AND COMPLIANCE	33
12.0	EDUCATIONAL ACTIVITIES	34
13.0	FUNDING	35
14.0	RECORD KEEPING	36
15.0	APPENDICES	39

1.0 INTRODUCTION

The Kwame Nkrumah University of Science and Technology (KNUST) is committed to applying values of equity, participation, transparency, service, tolerance and mutual respect, dedication, scholarship, responsibility and academic freedom to all its activities, including research conducted at the University. The University expects all those conducting research in the Humanities and Social Sciences, irrespective of whether they are employees, students or visiting researchers at the University and irrespective of the source of their funding or the field in which they conduct their research or the site where the research is conducted, to honour these principles. KNUST is also of the view that good science assumes ethical acceptability according to internationally acceptable norms and that the responsibility for this lies with every person conducting research under the auspices of the university.

2.0 POLICY OBJECTIVES

This Standard Operating Procedures (SOP) is an Ethical Review Policy Framework (ERPF) which establishes the fundamental principles of research ethics and scientific integrity. It serves as the foundation for the Humanities and Social Sciences research at the KNUST. To achieve this goal the Humanities and Social Science Research Ethics Committee (HUSSREC) shall:

- (i) Advise investigators to design and implement their research projects in order to minimize any potential harm to society.
- (ii) Review all planned research projects prior to implementation.
- (iii) Approve research that meets established criteria for the protection of human participants in the community.
- (iv) Monitor the implementation of approved research to ensure that the human participants are adequately protected.
- (v) Build the capacity of researchers on ethical and procedural issues.

3.0 SCOPE

For the purpose of this policy, the term **research** refers to original investigation involving the use of human beings, leading to the creation of knowledge and replication of an investigation for the purpose of developing the researcher. This includes undergraduate and postgraduate students' projects/theses/dissertations and also staff research projects.

Members of the KNUST include teachers, researchers, technicians or employees of the University, whether paid or unpaid and/or students enrolled at the KNUST. It also includes visitors and collaborators from other national or international institutions working with and/or using KNUST facilities for research or teaching.

All researchers are expected to consider the ethical implications of their research and to submit their research for ethical review as appropriate. The following activities, however, are particularly likely to raise ethical issues:

- Research that involves the participation (active or passive) of people in activities such as interviews, questionnaire administration, focus group discussion, testing, experiments or observations;
- Research that utilizes personal data from the living or the recently deceased; and
- Research that involves children or vulnerable populations such as pregnant women, patients, prisoners, orphans and other institutionalized persons.

This policy sets out the principles for ethical research and the procedures for ethical review. It is expected that this policy will be read in conjunction with the relevant subject-specific and professional

codes and guidance on ethics and research conduct as well as taking into account all relevant legislations.

4.0 MANDATE OF THE COMMITTEE

The Standard Operating Procedures for the Humanities and Social Sciences Research is backed by the University's policy on ethics and the laws of Ghana. The mandate of the Committee includes the following:

- (i) To review all research proposals involving human beings/ communities.
- (ii) To require from investigators revision in research proposals as a condition for initial or continual approval.
- (iii) To approve the initiation of new research projects.
- (iv) To 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) Initiating audits on approved projects periodically as required.
- (vi) To ensure prompt reporting of any adverse events occurring in approved projects, or in other related projects.
- (vii) To suspend or terminate a previously approved project.

5.0 ETHICAL PRINCIPLES

The Humanities and Social Sciences Research Policy is underpinned by the following key principles:

1. Justification
2. Informed consent of Participants
3. Voluntary Participation
4. Confidentiality must be ensured.
5. Avoidance of Harm
6. Good research practice.
7. Research governance and ethics policy.

5.1 JUSTIFICATION

Researchers should be able to demonstrate that the research is worthwhile and necessary. They should be able to show that the study will add new knowledge and not simply replicate research that already exists. The value of the new knowledge gained should outweigh the potential disruption and inconvenience caused to those involved in the research. In the case of students undertaking an undergraduate independent study or postgraduate dissertation it may be permissible for them to replicate existing research as part of their development as researchers.

5.2 INFORMED CONSENT

Those involved in the research as participants should be informed of the nature and purpose of the research, and any potential benefits, risks, obligations or inconvenience associated with the research before they choose to participate. It is therefore normal practice to provide

an information sheet to potential participants that sets out the details of the research in a form accessible to the non-expert and in a format appropriate to them.

Evidence of consent (either written or oral) should be obtained, documented and retained as appropriate. Participants should be informed that they are free to withdraw consent at any time without adverse consequences, and that any data provided by them will be destroyed should they request it.

Where consent is being sought to collect sensitive personal data, explicit consent must be given by the participant to collect this data. Sensitive personal data may include the following:

- a. Racial or ethnic origin of the data subject
- b. Political opinions
- c. Religious beliefs or other beliefs of a similar nature
- d. Membership of a trade union
- e. Physical or mental health or condition
- f. Sexual life or orientation
- g. Commission or alleged commission of any offence
- h. Proceedings for any offence committed or alleged to have been committed by the Participant, the disposal of such proceedings or the sentence of any court in such proceedings.

Particular care is needed in gaining consent from vulnerable groups such as children, prisoners, persons lacking mental capacity and persons whose first language is not English.

For research involving children, researchers should seek and gain the consent of a parent/legal guardian or next of kin, and perhaps more appropriately the assent of the child in keeping with Article 12 of the United Nations Convention on the Rights of the Child.

For research involving persons lacking mental capacity, researchers should:

- Assume a person to have the capacity to consent unless it is established that he/she lacks capacity
- Not treat a person as unable to make a decision unless all practicable steps to help him/her to do so have been taken without success
- Not treat a person as unable to make a decision merely because they make an unwise decision

Where a “gatekeeper” (those who have the power and authority to grant the researcher access to a group of normally vulnerable participants, for example: a head-teacher or a care home manager) controls access to participants, researchers should adhere to the principle of gaining informed consent/assent from the participants themselves, whilst respecting the legitimate interests of the gatekeeper.

- i. In the case of research in educational settings, the researcher must consider carefully the need to gain parental consent for participation in addition to that of the child. The school acts *in loco parentis* but it must not be assumed that this always negates the need to ask parents to consent to their child’s participation. This will particularly be the case where the research is of a sensitive nature or where the research requires children to undertake activities beyond those normally asked of them.
- ii. There may be some types of research design (for example, deception studies or covert research) that require the research to be undertaken without informed consent. Such design should be carefully considered and fully justified with procedures put in place to provide post research full debrief and/or granting of post research consent.

5.3 VOLUNTARY PARTICIPATION

As well as being informed, consent should also be freely given. Researchers should ensure that participants are taking part in the research voluntarily, that they do not feel pressured or obliged to participate, and are not subject to coercion.

Researchers should be aware that where there is power relationship between the researcher (or representative of the researcher, for example, a gatekeeper) and the participant – such as between a lecturer and his/her students, a lawyer and his/her client, or a doctor and his/her patients – a person might feel compelled to participate. In these circumstances, a researcher should endeavour to find ways of ensuring voluntary participation, for example, by using a neutral intermediary to gain consent.

Researchers should also be aware that the use of incentives to encourage participation might be viewed as coercion if such incentives are any more than a token. For example, giving those who complete a questionnaire access to a free prize draw will not normally be seen as coercive. On the other hand, paying individuals more than reasonable expenses to take part in an interview would normally be seen as coercive.

5.4 CONFIDENTIALITY

Except where explicit written consent is obtained to the contrary, researchers should protect the confidentiality and anonymity of all human participants and the data relating to them at all times.

Researchers should be aware of the risks to anonymity, confidentiality, privacy and security posed by the data they collect and store, and take measures to prevent accidental breaches of confidentiality. The collection, storage, use and disclosure of data must comply with the appropriate Data Protection Laws.

It is important to note that the duty of confidentiality is not absolute in law and may, in exceptional circumstances, be over-ridden by more compelling duties, such as the duty to protect individuals from harm.

5.5 AVOIDANCE OF HARM

Researchers should seek to minimize the risk of harm to any individual including the participants, the researchers themselves and other researchers or organizations participating in the research.

Harm is broadly conceived to include physical injury and psychological distress beyond that encountered in daily life and also negative impacts on economic or social standing.

Researchers should assess potential risks prior to the commencement of a project and accordingly make adjustments to the project design and make provisions to provide help and support for any individual who suffers harm.

Most fundamentally, researchers must always ensure that participants and other researchers are fully aware of any potential risk of harm. This will enable the individual to make his/her own risk assessment before choosing to participate and, if fully informed, the individual is best placed to make this judgment.

5.6 GOOD RESEARCH PRACTICE

Prior to, during, and following the completion of all research activities, researchers are expected to consider how they can ensure good practice. In preparation for and during research activity, especially that which involves human subjects, researchers are expected to consider the ethical implications of their research. Considerations include the nature of the research and the cultural, economic, psychological, physical, political, religious, spiritual and social consequences for all subjects.

The main principles of good research practice are:

- i. Honesty
- ii. Openness
- iii. Documenting results clearly and accurately
- iv. Being critical of your results
- v. Ensuring that data is stored securely and for the appropriate amount of time
- vi. Acknowledging fully the role of collaborators and other participants

- vii. Exercising a duty of care to all those involved in the research.

The following constitute research misconduct:

- i. Fabrication of evidence, data, results or consent
- ii. Misrepresentation of evidence, data, results or content
- iii. Undisclosed duplication of publication
- iv. Inappropriate attribution of interests
- v. Plagiarism – the copying of ideas, data or text without permission or acknowledgement
- vi. Mismanagement of data or evidence
- vii. Breach of duty care to subjects/participants.

5.7 RESEARCH GOVERNANCE AND ETHICS POLICY

Whilst the ultimate responsibility for good practice and the ethical conduct of research lies with each researcher, the policy is designed to support researchers in KNUST.

In accordance with University requirements, the Committee will ensure that all staff and students are made aware of the policy and provide opportunities for researchers to engage with institutional ethics training. The Committee will be responsible for monitoring compliance with the policy.

Benefits that are expected through compliance with the policy are:

- Further embedding a research culture based upon good research principles;
- Demonstrating commitment to high-quality, transparent and accountable research practices;
- Ensuring the protection of the dignity, rights, safety and well-being of the subjects of research;

- Codifying the KNUST's position on research governance and research ethics, affirming our commitment to high ethical standards;
- Providing clear guidance for staff and students;
- Ensuring that all risks relating to research are closely considered, allowing steps to be taken to minimize risks to research subjects;
- Reducing risks to the University and individual researchers; and
- Strengthening the eligibility and quality of research funding applications.

All research requires formal ethical review. These include:

- Research activity (including public engagement) involving human participants.
- Where there are issues that might raise ethical concerns (for example, potential conflicts of interest, the use of artefacts, environmental impact and financial inducements for subjects).
- Research activity involving the sharing of data or confidential information beyond the initial consent given (including where research relies solely on secondary data).

6.0 MEMBERSHIP OF HUSSREC

a) Composition

The HUSSREC shall include persons with relevant but diverse scientific expertise, who have the qualifications and experience to review research protocols. The Committee shall be composed of:

Chair:	Appointed by the Vice Chancellor
Deputy Chair:	Appointed by the Committee
Member:	Social Scientist
Member:	Social Scientist
Member:	A Lawyer
Member:	A Religious Leader
Member:	A Representative from Industry
Member:	A Representative from a recognized Non-Governmental Organization/Civil Society Organization.
Lay member:	A Representative from the general public (A cognate is suggested)
Secretary:	Appointed by the Committee (Assistant Registrar level or higher)

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.

- Efforts shall be made to ensure gender equity.

- Committee members shall be required to submit their curriculum vitae to the Administrator after nomination.
- Any member who has any vested interest in a proposal submitted to the Committee for review under the terms of reference of the Committee shall make known to the Chair and shall not participate in the deliberations on the protocol.
- Members shall sign and abide by a confidential agreement regarding meeting deliberations, applications, protocol submissions, information on research participants and related matters which they have had the privilege to have as a result of being members of the Committee.
- Members are required to participate in a certified Research Ethics Training programme
- The Committee 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 Committee.
 - (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 or voluntary withdrawal of a member.
 - (v) Death of a member.

c) Responsibilities:

The responsibilities of the Committee shall:

- i) Ensure that research activities at KNUST are carried out in compliance with the University's Research Ethics Policy as well as national and international regulations.
- ii) Consider applications for full ethical review.

- iii) Inform the University Ethical Committee of high-risk projects identified under review.
- iv) Refer cases to the University Ethical Committee where necessary.
- v) Provide advice and guidance on any matters relating to the ethical scrutiny and conduct of research.
- vi) Ensure the protection of the rights and wellbeing of research participants.
- vii) Ensure the security of research protocols and related materials.
- viii) Act as a vehicle for the dissemination of good practice in matters related to the ethical scrutiny and conduct of research.

d) Tenure of Committee Members

- i) The voting members shall serve a minimum of five (5) years renewable for another term only.
- ii) The maximum term of office shall be ten years.
- iii) 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 a Social Scientist 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.
- iv) The tenure of a permanently employed Secretary/Administrator is not limited provided they are still employed.

e) Honorarium to Committee Members

An 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.
- The 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 with the Committee.
- They will also have to sign confidentiality forms.

7.0 ADMINISTRATION AND FUNCTIONS

a) The Secretariat

- The HussREC shall have a permanent secretariat at KNUST
- The permanent officers of the Secretariat shall comprise an Administrator and an Administrative Assistant.
- KNUST shall provide the necessary funding for the operations of the HussREC.
- The Secretariat shall take charge of all documentation, records and archives related to applications as well as the management and administration of the HussREC.
- The Secretariat shall maintain a database of all related documents including minutes of Committee meetings, cvs of committee members and investigators, periodic and final reports.
- The Secretariat shall ensure that the Committee maintains up-to-date registrations with relevant national and international bodies.
- The Secretariat shall support the Committee in the discharge of its duties
- 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:

- 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 science community.
- Support the Committee in all its activities.
- Design and disseminate formats for application documents including research protocols, agreements, and periodic and final reports.
- Prepare and submit annual operational budget and plan to the KNUST management in consultation with the Committee.
- Accept, verify and distribute all submitted items to members.
- Create and distribute meeting agendas and arrange meeting logistics.
- Attend Committee meetings, take minutes during the meetings, and verify and distribute minutes in a timely manner.
- Correspond with applicants 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 any investigations and/or audits of the Committee.

d) Responsibilities of the Chairperson

- Provide leadership for the Committee and chair all its meetings
- Facilitate the provision of training and educational programmes to Committee members and the greater science community at KNUST. The training shall include but not limited to the basic principles of social research, current literature, regulations and guidelines affecting the Committee and KNUST.
- Determine submissions that are exempt from review, and notify the Committee and applicants of such exemptions.
- Check and accept revisions made as per the Committee's recommendation.
- Perform expedited review of applications that meet the criteria.
- Assign responsibilities and duties to the Vice-Chairperson or other members.
- Supervise the Administrator.
- Be available for and attend to any external investigations by the Committee.
- Provide an annual report to the University Ethical Review Committee in respect of ethical issues. Reports to the University Ethical Review Committee shall include the following:
 - The current Committee membership.
 - Details of any suggested changes to the approved procedures.
 - The number of applications considered by the Committee and the decisions taken (approved, referred), and any particular difficulties encountered or action taken.
 - Any issue for consideration by the University Ethical Review 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 research participants and communities.
- Undertake duties assigned to them by the Chairperson/Vice-Chair.
- Study documents submitted to them before meetings.
- 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 protocol to the Committee.
- Conduct research in a manner that imposes minimal risks to the community.
- Notify the Committee of major changes to an approved protocol.
- Inform the Committee of the completion of a project.

8.0 MEETINGS

A. Committee Meetings

- i) The Committee shall 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.
- ii) The Committee shall have an agenda for each meeting. The agenda will include listing and identifiers for all applications.
- iii) The Administrator shall notify all Committee members of an upcoming meeting at least two weeks in advance by e-mail. The notification will include a meeting agenda, which shall outline all protocol and related research submissions for consideration in the meeting, and shall include all related materials, including copies of protocols, continuing and final reviews, safety reports, minutes, amendments and any other necessary documents.
- iv) Meetings may be requested within 24 hours to deal with emergencies.
- v) A quorum shall be 50 percent of members.
- vi) In the case where the Administrator is unsuccessful in routing 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.
- vii) The Administrator shall notify all members of any changes in meeting time, date or agenda as soon as possible.
- viii) Members shall attend all meetings.

- ix) 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.
- x) Major decisions and voting cannot take place unless there is a quorum
- xi) A member with a conflict of interest on any application shall recuse himself or herself from voting on the application, and all discussion and decision making, verbal or written, in connection with the application or research.
- xii) Where necessary, investigators may be invited to meetings to enable them describe their proposed study and to respond to any issues raised by members.
- xiii) Generally, Committee meetings will not be open to the public.
- xiv) 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.
- xv) All new protocols must be submitted for full board review and approval.

B. Procedures at the meeting

- i) A quorum must include a Social Scientist 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 or 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.

C. Information Management

- i) The Committee will submit an annual report to the Vice Chancellor through the Ethical Review Committee. This report will include:
 - A list of members,
 - The number of applications processed,
 - Difficulties encountered,
 - Any complaints or recommendations received.
- ii) All information will be stored securely for a period of not less than 5 years, following the completion of the study. Access to this information will only be with the approval of the Chairperson.
- iii) Procedures to deal fairly and promptly with complaints by applicants, Committee members, other members of KNUST and the public are outlined in this document
- iv) A member of the Committee that is also an applicant is deemed to have a conflict of interest and must abstain from any discussion or vote on his/her application.
- v) Applicants seeking amendments to approved protocols are required to submit a Protocol Amendment Form, which will be subject to the same processes as new applications.
- vi) The Vice-Chancellor may institute an audit of the Committee at any time.

D. Minutes of Meeting

The Administrator shall prepare minutes of each meeting. The minutes will be in sufficient detail. It 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.
- It will be made available electronically for review by members.

E. Communicating decisions to applicants

- i) 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.
- ii) 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.
- iii) For disapproved, suspended or terminated projects, the reasons for these decisions shall be communicated to the Investigator.
- iv) 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 shall be stated.
- 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.

9.0 PROCEDURES FOR REVIEW

Depending on the risk involved, a research proposal may require an Exempt, Expedited or Full Review. Once approved, a research project is subject to continuing review annually or more frequently depending on the risk and complexity level.

A. Exempt Review

Research work that falls under this classification includes works that represents no more than minimal risk to the human participants. The Chair of the Committee and some selected committee members may review the study. The protocol will be approved within one week of receipt/after deadline. Examples of studies exempt from review are as follows:

- Research data to be obtained through the collection or study of existing data, documents and records.
- Research involving data that is publicly available or if subjects cannot be identified
- Observation

B. Expedited Review

This is used where there is no more than minimal risk to the participants. 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 some selected 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 human 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.

C. Full Review

Unless otherwise determined, all applications are assumed to require full review. The processes for conducting full review are reserved for the entire Committee and are used when there is potential risk to participants in the research. The protocol will be approved within four weeks.

D. Continuing Review

- The Committee is responsible for determining whether the research is reviewed annually, or more frequently appropriate to the degree of risk.
- The Committee is also responsible for determining whether an independent data and safety monitoring board is required.
- The Investigator of the research is responsible for keeping the Committee informed of significant findings that affect the risk/benefits ratio and thus the need for more frequent review. The Investigator is also responsible for following the continuing review procedures and deadlines as outlined in this SOP.
- If the Committee has not reviewed and approved a research study by the study's current expiration date, or the existing approval has expired, the research activities should be stopped and no new subjects may be enrolled in the study. However, if the investigator is actively pursuing renewal, and the Committee believes that an over-riding safety concern or ethical issue is not involved, the Committee may permit the study to continue for the brief time required to complete the review process.

- Should research methods ultimately differ from those presented within an approved application, the researcher will be responsible for ensuring that a new application is made to cover any additional activity.
- If a researcher subsequently embarks on a piece of clearly defined research, they will be required to submit another application for ethical approval specific to the project.
- At a research activity's initial review, the Committee will determine:
 - How often it will re-evaluate the research project. All research will be reviewed at intervals appropriate to the degree of risk, but not less than once per year but at least once before the end of the data collection stage.
 - The factors to be considered in setting the frequency of review should include the nature of the study, the degree of risk involved, and the vulnerability of the study subject population.
 - Whether these studies need verification from sources other than the investigator that no material changes in the research has occurred.

E. Applications for Initial Review

An Investigator, who intends to commence a Humanities and Social Sciences research project involving human participants, shall submit an application for review to the Committee. 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. In the application, all Principal Investigators must indicate that they have completed a course in Ethical Conduct of Research.

The application shall include:

- Completed application form.

- A submission cover letter
- Research protocol
- Participant information leaflet and consent form
- Research tools/Data capturing sheets (questionnaires, interview guides, etc.)
- Written approval/permission from research site/community/facility
- Written assurance of confidentiality and protection of participants
- The Principal Investigator's cv
- Ethical training certification of the Principal Investigator
- Any other relevant documentation.
- 5 hard copies and a soft copy of the application documents
 - i) The Secretariat shall check the application to ensure that all the necessary documents are submitted and completed. Each application shall then be assigned an individual (identification) number.
 - ii) The protocol shall be stamped and entered into a database.
 - iii) The Administrator shall distribute the application and documents to members two weeks prior to the meeting.

F. Applications for Continuing Review

- i. The Investigator will utilize the continuing review form to complete the annual review report. The report will submit all required elements, including the following:
 - Number and demographics of participants enrolled.
 - Changes in principal and/or associate investigator(s)
 - A summary description of subject experiences
 - Any serious adverse events experienced

- Numbers of and reasons for withdrawals from the research
 - The research results obtained thus far
 - A current risk-benefit assessment based on study results
 - Any new information since the Committee's last review.
- ii. If the Investigator cannot provide any of the required information, he/she will provide justification for the delay in the report, and a timetable for provision of the information. The Investigator will also submit a copy of the consent documents and procedures currently in use.
 - iii. The Investigator will submit one hard copy of the continuing review report, with original signature. The investigator is also required to submit an electronic copy of the review report via e-mail or disc.
 - iv. Upon receipt of the continuing review report, the Administrator will work with the Investigator to ensure all elements have been submitted. The Administrator will place the continuing review report on the next meeting's agenda.
 - v. The Chairperson may elect to invite an independent or alternative reviewer to the meeting.
 - vi. Committee members will consider and vote upon all continuing review reports in full meeting, utilizing the protocol voting procedure. The risk /benefit ration may change over time. The criteria the Committee uses to approve or disapprove continuation of research are the same as criteria for approval of an initial research project.
 - vii. The Committee will review the consent process and documents to determine whether they are still accurate and complete, whether new information that may have been obtained during the course of the study needs to be added, and whether the documents being used by the Investigator have current ethical approval.
 - viii. After reassessment, the Committee may require that the research be modified or halted. The Committee may also

impose special precautions or relax requirements it had previously imposed on the research protocol. They will also determine whether there are any important new findings that might affect the willingness of participants to continue participating in the research. If so, they will require the investigator to notify the participants of these findings.

- ix. The Administrator will archive continuing review reports and supporting materials with the relevant minutes of meetings.

10.0 PROCEDURES FOR COMPLAINTS

In the event that ethical approval is refused, the applicant will be invited in the first instance to revise their research proposal or further explain the reasons for the proposed research methodology. If this is not appropriate, the researcher has the right to appeal to the same committee in writing stating the reasons for the disagreement.

A researcher may appeal to the Committee on the following grounds:

- There existed material circumstances relating to the application of which the Committee was unaware.
- Procedural irregularities occurred during the review process, resulting in reasonable doubt that the committee would have reached the same conclusion regarding the application had the irregularities not taken place.
- There is demonstrable evidence of prejudice, bias or inadequate review.

Stage 1: Where a researcher is dissatisfied with the decision reached by the Committee, the researcher may request that the Committee reviews its decision. When requesting the review, the researcher, must clearly articulate the reason for the request, including the provision of additional information not originally made available.

Stage 2: Should the outcome of the review be contested by the researcher, he or she can submit an appeal to the same Committee. The Committee shall invite an external review of the protocol. The external reviewer(s) will be independent, having no previous involvement in the ethical review process leading to the appeal. The review report will be issued, and this report will be final and not subject to further review.

11.0 MONITORING AND COMPLIANCE

The Committee shall monitor research projects to oversee continued ethical propriety. Research must be monitored in accordance with the University's Ethical Review Policy and other codes of practice relevant to the field.

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 people in the Community.

12.0 EDUCATIONAL ACTIVITIES

All investigators are required to participate in certified Research Ethics Training programmes. The Committee shall be responsible for educating members on good research conduct, by providing literature and leading discussions. The Committee shall educate researchers including those who have active research projects involving the community. Resource persons who are experts in the subject matter may be invited to take part in these educational activities.

13.0 FUNDING

The University shall provide the necessary funding for the operations of the Committee.

14.0 RECORD KEEPING

1. The Committee shall maintain a database to facilitate tracking of research projects submitted for review. All documents of the Committee shall be dated, filed and archived. Hard copies of research projects approved by the Committee will be filed and archived for a minimum of ten (10) years. Each project folder will include the following types of documents, as conventional hard copies:
 - a. Initial Review Application Form – FORM A.
 - b. Study Protocol.
 - c. Investigator's Brochure (if applicable).
 - d. Investigator's abridged cv.
 - e. Insurance policy document (If applicable).
 - f. Certification documents from other agencies, as mandated by regulatory agencies.
 - g. Committee Approval Certificate.
 - h. Research Progress Report Form – FORM B (if applicable).
 - i. Research Final Report.
 - j. Protocol Amendment Application.
 - k. Statements on significant new findings.
 - l. Correspondence between the Committee and investigators of the project.
2. 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.
 - Agendas of meetings.
 - Minutes of meetings.
 - Reports of internal audits of the Committee.
 - 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.
3. Records on Committee members shall include the term and status of each member, curriculum vitae, appointment document and information about training received. Such information shall be maintained and updated as necessary and should be retained for at least ten (10) years after completion of service.
 4. The Chairperson must review and sign where appropriate, all Committee documents annually or whenever there is a change of Chairperson.
 5. Research investigators shall use the following revised 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)

6. The Committee at its own discretion may issue the following documents for investigators:
 - Ethical clearance
 - Approval letters
 - Notification letters
7. Investigators may use the following document as guidance when writing their study protocol.
 - Guidance for Preparation of Study Protocol

The Standard Operating Procedures shall guide the activities of Investigators and Committee Members in order to ensure ethical research.

15.0 APPENDICES

Appendix 1 Application Form (A1)

Appendix 2 Consent Form (A2)

Appendix 3 Proposal Submission Checklist

Appendix 4 Continuing Review Form (B)

Appendix 5 Application for Amendment to Approved Protocol (C)

Appendix 6 Serious Adverse Event Form (D)

Appendix 7 Final Project Report Template

APPENDIX 1

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
ETHICAL CLEARANCE FOR HUMANITIES AND
SOCIAL SCIENCES RESEARCH
APPLICATION FORM (A1)

Section A – Proposal & Researcher Details

1. Title of proposal:			
2. Has the protocol been submitted to any other ethical review Committee? (REC) <i>(Please circle your response)</i>		YES	NO
2.1 If so, list which Institutions and any Reference numbers			
2.2 What was/were the outcome(s) of the applications			
3. Is this proposal being submitted for ethical clearance for research related to or expanding on research previously approved by the Humanities and Social Sciences Research Ethics Committee? <i>Hint: Please circle your response</i>		YES	NO

4. Researcher Details

4.1 Principal Researcher

Title	Initials and Last Name		Department & Institution	
Phone	E-mail	Signature		Date

4.2 Co-researchers

Title	Initials and Last Name		Department & Institution	
Phone	E-mail	Signature		Date

Title	Initials and Last Name		Department & Institution	
Phone	E-mail	Signature		Date

Title	Initials and Last Name		Department & Institution	
Phone	E-mail	Signature		Date

5. Is the research being undertaken for a higher degree?	YES	NO
If yes,		
5.1 What degree?		
5.2 Student's Name:		
5.3 Supervisor's Name:		
5.4 In What Department is the degree to be awarded?		

Section B – Check List

		Please Tick
Detailed research proposal	5 hard copies + electronic copy	
Covering letter and all other relevant Correspondence	5 hard copies + electronic copy	
Consent forms (include translations if indicated)	5 hard copies + electronic copy	
Subject information sheet (if separate from consent form)	5 hard copies + electronic copy	
Approval from Head of Department or Research grouping (signature)	Departmental Stamp	

Section C – Research Information

15. Estimated number of participants:
16. Estimated duration of study:
17. Location of study:

Section D – Financial and Contractual Information

18. Is the study being sponsored or funded? <i>(Please circle your response)</i>	YES	NO
If Yes		
19.1 Who is the sponsor/funder of the study?		
19.2 What is the total budget/ sponsorship of the study?		
19.3 Into what fund is the sponsorship being paid?		

19.4 Are there any restrictions or conditions attached to publication and/or presentation of Study results?		
19.5 Does the contract specifically recognize the independence of the researchers involved?		
<i>(Note that any such restrictions or conditions contained in funding contracts must be made available to the committee along with the proposal)</i>		

Section E – Statement on Conflict of Interest

The researcher is expected to declare to the committee the presence of any potential or existing conflicts of interest that may pose a threat to the scientific integrity and ethical conduct of any research in the College. The Committee will decide whether such conflicts are sufficient as to warrant consideration of their impact on the ethical conduct of the study. Disclosure of conflict of interest does not imply that a study will be deemed unethical, as the mere existence of a conflict of interest does not mean that the study cannot be conducted ethically. However, failure to declare to the committee a conflict of interest known to the researcher at the outset of the study will be deemed to be unethical conduct. Researchers are therefore expected to sign either of the two declarations below.

As the Principal Researcher in this study, I (Name :.....), hereby declare that I am **not aware** of any potential conflict of interest which may influence my ethical conduct of this study.
Signature
Date

As the principal researcher in this study, I (Name :.....), hereby declare that I am **aware** of potential conflicts of interest which should be considered by the committee.
Signature
Date

APPENDIX 2

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

CONSENT FORM (A2)

Title of research project:

Names of Principal researchers:

Department /research group address:

Telephone:

Email:

Name of participant:

Nature of research:

Participant’s involvement:

What is involved? :

Risks:

Benefits:

Costs:

Payment:

- I agree to participate in this research project
- I have read this consent form and the information it contains and I had the opportunity to ask questions about them

- I agree to my responses being used for education and research on condition that my privacy is respected, subject to the following:
- I understand that my personal details may be included in the research /will be used in aggregate form only, so that I will not be personally identifiable (delete as applicable)
- I understand that I am under no obligation to take part in this project
- I understand that I have the right to withdraw from this project at any stage.

Signature of participant /Guardian (if under 18):

.....

Name of participant / Guardian:

.....

Signature of person who sought consent

.....

Signatures of principal researchers:

a)..... (Name)

b)..... (Name)

c)..... (Name)

Date:

APPENDIX 3

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

PROPOSAL SUBMISSION CHECKLIST

1	Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it? (Please circle your response)	YES/ NO
2	Is your research design appropriate for the question(s) being asked?	YES/ NO
3	Will you have access to all necessary skills and resources to conduct the research?	YES/ NO
4	Have you conducted a risk assessment to determine: Whether there are any ethical issues and whether ethics review is required; The potential for risk to the organisation, the research, or the health, safety and well-being of researchers and research participants; and What legal requirements govern the research?	YES/ NO
5	Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant?	YES/ NO
6	Will your research comply with all requirements of legislation and good practice relating to health and safety?	YES/ NO
7	Has your research undergone any necessary ethics review (see 4(a) above), especially if it involves human participants, human material or personal data?	YES/ NO
8	Will your research comply with any monitoring and audit requirements?	YES/ NO

9	Are you in compliance with any contracts and financing guidelines relating to the project?	YES/ NO
10	Have you reached an agreement relating to intellectual property, publication and authorship?	YES/ NO
11	Have you reached an agreement relating to collaborative work, if applicable?	YES/ NO
12	Have you agreed to the roles of researchers and responsibilities for management and supervision?	YES/ NO
13	Have all conflicts of interest relating to your research been identified, declared and addressed?	YES/ NO
14	Are you aware of the guidance from all applicable organisations on misconduct in research?	YES/ NO
15	When conducting your research: Are you following the agreed research design for the project?	YES/ NO
16	Have any changes to the agreed research design been reviewed and approved if applicable?	YES/ NO
17	Are you following best practice for the collection, storage and management of data?	YES/ NO
18	Are agreed roles and responsibilities for management and supervision being fulfilled?	YES/ NO
19	Is your research complying with any monitoring and audit requirements?	YES/ NO
20	When finishing your research: Will your research and its findings be reported accurately, honestly and within a reasonable time frame?	YES/ NO
21	Will all contributions to the research be acknowledged?	YES/ NO

APPENDIX 4

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

CONTINUING REVIEW FORM (B)

PROTOCOL TITLE: _____

HuSSREC#: _____ DATE OF INITIAL APPROVAL: _____

PRINCIPAL INVESTIGATOR: _____

DEPARTMENT: _____

CAMPUS ADDRESS: _____ PHONE: _____

1. NATURE OF THE PROTOCOL/STUDY
2. PROTOCOL STATUS. Please indicate (X) the status of this project.

Request Protocol Continuation:

- A. Active – project on-going.
- B. Currently inactive – project was initiated but is presently inactive.
- C. Inactive – project never initiated but anticipated start date is
_____.

3. 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.

4. FUNDING SOURCE: Specify the funding source.

5. 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

6. PROGRESS REPORT. If the status of this project is 2. A. (active; project on-going) or 2. B. (project was initiated, but is presently inactive), provide a brief update on the progress made in achieving the specific aims of the protocol.
7. PROBLEMS/ADVERSE EVENTS. If the status of this project is 2. A. (active; project ongoing) or 2. 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.
8. 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.
[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]

Other. Provide a brief explanation.

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

Signature of the Principal Investigator

Date

APPENDIX 5

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

AMENDMENT TO APPROVED PROTOCOL FORM (C)

This form is required for all proposed minor amendments to protocols already approved by the HuSSREC. New projects or substantial changes to previous applications must submit a full application.

Please send a copy of the completed form to the HuSSREC Secretariat.

1. Name(s) of applicant(s):
2. Department/Faculty/School/College:
3. Email:
4. Tel:
5. Title of application for which amendment is requested:
6. Please describe changes requested to approved protocols:
7. 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:
8. Expected date of completion of amended project (please justify any changes from the original completion date):

Approval:

Amendments Approved (Chairperson, HuSSREC):

Date:

Any Special conditions applying:

APPENDIX 6

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

SERIOUS ADVERSE EVENT FORM (D)

Protocol No:	Principal Investigator:		
Project Title:			
Participants:			
Date of incident:		Date of report:	
1	Please summarize the circumstances surrounding the event, and describe what action was taken.		
2	If an unexpected death has occurred, has an autopsy been performed? If no, state why not. If yes, state who performed it and provide a copy of the autopsy report.		

APPENDIX 7

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

FINAL PROJECT REPORT TEMPLATE

This form is required upon completion of all approved applications from the HuSSREC. The purpose is to provide the Committee with a record of your use of human participants 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 Secretariat.

1. Name(s) of applicant(s):
2. Department/Faculty/School/College:
3. Email:
4. Tel:
5. Title of application:
6. What was the total number of participants used in your project?
7. Summarise (in lay terms) the main findings of your study and what you view as its contribution to your discipline:
8. What outputs have resulted from this work (i.e., theses, publications, research seminars, conference presentations, etc.).

Thank you for your cooperation.

QUALITY ASSURANCE AND PLANNING UNIT

Vice-Chancellor's Office

Kwame Nkrumah University of Science and Technology

KNUST, Kumasi

PMB UPO, Kumasi-Ghana

Tel: +233 322060319

Email: info.qapu@knust.edu.gh

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