KENYATTA UNIVERSITY

INSTITUTIONAL SCIENTIFIC ETHICS REVIEW COMMITTEE

POLICY AND OPERATIONAL GUIDELINES FOR BIOMEDICAL, ENVIRONMENTAL, SOCIAL AND BEHAVIOURAL RESEARCH

2025-2029

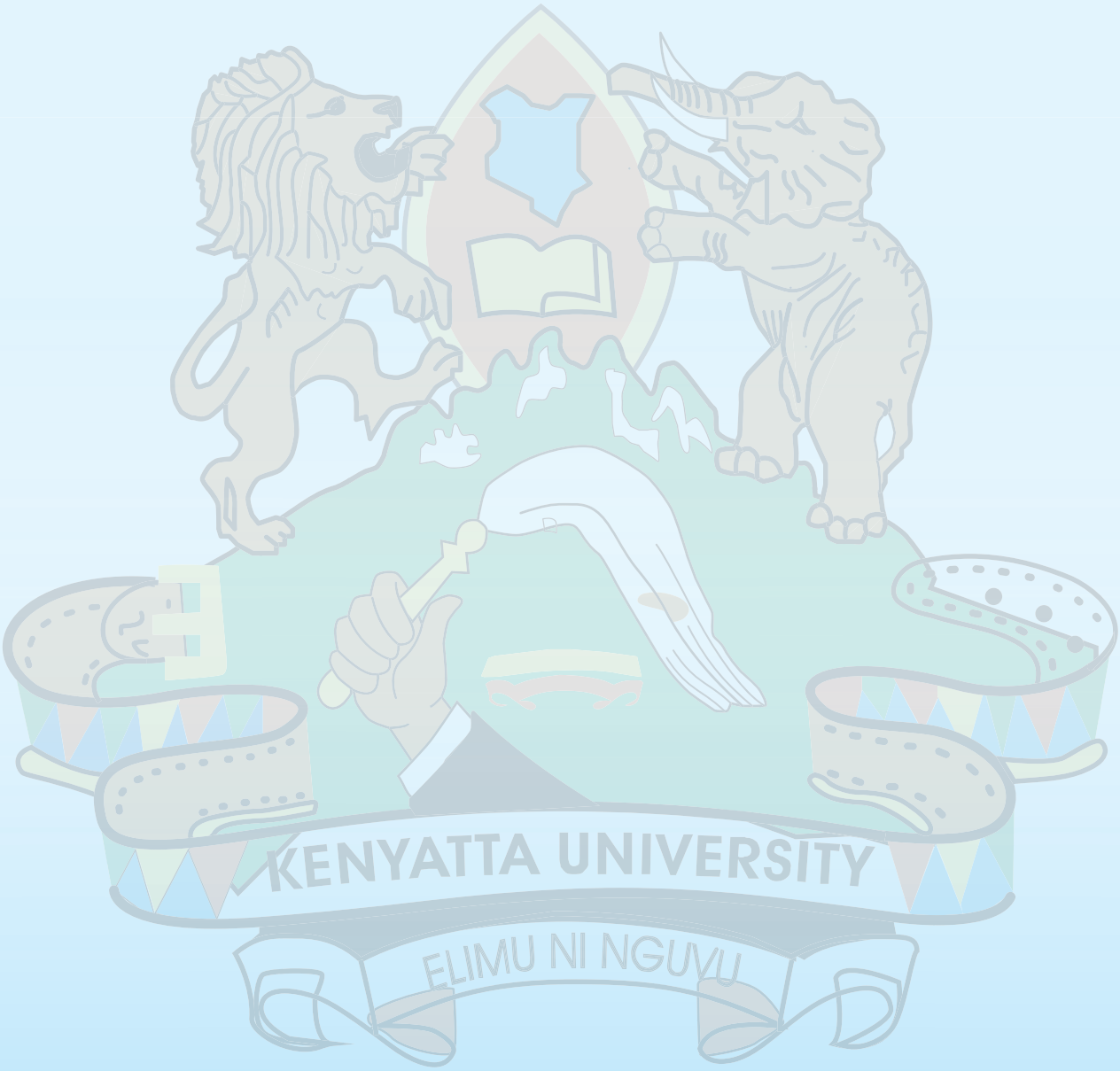
KENYATTA UNIVERSITY
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TABLE OF CONTENT

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1.0 FUNDAMENTAL STATEMENTS

1.1 The Vision Statement

The vision of Kenyatta University is to be a dynamic, an all-inclusive, globally competitive center of excellence in the provision of quality education, training and research for sustainable development.

1.2 Mission Statement

The mission of Kenyatta University is to provide quality education and training through knowledge generation, research, innovation, creativity and community service.

1.3 Identity Statement

Kenyatta University is a community of scholars committed to the generation and dissemination of knowledge and cultivation of wisdom for the welfare of society.

1.4 Philosophy Statement

Kenyatta University's philosophy is sensitivity and responsiveness to societal needs and the right of every person to knowledge.

1.5 KUISERC Philosophy Statement

Kenyatta University Ethics Review Committee's Philosophy is to provide independent, competent, and timely review of the ethics of proposed studies. To adhere to globally recognized guidelines such as the Declaration of Helsinki, the UNESCO Universal Declaration on Bioethics and Human Rights, and the guidelines set forth by the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and other relevant ethical frameworks.

In its procedures and decision-making, KU-ISERC will be independent from political, institutional, professional, and market influences.

2.0 PREAMBLE

Research is an essential part of advancing knowledge and improving the well-being of individuals and communities. However, it is imperative that research is conducted in a manner that respects the rights, dignity, and welfare of participants, while maintaining the integrity of the scientific process. The purpose of these guidelines, therefore, is to establish a framework for ensuring that all research activities adhere to the highest ethical standards.

The guidelines emphasize the importance of respect for persons, beneficence, and justice, drawing on widely recognized ethical principles such as those outlined in the Belmont Report and other international research ethics standards. By adhering to these principles, researchers and institutions can promote ethical behavior, ensure participant safety, and foster public trust in the research process. These research ethics review guidelines are designed to ensure that all research, whether focused on biomedical, environmental, social, or behavioral topics, adheres to the highest ethical standards. In biomedical research, the focus is on protecting the health, safety, and well-being of human participants, ensuring informed consent, and minimizing risks associated with medical interventions. Environmental research requires careful consideration of the ecological impact, sustainability, and long-term consequences of research practices, while respecting both human and non-human life. Social and behavioral research demands special attention to the societal implications, respect for cultural values, the prevention of harm, and the protection of vulnerable populations.

Emerging issues in research ethics reflect the evolving landscape of scientific inquiry, technological advances, and societal changes. As new methodologies, technologies, and interdisciplinary approaches emerge, researchers and ethics committees face complex challenges such as ethical use of artificial intelligence and machine learning, big data and privacy concerns, genetic research and gene editing, neuroscience and brain research, research involving vulnerable populations, environmental and sustainability ethics, global research and ethical standards, dual-use research and security risks, social media and research ethics, post-research ethical concerns and climate change research ethics. The ultimate goal is to ensure data protection through research integrity, observation of transfer of technologies and materials, protection of intellectual properties and hence security of beneficiaries, researchers and the nation.

These emerging issues reflect the growing complexity of research ethics in a rapidly evolving world. As technologies advance and the scope of research widens, ethical oversight must adapt to ensure that the rights of participants, the integrity of the research process, and societal benefits are always at the forefront of scientific inquiry.

This document outlines the procedures for the ethical review of research proposals, ensuring that studies are designed and conducted in a way that minimizes risk to participants, maximizes potential benefits, and complies with relevant laws, regulations, and ethical norms. These guidelines apply to all research involving human participants, as well as other forms of sensitive or high-risk research.

All researchers, regardless of their field or discipline, are expected to adhere to these guidelines as a condition of conducting research. These guidelines provide the foundation for a rigorous, ethical review process that is essential for conducting responsible and credible research across disciplines. By adhering to these principles, researchers can ensure that their work contributes positively to knowledge, public welfare, and sustainable development.

3.0 BACKGROUND

Research has the potential to bring about transformative changes in society, the environment, and public health. However, it is our collective responsibility to ensure that these endeavors are carried out in a manner that respects the rights, dignity, and welfare of all those involved—whether they are participants, communities, or the environment. We as Kenyatta University, are committed to fostering an environment where ethical reflection is integrated into every stage of the research process. These guidelines are not just a regulatory necessity; they represent our ongoing commitment to making research a force for good, with long-lasting benefits for society and future generations. As we continue to advance in the pursuit of knowledge and innovation, it is essential that we , remain committed to conducting research that is not only scientifically rigorous but also ethically sound.

In Kenya, research regulation is primarily governed by the "Science, Technology and Innovation Act" (STI Act) of 2013, which mandates that all research activities in the country require a license from the National Commission for Science and Technology (NACOSTI) and must adhere to ethical guidelines set by accredited Institutional Ethics Review Committees; essentially, anyone conducting research in Kenya needs to obtain NACOSTI approval before starting their study. In addition, the primary research ethics regulatory body, the National Commission for Science, Technology and Innovation (NACOSTI), oversees research ethics through its National Bioethics Committee (NBC), Animal use and care regulatory bodies and accredits Institutional Scientific and Ethics Review Committees (ISERCs) to conduct ethical reviews at the institutional level, essentially, researchers must obtain ethical clearance from an accredited ISERC before conducting research in Kenya.

The other primary research regulators are the Pharmacy and Poisons Board (PPB), which oversees clinical trials, the Kenya Plant Health Inspectorate Service (**KEPHIS**), who provide a science-based regulatory service by assuring plant health, quality of agricultural inputs and produce for food security, globally competitive agriculture, and sustainable development, while the National Commission for Science, Technology and Innovation (NACOSTI), which provides broader oversight for research activities within the country. Essentially, the PPB regulates the clinical research aspect while NACOSTI handles the wider research landscape.

In Kenya, the legal framework for science and technology came into existence in 1979 under the Science and Technology Act. The Act established the then National Council of Science and Technology (NCST).Later renamed the National Commission of Science, Technology and Innovation (NACOSTI), empowering it to coordinate all research in Kenya and advise the government on all matters related to research. The function of NACOSTI entails the documentation of all research in the country and all the institutions in which research is being conducted. For research of any nature to be conducted on humans in Kenya, ethical clearance is mandatory and this is done by accredited ISERCs in the respective institution.

The Ethical Review Committee in Kenyatta University is anchored in the Kenyatta University Research Policy and mandated to review ethics of proposals and projects in accordance with the University Research Policy. The guidelines herein are intended to facilitate the review and clearing of researches involving human subjects both locally and internationally

MESSAGE FROM THE VC

Kenyatta University, is the home to a growing body of scholars recognized nationally and internationally for the significance of their contributions to the humanities, social, physical, environmental sciences, business, economics, law, medicine, public health, engineering, education and the creative arts. We are committed to building on a dynamic research culture that enriches the academic experience for our students, creates new knowledge across a broad array of disciplines, and helps improve the economic, social, and cultural vitality of our country, region and beyond.

Kenyatta University's mission is to provide quality education and training, through knowledge generation, research, innovation, creativity and community service. Research and creative inquiry is at the heart of all Kenyatta University does and therefore, within a vibrant and supportive learning environment, Kenyatta University discovers, disseminates and applies new knowledge. We impact the quality of teaching and learning, collaborating with researchers in and out of the country, partnering with our local community, industry, government, and sharing evidence-based research with policy makers.

The vision of Kenyatta University is to be a dynamic, inclusive and competitive center of excellence in teaching, learning, research and service to humanity, with a mission to provide quality education and training, promote scholarship, service, innovation and creativity and inculcate moral values for sustainable individual and societal development. Kenyatta University is a community of scholars committed to the generation and dissemination of knowledge and cultivation of wisdom for the welfare of society with core values of truth, excellence, self-reliance, innovation, equal opportunity, corporate governance, institutional culture, competitiveness, academic freedom and respect and diversity. The Philosophy of Kenyatta University is to foster sensitivity and responsiveness to societal needs and the right of every person to knowledge.

In line with these fundamental statements within which Kenyatta University is anchored, the Center for Research Ethics and Safety, has the key mandate to promote quality research that is guided by strong ethical guidelines and principles through coordinating the review of research ethics in research in humans, animal care and use as well as biosafety, in compliance with the University Research Policy, the International and National guidelines.
The guidelines provide a comprehensive framework for researchers across disciplines to ensure that studies are designed and conducted with the utmost consideration for ethical principles. They highlight the importance of safeguarding human and environmental well-being, protecting vulnerable populations, promoting fairness, and minimizing harm. Whether the research involves clinical trials, environmental studies, ecological studies, or social behavioral assessments, the overarching goal is to advance knowledge in a responsible and just manner.

OFFICE OF THE VICE CHANCELLOR

4.0 RATIONALE

Kenyatta University has in the past undertaken research in diverse fields including those involving human subjects, animal use and care and biosafety. Ethical clearance has previously been sought and obtained from collaborating partners and existing clearing institutions recognized by the NACOSTI. Kenyatta University has also established several multidisciplinary programs which have generated more research on human subjects. Animals and biosafety, as well as taking into cognizance emerging issues such as data protection and security, emerging technology, information and material transfer, confidentiality, informed consent disclosures and conflict of interest, hence the need for ethical guidelines.

5.0 OBJECTIVES

The objectives of these guidelines are to;

- Contribute to quality and consistency in the Ethical Review of Research conducted at and/ or overseen by Kenyatta University.
- Complement existing policies and regulations governing research at Kenyatta University and other networking partners.
- Provide a basis for evaluation of the Standard Operating Procedures (SOPs) for Biomedical, Environmental, Social and Behavioral Research
- To be used by structural units of Kenyatta University in developing, monitoring, evaluating, capacity building and progressively refining SOPs

6.0 THE ROLE OF KU-ISERC

The role of KU-ISERC is to:

- Review and clear proposed research before its commencement.
- Provide independent, competent, and timely review of the ethics of proposed studies. In its procedures and decision-making, KU-ISERC will be independent from political, institutional, professional, and market influences.
- Review prospective and continuing research protocols so as to safeguard the dignity, rights, safety, and well-being of all actual or potential participants in biomedical, environmental, social and behavioral research. This is in cognizance of the fact that the goals of research, should never be permitted to override the health, well-being, and care of research participants.
- Take into consideration the principle of justice. This requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, cultural, political, religious, ideological, race and ethnic considerations.
- Review the adequacy of the informed consent document, particularly as to its description of the care and protection of subjects, confidentiality, risks and benefits to individuals and communities.
- Ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision.
- Evaluate reports for unanticipated problems, possible non-compliance, and other information and incidents that might affect approval of protocol or the subjects' willingness to continue to participate.
- Act in the interest of potential research participants and concerned communities, taking into

account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

- Conducting reviews concerning possible non-compliance.
- Promoting awareness and understanding of ethical issues in research throughout the University's research community (i.e. ethical issues that are relevant to research that involves human participants and also ethical issues that are relevant to other types of research);
- Providing advice on any ethical matters relating to research that are referred to it from within and outside the University
- Keeping abreast of new externally-driven developments, policies and regulations concerning research ethics and, where appropriate, ensuring that the University meets all necessary requirements

7.0 CONSTITUTION OF THE KU - ISERC

The constitution of the KU-ISERC will adhere to the national and internationally set requirements so as:

- To ensure that it is established in accordance with the policies of Kenyatta University and adherence to the values and principles of the communities they serve.
- To be multi-disciplinary and multi-sectorial in composition, including relevant scientific expertise, balanced age and gender distribution and laypersons representing the interests and the concerns of the community.
- to ensure that it establishes publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties of the ethics committee, membership requirements, the terms of appointment, the offices, the structure of the secretariat, internal procedures and the quorum requirements.

7.1 Membership requirements

The appointment of KU-ISERC membership will be direct appointment by the Vice Chancellor of Kenyatta University. The KU-ISERC shall be 9 (Nine) to19 (nineteen) members of whom at least 40% shall be drawn from human health related professions, taking into account the diversity of the disciplines. The committee shall also include at least 40% of each gender.

Eligibility of membership shall be as follows:

- Social and behavioral scientists, physician, epidemiologists, nurses, basic scientists, paramedical, , a lawyer, a statistician, a lay person, a religious representative, a community representative, a media person, Engineers, Psychology, Occupational Therapy, Physiotherapy, Dietetics and Pharmacy. 'This list is clearly indicative and not exhaustive'
- A rotation system will be adopted for membership in order to maintain continuity, development and maintenance of expertise within the KU-ISERC, and the regular input of fresh ideas and approaches.

7.2 Terms of appointment

The terms of appointment governing the KU-ISERC shall be as follows:

1. Duration of appointment: the duration of an appointment will be for a term of two (2) years but renewable.
2. Renewal of appointment: the appointment may be renewed at the end of every term for a maximum of two terms. To ensure continuity, two thirds of the members shall be reappointed each time.
3. Disqualification procedure: a member will be liable for disqualification on the following grounds:
   i. Engaging in gross professional misconduct.
   ii. Breaching the confidentiality agreement
   iii. Failure to attend more than three consecutive meetings without apology or acceptable explanation.
4. Resignation: a member can resign by tendering one month's notice to the appointing authority (copied to the chairman of KU-ISERC).
5. Replacement: replacement of a committee member shall be done upon resignation, retirement, disqualification or death of a member, taking into account expertise of the member being replaced.

6. Remuneration: KU-ERC members shall be compensated for time taken on proposal review. The allowance will be determined from time to time by the appointing authority based on the statutes of the university.

7.3 Conditions of appointment:

Conditions of appointment include the following:

- A member should be willing to publicize his/her full name, profession and affiliation.
- All reimbursement for work and expense, if any, within or related to KU-ERC should be recorded and made available to Kenyatta university upon request.
- A member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and other related matters.
- All KU-ISERC Administrative staff will sign a similar confidentiality agreement.
- All KU-ISERC members shall undergo introductory training in the work of ISERCs as well as undergoing opportunities to enhancing their capacity for ethical reviews.

7.4 The KU-ISERC Secretariat:

KU-ISERC secretariat will consist of the following officers for the effective and efficient running of the committee:

1. Chairperson – to be appointed directly by the appointing authority. The chairperson shall be a senior member of staff with experience in any area of biomedical and basic sciences, Social and behavioral sciences research and whose duties shall include inter alia:
    1. Presiding over meetings
    2. Communicating decisions of the ISERC
    3. Ensuring prompt and timely review of proposals.
    4. Overseeing the operations of the ISERC and the secretariat
    5. Coordinating capacity building workshops for ISERC members and researchers
    6. Preparing annual and work plan and budget for the ISERC operations
    7. Writing of annual reports
    8. Coordinating the renewal of accreditation of the ISERC
    9. Linking the ISERC with the national and international ISERC regulatory bodies
2. Secretary- to be appointed by the appointing authority and whose duties will include inter alia:
    1. Preparing the agenda and convening meetings
    2. Taking and circulating minutes
    3. Ensuring proper record keeping.
    4. Following up with ongoing research and approval renewals
    5. Supporting the ISERC and secretariat operations
3. Support staff- will be provided by KU to support the operations of the committee. These will include an office administrator, office clerk, a secretary and an office messenger, who's TORs will be determined by the chairperson in liaison with the appointing authority.

4. Any other sub committees –as may be constituted by KU-ISERC from time to time as need arises.

7.5 Quorum requirements

The quorum requirements for reviewing and deciding on an application shall be as follows:

1. The minimum number of members required to compose a quorum shall be one more than half.
2. The professional qualifications should reflect the diversity of membership and should comprise 40% healthcare related professionals and at least a member from other disciplines.
3. No quorum should consist entirely of members of one professional one gender; a quorum should include at least one member whose primary area of expertise is in a non-scientific area, and at least one member who is independent of the institution or research.

7.6 Independent consultants

KU-ISERC shall call upon, or establish, a standing list of independent consultants who may provide special expertise to the KU-ISERC on proposed research protocols. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups. Terms of reference for independent consultants shall be established by the KU-ISERC from time to time or on appointment.

7.7 Capacity building for the KU-ISERC.

KU-ISERC shall undergo initial and continued education regarding the ethics and science of biomedical and basic sciences, environmental, social and behavioral research. This education may be linked to co-operation arrangements with other ERCs in the country, the region, and at international level as well as other opportunities for the initial and continued training of KU-ISERC members.

Sensitization of researchers to be done quarterly on the importance of research ethics and the need to seek ethical approval for compliance.

8.0 SUBMITTING AN APPLICATION

8.1 Application

The KU-ISERC secretariat will receive Biomedical, Environmental, Social and Behavioral research proposals for ethical review from applicants in the manner and format prescribed in Appendix B.

An application for review of the ethics of proposed research should be submitted by an applicant responsible for the ethical and scientific conduct of the research.

8.2 Application requirements

The requirements for the submission of a research project for ethical review will be clearly described in an application procedure as set out in Appendix C.

These requirements will include the following:

1. The name(s) and address (es) of the ISERC secretariat to whom the application material is to be submitted.
2. The documentation (see Appendix C)
3. The language in which documents are to be submitted will be English or Kiswahili. [Documents submitted in any other language should be translated into English or Kiswahili by a competent and accredited interpreter at the expense of the applicant].
4. The deadline for submission of the application is 2 weeks prior to the next scheduled meeting.
5. Applications will be acknowledged and researchers shall be informed of the review date via shortest mode possible.
6. The acknowledgement of the application shall be communicated to the researchers within a week after receipt of the application.
7. In cases where the ISERC requests supplementary information or changes to documents from the applicant, such information should be provided to ISERC at least a week prior to the next meeting.
8. In cases where clarification is sought and researchers fail to respond within 3 months, ISERC will send a reminder and allow a further 3 months period for response. Beyond these 6 months, the application file will be closed.
9. Researcher may be asked to present their case in an ISERC meeting if required, including follow- up and end-report.
10. There shall be a fee for the review of every proposal which shall be determined from time to time by KU-ISERC.
11. The researcher shall be required to re-submit the application for review if there is any amendments (modification) to the original protocol, the recruitment procedure, the potential research participant information, or the informed consent form.

8.3 The Review

All properly submitted applications will be reviewed in accordance with the procedure established by KU-ISERC as follows;

8.3.1 Meeting requirements

Meetings shall be held by KU-ISERC on the following terms:

- Meetings will be held every second Tuesday of the Month.
- In the event that it is not possible to hold the meeting on the scheduled Tuesday (e.g. due to a public holiday), the committee shall meet on the following Wednesday.
- Meetings will also be held at such other times as the Committee may determine such as when they need to handle expedited reviews.
- Documents to be discussed during the meeting will be circulated to the reviewers at least a week before every scheduled meeting
- Minutes will be taken in all scheduled meetings and the same approved by the ISERC members.
- The applicant, sponsor, and/or investigator may be invited to present the proposal or elaborate on specific issues.
- Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements.

8.3.2 Elements of the review

The primary task of the KU-ISERC is to review research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the sustainability and feasibility of the protocol. KU-ISERC will take into account prior scientific reviews, if any, and the requirements of applicable guidelines as outlined in Appendix D.

The following should be considered, as applicable:

- Scientific design and conduct of the study
- Recruitment of research participants
- Care and protection of research participants
- Protection of research participant's confidentiality
- Informed consent process
- Community considerations

8.3.3 Approval conditions

a) Approval shall be given for a specified period. If the project takes longer than the specified period to complete, a request for an extension of the ethics clearance shall be sought.

b) Approval shall be given on condition that any alterations proposed to the approved protocol are submitted to the Committee for approval prior to the alterations being effected.

c) Approval shall be given on condition that a copy of the research project final report will be submitted to the KU-ISERC for reference

d) Approval shall be given subject to researchers notifying the Ethics Committee if and when a project is curtailed, terminated or completed.

e) Approval shall be given for therapeutic trials subject to the Principal Investigator notifying the KU-ISERC

within seven (7) days of any adverse event or occurrence that takes place during that trial.

f) Research may be audited by KU-ISERC during the research period to ensure compliance with these guidelines.

8.3.4 Decision making

In making decisions on applications for the ethical review of Biomedical, Environmental, Social and Behavioral research, KU-ISERC will take the following conditions into consideration:

a. A member shall withdraw from the meeting for the decision procedure concerning an application when there is conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

b. A decision shall only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g. the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of KU-ISERC staff.

c. Decisions will only be made at the meetings where a quorum (as stipulated in KU-ISERC's written operating procedures) is present.

d. The documents required for a full review of the application should be complete and the relevant elements mentioned above (see 8.1.1.) will be considered before a decision is made.

e. Only members who participate in the review will participate in the decision.

f. Decision shall be arrived at by consensus, failure to which a vote shall be taken in which case the majority vote will carry the day.

g. Advice that is non-binding may be appended to the decision.

h. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified.

i. All decisions on an application will be supported by clearly stated reasons.

j. A decision made by a fully constituted KU-ISERC shall be binding to the applicant who could appeal against a decision providing new grounds in support of the original application(in form and context)

k. An application that remains non-compliant with the KU-ISERC decision shall be disallowed.

8.3.5 Verdict Options

i. Approved

Where there are no amendments required

ii. Approved with advice

When there are minor amendments recommended

iii. Conditional approval

When there are major amendments (refer to 3.6.2) required

iv. Re-submission

When the application does not meet more than 80% of the review elements (refer to 8.1.1.)

v. Disallow

When a proposal is ethically unacceptable

8.3.6 Communicating decision

A decision will be communicated through the chairman's email to the applicant according to KU-ISERC procedures within one week of the meeting at which the decision was made. The communication of the decision will include, but not limited to the following:

a. The title of the research proposal reviewed.

b. The clear identification of the protocol of the proposed research or amendments dates and version number (if applicable) on which the decision is made.

c. The names and (where applicable) specific identification numbers (version numbers/ dates) of the documents reviewed including the potential research participants information sheet/material and informed consent form.

d. The name and the title of the applicant

e. The name of the site(s).

f. The place and the date of the decision

g. A clear statement of the decision reached

h. Any advice by the KU-ISERC

i. In the case of conditional decision, any requirements by the ISERC, including suggestions for revision and the procedure for having the application re-reviewed.

j. In the case of a positive decision, a statement of the responsibilities of the applicant for example:

- Confirmation of the acceptance of any requirements imposed by the KU-ISERC.
- For Clinical trials involving Pharmaceutical products and devices, approval will be sort from pharmacy and poisons Board. For animal use and care and biosafety approvals will be sought from the relevant regulatory bodies. For environmental, social and behavioral sciences approval will also be sought from the applicable regulatory agencies/organizations.
- submission of progress report(s)
- the need to notify the KU-ISERC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study)
- The need to notify the KU-ISERC in case of amendments to the recruitment procedure, the potential research participant information, or the informed consent form.
- The need to report serious and unexpected adverse events related to the conduct of the study.
- The need to report unforeseen circumstances, the termination of the study, or significant decisions by other ISERCs.
- Information the KU-ISERC expects to receive in order to perform ongoing review.

the final summary or final report

k. The schedule and or plan of ongoing review by the KU-ISERC.

l. In the case of a negative decision, clearly stated reason(s) for the negative decision.

m. Signature (dated) of the Chairperson of the KU-ISERC.

n. Appeal process: Issues to be channeled to The Institutional Research Ethics Review Board mandated to address issues of research integrity, data protection, technology transfer security, research misconduct and creation/provision of an enabling and competitive environment to conduct research; through the formulation of frameworks and policies to guide the operation and monitoring and evaluation of research activities at Kenyatta University.

9.0 MONITORING AND EVALUATION

All proposals that receive a positive decision shall be monitored and evaluated periodically throughout the project life cycle. The follow-up procedure should take the following into consideration:

a) The M & E review will be carried out by a sub-committee constituted by the KU-ISERC for the specific project. The quorum requirement, the review procedure, and the communication procedure for follow up reviews will be determined by the respective sub-committee.

b) The follow –up review intervals will be determined by the nature and the events of research projects but in the following instances or events, a follow-up review is mandatory:

- Any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study
- Serious and unexpected adverse events related to the conduct of the study or study product, and the response taken by investigators, sponsors and regulatory agencies
- Any event or new information that may affect the benefit/risk ratio of the study

c) A decision of a follow-up review shall be issued and communicated to the applicant, indicating modification, suspension, or termination of the KU-ISERCs original decision or confirmation that the decision is still valid

d) In the case of premature suspension/termination of a study, the applicant should notify the KU-ISERC of the reasons for suspension/termination

e) A summary of results obtained in a study prematurely suspended/terminated should be communicated to the KU-ISERC by the researcher

f) KU-ISERC will receive notification from the applicant at the time of the completion of a study

g) KU-ISERC shall receive a copy of the final summary or final report of a study

All documentation and communication of the KU-ISERC shall be dated, filed, and archived according to Kenyatta University Quality Management System (QMS) written procedures. Documents to be filed and archived include but not limited to:

a) The KU-ISERC guidelines

b) Written standard operating procedures of the KU-ISERC

c) Regular annual reports

d) The curriculum vitae of all KU-ISERC members

e) A record of all income and expenses of the KU_ISERC including allowances and reimbursements made to the secretariat and committee members

f) The published guidelines for submission established by KU-ISERC

g) The agenda of KU-ISERC meetings

h) The minutes of KU-ISERC meetings

i) A copy of all materials submitted by an applicant

j) The correspondence by KU-ISERC secretariat with applicants or concerned parties regarding application, decision and follow-up

k) A copy of the decision and any advice or requirements sent by an applicant

All written documentation received during follow-up

l) The notification of the completion, premature suspension or premature termination of a study

m) The final summary or final report of the student

n) All matters relating to data protection are anchored on the Data Protection Act 2019 as well as the KU ICT Policy on Data Protection

11.0 GLOSSARY

The definitions provided within this glossary apply to terms as they are used in these Guidelines.

Advice
Non-binding considerations adjoined to a decision intended to provide ethical assistance to those involved in the research.

Affiliation
An institutional affiliation means you have a formal connection with a nonprofit, sponsoring university, or place of employment that has agreed to be the legal recipient of the grant and to administer the funding and official paperwork on behalf of the primary applicant.

Applicant
A qualified researcher undertaking the scientific and ethical responsibility for a research project, either on his / her own behalf or on behalf of an organization/firm, seeking a decision from an ethics committee though formal regulation.

Assent
A minor research participant's affirmative agreement to participate in a research.

Community
A community is a group of people having a certain identity due to the sharing of common interests or to a shared proximity. A community may be identified as a group of people living in the same village, town, or country and, thus sharing geographical proximity. A community may be otherwise identified as a group of people sharing a common set of values, a common set of interests, or a common disease or condition.

Confidentiality
Actual treatment of the personal information, that an individual has disclosed in a relationship of trust, with the expectation that this information will not be divulged to others without permission.

Conflict of interest
A conflict of interests arises when a member (or members) of the ERC holds interests with respect to specific applications for review that may jeopardize his/her (their) ability to provide a free and independent evaluation of the research focused on the protection of the research participants. Conflicts of interests may arise when an ERC member has financial, material, institutional or social ties to the research.

Consent
An affirmative agreement by an adult research participant with legal capacity to participate in a research.

Decision
The response, (either positive, conditional or negative) by an ERC to an application following the review in which the position of the ERC on the ethical validity of the proposed study is stated.

Expedited Review
The research procedure presents no more than minimal harm to the research participants or communities

Fabrication
Making up data or results and recording or reporting them.

Falsification
Manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Investigator
A qualified scientist who undertakes scientific and ethical responsibility either on his/her own behalf or on behalf of an organization/ firm, for the ethical and scientific integrity of a research project at a specified site or group or sites. In some instances a coordinating or principal investigator may be appointed as the responsible leader of a team of co-investigators.

Minimal Risk
When the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Parental Consent
A parent's/guardian's affirmative agreement for a minor research subject to participate in a research.

Privacy
Having the control over the extent, timing of sharing oneself (physically, behaviorally or intellectually) or information about oneself with others.

Plagiarism
Appropriation of another person's ideas, processes, results or words without giving appropriate credit.

Protocol
A document that provides the background, rationale, and objective(s) of a Biomedical, Social, Behavioral and Environmental research project and describes its designs, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol.

Protocol amendment
A written description of a change to, or a formal clarification of a protocol.

Protocol Deviation
Occurs when, without significant consequences, the activities on a study diverge from the Institutional Review Board-approved protocol, e.g., missing a visit window because the subject is traveling.

Protocol Violation
A divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a subject's safety, rights, or welfare.

Requirements
In the context of decisions, requirements are binding elements that express ethical considerations whose implementation the ethics committee requires as obligatory in pursuing the research.

Research participant
An individual who participates in a Biomedical, Social, Behavioral or Environmental research project, either as the direct recipient of an intervention (e. g) study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with conditions unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated.

Sponsor
An individual, company, institution, or organization that takes responsibility for the initiation, management, and /or financing of a research project.

Scientific Misconduct
Improper and unprofessional behavior resulting from lack of integrity in executing a research misconduct

Vulnerability
Constitutes a special worthiness of protection measured in terms of the additional risk of suffering of a particular group of participants.

12.0 REFERENCES

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World Medical Association, *Declaration of Lisbon on the Rights of the Patient,* Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September /October 1981 and amended by the 47th General Assembly, September (1995). Bali, Indonesia.

World Medical Association *Declaration of Tokyo, Guidelines for physicians concerning torture and other cruel, inhuman or degrading treatment or punishment in relation to detention and imprisonment*. Adopted by the 29th World Medical Assembly, (October 1975).Tokyo, Japan,

The Data Protection Act No. 24 of 2019, published by the National Council for Law Reporting

The Kenya Science,Technology and Innovation Act (STI Act) of 2013,Revised 2022 by NACOSTI

The African Union Commission Agenda 2063 'A shared strategic framework for inclusive growth and sustainable development and a global strategy to optimize the use of Africa's resources for the benefit of all Africans

The Kenya National Commission UNESCO (KNATCOM) UNESCO ACT 2013 Research Ethics: Promoting ethical practices in Scientific Research

The Data Protection Act No. 24 (2019)

Kenyatta University ICT Policies 2025 - 2030 Data Protection Policy (Chapter 6)

APPENDICES

A	Proposal Format	
B	Application form	
C	Checklist (Requirements for application)	
D	Reviewers guidelines	
E	Consents and Assent/Informed consent form	
F	Informed assent for children	
G	Deviation or violation report form	
H	Adverse Events report Form	
I	Annual Project/Research Progress Status	
J	Waiver/exemption form	
K	SOP Monitoring	
L	Sample transfer /Collaborative Research	

KENYATTA UNIVERSITY

OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

APPENDIX A: Proposal Format

1. Title
2. Investigators
3. Table of Content
4. Abstract
5. Background
6. Rationale of the study
7. Objectives
8. Significance of study
9. Review of Literature
10. Methodology
11. Ethical Considerations
12. References
13. Informed Consent
14. Data Collection Tools
15. Time Frame
16. Budget
17. Any authorizations
18. **NB: Guidance on length of submitted protocols (conciseness and clarity) to avoid overly lengthy documents??**

APPENDIX B: Application form

KENYATTA UNIVERSITY

OFFICE OF THE CHAIRMANETHICS REVIEW COMMITTEE

KU-ERC/FORM/ 1

Kenyatta University Ethics Review Committee Application form

To be completed in triplicate by each applicant for submission to KUERC.

1. TITLE OF THE STUDY

……

……

……

……

……

2. Description of the Investigators

Name of Principal Investigator (PI)……
……

Qualifications……
……

Institutions(s) of affiliation……
……

Postal Address ……
……

Email Address……
……

Telephone number ……
……

Cell Phone number……
……

Name of 1st Co-investigator/Supervisor……
Qualifications……

Institutions(s) of affiliation……
……

Postal Address ……
……

Email Address……

.....

Telephone number .....
.....

Cell Phone number.....
.....

Name of 2nd Co-investigator/Supervisor.....
Qualifications.....

Institutions(s) of affiliation.....
.....

Postal Address .....
.....

Email Address.....
.....

Telephone number .....
.....

Cell Phone number.....
.....

Name of 3rd Co-investigator./Supervisor.....
Qualifications.....

Institutions(s) of affiliation.....
.....

Postal Address .....
.....

Email Address.....
.....

Telephone number .....
.....

Cell Phone number.....
.....

(Add more investigators as need be)

3. Study Details:

a) Study/Project site: …….....……
……

b) Study / project
duration…….....…….

c) Funding Source.....
.....

4. Contact Person:

Name and address of contact person (if not PI) Institution(s) of
affiliation.....

Postal Address.....
.....

Email Address.....
.....

Telephone number.....
.....

Cell Phone number.....
.....

Date.....
Signature.....

NB:
The application form together with supporting documents should be submitted via email to chairman.kuerc@ku.ac.ke.

Documents for Submission

All documentation required for a thorough and complete review of the ethics of proposed biomedical research should be submitted by the applicant.

These include:

1. The KUERC application form(see annexure B) should be submitted .Application forms will be available online on www.ku.ac.ke/research.ku.ac.ke
2. The research protocol (clearly identified and dated), together with supporting documents and annexes. This should include description of the ethical considerations involved in the research.
3. Application along with research protocol may be submitted through the email chairman.kuerc@ku.ac.ke
4. Questionnaire (if applicable) intended for research participants should be included.
5. When the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmaceutical and toxicological data available on the study product to date (e .recent investigator's brochure, published data, a summary of the product's characteristics)
6. A description of the process to be used to obtain and document consent
7. A statement of agreement to comply with ethical principles set out in relevant guidelines.
8. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants
9. CIOMS guidelines''Research subjects who suffer physical injury as a result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death, their defendants are entitled to material compensation. The right to compensation may not be waived"
10. A description of the arrangements for insurance coverage for research participants, if applicable.
11. All significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ERC's or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on the account
12. .The reasons for previous negative decisions should be provided.
13. Any other relevant material.

APPENDIX C-CHECKLIST (Requirements and process for application/submission for review

- Duly signed and dated application forms;
- A dated protocol of the proposed research together with supporting documents and annexes;
- A synopsis of the protocol:
- A detailed description of the ethical considerations involved in the research which should include the following components;

  - The Scientific design applicable to type of study,
  - Sampling framework, technique and sample size determination, recruitment and distribution of participants
  - Data collection tools and procedures for data collection and analysis,
  - Ethical considerations in terms of care and protection of research participants, observation of research participants' confidentiality and data protection, handling, management and disposal,
  - Informed consent (adults)/assent (minors), should be in KUERC format.
  - Community and Caregivers/guardian considerations; stating the benefits to the relevant community, how will they be involved, how will they be protected, how will the findings be disseminated/shared with the relevant stakeholders, including the beneficiaries

- All investigators updated curriculum vitae
- Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood) by the potential research participants and ,when required in other languages;
- Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and ,when required, in other languages ;
- A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants;
- A description of the arrangements for indemnity, if applicable
- A description of the arrangements for insurance coverage for research participants; if applicable;
- A statement of agreement to comply with ethical principles set out in relevant guidelines;
- All significant previous decisions (eg those leading to negative decision or modified protocol) by other Ethics or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification (s) to the protocol made on that account .The reason for previous negative decisions should be provided.

REQUIREMENTS FOR REVIEW OF PROTOCOLS BY KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE

Requirements for Students

1. Filled application form from Ethics Operational Guidelines for Biomedical Research. Form available at Kenyatta University Website, Research, under resources,
2. Approval of Research Proposal from Graduate School;
3. Research Authorization to the National Commission for Science Technology and Innovation from Graduate School;
4. Attach your Curriculum Vitae at the back of your proposal;
5. If the supervisors are not from Kenyatta University, attach their Curriculum Vitae at the back of the proposal;
6. Ensure that your proposal has a work plan, budget and informed consent for participants;
7. Refer to the ethical review regulations and guidelines provided on the website for guidance on criteria for presentation of the proposal;
8. Must attach Turn it in Report for the proposal.

Requirements for Research projects

1. Filled application form for Ethics Operational Guidelines for Biomedical Research. Form available at Kenyatta University Website, Research, under resources
2. Research Authorization to the National Commission for Science Technology and Innovation
3. Full Research Proposal
4. Attach the Curriculum Vitae of the PI and CO-PI at the back of each proposal
5. Ensure that your proposal has a work plan, budget and informed consent/assent for participants
6. Refer to the ethical review regulations and guidelines provided on the website for guidance on criteria for presentation of the proposal.

NB: All applications are to be done online. The application documents and attachments are to be submitted to the email chairman.kuerc@ku.ac.ke for processing

PAYMENTS

1. PROPOSALS

	KU STUDENTS		NON KU STUDENTS	
PhD	$60	Kshs. 5,000	$70	Kshs.6,000
Masters	$20	Kshs. 2,000	$30	Kshs.3,000
Undergraduate	$10	Kshs. 1,000	$20	Kshs.1,500

2. PROJECTS

	KU STAFF		NON KU STAFF	
Non funded	$60	Kshs. 5,000	$120	Kshs. 10,000
Funded				
• Up to 5 million	$250	Kshs. 20,000	$500	Kshs. 40,000
• Beyond 5 million	$450	Kshs. 40,000	$900	Kshs. 80,000

NB: Expedited requests will be considered only for low risk and non-sensitive researches. All expedited requests are charged at twice the relevant amount.

Pay the amount listed to:

KU National Bank
A/C Name: K.U.PYT
A/C. No: 01003059002400

Applicants are advised to take the bank slip to the Finance Department, Central Administration Complex, Ground Floor, Room 21, to be given an official KU receipt.

SUBMITTING AN APPLICATION

Requirements for different categories of researchers

S/No.	Type of application	Requirements	To note
1.	Student Applications	1. Application form 2. Letter from Graduate school 3. Turn-it in report 4. Payment receipt 5. Duly signed research proposal	1. Informed consent/ assent form should be in KUERC format 2. CVs to be attached as the last document of the proposal 3. The proposal to be submitted in Word format
	Project Applications	1. Application form 2. Payment receipt 3. Duly signed proposal	1. Informed consent/ assent form should be in KUERC format 2. CVs to be attached as the last document of the proposal 3. The proposal to be submitted in Word format

TYPES OF REVIEWS

S/N.	Type of Review	
1.	Normal Review	Meetings scheduled for every second Tuesday of the month except December Verdicts communicated one week after review meeting Payment as per the provided schedule
2.	Expedited Review	Is available where the research procedure is no more than minimal harm to research participants or communities. Payment is twice that provided on the payment schedule. Verdict is communicated one week upon request and submission of documents.
3.	Exemption	Is available where the research procedure does NOT involve involve human/animal subjects or biosafety. Verdict is communicated 2-3 days upon receipt of documentation.

PROCEDURE UPON RECEIPT OF VERDICT LETTER

1. The researcher will sign and date the verdict letter
2. Write a signed response letter addressed to the Chair KUERC, detailing how the queries raised have been addressed, indicating the corresponding relevant pages in the revised proposal
3. The duly signed and revised research proposal.
4. All these to be submitted via email to enable the re-review process for approval.

NB:

1. Proposals are to be submitted 2 weeks before the scheduled review meeting (see schedule on KU research website).
2. Verdicts are sent out to the applicants one week after the review meeting.
3. All documents to be submitted in soft copy via the email **chairman.kuerc@ku.ac.ke**. Hard copies are **not** accepted.
4. All applicants are required to familiarize themselves with the KU-ISERC guidelines for compliance.

N.B:
Upon receipt of approval from the KU-ISERC, the researcher is to seek clearance from relevant government authorities and research regulatory institutions including a Research Permit from NACOSTI.

APPENDIX D: REVIEWERS' GUIDELINES

This is a guide for reviewers to handle both scientific and ethical components of the proposal.

Background information

1. Is the rationale for the study clearly stated in the context of present knowledge? Yes 0 No 0
2. Is a review of literature with references included? Yes 0 No 0
3. Is the study setting described? Yes 0 No 0
   Comments: …

Goals and objectives

4. Are the objectives and/or hypothesis to be tested clearly stated? Yes 0 No 0 Comments: …

Study Design

5. Does the protocol provide a clear description of the study design (e.g. whether it is basic science research, social science research, or epidemiological - observational or intervention - research) and the study participants, outcomes and intervention and control groups (if relevant)? Yes 0 No 0

   Comments: …

Methodology

6. Is an estimate of sample size provided, along with the assumptions on which it is based? Yes 0 No 0
   Is this adequate? Yes 0 No 0
7. Are the inclusion and exclusion criteria clearly stated? Yes 0 No 0
8. Are the procedures for participant recruitment, admission, follow up and completion fully described and appropriate? Yes 0 No 0
9. Is protection of participants fully described and is it adequate? Yes 0 No 0
10. Are the drugs and/or devices to be used fully described? Yes 0 No 0 N/A 0
11. Are the clinical procedures to be carried out, fully described and appropriate? Yes 0 No 0 N/A 0
12. Are the laboratory tests and other diagnostic procedures fully described and appropriate?
    Yes 0 No 0 N/A 0
13. Does the protocol include information on procedures that are experimental and part of the research, as opposed to those that are part of routine care? Yes 0 No 0 N/A 0
14. Does the protocol describe how the specimens and/or data will be coded/anonymised? Yes 0 No 0
15. If the study is an intervention study, including placebo controlled trials, is justification for the control group provided? Yes 0 No 0 N/A 0
    Is the justification satisfactory? Yes 0 No 0 N/A 0
16. If the study is an intervention study, are the types and methods for subject allocation to intervention and control group clearly explained and appropriate? Yes 0 No 0 N/A 0
    Comments: …
17. **Population of study:**

    Children Yes 0 No 0 N/A 0

    Pregnant Women Yes 0 No 0 N/A 0

Prisoners Yes 0 No 0 N/A 0

People with special needs Yes 0 No 0 N/A 0

18. Participant safety/protection

a) Have any risks to participating in the research been identified and does the protocol state how these will be minimized? Yes 0 No 0

b) If the study is an intervention study, is a plan for adverse event reporting included in the protocol?

Yes 0 No 0 N/A 0

19. Does the protocol include a discussion of ethical issues? Yes 0 No 0 N/A 0

20. Is there a consent /assent form? Yes 0 No 0 N/A 0 b) Is it adequate? Yes 0 No 0 N/A 0

Comments: …

Data Management and Statistical Analysis

21. Does the protocol include a discussion on the quality assurance mechanisms for data collection, storage and analysis? Yes 0 No 0

22. Is the plan for statistical analysis provided? Is the study appropriately powered to answer the research question? Yes 0 No 0

Comments: …

Expected outcomes and dissemination of results/Community Consideration

23. Does the protocol indicate how the study will contribute to advancement of knowledge and how the results will be utilized? Yes 0 No 0

24. Does the protocol describe any community considerations? Yes 0 No 0

25. Does the protocol discuss how the research contributes to identifying and/or reducing inequities between women and men in health and health care or does not perpetuate gender imbalances? Yes 0 No 0

Comments: …

Project Management/Study Instruments

26. Does the protocol state the expected duration of the project (Time frame)? Yes 0 No 0

27. Where questionnaires, diary cards and other materials are used, are these relevant to answer the research questions? Yes 0 No 0 N/A 0

28. Are they provided in the participant language /English? Yes 0 No 0 Comments: …

Overall Comments

a) Approved:.....

b) Approval with advice.....

c) Conditional approval.....…

d) Resubmission.....

e) Rejected.....

Protocol Title and Version/Date: _____

Reviewer Name and Title: _____

Reviewer Signature: _____Date: _____

APPENDIX E. INFORMED CONSENT FORM-TEMPLATE

KENYATTA UNIVERSITY

OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

Informed Consent (Sample - please customize to your study)

My name is .....(name of organisation/I am a Ph.D/Master/Bachelor student from Kenyatta University). I am conducting a study titled "....."The information will be used (indicate the purpose of the study and significance).

Procedures to be followed

Participation in this study will require that I ask you some questions and I also examine you in order to screen you for ..... Some specimen (indicate type of specimen, amount and from where) will be taken from you for further tests. I will record the information you provide in a questionnaire.

Voluntarism

You have the right to refuse participation in this study. You will get the same services and care whether you agree to join the study or not and your decision will not change the care you will receive. Please remember the participation in this study is voluntarily. You may ask questions related to the study at any time.

You may refuse to respond to any questions and you may stop an interview at any time. You may also stop being in the study at any time without any consequences to the services you receive here or any other organization now or in the future.

Discomforts and Risks

Some of the questions you will be asked are on intimate subject and may be embarrassing or make you uncomfortable. If this happens, you may refuse to answer these questions if you so choose. You may also stop the interview at any time. The interview may add approximately half an hour to the time you wait before you receive your routine services. During the removal of blood there will be some pain or discomfort but we will try our best to minimize this by being gentle.

Benefits

If you participate in this study you will help us to learn how to provide effective screening services that can improve ……..…. You will also benefit from being screened for
….....and if you are found to have a problem you will be advised on the treatment.

Reward

If you agree to participate in this study, lunch will be provided and transport expenses will be reimbursed at 200/- per visit.

Or there are no rewards or any payment to you if you participate.

Confidentiality

The interviews and examinations will be conducted in a private setting within the clinic. Your name will not be recorded on the questionnaire. The questionnaires will be kept in a locked cabinet for safe keeping at Kenyatta

University. Everything will be kept private and only shared with the study team.

Contact Information

If you have questions about the study call the Dr... 07.....or .Supervisor...07. /
Investigators tel nos. to be inserted

However, if you have questions about your rights as a study participant: You may contact Kenyatta University Ethical Review Committee Secretariat on chairman.kuerc@ku.ac.ke,

Participant's statement

The above information regarding my participation in the study is clear to me. The study has been explained to me and I have been given a chance to ask questions and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary. I understand that my records will be kept private and that I can leave the study at any time. I understand that I will still get the same care and medical treatment whether I decide to leave the study or not and my decision will not change the care that I will receive from the clinic today or that I will get from any other clinic at any other time.

Name of Participant…….....

Signature or Thumbprint ..... Date.....

Name of Representative/Witness (where necessary) .....

Relationship to Subject .....

Investigators statement

I, the undersigned, have explained to the volunteer in a language s/he understands, the procedures to be followed in the study and the risks and benefits involved

Name of Interviewer …….....

Signature .....Date .....

APPENDIX F: INFORMED ASSENT FOR CHILDREN (MINORS)

KENYATTA UNIVERSITY

OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

Project Title: .....

Protocol Number:.....

Principal Investigator:.....

The investigators named above are doing a research study.

These are the things we want you to know about research studies:

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Whether or not to be in this research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

What is the study about?

Explain the purpose of study and what it entails in simple language here Why am I being asked to be in this research study?

You are being asked to be in the study because (detail you chose the participant What will happen during this study?

Indicate all the procedures and what the study expects from the participant. If you agree to be in this study, you will .....

Will the study hurt/risks?

Some of the tests might hurt. The doctor will need some of your blood. The needle stick hurts for a little bit as the blood is taken. When _____, you may get dizzy or feel short of breath. Having a __ sometimes makes people feel _____.

What else should I know about the study?

If you feel sick or afraid that something is wrong with you, tell an adult at once. You do not have to answer any questions that are asked of you.

What are the good things /benefits that might happen?

People may have good things happen to them because they are in a research study. These are called "benefits." Describe any if available what the researchers are hoping to answer with their research.

What if I don't want to be in this study?

You do not have to be in the study if you do not want to. You will not lose any care or service Who should I ask if I have any questions?

If you have any questions about this study, you or your parents can call Dr. Supervisor 1/PI. On 07******** or Dr. Supervisor 2/PI. On 07yyyyyyyy or the Kenyatta University Ethical Review Committee Secretariat on chairman. kuerc@ku.ac.ke, secretary.kuerc@ku.ac.ke

Do I have to be in the study?

No, you do not have to be in the study. Even if you say yes now, you can change your mind later. It is up to you. No one will be mad at you if you don't want to do this.

Signatures

Before deciding if you want to be in the study, ask any questions you have. You can also ask questions during the time you are in the study.

If you sign your name or put a mark below, it means that you agree to take part in this research study.

Your Name (Printed)	Age
Your Signature	Date
Signature of Person Obtaining Consent	Date
Signature of Witness	Date

APPENDIX G: DEVIATION OR VIOLATION REPORTING FORM

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

Title of Proposal: _____

Applicant/Investigator(s): _____

PKU Number: _____Date: _____

1. Date of Deviation/Violation: _____

2. Type of non-conformity: Deviation or Violation (_____)

3. Provide a description of deviation or violation: State whether the study/project participants/ groups were adversely affected, placed at greater risk and were informed of the deviation or violation (Description, what, where, who, how)_____
_____
_____

4. Provide an explanation as to why deviation or violation occurred. _____
_____
_____

5. Describe measures taken to address the deviation or violation. _____
_____
_____

6. Describe measures taken to prevent future recurrence of deviation or violation. _____
_____
_____

7. Indicate whether study/project sponsor (if applicable) has been notified. _____
_____
_____

Name and Signature of the applicant/Investigator_____ Date_____

Address:.....

Telephone .....

Cell phone:.....

APPENDIX H: ADVERSE EVENT REPORTING FORM

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

Title of Proposal: _____
Applicant/Investigator(s): _____
PKU/Number: _____
Date:_____

1. Type of Report: Initial or Follow-up (_____)
2. Study study/project participant/group information: Identification number, age, height, weight, etc _____
3. Adverse event start date: _____ Adverse event stop date: _____ or Ongoing _____
4. State/Indicate location of the event, if applicable: _____
5. Describe the adverse event: Describe the signs, symptoms, severity, time course, relevant medical history, and laboratory data. Include confirmatory results, if any. Indicate any medication required to treat the event and the outcome. _____
6. Describe the investigational drug, medical treatment or procedure or device causing the event:
7. Describe circumstances of the event, where applicable: Death (whether an autopsy was done), congenital abnormality, indicate whether it is life-threatening, if prolonged hospitalization is required, if persistent or significant disability occurred, if the study/project participant/group requires medical or surgical intervention to prevent other outcomes._____
8. Describe the action taken_____

9. Specify any simultaneous treatment.

_____

_____

_____

10. State relationship to drug/participation in a project: not-related, possibly, probably, definitely unlikely related to drug/participation and explain why. _____

_____

_____

11. State if adverse event is described in current approved informed consent/assent document.

_____

_____

12. State if event requires a change or changes in consent/assent documents and to the study/ project procedures.

_____

_____

13. State whether or not enrolled study/project participants/groups shall be advised of the event. If yes, explain how this new information will be conveyed. If not, explain why. _____

_____

_____

14. Describe any other information not included/ covered above _____

_____

_____

Name and Signature of the Applicant/Investigator_____Date_____

Address:.....

Telephone .....

Cell phone:.....

APPENDIX I: ANNUAL PROJECT PROGRESS STATUS

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

Title of Proposal: .....

Applicant(s) PKU No:.....

Project start date: _____End date: _____

Project period covered: Indicate project period covered by the report (e.g . 17 July 20…..to 16 June 20.....). .....
.....

Research objectives: Briefly describe purpose of the study/project. .....
.....

3. Research progress summary: Briefly describe the progress made during reporting period, highlighting key findings and achievements during the period. Include number of new study/project participants/groups enrolled/recruited into the study/project, the number of study/project participants continuing participation and the number of new study/project participants expected to enroll or leave the study/project during this period and reasons for their departure. Summarize on-going activities.....
.....

4. Amendments: Indicate any amendments made and approved during the reporting period.....
.....

5. Adverse events reports: If applicable, report any adverse events expected or unexpected.....
.....

6. Projects outputs: State if there were any publication, abstract, a product, patent application, e.t.c during the reporting period.
.....
.....

7. Constraints: State any constraints experienced during the reporting period, and whether or not they adversely affected project progress.

.....
.....

8. Any other relevant information: Include any information that might be relevant to this report but not captured in the items listed. State whether or not a continuation approval is required for the study/project.

.....
.....

9. Plans for the next study/project year: State study/project activities planned for the coming year or continuing into next year. Indicate if this is the last project year.

.....
.....
.....

10. Has The Kenyatta University Ethics Review Committee Approval Period Expired? Yes 0 No 0 If yes, do you wish to apply for an extension of the Approval Period? Yes 0 No 0

If YES, please state the new expiry date requested and the reason for request for extension. New expiry Date Requested Reasons for Extension.....

.....

Note that any amendments to the approved protocol require further specific approval by KUERC.

11. Attachment: Enclose one copy of current approved study/project protocol and current stamped and signed consent documents.

Name of Applicant(s)/Investigator(s)

Department

Signature Date

Chairman Kenyatta University Ethics Review Committee Signature & Date

APPENDIX J: WAIVER/EXEMPTION FORM

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

APPLICATION FOR EXEMPTION OF RESEARCH FROM ETHICAL REVIEW

2. Principal Investigator	Name	Department

3. Co-PI's	Names	Department

Please mark the appropriate box as √

5. Types of study		Yes	No
a.	Retrospective review of patient's charts		
b.	Prospective data collection from patient's charts		
c.	Analysis of laboratory/ radiology data		
d.	Clinical audit		
e.	Evaluation of practice guidelines		
f.	Case reports		
g.	Others; please specify		

6. Period of data collection			
From		to	

7. Starting date of study			
From		To	

8. Summary of data to be collected		Yes	No
a.	Demographics of the patients i.e. name addresses, phone numbers, e-mail address		
b.	Clinical notes		
c.	Photographs		
d.	Laboratory data/ radiology data		
e.	Management data		
f.	Other, please specify		

9. Utilization of data to be collected: Will it be used for		Yes	No
a.	Publication of papers in journals / newspapers		
b.	Oral / poster presentation in meetings / conferences		
c.	Students / residents' teaching		
d.	Planning subsequent larger studies		

10. Summary of Objectives & Methods of Study including selection and exclusion criteria of study subjects, sample size, analysis plan etc.

11. Please answer the following questions and mark the appropriate box as √

		Yes	No
a.	Will any photographs be used/taken for publication?		
b.	If yes, has written permission been obtained from study subject or guardian?		
c.	Has the study been reviewed be departmental research / review committee		
d.	Was any ethical concern raised by departmental committee?		
e.	If yes, what were the ethical issues?		
f.	Were those ethical concerns resolved?		

Certificate of review by the Kenyatta University Ethics Review Committee And Chair of the Department

The above study has been reviewed by the Ethics Review Committee (ERC). The Committee members are satisfied that the study falls in the exemption category and has no ethical issue. The study is being submitted to ERC for granting of an exemption letter.

Signature of Supervisor_____

APPENDIX K: REQUEST FOR EXPORTATION OR STORAGE OF HUMAN SAMPLES AND OTHER BIOLOGICAL MATERIALS FOR RESEARCH

KENYATTA UNIVERSITY

OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

PART A: Project Information

i. Project Title:----------PKU No.. ----------

ii. KUER Centre of Affiliation:----------

iii. Principal Investigator(s):

1.

2.

3.

iv. Other Investigators:

1.

2.

3.

4.

PART B: Specimen Details:

i. Is the request for specimen exportation or storage or both

(Request for storage is necessary if the samples are to be stored beyond the duration of the present study)

ii. Description of specimen(s) to be exported/ stored:

iii. Reason(s) for exportation/storage of samples:

1.

2.

3.

iv. Duration of specimen storage:

v. For samples originating from human subjects, state whether or not written consent for specimens exportation or storage:

vi. Name and address of recipient institution/department responsible for the specimens:

(If samples are to be sent to more than one institution/department, a separate request form should be completed for each recipient)

vii. Name(s) and address of person(s) responsible for the specimens in the recipient institution:

vi. Name and role in the project of the Kenyan investigator(s) expected to carry out investigations on the specimens in the overseas institution:

PART C: Declarations: (To be completed every time prior to shipping samples)

i. Declaration by the person requesting exportation/storage of research specimens:

I certify that the information provided in this request form is true and correct to the best of my knowledge, and I hereby declare that the specimens referred to herein will be utilized for the stated purpose only

Name:- ---------- Role in the Project:----------

Signature:----------Date:----------

ii. Declaration by Recipient Institution:

This is to certify that the specimens referred to herein being sent to ---------- (Name of Institution) for further analyses/experimentation will be in the custody of the Department of, and I hereby confirm that they will be utilized for the purpose stated in this request form, and I accept full responsibility and control over the usage of these samples

Name of Department/Institution Head:----------

Signature:_____Date:_____

iii. Declaration by Centre Director:

I certify that the protocol PKU No ----------referred to in this request was approved by the KU-ERC Committee on ----------and that the request to export the biological specimens referred to in this request was found to be valid and justifiable. I further confirm that the study participants in this project have consented in writing to the exportation/ storage of samples taken from them, for use in further research.

Name: ----------Signature: ----------

Centre:_____ Date: _____

PART D: (For KUERC Use Only)

i. Request Approved by the KUERC on ----------

Name of the Officer---------- Sign----------

ii. Request Not Approved by the KUERC on ----------

Name of the Officer--------- ---------- Sign----------

iv. Request Considered and Deferred Due to the Following Reasons:

1)
2)

3)

4)

5)

PART E:

Approvals Request Approved By:

i. Chairman, KUERC: Date:

APPENDIX L: AUTHORITY TO EXPORT BIOMEDICAL RESEARCH MATERIALS.

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

This is to certify that _____

Principal Investigator/Co-Principal Investigator/Investigator in the research project titled:

and referenced KUERC No: _____being undertaken in collaboration with the Kenyatta University Ethics Review Committee (KUERC) has been granted permission to send out

(Number and Description of the Samples)

to _____

(Name of Department and/or Institution)

in _____

(Country of Destination)

for the purpose of _____

(Description of the type(s) of investigations or analyses to be conducted on the samples)

This certificate is issued with the understanding that the investigator will not use the samples for purposes other than those stated above. The investigator will submit a copy of the results of the investigations/analyses undertaken on these samples to the CHAIRMAN, KUERC; and will ensure that KUERC's intellectual property rights arising from work on the stated samples will be protected and safeguarded, and the findings thereof are published with the approval of the Chairman, KUERC.

Recommended by:_____

Name and Signature of Chairman KUERC Date

Authorized by:_____

Name and Signature of Chairman, KUERC Date

*This certificate is valid for a period of 90 (Ninety) days with effect from the date of authorization. Please direct any queries to the Chairman, KUERC, and P.O. Box 43844-00100 Nairobi, Kenya; Phone:ext.4389

; E-mail: chairman.kuerc@ku,ac.ke

APPENDIX M: REQUEST FOR IMPORTATION OR STORAGE OF HUMAN BLOOD AND OTHER BIOLOGICAL MATERIALS FOR RESEARCH

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

PART A: Project Information

i. i. Project Title: _____

PKU No: _____

ii. KUERC/Unit/Project of Affiliation: _____

iii. Principal Investigator(s):

NAME	INSTITUTION	TELEPHONE	EMAIL ADDRESS

iv. Other Investigators:

NAME	INSTITUTION	TELEPHONE	EMAIL ADDRESS

PART B: Specimen Details:

i. Is the request for specimen IMPORTATION or storage or both?

(Request for storage is necessary if the samples are to be stored beyond the duration of the present study)

ii. Description of specimen(s) to be imported/stored:

iii. Reason(s) for importation/storage of samples:

1.

2.

3.

vi. Duration of specimen storage:

For samples originating from human subjects, state whether or not written consent for specimens importation or storage _____
_____
_____
_____

PART C: Declarations: (To be completed prior to requesting for importation)

i. Declaration by the PI/ Investigator requesting importation/storage of research specimens: I certify that the information provided in this request form is true and correct to the best of my knowledge, and I hereby declare that the specimens referred to herein will be utilized for the stated purpose only

Name:_____Role in the Project:_____

Signature:_____Date:_____

ii. Declaration by Exporting Institution:

This is to certify that the specimens referred to herein being sent to----------(Principal Investigator-Centre/Unit/project) for further analyses/experimentation will be in the custody of the (Name of the recipient Institution) _____ , and I hereby confirm that they will be utilized for the purpose stated in this request form, and_____ (Name of PI) will accept full responsibility and control over the usage of these samples.

I further confirm that the study participants in this project have consented in writing to the exportation/ storage of samples taken from them, for use in further research.

Name of the Exporting officer: _____

Designation: _____

Name of Department/Institution Head: _____

Signature: _____

Date: _____

PART D: Approvals of Importation of Biomedical samples Request

Approved By:

i. Chairman KUERC; _____Date_____

Signature: _____

ii. Head of Department, Office of Health, Safety and Environment:

_____Date: _____

Signature: _____

iii. Chairman; KUERC: _____Date:_____

Signature: _____

APPENDIX N: AUTHORITY TO IMPORT BIOMEDICAL RESEARCH MATERIALS

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

This is to certify that _____
Principal Investigator/Co-Principal Investigator/Investigator in the research project titled: .....
.....
.....

Being undertaken in collaboration with the Kenya Medical Research Institute (KEMRI) has been granted permission to ship in .....
.....
.....

(Number and Description of the Samples)
to _____
(Name of Department and/or Institution)
in_____
(Country of origin)
for the purpose of .....
.....
.....
(Description of the type(s) of investigations or analysis to be conducted on the samples)

This certificate is issued with the understanding that the investigator will not use the samples for purposes other than those stated above. The investigator will submit a copy of the results of the investigations/analyses undertaken on these samples to the Chairman KUERC; and will ensure that Kenyatta University's intellectual property rights arising from work on the stated samples will be protected and safeguarded, and the findings thereof are published with the approval of the Chairman ;KUERC

Recommended by:
_____Date _____
Name and Signature of Chairman; KUERC

Authorized by: _____ Date _____
Name and Signature of Chairman; KUERC

This certificate is valid for a period of 90 (Ninety) days with effect from the date of authorization. Please direct any queries to the Chairman KUERC, P.O. Box 43844-00100 Nairobi, Kenya; Phone: Ext.4389 E-mail: chairman.kuerc@ku.ac.ke

APPENDIX M: AUTHORITY TO IMPORT PLANT RESEARCH MATERIALS

Criteria for review of applications

"Risk assessment" means the identification, evaluation and estimation of the levels of risk involved in a situation including evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing country according to the sanitary or phytosanitary measures which might be applied and of the associated biological economic consequences; or the evaluation of potential adverse effects on plant, human or animal health and environment from the presence of additives, contaminants, toxins or disease causing organisms in food beverages or feedstuff. In this regard, the following criteria has been set for review of applications:

No.	Item	Yes	No
	DETAILS OF THE APPLICATION		
	Name of applicant: Biological Material: Source of material (country) etc)		
	RISK ASSESSMENT		
	1) Potential to be a pest, vector or invasive species Does the biological material have the ability to be injurious to plants or plant products? **No**		
	Brief information (if available) on an immediate or long-term harmful effect on the environment or its biological diversity.		
	Does the biological material have Potential to transmit disease?		
	Brief information (if available) on mode of transmission of the named agents, disease caused and symptoms **No information is available on disease transmission by this organism**		
	Does the biological material have the ability to establish itself, persist, out-compete indigenous species, take over new environments and threaten biological diversity?		
	Provide a brief description on invasiveness:		
	2) Potential to be infective		
	Brief description on infectiveness		
	3) Potential to be allergenic Does the biological material have the ability to cause hypersensitivity or adverse effect(s) on humans and/or other organisms (e.g. due to production of toxin, secondary metabolites, and/or structural components)?		
	Brief description on specific hypersensitivity		

	4) Toxicological effects on mammals Does the biological material produce toxin or biologically active substance which might be present and may pose a hazard to mammals?		
	List the harmful chemical toxins present and Indicate routes of exposure		
	5) Eco-toxicological effects on non-targets Does the biological material produce toxin or biologically active substance which might be present and may pose a hazard to non-targets (e.g. bees, earthworms, fish etc)?		
	Provide a brief description		
	6) Behaviour in the environment i.e. persistence, mobility, in soil, water or air How does the biological material behave in the environment?		
	Brief description;		
	7) Presence of contaminants in acceptable limits Does the biological material contain any contaminants?		
	Check and provide acceptable limits.		
	8) Genetic and environmental stability Is the product genetically and environmentally stable?		
	Provide a brief description The organism is very stable and with no evidence of any other strains that have been reported		
	9) Uncertainties What are the uncertainties?		
	Any other comment/information		
	DETAILS OF REVIEWER		
	Name of reviewer		
	Institution		
	Contacts (Postal & physical address, Email, Mobile)		
	Signature	Date	

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