2017 Edition

THE Catholic University of Eastern Africa

ETHICS REVIEW STANDARDS OPERATING PROCEDURES

Directorate Research, Innovation &Graduate Training

The Catholic University of Eastern Africa
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ABBREVIATIONS AND ACRONYMS

CUEA	The Catholic University of Eastern Africa
CUEA- RERC	The Catholic University of Eastern Africa Research Ethics Review Committee
DVC	Deputy Vice Chancellor
SOP	Standard Operating Procedure

I. Introduction

The Catholic University of Eastern Africa (CUEA) had humble beginnings in 1984 as Catholic Higher Institute of Eastern Africa (CHIEA). The Institute (CHIEA) was founded in 1984 by the regional ecclesiastical authority known as the Association of Member Episcopal Conferences of Eastern Africa (AMECEA). Eritrea, Ethiopia, Kenya, Malawi, Sudan, Tanzania, Uganda and Zambia are the member countries of AMECEA. It commenced as a graduate school of theology. It is authorized by the Congregation for Catholic Education, Vatican City (cf. Prot. N. 821/80/34) to offer two-year Licentiate/MA programmes in Theology.

The University was granted a Civil Charter on 3 November 1992. The University offers diverse postgraduate diploma and degree programmes with a population of about eight thousand (8,000) spread in its three Campuses of Langata, Kisumu. Gaba and the City. Its academic programmes are organized into faculties/schools, centres and institutes. These respectively comprise the Faculty of Theology; Faculty of Arts and Social Sciences (FASSC); Faculty of Education; Faculty of Science; Faculty of Law; School of Business; Centre for Social Justice and Ethics (CSJE), Institute of Canon Law and Institute of Regional Development and Integration (IRID).

The University's vision is *To be a world class University producing transformative leaders for Church and Society.* Its mission is, *To promote excellence in Research, Teaching and Community Service by preparing morally upright leaders based on the intellectual tradition of the Catholic Church*. Promotion of the University's research mandate is vested the *Directorate of Research, Innovation and Postgraduate Training*.

1.1 Definition and Scope of Research

Research is here broadly defined to include all investigation undertaken in order to acquire knowledge and understanding, across the full range of academic disciplines, from the arts and humanities to the natural sciences (whether funded or not), and also encompassing administrative research undertaken within, or on behalf of, professional services departments. This definition includes:

•work of educational value designed to improve understanding of the research process;

•work of relevance to commerce and industry;

•work of relevance to the public and voluntary sectors;

•scholarship supporting the intellectual infrastructure of subjects and disciplines (such as dictionaries, scholarly editions, catalogues, and contributions to research databases);

•the invention, design and generation of ideas, images, performances and artefacts, where these lead to new or substantially improved understanding; and

•the experimental use of existing knowledge to develop, design and construct new or substantially improved materials, devices, products and processes.

This definition of research however excludes:

•the routine testing and analysis of materials, components and processes -

e.g. as part of the observance of national standards -as distinct from the development of new analytical techniques;

•routine audit and evaluation, within the established management procedures of organisations; and

•the development of teaching materials that do not embody original research

CUEA recognizes that its search for new knowledge and innovation involving humans and animals has potential for violation of fundamental ethical principles. Consistent with its motto to *Consecrate in the truth* (John 17:17), CUEA promotes ethical and socially responsible research and innovations. In addition, the University proposes to establish a fully operational institutional Research Ethics Review Committee (RERC). The proposed policy will ensure that any research involving human and animal subjects must be approved by the CUEA – RERC. The CUEA-RERC will be expected to report to the Senate, through its Chair.

1.2 Definition of Ethics

The word 'ethics' derives from the Greek, 'ethos', meaning custom, mores or character. It refers to systems of moral principles or values, principles of right or good behaviour in relating to others, and the rules and standards of conduct binding together members of a profession.

'Research ethics' refers to the principles of appropriate conduct that govern research, as defined above. The principles of research ethics apply to all types of research. Research ethics may also inform decisions about what types of research an organisation will support; these decisions

concern organisational ethics. This policy, however, applies only to research involving human participants, personal data and human tissue.

1.3 Definition of Human Participants

Human participants can be broadly defined as research that:

•directly involves people in research activities through their actual participation as research subjects: 'actual participation' may involve invasive research processes (e.g. surgery) and/or non-invasive research processes (e.g. interviews, questionnaires, surveys or observational research carried out face-to-face, or via telephone, email or the internet), and may mean the active or passive involvement of a person;

•indirectly involves people in research activities as research subjects, through their provision of, or access to their, personal data and/or tissue; or

•involves people in research activities while they are acting on behalf of others who are research subjects (e.g. as parents or legal guardians of children or mentally incapacitated people, or as supervisors of people in controlled environments, such as prisoners, pupils, asylum seekers, sectioned psychiatric patients, etc.

Personal data may be defined as that which relates to a living individual who can be identified from those data, or from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual. Sensitive' personal data consists of information about:

•the racial or ethnic origin of the data subject;
•his or her political opinions;
•his or her religious beliefs or other beliefs of a similar nature;
•whether he or she is a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992);
•his or her physical or mental health or condition;
•his or her sexual life;
•the commission or alleged commission by him or her of any offence, or any proceedings for any offence committed or alleged to have been committed by him or her, the disposal of such proceedings, or the sentence of any court in such proceedings (Data Protection Act 1998).

The United Kingdom 2004 Human Tissue Act (HTA) defines human tissue as: 'Relevant material that has come from a human body and consists of, or includes, human cells'.
The 'relevant' materials covered by the HTA include materials that have come from a human body, whether living or dead, including body parts, organs and human cells. Cell lines are not relevant material (although primary cell cultures are). Storage of cell lines for research does not require a license nor do research using cell lines require ethical review.

1.4 Research Involving Animals

CUEA recognizes that animal research has had a vital role in many scientific and medical advances of the past century and continues to aid our understanding of various diseases. Clearly, throughout the world, people enjoy a better quality of life because of these advances, and the subsequent development of new medicines and treatments—all made possible by animal research. However, the use of animals in scientific and medical research has been a subject of heated debate for many years around the world.

Opponents to any kind of animal research—including both animal-rights extremists and anti-vivisectionist groups—believe that animal experimentation is cruel and unnecessary, regardless of its purpose or benefit. There is no middle ground for these groups; they want the immediate and total abolition of all animal research. If they succeed, it would have enormous and severe consequences for scientific research. These opponents of animal research argue that, like human participants, animals have capacity to experience pain, distress and suffering during laboratory experiments.

The following five features are generally used qualify animals as moral subjects, imposing constraints or limits on how they may be treated in experimental research:

1.4.1. Sentience-Capacity to feel pleasure or pain

1.4.2. Higher cognitive capacities- Capacity to know good or evil; possession of self-conscience; possession of freedom; and possession rational will

1.4.3. The capacity to flourish- Having specie-specific needs. Requires need to determine when life is best for an animal (i.e. natural vs unnatural environments). The laboratory environment may significantly affect the specie-specific needs leading to deaths and procreation

1.4.4. Sociability-Animals like dogs, cats and horses live in community with human beings for which there are rights and obligations. Some high cognitive order animals like monkeys live in communities with defined rights and obligations.

1.4.5. Possession of Life-Does animals possess life? Is that life important?

Studies have demonstrated that animals experience significant pain and distress as a result of their use in experimentation For example, even in response to being handled, animals experience marked changes in physiological and hormonal markers of stress.

Scientific advancements regarding animals' cognitive and emotional capacities should be reflected in the development and refinement of guidelines regarding their use in research. No responsible scientist wants to use animals or cause them unnecessary suffering if it can be avoided, and therefore scientists accept controls on the use of animals in research. More generally, the bioscience community accepts that animals should be used for research only within an ethical framework.

Animal research in CUEA will be guided by the principles of animal experimental technique: the Three Rs:

1.4.6 Refinement-Any decrease in the incidence of severity of inhuman procedures applied to those animals which are used;

1.4.7 Reduction-Reduction in the number of animals used to obtain information of given amount and precision;

1.4.8 Replacement- The substitution of conscious living higher animals with insentient material. CUEA will encourage the use statistical methods to minimize the use of animals. Staff and students will explore the use of alternatives to animals such as cell cultures and computer simulation techniques, eventually completely replaced animals with computer modeling, manikins and visual illustrations. CUEA has established the Research Ethical Review Committee (CUEA-RERC) review or monitor protocols using animals.

The proposed CUEA-RERC will operate under National Commission of Science, Technology and Innovation (NACOSTI), which is charged with promoting, reviewing and regulating research within CUEA and AMECEA Region. Ethical Research is an integral part of the mission of the Catholic University of Eastern Africa. It is a necessary activity to assist the university to achieve and maintain the status of leading centre of excellence in teaching and community service in Eastern Africa Region.

II. Mission Statement of the Department of Research

The Directorate of Research, Innovation and Graduate Training (DRIGT) aims at undertaking independent and collaborative research work across Institutions, Departments and Faculties within the university in order to inform social and economic policy and monitor implementation of programmes.

III. Vision

DRIGT is committed to increasing opportunities for high quality research and special initiatives, thereby becoming a centre of excellence in research and innovation.

IV. Objectives

The following are the objectives of the Research Ethics Committee (RERC):

- Protect the mental, social, physical, welfare, rights, dignity and safety of participants of research.
- Facilitate ethical research through efficient and effective review processes.
- Promote ethical standards of human research.
- Review research in accordance with current core values of Ministry of Science and Technology Strategic Plan 2013-2018 which promotes respect for human rights as well as those of the Council for International Organizations for Medical Sciences (CIOMS) guidelines.

V. Overall Objective of the Standard Operating Procedures (SOPs)

The overall objective of the Standard Operating Procedure (SOP) is to ensure quality and consistency in review of scientific research proposals and to follow the committee's and national ethical guidelines for scientific research.

VI. Scope and Responsibility of CUEA- RERC

The basic responsibility of the CUEA-RERC is to ensure a competent and objective review of all ethical aspects of submitted research project proposals involving humans. The review will be done for students, staff and other clients of the AMECEA Region Institutions, constituted under CUEA. However the terms of reference of CUEA-RERC does not prohibit the institutions from accepting an ethical approval undertaken by another human research ethics committee. It also seeks to serve as a national ethical review centre for researchers on behalf of the National Council of Science and Technology.

VII. Accountability of the RERC

- The CUEA – RERC is accountable to the Senate
- All minutes of RERC meeting shall be copied to the DVC Academics, upon confirmation.
- The RERC shall provide an annual report to the Senate at the end of each calendar year, which shall include information on membership, the

Number of proposals reviewed, status of proposals, a description of any complaints received and their outcome, and general issues raised.

- The RERC may from time to time bring to the attention of the Academic Committee issues of significant concern.
- A copy of all the committee deliberations will be sent directly to the National Council for Science and Technology.

VIII. Functions of CUEA RERC

The principle functions of CUEA- RERC can be defined as follows: - The Committee

a) Shall ensure independent, competent and timely review of ethical issues of the proposed studies before the commencement of a study and regularly monitor the ongoing researches.
b) Shall review and approve all research and grant proposals with a view to safeguarding the dignity, rights, safety, and well-being of research participants irrespective of the source of funding.
c) Shall ensure all the cardinal principles of research ethics are taken care of in planning, conducting and reporting of a proposed study. It will review proposals before the start of the study as well as monitor the research throughout the study until and after completion of the study through periodic progress reports and final reports.
d) The committee shall ensure compliance with all regulatory requirements, applicable guidelines and laws commensurate with ethical practices elsewhere while making sure that the research complies with Kenyan laws.
e) Shall ensure that universal ethical values and scientific standards are explicitly expressed e.g. in terms of local community values and customs, protection of human and non-human research subjects, as well as conformity to the guidelines of international organizations.
f) Shall ensure scientific soundness and technical appropriateness of the proposed research.
g) Upholding adherence to this Policy and the University's Ethics Standard Operating Procedure, including:

- auditing and accrediting the ethics review arrangements in place within academic departments and reviewing accreditation on at least a five yearly basis;

- monitoring the ethics review arrangements in place within academic departments, which includes reviewing ethics decision making reports from academic departments on an annual basis;
- providing guidance on cases of uncertainty and for making decisions on cases that cannot be resolved by ethics review panels;
- hearing appeals against the decisions made by academic departments' ethics review panels (the Committee can overrule the decisions of ethics review panels);
- in the event of concerns arising about whether a research proposal or ongoing research activity complies with the University's Research Ethics Policy, suspending the approval process for that proposal, or suspending the research activity in question, pending further investigation.

h) 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);
i) To provide advice on any ethical matters relating to research that are referred to it from within the University;
j) Keeping abreast of new externally-driven developments, policies and regulations concerning research ethics and, where appropriate, ensuring that the University meets all necessary requirements;
k) Reviewing the Ethics Policy and associated documentation on at least a five-yearly basis, and more frequently should it be felt appropriate;
l) Ensuring high quality representation of Faculty perspectives to the Committee through:

- Asking that Faculty representatives commit to serve on the Committee for a minimum of two years in the first instance;
- Asking that Faculty representatives usually serve for no longer than two full terms of three years each (therefore six in total) in that role on the Committee.

m) Enabling specific funder requirements regarding ethical review to be met though the provision of relevant members of the Committee to act as ethics reviewers for specific projects.

IX. Composition of CUEA- RERC

The CUEA RERC shall be multidisciplinary and interdisciplinary in composition. The number of committee members shall be between 7 – 15 members to make it easier in reaching consensus and getting the required quorum. The external members shall be the majority to ensure independence of the committee. The Management shall appoint the chairperson of the committee. The secretary of the committee shall conduct the business of the committee. Other

members shall consist of a mix of multidisciplinary researchers to reflect the different viewpoints within and outside the university.

The CUEA RERC shall include members from other private and public institutions. There shall be adequate gender and disciplinary representation of in the committee to safeguard interests and welfare of all sections in the society.

X. Constitution of CUEA – RERC

The DVC Academic shall constitute the CUEA RERC in consultation with the Senate as follows:

a) Chairperson
b) Secretary to the committee
c) Director of Research
d) Up to seven (7) members from different specialties.

The committee will be reconstituted after every three (3) years.

XI. Membership duration and responsibilities

a) The duration of the membership shall be three years
b) The member shall be with the CUEA, DVC (Academics, Research and Innovation).
c) Membership shall maintain confidentiality of all discussions held during the meeting.
d) Conflict of interest (if any) shall be declared by members of CUEA – RERC at the beginning of every meeting.
e) There will be no term limit for members serving more than one term. However, it is desirable to have around a third of fresh members at the commencement of a new committee.
f) Newly appointed members shall be trained with Research Ethics Review Issues.
g) Throughout their tenure, members shall be supported to attend conferences and workshops relevant to the work and responsibilities of the CUEA – RERC, at the expense of the University.

XII. Review Procedures

a) CUEA –RERC shall hold meetings as and when proposals are received for review. However, additional meetings will be held as and when necessary.

b) The proposals will be sent to members at least one month in advance.
c) Decisions will be taken by consensus after discussions
d) Researchers may be invited to offer clarifications on issues emerging from their proposals and which are not clear to members of the committee.
e) Independent researchers may be invited to offer their opinions on specific research proposals.
f) The decisions of the committee meetings shall be minuted and shall be confirmed during the next meeting and chairperson's approval taken in writing.

XIII. Decision making

a) Members shall discuss the various issues before arriving at a consensus decision.
b) Only members shall make the decision in meetings where quorum is complete. The decisions shall be made in the absence of the research clearance applicants. However, expert consultants may offer their opinions.
c) Decisions may be to approve, reject or modify proposals. Suggestions for modifications and reasons for rejection shall be given.
d) Modified proposals may be reviewed by an interim review appointed by the chairperson.

XIV. Notification of the decision CUEA – RERC

The RERC is an advisory committee of the Catholic University Eastern Africa Academic Committee. The committee is mandated with the all decisions which shall be communicated by the chair person in writing. This shall include: Granting Ethical approval; withholding Ethical Approval and finally withdrawing Ethical Approval for Research to be carried out within the institutions. Reasons for rejection shall be communicated to researchers.

XV. Follow up procedures

a) Research progress reports shall be submitted for regular review after every six months or one year depending on the nature of the research. CUEA –RERC shall continue to review approved projects for continuation, new information, adverse event monitoring, follow-up and later after completion if need be.

b) Final report shall be submitted at the end of the study in the prescribed CUEA research format or in case of a non-CUEA research, can be in any format recommended to the researcher by the funding institution or organization.
c) Change of investigators shall be done with approval of CUEA- RERC.
d) Any new information related to the study should be communicated to the committee.
e) Premature termination of the study shall be notified with reasons and summary of the studies done so far.

XVI. Record keeping and Archiving

a) Curriculum Vitae of all CUEA-RERC members.
b) Minutes of all meetings with chairperson's signature.
c) Copies of all correspondence with regulatory bodies, members and researchers.
d) Final reports of the approved projects which shall be archived for minimum of ten years after the study is complete.
e) Copy of existing national, international guidelines and on research ethics.

XVII. Procedures for Application

a) All proposals shall be submitted in the prescribed CUEA research format or that of an affiliate institution.
b) All applicants shall complete a prescribed application form providing for such comprehensive information including project details; description of the research, potential risks to participants; description of participants; disclosure of confidentiality and handling of data; and indication conflict of interest (see Appendix 3). All relevant support documents shall be attached to the application form.
c) The required number of copies of the proposal shall be forwarded to the committee's chairperson.
d) The secretary to the committee shall acknowledge receipt of the applications; indicate any missing documents or information which should be supplied within two weeks.

e) The decision of CUEA – RERC shall be communicated in writing. If there is any revision to be made, the required number of copies of the proposal shall be submitted within the stipulated time period specified in the communication.

XVIII. Approval Levels

Level 1: Your research project is completely desk-based (i.e. does not involve participants) and does not use information about living, identifiable individuals ('data subjects').

Level 2: Applies to non-intervention research where you have the consent of the participants and data subjects. This may include, for example, analysis of archived data, classroom observation, or questionnaires on topics that are not generally considered 'sensitive'. This research can involve children or young people, if the likelihood of risk to them is minimal.

Level 3: Applies to novel procedures, research without consent, sensitive personal data, or the use of atypical participant groups. Also projects in which ethical issues might require more detailed consideration but are unlikely to prove problematic.

Level 4: Applies to research which is potentially problematic in that it may incorporate an inherent physical or emotional risk to researchers or participants; involve covert surveillance or covert data collection; or includes research studies involving humans, their tissue and/or data.

XIX. Approval for Students

Humanities and Social Sciences

Level 1 & 2: Applications must be authorised by approved supervisor and submitted to the RERC. The RERC will hold your application for auditing purposes only and no feedback will be given.

Level 3 & 4: Applications must be authorised by a supervisor and submitted to the RERC. The RERC will review your application and provide feedback and authorisation.

Sciences

Level 1, 2 & 3: Applications must be authorised by your supervisor and submitted to the Ethics Committee. The Ethics Committee will hold your application for auditing purposes only and no feedback will be given.

Level 4: Applications must be authorised by a supervisor and submitted to the Ethics Committee. The Ethics Committee will review your application and provide feedback and authorisation.

XX. Training (Updating CUEA-RERC members and researchers)

a) Relevant information regarding research ethics will be brought to the attention of the members.
b) Members and/or researchers will be encouraged to attend national and international training programmes on research ethics in conferences/workshops to aid in maintaining ethical quality and make them informed of the latest developments in the area.

XXI. Complaints handling procedures

a) All complaints will be lodged to the committee through the Chairman, specifically indicating the nature and type of complaint.
b) The person lodging a complaint will be expected to provide their full names and official address.
c) The committee will not respond to anonymous complaints.
d) Each complaint will be investigated and findings reported to the committee at a full seating for action.
e) Any complaints will be handled in confidence and the identity of the complainant shall be protected.

XXII. Monitoring of approved procedures

a) The committee will use a simple procedure form for monitoring of its activities.
b) The form will conform to the CUEA format of procedural movement.

XXIV. Linkages with other research ethics review committees

a) CUEA RERC will be linked to other ethics review committees in Kenya.

APPENDICES

Appendix 1: Confidentiality Declaration Form

The Catholic University of Eastern Africa Ethics Review Committee

SECRECY UNDERTAKING BY MEMBER OF CUEA RERC

Name: _____

Designation: _____

I understand that as a member of the Catholic University of Eastern Africa Research Ethics Review Committee I may receive documents containing confidential or privileged information. I agree not to disclose or discuss such information or minutes of the meeting with persons not entitled to have them. I also agree to return all confidential/privileged documents to the committee's chairperson or destroy them after perusal.

Date: _____

Signature: _____

Appendix 2: CUEA - RERC Membership (2016 – 2019)

1. Dr. Bethwell Owuor, Science, CUEA	**Chairman**
2. Prof. Aloys Ayako, Director, Department of RIGT,	Member
3. Dr. Benson Mulemi, Coordinator, Research, CUEA	Member **Secretary**
4. Rev. Prof. Richard Rwisa, Theology	Member
5. Rev. Dr. Albert Ngengi Mundele, Coordinator Graduate Training, CUEA	Member
6. Prof. Winston Akala, Dean of Education, University of Nairobi	Member
7. Prof. Ernest Beyaraza, Law, CUEA	Member
8. Prof. Paul Achola, Kisumu, CUEA	Member
9. Rev. Dr. Peter Mbaro, Town Campus, CUEA	Member
10. Sr. Dr. Theo. Katundano, CSJE, CUEA	Member
11. Sr. Dr. Sabina Mutisya, Education, CUEA	Member
12. Dr. Evans Ogoti Okendo, Gaba Campus, CUEA	Member
13. Mr. Stephen Mailu, Research Fellow, CUEA	Member
14. Ms. Jane Nambiri, Assistant Research Fellow, CUEA	Member
15. Ms. Faith Wamwayi, Administrative Assistant, CUEA	Member

The Catholic University of Eastern Africa, Research Ethics Review Committee Members

Name	Areas of Experience/Expertise	Category	Gender M/F	Date of Appointment	Professional Affiliation	Nomination
Dr. Bethwell Owuor,	Science	**Chair**	**M**			Institution
Dr. Benson Mulemi	Anthropology	**Secretary**	**M**			Institution
Prof. Aloys Ayako,	Commerce	**Director, RIGT.**	**M**			Institution
Rev. Prof. Richard Rwisa	Theology		**M**			Institution
Rev. Dr. Albert Ngengi Mundele	Theology		**M**			Institution
Prof. Ernest Beyaraza	Law		**M**			Institution
Prof. Paul Achola	Sociology		**M**		OSSREA	Institution
Rev. Dr. Peter Mbaro	Theology		**M**			Institution
Sr. Dr. Theo. Katundano	Educational Policy & Leadership		**F**			Institution
Sr. Dr. Sabina Mutisya	Psychology		**F**			Institution
Dr. Evans Ogoti Okendo	Educational Administration		**M**			Institution
Mr. Stephen Mailu,	ICT Planning, Urban Application		**M**			Institution
Ms. Jane Nambiri	Educational, Research & Evaluation		**F**		TWB	Institution
Ms Faith Wamwayi	Commerce		**F**			Institution

Appendix

THE CATHOLIC UNIVERSITY OF EASTERN AFRICA

RESEARCH ETHICS REVIEW COMMITTEE

Re: Appointment as a member of the Catholic University of Eastern Africa, Research Ethics Review Committee (CUEA-RERC)

Dear **xxx**,

I am delighted to let you know that you have been recommended for appointment by the Directorate of Research, Innovation and Graduate Training of the Catholic University of Eastern Africa Research Ethics Review Committee (CUEA-RERC).

The purpose of the Catholic University of Eastern Africa, Research Ethics Review Committee is to improve the efficiency and effectiveness of the ethical review process. In order to ensure that all human research participants are adequately protected and that their rights and welfare is safeguarded, all research protocols to be carried out in the Catholic University of Eastern Africa will undergo a review process undertaken by the Catholic University of Eastern Africa Research Ethics Review Committee. This is a requirement from the Republic of Kenya, National Council for Science and Technology.

Serving as a member of the CUEA-RERC is not only a great honor but also an important, critical professional activity that comes with great responsibility as well. You are being trusted to provide leadership and assistance in mentoring young scholars by being a role model.

On behalf of the Directorate of Research, Innovation and Graduate Training of the Catholic University of Eastern Africa Research Ethics Review Committee.

Prof. Aloys Ayako, Director of Directorate of Research, Innovation and Graduate Training.

If you are willing to serve as a member of CUEA-RERC, please sign and return a copy to the Director of Department of Research, Innovation and Graduate.

Signature: **Date**:

Important areas to be covered in the training of Research Ethics Review Committee.

- Historical perspectives
- Informed consent and vulnerable persons
- Minimum standards of care in clinical research
- Essential Elements of a Research Proposal
- Study design and Clinical trials
- Ethical considerations in Humanities and Social Science Research
- Data and Safety Monitoring Board (DSMB)
- Serious and Adverse events reporting
- Standard Operating Principles
- Protocol Review process
- Biological Material Transfer
- Role of Ethics Committees
- Legal aspects of Bioethics
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)
- Good Clinical Practice/ minimum requirements for clinical research
- National Research Ethics review Guidelines

APPENDIX

THE CATHOLIC UNIVERSITY OF EASTERN AFRICA

A.M.E.C.E.A

Directorate of Research, Innovation & Graduate Training

RESEARCH ETHICAL REVIEW COMMITTEE

APPLICATION FORM

(INFORMATION SHOULD BE TYPED)

This form should be used for all research carried out by students, staff at the Catholic University of Eastern Africa (CUEA) and other researchers seeking affiliation to the university. A four-tier system of ethical approval has been developed to be administered by the RERC. The levels within the system are explained below. Please tick the appropriate box to indicate which level applies to your research. The form applies to research involving human participants, personal data, and human tissue.

All applications should be submitted well in advance of a required date of approval, particularly in case of level 4. Applications will normally be reviewed within 2-6 weeks, but this cannot be guaranteed for all the applications submitted.

Level 1: Your research project is completely desk-based (i.e. does not involve field participants) and does not use information about living, identifiable individuals ('data subjects').

Level 2: Applies to non-intervention research where you have the consent of the participants and data subjects. This may include, for example, analysis of archived data, classroom observation, or questionnaires on topics that are not generally considered 'sensitive'. This research can involve children or young people, if the likelihood of risk to them is minimal.

Level 3: Applies to novel procedures, research without consent, sensitive personal data, or the use of atypical participant groups. Also projects in which ethical issues might require more detailed consideration but are unlikely to prove problematic.

Level 4: Applies to research which is potentially problematic in that it may incorporate an inherent physical or emotional risk to researchers or participants; involve covert surveillance or covert data collection; or includes research studies involving humans, their tissue and/or data.

Applicants must indicate their commitment to following ethical guidelines appropriate to their research.

Name……Date……..Department…….

Has your Head of Department/Supervisor approved this application? YES/NO

SECTION 1: DETAILS OF APPLICANT/PRINCIPAL INVESTIGATOR		
1.1Title, First name, Surname:	**Staff/Student number:**	***PROJECT ID NUMBER***
1.2 Professional Status:		
1.3 University DIVISION:		
1.4 University DEPARTMENT:		
1.5 Complete Postal Address:		
1.6 Telephone No:	**1.7 E-mail address:** *Please provide your email address as registered with the University***	

SECTION 2: PROJECT DETAILS
2.1 Title of Research Project:
2.2 Proposed Start Date
2.3 Duration of the Project
2.4.Is this a sub-study (new research question) linked to an existing/main study? ☐ Yes ☐ No If yes, RERC #:

SECTION3: DETAILS OF CO-INVESTIGATORS			
Name and Title	**Contact Details**	**If investigator is a student, please indicate whether postgraduate or undergraduate**	**Division AND Department**
1.			

2.			
3.			
4.			

Is this a sub-study (new research question) linked to an existing/main study? ☐ Yes ☐ No	**If yes, RERC #:**

SECTION 4: STUDY FOR DEGREE PURPOSES	☐ Yes ☐ No	**Undergraduate** ☐	**Postgraduate** ☐

Name of Degree:	**Supervisor:**
Division:	**Contact No:**
Department:	**E-mail:**

Is this a group student project? (if yes, please list names of all students in group under Section 4) ☐ Yes ☐ No

Students Names: 1	**2**
3)	**4**

SECTION 5: SPONSORSHIP/FUNDING	
5.1 Is funding necessary to proceed with this study, has it been secured? YES/NO	
5.2 If YES to 5.1, give details of the agency/agencies supporting the project. If a funding submission is planned, give details of the agency/agencies to which a funding application (s) has been made.	
5.3 Does the project require the approval of any other institution and/or ethics committee?	
5.4 If YES to 5.3, give details and indicate the status of the application at each other institutions or ethics committee (i.e. submitted, approved, deferred, rejected)	
5.5 If application was rejected, state the reason given	
SECTION 6: DESCRIPTION SYNOPSIS) OF THE RESEARCH (About 500 words)	
Please provide a protocol synopsis or summary of the proposed research, in addition to the full protocol, no longer than 2 pages. The Protocol Synopsis or summary on separate sheets of paper should contain the following: ▪ **Title** ▪ **A short introduction, motivation and literature overview (1 paragraph only)** ▪ **Research question or hypothesis**	

▪ **Aims and Objectives** ▪ **A concise summary of the methodology** ▪ **Description of subject population including characteristics, age range and number of subjects** ▪ **If the research will require blood draws, bone marrow biopsy samples, other biopsies or the collection of tissues, etc., performed solely because of participation in the research, please indicate the exact amounts and frequency with which the samples will be taken.** ▪ **Anticipated risks as well as the precautions taken to minimize risk** ▪ **Anticipated benefits** ▪ **Ethical Considerations**	
SECTION 7: POTENTIAL RISKS TO PARTICIPANTS	
7.1 Could the research induce any psychological stress or discomfort in the participants?	☐ Yes ☐ No
7.2 If YES to 7.1, state the nature of the risk and what measures will be taken to deal with such problems Research involve Human Subjects who are Alive?	
7.3 Does the research require any physically invasive or potentially physically harmful procedures?	☐ Yes ☐ No
7.4 If YES to 7.3, give details and outline procedures to put in place to deal with potential problems	
7.5 Does the research involve investigation of illegal behaviours?	☐ Yes ☐ No
7.6 If YES to 7.5, give details	
7.7 Is it possible that this research will lead to disclosure of information about child abuse or neglect?	☐ Yes ☐ No
7.8 If YES to 7.7, indicate the likelihood of such disclosure and your proposed response to this. If there is a real risk of such a disclosure triggering an obligation to make a report to police, Social Work or other authorities, a warning to this effect must be included in the Information and Consent documents	
7.9 Is there any purpose to which the research findings could be put that could adversely affect the participants?	☐ Yes ☐ No
7.10 If YES to 7.9, describe the potential risk for participants of this use of the data. Outline any steps that will be taken to protect the participants	
7.11 Could the research affect the participants in any other way?	☐ Yes ☐ No
7.12 If YES to 7.11, give details and outline procedures to put in place to deal with the problems	
7.13 Could this research adversely affect members of particular groups of people?	☐ Yes ☐ No

7.14If YES to 7.13, describe these possible adverse effects and the protection to be put in place against them	
7.15Is this research expected to benefit the participants directly or indirectly?	☐ Yes ☐ No
7.16If YES to 7.15 , give details	
7.17Will the true purpose of the research be concealed from the participants?	☐ Yes ☐ No
7.18If YES to 7.17, explain what information be concealed and why. Will participants be debriefed at the conclusion of the study? If not, why not?	
7.19At any stage in this research could researcher's safety be compromised or could the research induce emotional stress in the researchers?	☐ Yes ☐ No
7.20If YES to 7.19, to either or both, give details and outline procedures to be put in place to deal with the potential problems.	

SECTION 8: HUMAN SUBJECTS RESEARCH PROTECTION	
8.1 Does the Research involve Human Subjects who are Alive?	☐ Yes ☐ No
8.2 Does the Research involve Human Subjects who are dead (includes identifiable tissues specimens)?	☐ Yes ☐ No
8.3 How many participants is it hoped to include in the research?	☐ Yes ☐ No
8.4 Are any of the participants in 8.3 likely to be under 16 years of age?	☐ Yes ☐ No
8.5 Are any of the participants in 8.3 likely to be children under the care of local authority?	☐ Yes ☐ No
8.6 Are any of the participants in 8.3 likely to have a special need?	☐ Yes ☐ No
8.7 Are any of the participants in 8.3 likely to be physically or mentally ill?	☐ Yes ☐ No
8.8 Are any of the participants in 8.3 likely to be vulnerable in other ways?	☐ Yes ☐ No
8.9 Are any of the participants in 8.3 likely to be members of a racial or ethnic minority?	☐ Yes ☐ No
8.10 Are any of the participants in 8.3 unlikely to be proficient in English?	☐ Yes ☐ No
8.11 Are any of the participants in 8.3 likely to be in a client or professional relationship with the researchers?	☐ Yes ☐ No
8.12 Are any of the participants in 8.3 likely to be in a student-teacher relationship with the researchers?	☐ Yes ☐ No
8.13 Are any of the participants in 8.3 likely to be in any other a depedent relatioship with the researchers?	☐ Yes ☐ No
8.14 Are any of the participants in 8.3 likely to be in any other a depedent relatioship with the researchers?	☐ Yes ☐ No
8.15 Are any of the participants in 8.3 likely to have difficult in reading and/or comprehending any printed material distributed as part of the study?	☐ Yes ☐ No
8.16 If YES to any of 8.4-8.15, explain and describe the measures that will be used to protect and/or inform participants	
8.17 Will participants receive any financial and/or material benefits because of participation?	☐ Yes ☐ No
8.18 If YES to 8.17, what benefits will be offered to participants and why?	☐ Yes ☐ No
SECTION 9: CONFIDENTIALITY AND HANDLING DATA	
9.1 Will the study require the collection of personal data, e.g. from universities, schools,, employers or other agencies about individuals with their direct consent?	☐ Yes ☐ No
9.2 If YES to 9.1, state what information will be sought and why written consent for access to this information will not be obtained from the participants themselves	
9.3 Will any part of the research involving be audio/film/video taped or recorded using any other electronic media?	☐ Yes ☐ No
9..4 If YES to 9.2, what medium is to used and how will theb recording be used (e.g. digital audio recording to create interview transcripts/summaries)?	☐ Yes ☐ No

9.5 Who will have access to the raw data (e.g. myself as researcher)?	
9.6 How will confidentiality of the data, including identity of participants be ensured? E.g. by anonymization, keeping codes separately, and making sure all information is stored securely.	
9.7 Specify where the data files/audio/video tapes, etc. will be retained after the study, how long they will be retained and how they will eventually bd disposed off. Data to be retained only as long as writing up and reporting on the project are underway, with a maximum time of three years from the formal end of the project being placed on the retention of data.	
9.8 How do you intend for results of the research to be used?	
9.9 Will feedback of findings be given to participants?	☐ Yes ☐ No
9.10 If YES to 9.9, how and when will this feedback be provided? E.g. All participants will be provided with summary feedback on the main findings	
SECTION 10: PARTICIPANT INFORMATION AND CONSENT	
10.1 Will written consent be obtained from participants?	☐ Yes ☐ No
10.2 If YES to 10.1, attach a copy of information sheet and consent forms (covering project details, confidentiality, freedom to withdraw at any stage of the project). *E.g. YES, in relation to any participants I wish to involvein the project, I will provide a written information sheet outlinining the nature of the project and the potential contribution, plus a formal consent request which makes it clear*	
10.3 If NO to 9.1, explain why not. *E.g. Not necessary formally to members of staff with whom the project will be pursued on colleagial basis. At the same time it will be made clear to staff how the confidentiality of data will be handled and they will also be assured standard good research practice will*	
10.4 Administrative may be deemed sufficient:	
10.4a for studies where the data collection involves aggregated (not individual) statistical information and where the collection of data presents i) no invasion of privacy and ii) no potential social or emotional stress	
10.4b for studies which focus on development and evaluation of curriculum materials, resources, guidelines, test items, or programme evaluations rather than the study observation, and evaluation of individuals.	
10.5 Will administrative consent (e.g. from head teacher) be obtained in lieu of participants consent?	☐ Yes ☐ No
10.6 If YES to 10.5, explain why individual consent is not necessary	
10.6 In the case of of minors participating in the research on an individualn basis, will consent or assent of parents be obtained?	☐ Yes ☐ No

10.7 If YES to 10.6, explain how this consent or assent will be obtained	
11. CONFLICT OF INTEREST-COMPROMISING RESEARCH OBJECTIVITY OR INDEPENDENCE IN RETURN FOR FINANCIAL OR NON_FINANCIAL BENEFIT HIM/HERSELF OR FOR RELATIVE OR FRIEND	
11.1 Does your research involve a conflict of interest as defined in 11?	☐ Yes ☐ No
11.2 If YES to 11.1, give details	

SECTION 12: SIGNING OF APPLICATION		
Applicant	**Supervisor** *(only for student research)*	**Head of Division**
…… Print name	…… Print name	…… Print name
…… Signature	…… Signature	…… Signature
…… Date	…… Date	…… Date