



**KILIMANJARO CHRISTIAN MEDICAL UNIVERSITY
COLLEGE**

(A Constituent College of Tumaini University Makumira)

**COLLEGE RESEARCH ETHICS
AND REVIEW COMMITTEE
(CRERC) CHARTER**

SEPTEMBER 2024

CHARTER INDEXING INFORMATION

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PREFACE

In the ever-evolving landscape of medical research and healthcare, the ethical considerations surrounding the treatment of human subjects have become paramount. The KCMUCo Institutional Review Board (IRB) known as the College Research Ethics Review Committee or (CRERC) stands as a guardian of these ethical principles, ensuring that all research conducted under its auspices adheres to the highest standards of integrity, respect, and responsibility.

This Charter serves as a foundational document for the operations of the KCMUCo IRB or CRERC, reflecting our unwavering commitment to safeguarding the rights and welfare of research participants while fostering an environment that encourages scientific inquiry and innovation. However, with this potential comes the responsibility to conduct research ethically and transparently. The IRB plays a critical role in this process, providing oversight and review of research proposals to ensure that they meet ethical standards and comply with applicable country and international research laws and regulations.

The Charter outlines the roles and responsibilities of IRB/CRERC members, the set-up of IRB/CRERC and its operationalization. With this background we invite all members of the College community—researchers, faculty, students, and our partners—to engage with the IRB/CRERC process actively to ensure our research endeavors not only contribute to scientific advancement but also uphold the dignity and rights of those who participate in our studies.

Prof. Ephata E Kaaya

PROVOST

Kilimanjaro Christian Medical University College

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ABBREVIATION

CRERC	College Research Ethics Review Committee
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
ICH-GCP	International Conference on Harmonization Good Clinical Practice
IEC	Independent Ethics Committee
IRB	Institutional Review Board
NatHREC	National Health Research Ethics Committee
PI	Principal Investigator
SOPs	Standard Operating Procedures

GLOSSARY OF TERMS

Conflicting interest: This refers to when an individual's personal interests – family, friendships, financial, or social factors could compromise his or her judgment, decisions, or actions in the review and or providing an impartial opinion on the study being reviewed by CRERC. Such factors can include having a family relationship with the project PI, being directly involved in the study as a sponsor, investigator, or being a direct beneficiary of the study.

ICH-GCP guidelines: These are the harmonized standard that protects the rights, safety and welfare of human subjects. These guidelines were developed following the International Conference on Harmonization of ethical standards for Research involving human subjects first produced in 1996. The current version of ICH-GCP guidelines is of 2016 (ICH E6 (R1) document).

1.0 BACKGROUND

The College Research Ethics Review Committee or CRERC is the Institutional Review Board (IRB) of Kilimanjaro Christian Medical University College (KCMUCo), the Kilimanjaro Christian Medical Centre (KCMC) and Kilimanjaro Clinical Research Institute (KCRI). This charter is derived from and governed by the International Conference on Harmonization Good Clinical Practice (ICH-GCP) guideline and is regulated and guided by rules and regulations of the National Health Research Ethics Review Committee (NatHREC).

This charter facilitates the establishment of the CRERC for the purpose of ensuring independent process of approving, reviewing and monitoring research studies operating in the institutions while safeguarding the safety, rights and wellbeing of human subjects participating in the studies as well as ensuring credibility of the data generate from such studies.

2.0 AUTHORITY

The College Research Ethics and Review Committee shall operate under the NatHREC which has been mandated by Parliamentary Act No. 23 of 1979 with the functions to monitor, control, coordinate and evaluate health research undertaken in the country.

3.0 FUNCTIONS OF THE CRERC

In line with the ICH-GCP guidelines CRERC functions shall be:

- (i) To safeguard the dignity, rights, safety and wellbeing of all research study participants and communities with emphasis on vulnerable groups.
- (ii) To review health research protocols submitted to it within a reasonable time and document its views in writing to the applicant(s).
- (iii) To forward approve research proposals and CRERC certificates to NatHREC in case foreign nationals are involved in the submitted research protocol.
- (iv) To review and monitor progress reports of approved research projects.
- (v) To plan and conduct monitoring visits to approved research projects.
- (vi) To evaluate final reports and research outcomes before dissemination (i.e. publications, presentations).
- (vii) To periodically review or update this Charter based on NatHREC charter, World health Organisation's operational guidelines for ethics committees that review biomedical research, the ICH-GCP guidelines for good clinical practices (GCP) and guideline for good clinical laboratory practice (GCLP).

4.0 COMPOSITION OF THE CRERC

4.1 Composition and Eligibility

- (i) The CRERC shall consists of a minimum of seven (7) members who collectively have the qualifications and

experience to review and evaluate the science, medical and ethical aspects of research protocols. It shall be composed of both scientific and non-scientific members with varying background to promote complete and adequate review of research protocols. The committee shall consist of:

- (a) A chairperson who shall be a person holding a senior position from Senior Lecturer or above, or equivalent position, with reasonable experience in conducting medical research.
 - (b) The chairperson shall be from outside KCMUCo.
 - (c) Vice-Chairperson who shall be appointed from within KCMUCo and shall be a senior lecturer or above with reasonable experience in conducting research as well as experience in CRERC as a member for not less than three years.
 - (d) Secretary who shall be a person with at least a Bachelor's degree and with background in social, medical or biomedical sciences.
 - (e) Members appointed on the basis of their qualifications as prescribed in section 4.2 (iii).
- (ii) The CRERC shall be supported by a Secretariat headed by a secretary.
 - (iii) Members of the secretariat must have good knowledge on GCP and Bioethics.

4.2 Membership of the CRERC

- (i) Membership shall be constituted according to ICH-GCP guidelines on IRB (IECs) and the guidelines on ethics for health research in Tanzania. CRERC members shall be appointed by the KCMUCo Provost.
- (ii) In appointing the members for the CRERC the Provost shall:
 - (a) Appoint the Chairperson and Secretary first, who shall then propose to the Provost, based on the rules of this charter, names of other members who shall constitutively form the committee as described herein under.
 - (b) Ensure gender balance for fair representation of both male and female gender.
 - (c) Ensure the qualifications and experience of members represent the various health disciplines
 - (d) Appointed at least one non-scientific member preferably from outside KCMUCo to represent the views of the community in general.
 - (e) Appoint members in their personal capacities based on their interest, ethical and or scientific knowledge, and expertise as well as their commitment and willingness to volunteer their necessary time and effort for the committee's work.
- (iii) Membership composition of CRERC shall include the following representation:
 - (a) Medical practice expertise
 - (b) Pharmacology/Pharmacy expertise

- (c) Biomedical Health Laboratory sciences expertise
- (d) Social or behavioral sciences expertise
- (e) Legal expertise

NON-SCIENTIFIC COMMUNITY REPRESENTATIVE

5.0 TENURE FOR CRERC CHAIRPERSON AND MEMBERS

- (i) CRERC chairperson and members shall hold office for three (3) years subject for reappointment upon satisfactory performance.
- (ii) CRERC members shall also be appointed and/or reappointed for three years.
- (iii) CRERC chairperson and members shall not serve for more than six (6) consecutive years.
- (iv) There shall be no limit of tenure for CRERC secretary and administrator.
- (v) Where the CRERC Secretary or a member shall be proven incompetent to continue serving in CRERC, or conducts himself/herself against ethical principles, the chairperson through a normal or a special meeting shall cause for discussion on the matter and the decision to make a replacement shall be communicated to the Provost by the Chairperson.

6.0 RESPONSIBILITIES OF CRERC MEMBERS

The responsibilities of the CRERC members shall be:

- (i) To support the CRERC in discharging its duties
- (ii) To maintain confidentiality of documents and deliberations of the CRERC meetings
- (iii) To attend CRERC meetings and participate actively during deliberations
- (iv) To participate in continuing education activities for purpose of enhancing their capacity in discharging CRERC functions
- (v) To adhere to high ethical conduct standards in conducting their duties.
- (vi) To remain impartial in every deliberation and declare conflict of interest if any in all meetings and/or other CRERC duties.

7.0 CRERC MEETINGS

7.1 Schedule of meetings

CRERC meetings shall be monthly in which case the meeting day shall be every first Friday of the month except on Good Friday and other holidays whereby another day in the month shall be set.

7.2 Format of the meetings

- (i) CRERC meetings shall be held in-person, by teleconference or by video conferencing or a mixture of the three.
- (ii) The secretariat shall determine the best format of a meeting based on circumstances and members availability.

7.3 Call for the meetings

- (i) The Secretary shall notify all CRERC members of an upcoming meetings at least a week in advance.
- (ii) Meeting notification shall be by email, letter or both.

7.4 Meeting procedures

- (i) The following shall be the standard procedures for CRERC meetings:
 - (a) The quorum for meetings shall be half plus one, the number of CRERC members. However, if an expertise for a particular proposal under review is not represented in the quorum, the meeting shall not discuss that proposal.
 - (b) The Chair shall lead the meeting. In his/her absence, the Vice chairperson shall lead the meeting.
 - (c) Each member shall sign a conflict-of-interest form at each meeting to declare whether they have/not have conflict of interest in any of the study protocols or matters to be discussed in that meeting.
 - (d) Approval for proposals shall be by consensus. However, voting can be exercised to resolve a contentious decision. An absentee member shall be allowed to send in his/her comments but shall not vote.
- (ii) CRERC meeting proceedings shall be documented by the Secretary.

7.5 Voting rights

- (i) Approval for proposals is usually by consensus. However, voting can be exercised to resolve a contentious decision. An absentee member is allowed to send in his/her comments but cannot vote.
- (ii) A member with conflicting interest in a proposal submitted for approval is not allowed to participate in the review, discussion and voting.
- (iii) In case of equal votes, the Chair shall have a casting vote.

7.6 Approval of clearance certificates

- (i) Approval for a proposed study shall be issued with a certificate.
- (ii) Following a favourable opinion by the CRERC meeting on a proposed study, the secretariat shall prepare a certificate and request for approving signature from the Provost or his designee.
- (iii) The CRERC certificate shall bear the signature of the CRERC Chairperson and the Provost.

8.0 CONFIDENTIALITY

Each of the Committee members shall sign a confidentiality agreement at the time of their appointment, indicating their agreement to maintain confidentiality, security and integrity of all materials during and after their term on the Committee.

9.0 MISCELLANEOUS PROVISIONS

9.1 CRERC Secretariat

The CRERC office shall be composed of the following:

- (i) CRERC Secretary appointed by Provost
- (ii) Office secretary and an administrator.

9.2 Functions of the Secretariat

The following shall be the functions of the secretariat:

- (i) Organize effective and efficient tracking procedures for each proposal received.
- (ii) Prepare, maintain, and distribute study protocols.
- (iii) Organize regular CRERC meetings according to the Almanac.
- (iv) Proper documentation and archiving of all CRERC documents in soft and hard copies with back up.
- (v) Arrange for appointment and relevant research ethics training for CRERC secretariat and members.
- (vi) Organize the preparation, review, revision and distribution of SOPs and guidelines.
- (vii) Provide updates on relevant and current issues related to ethics in health research, as well as relevant current literature to Committee members.
- (viii) Follow up with the financial matters related to CRERC.
- (ix) Communicate with the National Ethics Committee and other research regulatory authorities in the country in matters related to CRERC functions and responsibilities.

9.3 Responsibilities of the Chairperson and Vice Chairperson

- (i) Shall Chair the CRERC meetings in accordance with all regulations.
- (ii) Facilitate the preparation and provision of ethical clearance certificates.
- (iii) Review and accept revisions that were made as per CRERC recommendations pending protocol approval.
- (iv) Facilitate the provision of training and continuing education to CRERC members.
- (v) Determine submissions that could be exempted from review and notify the CRERC and the PIs of such exemptions.
- (vi) Arrange expedited review of research protocols that meet the expedited review criteria.
- (vii) Assign responsibilities and duties to any other member in his or her absence and assign responsibilities to other members of the CRERC.
- (viii) Oversee the Secretariat and ensure maximum performance and support.

9.4 Responsibilities of CRERC Administrator

- (i) Oversee all CRERC documents and archives.
- (ii) Perform a pre-review of each protocol submission to ensure adherence to guidelines.
- (iii) Support the Chair in preparing and providing ethical clearance certificates.

- (iv) Design and disseminate CRERC templates (e.g. guidelines, annual reports, etc.) to principal investigators according to relevant SOPs.
- (v) Assist the Chair in conducting CRERC meetings.
- (vi) Take minutes of CRERC meetings.
- (vii) Cooperate and attend any relevant investigations or audits of CRERC.
- (viii) Prepare and submit annual operational budget to CRERC.
- (ix) Undertake all other administrative procedures as instructed by appropriate authorities

10.0 OWNER OF THE CHARTER

This Charter is owned by the College Academic Committee

11.0 AMENDMENTS OF THE CHARTER

- (i) This charter shall be reviewed and evaluated for relevance and accuracy regularly, and in case there is requirement for amendment the secretariat shall initiate a minor review process.
- (ii) Major revision of the Charter shall be done after five (5) years from the date of approval.

12.0 CHARTER STATUS

This is a new Charter.

13.0 APPROVAL DETAILS

This Charter was recommended by the KCMUCo Academic Committee (CAC) on 06th September 2024.

This Charter is approved by the TUMA SENATE this 25th day of September 2024.

Submitted by:

Prof. Ephata E. Kaaya

PROVOST

KCMUCo

Date: 25th September 2024

Approved by:

Rev. Prof. Dr. Joseph W. Parsalaw

CHAIRPERSON

TUMA SENATE

Date: 25th September 2024

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