KCMC UNIVERSITY

INSTITUTIONAL REVIEW BOARD (KCMC University-IRB)

Standard Operating Procedures (SOP)

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ABBREVIATIONS

AMANET	African Malaria Network Trust
IRB	Institutional Review Board
DSMB	Data and Safety Monitoring Board
IRB	Institutional Review Board
KCMC University	KCMC UNIVERSITY
KCMC	Kilimanjaro Christian Medical Centre
NIMR	National Institute for Medical Research
MOHSW	Ministry of Health (Tanzania) and Social Welfare
NatHREC	National Health Research Ethics Review Committee Standard Operating Procedures
PI	Principal Investigator
TMMDA	Tanzania Medicines and Medical Devices Authority

INTRODUCTION

The IRB started operating since 1985 under the Kilimanjaro Christian Medical Centre (KCMC). The functions of the Committee transferred to the Kilimanjaro Christian Medical College (KCMC University) of the Tumaini University in 2001. Since then, the college Directorate of Research and Consultancies has been vested with the responsibility of overseeing the operations of the Committee.

These SOP is based on the following documents:

- Helsinki declaration (2008)
- ICH-GCP guidelines (2016)
- Tanzania National Health Research Ethics Review Committee (NatHREC)
- Standard Operating Procedures for National Health Research Ethics Review Committee, Tanzania

Rationale for review

The Institutional Review Board (IRB) of KCMU College.

In order to increase efficiency and effectiveness, it was found necessary to review the previously Standard Operating Procedures (2016) in order to align with those of the NatHREC and the ICH-GCP guidelines (2016). This document will facilitate the reviewing, authorising, monitoring and evaluation of research activities

In the conduct of research, researchers/investigators are advised to be conversant with the following college documents: College policy and guide lines on Research, Consultancy and Innovation policy, HIV and AIDS policy, Intellectual Property Right policy and guide lines, Conflict of Interest, and Disclosure.

Statement of Purpose

This SOP is expected to promote efficiency and effectiveness in reviewing research proposals, grants application, project implementation and reporting results from research projects with maximum transparency while adhering to ethical values and scientific standards.

Scope

This SOP will guide all type of research conducted at KCMC University and or its affiliated institutions (KCMC hospital and KCRI), with or without collaboration with KCMC University staff and students, and any research approved by KCMC University IRB.

SOP 01: IRB MEMBERSHIP

The IRB consists of minimum of nine (9) and maximum of 15 members who collectively have the qualifications and experience to review and evaluate the science, medical aspect, and ethics of research protocols. It is composed of both scientists and non- scientists with varying background to promote complete and adequate review of research protocols.

Composition

- Membership is constituted according to the guidelines on ethics for health research in Tanzania. In appointing the members for the IRB the KCMU College Provost takes into consideration the following parameters:
- Members are selected 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.

1. Gender balance to ensure fair representation of both men and women.
2. Qualified and experienced staff members from various disciplines.
3. A non-scientist/lay person member to represent the views of the community in general/vulnerable population
4. Representative from faith community.
5. In some circumstances people with special skills, knowledge or experience may be co-opted.
6. Alternate Members

- **Tenure**

1. Members are appointed for a period of 4 years.
2. Membership may be renewed for up to two consecutive terms.

Functions of the IRB

1. To safeguard the dignity, rights, safety and well-being of study participants and communities with emphasis on vulnerable groups.
2. To review submitted protocol/protocols and document its opinion timely
3. To forward approved research proposals/protocols and certificates to NatHREC where foreign nationals are involved.
4. To monitor progress of approved research projects.
5. To evaluate research outcomes before dissemination (i.e. publications, presentations and products) and final reports.
6. To develop/ review SOPs periodically

Responsibilities of members

1. Support the IRB secretariat in discharging its duties
2. Attend IRB meetings and participate actively during deliberations
3. Utilize the IRB review checklist when reviewing proposals
4. Maintain confidentiality of documents and deliberations of the IRB meetings
5. Participate in continuous professional education activities related to ethics
6. Declare conflict of interest

Responsibilities of protocol reviewers

1. Support the IRB secretariat in discharging its duties
2. Attend IRB meetings and participate actively during deliberations
3. Utilize the IRB review checklist when reviewing proposals
4. Maintain confidentiality of documents and deliberations of the IRB meetings
5. Participate in continuous professional education activities related to ethics
6. Declare conflict of interest

Loss of IRB membership

1. Members may resign their position by submitting a letter of resignation to the Provost
2. Serious misconduct

Replacement of IRB membership

The IRB chair shall propose to the Provost for a replacement of any member under the following circumstances:

1. Protracted illness of a member, which does not permit him/her to participate in the deliberations of the Committee
2. Persistent absenteeism m in four consecutive meetings without genuine reasons
3. Voluntary withdrawal by a member
4. Any other reason which does not permit participation to CRERC

Dissolution of the Committee

Under rare circumstances, NatHREC, following written notificationon to the secretariat each member, may dissolve the Committee at any time for good reasons in the interest of the KCMU College and the Public.

SOP 02: CONFLICT OF INTEREST STATEMENT

It is the responsibility of all IRB members and reviewers to, declare and sign the Conflict-of-Interest form (IRB Form 01) before beginning their tasks.

SOP 03: ADMINISTRATION AND FUNCTIONS OF THE IRB Secretariat

The purpose of this SOP is to describe the leadership and management of the IRB and their key functions.

A. Composition of the IRB secretariat

- **Chairperson** - Appointed by the Provost
- **Vice Chairperson** - Elected from among the Committee Members
- **Administrator** - IRB secretary

B. Functions of the Secretariat

1. Organize effective and efficient tracking procedures for each proposal received.
2. Receive protocols and identify reviewers
3. Organize regular and extraordinary IRB meetings
4. Document and archive IRB documents with back up.
5. Organize relevant capacity development for IRB secretariat, members and reviewers.
6. Organize the development, review, and distribution of SOPs and guidelines.
7. Provide updates on relevant and current issues related to ethics in research, as well as relevant current literature to Committee members and reviewers.
8. Ensure smooth operation of IRB and review process.
9. Ensure investigators responses are in compliance with IRB recommendations pending protocol approval.
10. Determine submissions that could be exempted from review, and notify the IRB and the PIs of such exemptions. (Risk –based review)
11. Any other functions that may be assigned by the IRB and NatHREC

C. Responsibilities of the Chairperson / Vice Chairperson

1. Chair the IRB meetings.
2. Approve ethical clearance certificates.
3. Facilitate the provision of training and continuing education to IRB members.
4. Arrange expedited review of research protocols that meet the expedited review criteria.
5. Oversee the Secretariat and ensure maximum performance and support.
6. Submit regular IRB reports to the college management

D. Responsibilities of IRB Secretary

1. Receive, manage and archive IRB documents
2. Perform screening of submitted protocols to ensure compliance format and guidelines.
3. Support the Chair in preparing and providing ethical clearance certificates.
4. Disseminate IRB templates (e.g. guidelines, reports, etc) to IRB members and principal investigators
5. Assist the Chair in organising IRB meetings and other activities.
6. Document minutes of IRB meetings.
7. Perform administrative duties (e.g organise M & E, budgeting,) as instructed by appropriate authorities

SOP 04: COMMITTEE MEETINGS

A. CALL FOR MEETINGS

1. IRB shall meet at least once a month
2. The Secretary shall formally notify (by email and or written letter) all IRB members of an upcoming meeting at least 7 days in advance.
3. The quorum shall be 50% of IRB members.
4. In the event where an expertise for a particular proposal under review is not represented in the meeting, the proposal/protocol shall not be discussed
5. The Chair shall lead the meeting. In his/her absence, the Vice chairperson will lead the meeting.

PROTOCOL/PROPOSAL APPROVAL

1. Approval of proposals shall be by consensus.
2. A member with conflict of interest in a proposal submitted for approval shall not participate in the review and, discussion of that proposal
3. Review comments shall be communicated to the PI using IRB Form #06.
   Research proposals resubmitted after minor corrections shall be cleared by the Secretariat while those with major corrections shall be cleared by CRERC.
4. Approval is given in a form of Ethical Clearance Certificate (IRB Form 07).
5. Approval is given for a maximum period of one year for all research projects and extension is subject to a satisfactory annual progress report and good ethical conduct.
6. Under an expedited review procedure, the review may be carried out by a sub-committee of two (2) to three (3) experts and the IRB Secretariat.

B. Meeting procedures

1. The Chair or Vice chair of the Committee shall call the meeting to order only when a quorum of members is reached. If a quorum is not reached, the meeting shall be rescheduled.
2. Minutes of previous meeting shall be read and approved.
3. The Chair shall follow the agenda for the progress of the meeting.

Where necessary a PI may be invited to answer questions on the protocol but must leave when deliberations are being made

C. Minutes of the Meeting proceedings

1. During IRB meetings, all deliberations shall be recorded.
2. The minutes shall include a list of attendees and non-attendees, and a written summary of the discussions and deliberations.
3. The IRB secretary shall produce copies of the minutes and send electronic copies of minutes, matters arising and agenda for the next meeting to IRB members at least one 7 days before.

4. The IRB members shall confirm the accuracy and completeness and chair shall sign the minutes during the next meeting.
5. The IRB secretary shall archive all documents.

SOP 05: PROTOCOL REVIEW PROCEDURES

It is the responsibility of the PI to submit an application for assessment by filling in the application for Ethical clearance form (IRB Form 02). The IRB secretary is responsible for receiving and processing of submitted proposals and for ensuring that IRB Form 02 is adequately filled in; and that proposal complies with IRB guidelines.

A. Instructions to Principal Investigator (PI)

1. The PI shall submit a soft copy of the research proposal document through electronic link available at eirb.KCMC University.ac.tz
2. The proposal shall be written in Times New Roman, Font 12, and double spaced.

The Proposal document should include the following:-

- Covering letter
- Research proposal
- An IRB approval certificate from collaborating institutions
- Consent forms and questionnaire (English and Swahili versions for both)
- Up to date Curriculum Vitae of all investigators in the (IRB Form 14) CV format.
- Budget which shall include 20% institutional overheard cost. Unless stated otherwise by the funder
- Payment in accordance to IRB fees
- Any other relevant documents, (e.g. questionnaires, enrolment forms, a copy of payment receipt).
- Memorandum of understanding of the involved institutions

Table 1: IRB fees

S/No.	Category	Locally funded research*	Internationally funded research	Tanzanian students	International students
1.	Ordinary health research	300 USD	500USD	Masters 50 USD PhD 300 USD	Masters 500 USD PhD500 USD
2.	Clinical trial	300 USD	700 USD	Masters 50 USD PhD 300 USD	700 USD
3.	Renewal of ethical approval	100 USD	100 USD	100 USD	100 USD
4.	Expedited review	300 USD	600 USD	N/A	Masters 500 USD PhD 600 USD
5.	Expedited review clinical trial	400 USD	1000 USD	N/A	

* Locally funded: funded by KCMC University/GSF internal funds

B. Instructions to Secretariat

1. Upon receipt, the proposal is given a number according to IRB Form 02
2. The proposal is sent out to relevant reviewers, accompanied and guided by instructions on IRB Form 05.
3. The secretariat shall determine whether a proposal qualifies for expedited review refer SOP 07.

SOP 06: REVIEW OF PROTOCOL AMENDMENT

The purpose of this procedure is to describe how protocol amendments are managed and reviewed by the IRB. This SOP applies to previously approved study protocols but which are being amended and submitted for approval. Amendments made to protocols may not be implemented until approval has been given. Investigators may amend the contents of protocols from time to time. Protocol amendments must be submitted to the IRB for either "expedited" review or "Full/regular" review (see IRB Form 08).

Detailed instruction for protocol amendment

1. The PI shall prepare the amendment package and submit to the CRERC.
2. Upon receipt of the amendment package, the Secretariat shall follow the receiving guidelines in pproposal amendment form (IRB Form 08)
3. A request for the amendment of a previously approved protocol shall describe the amendments made and reasons for the amendments
4. The Secretariat shall check the original proposal for completeness. Changes or modifications in the amended version shall be underlined or highlighted (This also applies for soft copies).
5. After review of the materials, the Chairperson in collaboration with the Secretariat shall determine whether the protocol requires expedited or full review.
6. Under any circumstances, amendments should never constitute more than 25% of the original work.
7. Any amendments made by the PI must be agreed upon by all the other investigators in the proposal.
8. Change of PI should be reported to IRB immediately with support of well documented meeting proceedings among all Investigators and reasons for the change. IRB which shall approve or disapprove a proposed new PI.

SOP 07: EXPEDITED REVIEW

Research Review: Definition:

In the context of research, an expedited review may refer to a faster review process for research proposals or projects that involve minimal risk to participants. Expedited reviews are often used for studies that meet certain criteria, allowing them to undergo a quicker review process compared to full board reviews.

The Chairperson in collaboration with the Secretariat shall determine which proposals may require expedited review. The following categories may qualify as

Research proposals that present no more than minimal risk to human subjects:

1. Minor changes in previously approved research proposals.
2. Proposal involving collection of non-confidential information and not likely to harm the status or interest of study participants.
3. Studies that involve collection of small amounts of biological specimens by non-invasive means (e.g. body fluids; saliva, sweat, tears, stool, excreta, hair or nail in non-disfiguring or threatening manner).
4. Collection of data/samples through non-invasive procedures (e.g. not involving general anaesthesia or sedation), routinely employed in clinical practices and using medical devices which have been approved for use, e.g. electrodes, acoustic testing, Doppler principle tests, and other routine clinical measurements.
5. Research involving data, documents or specimens that have already been collected or shall be collected for ongoing medical treatment or diagnosis.(add details from Prof Manongi)

Procedures for Expedited Review

1. Expedited review shall be conducted by the Chairperson/Vice Chairperson and at least two or more experienced reviewers
2. The expedited review shall be carried out on the complete study protocol with all required attachments (IRB Form 02) review shall be done based on checklist no. xy.
3. Results of the review process may be communicated to the PI before discussion in the IRB meeting and reported retrospectively to the CRERC.
4. The reviewer's comments will be communicated to the PI through the secretariat Based on PI response and reviewers satisfaction, the secretariat may approve the proposal or call for full board meeting, Expedited review shall take a maximum of 2 weeks

SOP 08: CONTINUING REVIEW OF STUDY PROGRESS.

The purpose of continuing review is to monitor progress of the entire study, to ensure continued protection of rights and welfare of research participants.

Procedures of Continuing/Annual Review

1. At a research activity's initial review, the Committee shall determine that:all approved research shall be reviewed at intervals based on the nature, degree of risk, vulnerability of the study population and duration of the study. This will be at least once in a year.

   i. .

2. The investigator shall use (IRB Form 13) to fill the continuing/annual review report which includes ;
   i. Demographic information of the study participants
   ii. Changes in principal and/or associate investigator(s), (Ref SOP 6.08)
   iii. A summary description of subject experiences

iv. Any serious adverse events experienced how it was reported and handled (Refer SOP 21).

v. Numbers of study participants withdraw/suspended/terminated and reasons The research results obtained thus far combine with iii above and prepare progress report

vi. Any protocol deviations/violations, reasons for these how it was reported and handled(Refer SOP 22)

vii. Any new information since the Committee's last review.

3. The PI shall submit one hard copy of the report, with original signature and an electronic copy.
4. The IRB criteria for assessment (approval or disapproval) of a report are the same as the criteria for approval of an initial research project.
5. After assessment, the Committee may require that the research be modified, suspended or halted.
6. The IRB shall also determine whether there are any important new findings that may have ethical implications to the participants. If so, the IRB shall notify the PI who shall notify the participants of these findings.
7. The report should comply with IRB Format. No research activities should continue after expiration of ethical approval

SOP 09: FORMATION OF DATA AND SAFETY MONITORING BOARD (DSMB)

The IRB requires each project to form a DSMB. The primary responsibility of a DSMB is to safeguard human subjects by analysing accumulating data relevant to the risks and benefits on a regular basis. Clinical trials involving greater than minimum risk must include a DSMB - Greater than minimum risk involves those that the probability and magnitude of harm/discomfort anticipated in the proposed study are greater than those ordinary encountered in daily life and routine care. For clinical trials conducted in Tanzania the DSMB must include representation from Tanzania. For multi country clinical trials, DSMB must include regional representation and keep the IRB up-to-date of the balance between risks and benefits. The clinical trial PI should make sure all the DSMB reports related to their trial are submitted to CRERC.

Composition of Data Safety Monitoring Board

Objective: To establish a standardized approach for the composition DSMB in clinical trials, ensuring independent oversight, ethical conduct, and scientific integrity.

Scope: This SOP applies to all clinical trials where a DSMB is deemed necessary for monitoring safety, efficacy, and overall trial conduct.

Responsibilities of DSMB

Selection of DSMB Members:

1. Statisticians:

At least one independent statistician with expertise in clinical trial design and analysis.

2. Clinical Experts:

A qualified medical professional with expertise in the relevant therapeutic area

3. Ethicists:

An independent ethicist to provide guidance on ethical considerations.

4. Patient Advocates:

Individuals representing patient interests, ensuring a patient-centred approach.

5. Independent Members:

Non-affiliated individuals with no direct involvement in the trial to maintain objectivity

6. Safety Experts:

Professionals with expertise in monitoring and assessing adverse events.

Composition Approval:

The selection of DSMB members must be approved by the trial sponsor and regulatory authorities.

The independence and expertise of each member should be documented.

DSMB Meetings:

Regular meetings shall be scheduled to review safety data, trial progress, and any emerging issues. Meetings may be convened in response to specific safety concerns or milestones.

Roles and Responsibilities:

Statisticians: Analyze trial data for statistical significance.

Clinical Experts: Evaluate clinical aspects, including patient safety and adherence to the protocol. C. Ethicists: Provide guidance on ethical considerations and dilemmas.

Patient Advocates: Represent patient perspectives and contribute insights into the impact on participants. Independent Members: Ensure objectivity and independence from the trial sponsor and investigative team.

Safety Experts: Monitor and assess adverse events, contributing to safety evaluations.

Decision-Making Process: The DSMB will make recommendations on trial continuation, modification, or termination based on the reviewed data. Consensus among DSMB members or a predefined decision-making process shall guide recommendations.

Documentation: All DSMB activities, recommendations, and decisions shall be documented in meeting minutes and reports. These documents are to be maintained for regulatory inspections and trial transparency.

SOP 10: INQURIES FROM RESEARCH PARTICIPANTS/COMMUNITY MEMBERS OR ANY PERSON INTERESTED IN THE STUDY

In safeguarding the rights and welfare of the study participants, IRB shall respond to all requests by participants regarding their rights

Handling Participants 'requests

1. Upon receiving an inquiry from a study participant/community, the IRB secretariat shall record the request and information on the Request Record Form (IRB Form 09) and communicate with the IRB about study participant rights for instruction.

2. The IRB secretariat shall document the communication, request follow-up information, and provide advice as required for decision making.

SOP 11: MONITORING AND EVALUATION OF SAFETY/ADVERSE EVENTS (SAE) REPORT

The primary responsibility of the IRB is to review and address SAE's and unexpected events involving risks to participants or others as well as ethics complaints or SAE reports submitted by PI, DSMB, local safety monitor and any other intended parties. Information that may impact on the risk/benefit ratio must be promptly reported to, and reviewed by, the IRB to ensure adequate protection of the welfare of the study participants.

Feedback from IRB

After reviewing the report, the Chairperson may call for a consensus from IRB members on whether to:

i. Request an amendment to the protocol or consent
ii. Request further information
iii. Suspend or terminate the study

If any of the above actions are taken, the IRB Secretariat shall notify the PI of the action taken. If the Committee takes no action, it shall be noted in the minutes.

SOP 12: NON–COMPLIANCE WITH STUDY PROTOCOL

If the PI fails to comply with or violate the study protocol or fails to respond to the IRB directives, the following should be followed:-

1. The IRB may suspend or terminate approval of study. Depending on the nature of the non-compliance IRB may refuse subsequent applications from the PI in question.
2. The IRB decision shall be formally communicated to the PI with copies sent to the relevant National Authorities, the sponsor/s or the sponsor's representative. In case of deviation the IRB will decide on the action to be taken.
3. The PI must respond in writing with description of any corrective action to be taken within seven (7) working days.
4. The IRB decision shall be made within seven (7) working days.

SOP 13: REVIEW OF FINAL STUDY REPORTS

Final Study Report Form shall be submitted using IRB Form 11. Additional information may be required by IRB

Procedures

1. IRB secretariat will screen the report to ensure if it is complete/adequate
2. During the IRB meeting, final study report shall be presented by the secretariat and the Board shall determine if there is any follow-up needed. .

3. The IRB Secretariat shall acknowledge to the PI in writing on the acceptance of the report. .

SOP 14: STUDY SITE MONITORING VISITS

The IRB shall perform on-site inspection of the approved research projects using Form no 11.

Types of monitoring visits

1. Routine monitoring visits

In routine monitoring visits, the IRB shall notify the PI in writing 10 working days prior to the visit. There will be least once in a year.

2. Unannounced monitoring visits

An unannounced monitoring visit may be conducted under the following circumstances:-

i. Failure to submit progress or final reports
ii. Failure to respond to Audit concerns
iii. Complaints from participants, co-investigators, and other stakeholders
iv. Report of frequent serious adverse events
v. Alleged research misconduct

During the routine or unannounced visits, the team shall use the IRB Form No. 10 to:-

i. Conduct entry meeting
ii. Review at least 25% of the study participants documents, other relevant documentation and recommend urgent action, if any
iii. Conduct exit meeting and communicate findings with actions to be taken
iv. Write a report and submit to IRB within seven (7) days after the visit. IRB shall send a copy of the report to the PI for action.
v. The PI should respond to IRB queries within seven (7) days.

SOP 15: ENGAGEMENT AND THE ROLE OF INDEPENDENT REVIEWERS

The IRB may engage an independent reviewer for the expertise that is not available within the Committee. The independent reviewer may either attend the meeting to participate in the review of the study as a non-voting member and/or may review the documents and prepare a report to be discussed by the IRB Committee in the regular or extraordinary meetings. The reviewer's report shall become a permanent part of the master file. Procedure for review by external reviewers shall be the same as those of IRB members

SOP 16: MAINTAINING CONFIDENTIALITY OF IRB DOCUMENTS

This SOP describes how to handle documents in order to protect confidentiality. Confidential documents shall include protocol and related documents, case report forms, informed consent documents, diary forms, scientific documents, expert opinion or reviewer's comments, meeting minutes and

correspondences. It is the responsibility of all members of the Committee and staff of the Secretariat to enforce confidentiality.

Procedures for maintaining confidentiality:-

- **Confidentiality agreement**

Committee members and the Secretariat shall sign the Confidentiality Agreement at the beginning of their term of service to the Committee (IRB Form # 01). Signing of the Confidentiality Agreement is also mandatory for independent reviewers.

- **Accessing confidential documents**

If any researcher/academician needs copies of original proposal/reports, he/she shall write a letter to the IRB chair explaining the purpose of the request. Approval shall be made by the Secretariat. IRB Form No 12 shall be used for documentation.

SOP 17: INTERNATIONAL RESEARCH STUDENTS

Registered International Students involved in research must:

- Comply with Relevant immigration requirements,
- Have approved local supervisor

IRB approval

SOP 18 FEEDBACK TO COMMUNITY INVOLVED IN A STUDY

- It is the responsibility of the study team to communicate with the community involved in the study or where the study has been done so as to give them feedback of the summary from the research finding.

SOP 19 ADVERSE EVENTS

Purpose: The purpose of this SOP is to establish guidelines and procedures for the prompt and accurate reporting of adverse events during the course of research studies conducted under the oversight of the KCMC University IRB

Scope: This SOP applies to all Principal Investigators, research staff, and individuals involved in the conduct, oversight, or monitoring of research studies approved by the KCMC University IRB

Definitions

a) Adverse Event (AE): Any untoward medical occurrence in a research participant that does not necessarily have a causal relationship with the intervention being studied.

b) Serious Adverse Event (SAE): Any adverse event that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

c) Unexpected Adverse Event: An adverse event that is not listed in the protocol as an expected occurrence.

4. Reporting Responsibilities:

The PI is responsible for promptly reporting all adverse events to the IRB, sponsor, and other relevant regulatory authorities in accordance with regulatory requirements and the study protocol.

SAEs must be reported to the IRB within twenty-four hours of the PI becoming aware of the event

5. Documentation: All adverse events and their resolutions must be documented in the study records. The IRB will maintain records of all adverse event reports and actions taken. The IRB may request additional information or documentation related to reported adverse events.

The IRB may convene a meeting to review the adverse event and take appropriate actions, including modifications to the study protocol or suspension of the study.

SOP 20 RISK-BASED REVIEW SOP FOR RESEARCH INVOLVING CHILDREN AND VULNERABLE POPULATIONS

Objective: To ensure the ethical conduct of research involving children and vulnerable populations by implementing a risk-based review process that prioritizes participant safety and well-being

Scope: This SOP applies to all research projects conducted within KCMC University IRB that involve children and vulnerable populations, as defined by applicable regulations and guidelines

Procedure:

Submission:

Researchers must clearly indicate in their protocol submission if the research involves children or vulnerable populations.

Include a detailed risk assessment, addressing potential physical, psychological, social, and legal risks.

Risk Assessment: The IRB will evaluate the level of risk associated with the research, considering the vulnerability of the population involved. Assessments will include potential harm, discomfort, and the adequacy of safeguards in place to protect participants. The PI is responsible for implementing safeguards, which may include monitoring, parental consent, assent procedures, and other protective measures. The IRB will assess the adequacy of proposed safeguards to ensure participant protection.

Documentation:

The IRB will maintain detailed records of risk-based reviews and decisions related to research involving children and vulnerable populations.

Researchers must maintain comprehensive documentation of the informed consent process, including assent forms and parental consent where applicable.

Ongoing Monitoring: The IRB will conduct periodic reviews to ensure ongoing participant safety and adherence to the approved protocol. Any modifications to the protocol or new risks identified during the course of the research must be promptly reported to the IRB.

SOP 21 EMERGENCY SITUATIONS E.G COVID 19

This SOP outlines the procedures for adapting and conducting research activities while prioritizing the safety and well-being of participants, researchers, and the community in times of crisis.

The Principal Investigators (PIs) are responsible for promptly assessing the impact of the emergency on ongoing research, implementing necessary modifications to protocols to ensure participant safety, and notifying the Institutional Review Board (IRB) of any changes.

The IRB will expedite the review of emergency-related protocol amendments, considering the ethical implications and potential risks.

PIs must also establish clear communication channels with participants, maintain the confidentiality of collected data, and adhere to public health guidelines.

This SOP provides guidance for the ethical and efficient continuation of research activities during unforeseen emergencies, promoting flexibility and adaptability to safeguard the integrity of the research process.

Regular updates and post-emergency evaluations will be conducted to assess the effectiveness of implemented measures and inform future emergency response strategies

Objective: This SOP is established to provide a systematic and transparent process for identifying, documenting, and addressing violations and deviations from approved research protocols. The primary goal is to ensure the integrity of research data, protect the rights and well-being of participants, and maintain compliance with ethical standards and regulatory requirements.

Scope: This SOP applies to all researchers, study staff, and personnel involved in research activities conducted within the KCMC University IRB. Violations and deviations include but are not limited to non-compliance with protocol requirements, informed consent procedures, or other regulatory obligations.

Responsibilities:

The Principal Investigator should promptly report any violations or deviations to the IRB and other relevant oversight entities, investigate the root cause of the violation or deviation, and develop corrective and preventive action plans.

The research team must immediately document and report any observed or suspected violations or deviations to the PI, cooperate with the PI in conducting investigations and implementing corrective actions.

The IRB will review and assess reported violations or deviations in a timely manner, determine the severity of the incident, and recommend appropriate actions, including modifications to the protocol, additional training, or suspension of the research.

Procedure:

Reporting violation and deviations

a) Researchers must report violations or deviations to the IRB promptly and provide a detailed description of the incident. b. The PI is responsible for ensuring that all necessary information is submitted, including the impact on participant safety, data integrity, and regulatory compliance.

b) The PI will conduct a thorough investigation to determine the root cause of the violation or deviation. b. Document findings, including any contributing factors, and propose corrective and preventive actions

c) The IRB will review the investigation report and assess the severity of the violation or deviation. The IRB may convene an ad-hoc meeting to expedite the review process, especially in cases of serious non-compliance.

Corrective and Preventive Actions: Based on the IRB's recommendations, the PI will implement corrective actions to address immediate concerns and preventive actions to avoid future occurrences. Follow-up reports will be submitted to the IRB, detailing the status of implemented actions and their effectiveness.

Documentation:

Maintain detailed records of all reported violations, deviations, investigations, and actions taken.

Document communication with the IRB, regulatory authorities, and any external entities involved in the resolution process.

Any deviation and or violations from the approved protocol shall be reported to the IRB as spelled out in the application Form (IRB Form 02). (To be shifted to adverse events reporting)

SOP 23 NON-COMPLIANCE

Objective: This SOP outlines the procedures for identifying, reporting, and addressing instances of non-compliance with research protocols, ethical standards, and regulatory requirements. The primary objective is to ensure prompt and effective resolution of non-compliance while upholding the integrity of research activities and safeguarding the rights and well-being of participants.

Scope: This SOP applies to all research personnel involved in projects conducted within KCMC University. Non-compliance includes deviations from approved protocols, failure to adhere to ethical guidelines, or any actions that compromise the validity and ethical conduct of research.

Procedure:

Researchers must promptly report instances of non-compliance to the Principal Investigator (PI).

The PI is responsible for documenting the incident, including relevant details such as the nature of non-compliance, contributing factors, and potential impact on participants and data integrity.

The PI will initiate a thorough investigation to determine the root cause and extent of non-compliance. The investigation will include identifying corrective actions to address immediate concerns and preventive measures to mitigate the risk of future non-compliance.

The PI will report the non-compliance incident to the IRB in a timely manner.

The IRB will review the report, assess the severity of the non-compliance, and provide recommendations for resolution. Based on the IRB's recommendations, the PI will implement corrective actions to address the immediate concerns identified in the investigation.

The PI will also establish preventive measures to minimize the risk of similar non-compliance in the future.

Documentation:

Maintain detailed records of reported non-compliance, investigation findings, actions taken, and communication with the IRB.

Ensure documentation is comprehensive and accessible for auditing purposes.

Progress report template

SOP 24: REVIEW OF SOPs

These SOPs shall be reviewed every three years. However minor revision can be done when required.

SOP Name	KCMC University - IRB SOPs
Statement of Purpose	Efficiency and effectiveness in research proposal review
Owner of the SOPs	KCMC University
Custodian	Directorate of Research and Consultancy
Scope	KCMC University, KCMC and KCRI staff and students
Approving authority	
Date of approval	
Index Number	
Reviewed Date	21st , December, 2023
Next review Date	21st December, 2026

References

1. National Institute for Medical Research. Standard Operating Procedures for the National Health Research Ethics Review Committee, Tanzania, 2007
2. Tanzania National Health Research Forum, Guideline on Ethics for Health Research in Tanzania, 1st Version 2001
3. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
4. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
5. 45 Code of Federal Regulations 46.115 IRB Records, .108.b IRB Functions and Operations.
6. The Belmont reports
7. CIOMS guidelines
8. 21CFR56.115 IRB Records
9. Ethical Guidelines for Biomedical research on Human Subjects, 2000
10. Helsinki declaration (2008)

KCMC UNIVERSITY

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Email: info@kcmcu.ac.tz Web site: http://www.kcmcu.ac.tz

CONFIDENTIALITY AND NON DSICLOSURE

In the course of your activities as a member of the IRB, you may be provided with confidential information and documentation (referred to as the "Confidential Information"). You agree to take reasonable measures to protect the Confidential Information: subject to applicable legislation, including the Access to Information Act, not to disclose confidential information to any person; not to use confidential information for any purpose outside the committee, and for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to yourself or any third party, and to return all confidential information (including any minutes or notes you have made as part of your committee duties) to the Chairperson upon termination of your functions

Please sign and date this agreement, if the undersigned agrees with the terms and conditions set forth above. The original shall be kept in file in the custody of the regularly compliance office. A copy shall be provided for your records.

I (name) .....

Address.....

.....

Have read and accept the aforementioned terms and conditions as explained in this agreement.

....
Undersigned Signature Date

....
Legal officer Date

IRB FORM NO. 02 CONFLICT OF INTEREST

KCMC UNIVERSITY

P. O. Box 2240, MOSHI Telephone 255-027-2753616.Tanzania.
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It is a policy of the IRB that no member may participate in the review or approval for activities in which that member has a conflict of interest except to provide information as requested by the IRB.

You shall immediately disclose to the Chairperson of the IRB any actual or potential conflicts of interest that you may have in relation to any particular proposal submitted for review by the Committee and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that a IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and shall not participate in the review or approval of a proposal except to provide information if the Committee requests such. Conflict of interest cases include, for examples:

- A member is involved in a potentially competing research grant.
- Access to funding or intellectual information that may provide an unfair competitive advantage.
- Personal biases that may interfere with his or her impartial judgment.

A member or members who may have a conflict of interest may not be counted toward a quorum and may not vote.

Use form from the legal officer

KCMC UNIVERSITY

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Email: info@kcmcu.ac.tz Web site: http://www.kcmcu.ac.tz

To: The IRB Secretary

We are applying for Ethical Clearance for our research proposal entitled: -

……..

Proposed study area ……..

Applicants: { } Staff { }Postgraduate { }Undergraduate

Principal Investigator (must be local)

…….……..

Other Investigators:

Local ……..

Foreign ……..

Funding Agency…… Project duration ……

Project host institution/s**……**

IRB fees Receipt No. ……..

GCP Certificates (Research Ethics/Safe-guarding)- All investigators should have attached recent GCP certificates

If granted the approval, we agree to:

- Read and abide by all IRB research guideline during the project implementation and dissemination of study outcomes
- Make available to the IRB annual progress and final reports.

I declare that I ……the PI I have been fully involved in the development of the protocol and I will oversee the implementation of the project and also will take the leading role in dissemination of the results.

I further declare that I will present results to the IRB before dissemination.

Signature …….. Date ……..

Name of the Witness ……

Designation…….. Signature ……

Date……

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Part One to be filled by IRB Secretariat

Proposal No……..

Study Title

……

……

Study Area: ……

Principal Investigator ……..

Other Investigators

Local ……

Foreign ……

1. Reviewer (1)…… Institution……
2. Reviewer (2) …… Institution……..
3. Reviewer/Coopted (3) …… Institution……..

1. Date received ……
2. Date sent for review ……..
3. Date received from reviewer (1) ……(2)……(3)……..
4. Date presented to IRB……
5. Committee's decision
   - Approved outright [ ]
   - Approved with minor corrections [ ]
   - Not approved due to major corrections [ ]
   -
6. Date returned to P.I……
7. Date of resubmission by P.I……..
8. Committee's decision after Resubmission
   - Not approved [ ]
   - Approved [ ]
   -
   - IRB Certificate No…….. Date Issued ……..

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Dear …….

In recognition of your knowledge and expertise on the proposed study topic the IRB is requesting you to review the attached proposal using IRB guideline (From no 5)

Proposal Title
……
……
……

Please return the duly completed review sheet and results form to the office of the IRB on

-----/-----/------ (date) at ---------- time

You will be paid a token amount of … …… upon submission of the reviewed proposal.

NB: Information on the results of your review is confidential and cannot be shared onto the authors of the proposal. Please sign the attached Conflict of interest and Confidentiality forms.

Thank you for your cooperation.

Research Administrator

KCMU COLLEGE RESEARCH ETHICS REVIEW COMMITTEE

I agree to review the proposal for the above specified period.

Date: …….. Signature ……..

IRB FORM 06 REVIEWERS COMMENTS

KCMC UNIVERSITY

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Title.....

Item	What to look for	Total = 100	Scores	Remarks
1. Format	Compliance with Institutional Research guidelines: • Summary, introduction, literature review • Problem statement, justification • Broad and specific objectives • Methodologies, dissemination of results • Ethical considerations and study limitations	Total score=5		
2. Scientific soundness	• Is title in line with specific objectives? • SMART* (Broad and specific objectives) • Study site, & Study design, , • Study population, Inclusion & exclusion criteria • Study variables • sample size calculation, sampling procedures	Total score=20		
	• Data collection methods and tools • Data management and analysis plan • Relevance of statistical evaluations	Total score=20		
3. Significance and impact	• Does the study address an important problem or a critical barrier to progress in the field? • How will successful completion of aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?	Total score=10		
4. Ethical Issues	(a) Recruitment procedures indicating justification for selected study population (b) Participants safety and welfare (c) Protection of vulnerable population (d) Risk to subjects and risk management plan Potential benefits to subjects & others	Total score=15		
	Approved and validated interventions/methods Material and data transfer agreements Valid GCP/GCLP certificates	Total score=5		
5.	Participants information sheet	Total		

Informed consent	Written Informed consent and assent processes Voluntary withdrawal criteria Compensation and reimbursement criteria and confidentially	score=20		
6. Budget	(a) Capacity building and mentorship plans: • Human resource development • Equipment and technology transfer • Mentorship and supervision (b) Overhead and coordination/administration costs (c) Ethical clearance and permit fees (d) Adequate funding	Total score=5		
	TOTAL SCORE			
Verdict: { } Approved outright { } Approved with minor correction { } Not approved –Major correction needed { }, Rejected General Comment:				

…….. …….. ……
…….

Name of Reviewer Signature Date submitted Date due

KCMC UNIVERSITY

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Email: info@kcmcu.ac.tz Web site: http://www.kcmcu.ac.tz

Date.....

To: ……

Proposal No.....

Study Title: ……

- The above proposal was reviewed by IRB on ……..and **approved** subject to major/minor corrections as indicated on the attached comments. Please revise your proposal taking into account the observed shortcomings, and resubmit within two weeks (minor) / three weeks (major). Late submission will be considered as new application
- The above proposal was reviewed by IRB on ……..and **rejected** as indicated on the attached comments.

Sincerely,

Administrator - IRB

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Certificate No. ST/PG/UG ……

Research Proposal No. ……

Study Title: ……

Study Area……

P. I Name: ……

Co-investigator (s): ……

Institution (s): ……

Funding Agency: ……

The Proposal was approved on: ……

Renewal No:……

Duration of Study: ……

From……to……

*This certificate is valid for one year only

Signature: _____ **Signature**

Name…… **Name: ……**

IRB Chair **Provost**

IRB FORM 09 PROPOSAL AMENDMENT FORM

KCMC UNIVERSITY

P. O. Box 2240, MOSHI Telephone 255-027-2753616.Tanzania.
Email: info@kcmcu.ac.tz Web site: http://www.kcmcu.ac.tz

Study title:	
Proposal No. …… Certificate No. …… Amendment No:	
P. I	
Amendment requested	

Reasons for amendment requested: (Refers to any information appeared in the literature that might affect the committee's evaluation of the risk/ benefit analysis of human subjects involved in this protocol?

Signatures …… Date ……

Name of P.I…… Date ……

For office Use

Received: IRB Secretary…… Date ……

Comments by Chairperson CRERC……

IRBChairperson ……Signature ……Date:……

Committee Decision

I……
……..
IRBSecretary …….. Signature ……

Date ……

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Date Received	
Received by:	
Mode of communication	Telephone/SMS/ WhatsApp/Email/letter/Physical Date: ……..Time:……
Name of participant:	
Address:	
Title of the protocol being participated in/Name of investigator	
Starting date of participation:	
Type of inquiry	
What is requested:	
Date and Action taken by IRB	
Outcome	
Name and Signature	

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A. Study background	
Proposal No ST222……. Certificate No. …….	Date of visit ……. Number of visit ……
Study start date	Study end date
Protocol version number and date (ST 222.Vr2, or 3 etc	Amendment No: Letter of amendment: Yes/No
Principal Investigator Other Investigator (s)	Name:
Funding agency	Address
B. **Detail of the study** 1.Study title:	
2.Study site: Implementing Institution:	
Consenting procedures • Recruitment	Comments
• Verbal	
• Written	
• Minor	
Authenticity of the signature	

3.Total no. of expected study participants No of participants recruited No of Refusal and Reasons: No of withdrawal and Reasons: Lost to follow and Reasons:	
3. SOPs/ Research Proposals	Comments
1. Types of Specimen/devices • Safety • Amount • Storage • Labelling • Archiving N.B. Check compliance with SOPs	Comments
2. Drugs/Medicine • Safety • Amount • Storage • Labelling N.B. Check compliance with SOPs	Comments
3. Any adverse events observed? Yes [ ] No [ ]	Comments
4. Are the adverse event reported? Yes [ ] No [ ]	Action: Check if submission letters for AE are available
5. Any proposal non-compliance/violation? Yes [ ] No [ ]	Comments
6. Are all case record forms up to date? Yes [ ] No [ ]	Comments
7. How well are study participants protected?	

Confidentiality Appropriate interview area Coding of study participants Filling system	Good [ ] Fair [ ] Not good [ ] Good [ ] Fair [ ] Not good [ ] Good [ ] Fair [ ] Not good [ ] Good [ ] Fair [ ] Not good [ ] Good [ ] Fair [ ] Not good [ ] General comments:
8. Consent: Any consent violation noted	
9. Data Safety Confidentiality Quality of Data Record keeping Key locked cabinet	
10. Any outstanding issues from previous visit? Yes [ ] No [ ]	Comments
11. Availabilityof documents a) Ethics renewals b) The right study version c) The right consent version d) Amendment approvals	
12. Any manuscript or publication so far?	
Summary of key findings	
Recommendations and action needed	
Duration of visit …….hours/days	Starting from ……Finished ……
Debriefing done and number of people participating	Date…….Time…….Number…….
Name of visiting Committee member/representative Monitor 1. ……	

2. ……	
1. Name of PI 2. Representative	
Completed by	Signature ……. Date ……

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Protocol Title	
Protocol No.	
Name of PI	
PI's Telephone	
PI's Email Address	
Name of the Sponsor	
Address of Sponsor	
Sponsor's Telephone	
Sponsor's Email Address	
Study site (s)	
Study design/s	
Duration of the study	
Total number of participants	
No. of participants enrolled by arms ,if any	
Description of the intervention (dosage, device, education, (Maximum 400 words	
No and types of SAE, Lost to Follow-up	
Study outcomes as per Objectives (attach papers or innovation if any) (maximum 2000)	1. 2. 3.

	4.
Study Implication (policy, procedures etc)	
Follow-up activity if any	
Name of PI Signature ..... Date	

IRBForm 13 APLICATION FOR ANNUAL RENEWAL/STUDY EXTENSION

KCMC UNIVERSITY

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NB : Before renewal/extension request is considered, compliance with regular report as per requalatory SHALL BE evaluated first

STUDY INFORMATION	**REMARKS**
Study title:	
Protocol:	
PI Name:	
Reasons for extension/renewal requested	
Have there been any amendments since last extension/renewal. If Yes give details • Changes in the participant population • Changes in Study site • Recruitment or selection criteria • Informed consent process • Withdraw/Lost to follow-up • Documentation • No of Accrual Exclusions • Changes in PI/Collaborating partners • Any conflict of interest	
Have any unexpected complications or side effects been noted since last approval? If Yes action taken?	
Reasons for renewal/extension	
Name of PI Signature Date:	
Committee Comment / decision	
Approvals	Chairperson, IRB..... Date..... Provost: .....Date.....

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1. 1.1 Name ……

   1.2. Nationality ……..

2. Contact :

   2.1. Address: ……

   2.2. Phone: ……

   2.3. Email: ……..

3. Academic Qualifications (University degrees)

   3.1 ……

   3.2 ……

   3.3 ……..

4. Employment

   4.1 Employer (Institution)……

   4.2 Current position ……

   4.3 Profession ……

5. Selected Publications (maximum 5)

   5.1 ……

   5.2 ……

   5.3 ……

   5.4 ……

6. Current Research Engagement (maximum 5)

   6.1 ……

   6.2 ……

   6.3 ……

   6.4 ……

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Email: info@kcmcu.ac.tz **Web site: http://www.kcmcu.ac.tz**

A. CONSENT INFORMATION:

Consent information should include:-

- Title of the study:
- Who are the researchers and what is the purpose?
- What is involved?
- Confidentially of the information
- The benefits of participating in this study
- The risks of participating in the study
- Rights to withdraw from the study
- What if I want more information**?**

Kama unahitaji kutoa taarifa au kupata taarifa za uratibu na maadili yanazohusiana na utafiti huu wasiliana na ofisi ya watoa vibali vya utafiti kwa:-

- Simu namba:+255- 272753616
- B, barua pepe: drcp@kcmcu.ac.tz
- Namba ya Mtafiti Mkuu
- Namba ya mratibu wa mradi
- Namba ya Shirika la Utafitii wa magonjwa ya binadamu (NIMR

B. CONSENT FORM

I have read the information for this study and my questions have been fully answered by a member of the research team

I agree to participate in the study.

Name …… Signature…….. Date……..

I have read and explained the study information to this person and have answered all question raised

Name …… Signature…….. Date……..

Witness only for people who cannot read or write

I have witnessed that this person has read the information for the study and has had his/her questions answered and has agreed to participate in the study

Name …… Signature…….. Date……..

FOMU YA MAELEZO NA RIDHAA YA USHIRIKI

KCMC UNIVERSITY

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Email: info@kcmcu.ac.tz **Web site: http://www.kcmcu.ac.tz**

A. Maelezo ya utafiti

Maelezo ya utafiti yatahusu:-

- Jina la Utafiti:
- Watafiti ni nani na nini lengo la utafiti huu?
- Yatakayohusika katika utafiti huu?
- Utunzajiwasiri
- Kuna faida na athari gani za kushiriki katika utafiti huu?
- Faida za kushiriki katika utafiti huu
- Athari za Kushiriki katika utafiti huu
- Itakuwaje kama sitaki kushiriki?
- Nifanyeje ikiwa nahitaji taarifa zaidi?

B. FOMU YARIDHAA YA USHIRIKI

Nimesoma taarifa za utafiti huu na maswali yangu yamejibiwa yote kwa usahihi na Watafiti. **Nakubali kushiriki** Jina……..Saini……Tarehe…… Nimesoma na kueleza taarifa za utafiti huu na nimejibu maswali yake na amekubali kushiriki katika utafiti huu. Jina ……Saini……Tarehe
Shahidi (kwa wale tu wasiojua kusoma au kuandika) Nimeshuhudia kuwa mtu huyu amesomewa taarifa za utafiti na maswali yake yamejibiwa na amekubali kushiriki kwenye utafiti huu. Jina……..Saini…… Tarehe……

Kama unahitaji kutoa taarifa au kupata taarifa za uratibu na maadili yanazohusiana na utafiti huu wasiliana na ofisi ya watoa vibali vya utafiti kwa:-

- Simu namba:+255-272753616
- Barua pepe: drcp@kcmcu.ac.tz
- Namba ya Mtafiti Mkuu
- Namba ya mratibu wa mradi
- Namba ya Shirika la Utafitii wa magonjwa ya binadamu (NIMR)

IRB MEMBERS (2023)

S/NO	MEMBER	GENDER	CURRENT PROFESSION	QUALIFICATION
1.	Dr. Blandina Mmbaga	F	Paediatrician& Epidemiologist	PhD, M.Med, MD.
2	Prof. Noel Sam	M	Microbiologist/ Immunologist	M.Med, MD.
3	Prof. Rachel Manongi	F	Health promotion specialist	PhD, MPhil, MD.
4.	Mrs. Marycelina Msuya	F	Nurse	MPH, Adv (Nursing)
5.	Prof. Venance Maro	M	Physician	M.Med, MD.
6	Dr. Sia Msuya	F	Epidemiologist	PhD, MPhil, MD.
7	Dr. Gloria Temu	F	Physician	MMED, MD
8.	Prof. Elton Kisanga	M	Pharmacist/Director Research and Consultancy	PhD, MSc, B.Pharmacy.
9	Dr. Reginald Kavishe	M	Biomedical Scientists	PhD, MSc, BSc.
10.	Dr. Declare Mushi	M	Social Scientist/Public Health	PhD, MA, BA.
11	Rev. Deogratius Msanya	M	Theologian	BD, MTh
12.	Adv. Rachelly Mboya	F	Lawyer	LLB
13.	Eng. Fredrick Monyo	M	Community Activist	Aeronautical Eng.
IRB– SECRETARIAT				
1.	Prof. Mramba Nyindo	M	Chairperson/Immunologist Parasitologist/Microbiologist	PhD, MSc, DVM.
2.	Ms. Rose Mwangi	F	Vice Chairperson/Bioethist	MPhil, Bioethics, B.A,
3.	Ms. Beatrice Temba	F	Secretary	MPH, BSc,
4.	Mr. Frank Dubi	M	IT specialist	BCS