Meru University of Science & Technology (MUST)
MUST Institutional Research Ethics Review Committee (MIRERC)
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STANDARD OPERATING PROCEDURES

Of

THE MUST INSTITUTIONAL RESEARCH ETHICS REVIEW COMMITTEE (MIRERC)

Foreword

Large segments of Kenya's population are potentially vulnerable to unscrupulous, unethical, exploitative and unnecessary research conduct. This is due to several factors, including: substantive adult illiteracy rate; general uncertainty and lack of knowledge/information on possible impacts of biotechnology; inaccessibility to information on impacts of various forms of research on human health; cultural reverence of medical practitioners; widespread income poverty; heavy burden of communicable diseases, non-communicable diseases and injuries; large unmet basic needs, e.g. clothing, food, water, sanitation, education, shelter; inequities in access to human development services; large numbers of special groups (minors, mentally handicapped, refugees) and low financial and social protection mechanisms exposing people to catastrophic expenditures. The existing situation is compounded by the rapid scientific and technological advancements in economically developed and emerging economies, and the accelerated technological transfer to Africa; increased numbers of clinical and randomized controlled trials (conducted by nationals in collaboration with international partners); emerging and re-emerging health threats; and increased need for research to support the achievement of the Kenya's Vision 2030 and the United Nations Sustainable Development Goals (SDGs).

The ethical and scientific standards for carrying out research among human subjects have been developed and established in international guidelines, including the 1947 Nuremberg Code, the 1979 Belmont Report, the 1964 Declaration of Helsinki, the Council for International Organizations of Medical Services (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects. Compliance with these guidelines helps to ensure that the dignity, rights, safety, and well-being of research participants are promoted and that the results of the investigations are credible.

All international guidelines require the ethical and scientific review of research alongside informed consent and the appropriate protection of those unable to consent as essential measures to protect the individual person and the communities who participate in research. In Kenya, the National Commission for Science, Technology and Innovation (NACOSTI) has been championing the establishment and accreditation of institutional research ethics review committees to regulate research and ensure compliance with international ethical guidelines, and by so doing contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants.

The Meru University of Science and Technology (MUST) Institutional Research Ethics Review Committee (MIRERC) was established in April 2017 to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential participants in research conducted by staff, students and collaborators. The activities of MIRERC in review of research proposals may be prone to various forms of abuse that can hamper instead of fostering a research culture. It is therefore imperative that a standardized system and procedures for receiving, reviewing and approving research proposals are put in place to allow expeditious, objective and reproducible review of proposals. The development and dissemination of the Standard Operating Procedures (SOPs) of MIRERC should therefore be viewed as an important step in fostering an ethical and humane research culture at MUST. It is understood that, new ethical issues in human development related research will keep emerging, and hence, there will be need for regular revision of these SOPs to maintain their relevance to national and international contemporary developments.

All the MUST staff, students and our research collaborators are urged to familiarize themselves with these SOPs and to apply them.

Professor Japhet Magambo

Vice-Chancellor

Meru University of Science and Technology

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Glossary

Adverse Event: Any untoward medical occurrence that may present during treatment, with a medicine or intervention, but which does not necessarily have a causal relationship with this treatment.

Adverse Drug Reaction or Adverse Reaction: A response to a medicine or intervention which is noxious and unintended. The phrase response means that the causal relationship between the medicinal product/intervention and the adverse event is at least a reasonable possibility.

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

Assent: A variation on consent where a person who does not possess full competence to give informed consent gives affirmative agreement to participate in research. For instance, a child or mentally handicapped should give assent before being enrolled in research. However, it is important to note that assent does not eliminate the need for obtaining the permission of a parent or other legally authorized representative (LAR).

Bioethics: A field of ethical enquiry that examines ethical issues and dilemmas arising from health, health care and research involving humans.

Conflict of interest (COI): A COI arises when a member (or members) of the MIRERC hold interests with respect to specific applications for review that may jeopardize his/her (their) ability to provide a free and independent evaluation of the research focussed on the protection of the research participants.

Community: A community is a group of people understood as having a certain identity due to the sharing a common set of values, a common set of interests, a common disease, or a shared proximity.

Competence: Refers to a potential or enrolled participant's mental capacity to provide informed consent.

Confidentiality: A fundamental ethical principal of safeguarding all personal information from unauthorized disclosure.

Consent form: An easily understandable written document that documents a potential participant's consent to be involved in research and describes the rights of an enrolled research participant.

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

Ethical guidelines: Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice.

Evaluation of the risk/benefit ratio: A scrupulous evaluation of the relationship between the risks and the potential benefits for the participants and/or their communities.

MUST Institutional Research Ethics Review Committee (MIRERC) (also known as ethical review board (ERB), ethical review committee (ERC), human research ethics committee (HREC), institutional review

board (IRB)): Group of individuals who undertake the ethical review of research protocols involving humans, applying agreed ethical principles.

Personal data: Data that relate to a living person and contain personally identifying information.

Principal investigator (PI): The main researcher overseeing or conducting the research process.

Protocol: A document that provides the background, rationale, and objective(s) of a research project and describes its design, methodology, and organization, including ethical and statistical considerations.

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

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

Research participant: An individual who participates in research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. It also includes individuals who participates in non-interventional research projects, e.g. questionnaire surveys, focussed group discussions, etc.

Researcher: A person who engages in the methodical and systematic investigation of hypotheses with the goal of contributing to new knowledge.

Research involving human participants: Any social science, biomedical, behavioural or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge.

Revision: Requirement by the research ethics committee to alter the protocol in some way prior to approval or additional review by the committee.

Serious Adverse Event or Serious Adverse Drug Reaction: Any untoward medical occurrence that: results in death, is life-threatening, requires patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

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

Unexpected Adverse Reaction: One in which the nature, specificity, severity and outcome is not consistent with the applicable product information (i.e. with the approved package inserts for registered products, or the investigator's brochure or other product information for unregistered products). These definitions of terms are from the WHO publications on research ethics committees (WHO, 2000, 2009).

Abbreviations

APA – American Psychological Association

CIOMS - Council for International Organizations of Medical Sciences

COI – Conflict of Interest

CV – Curriculum Vitae

GCP – Good Clinical Practice

ICF – Informed Consent Form

ICH – International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

KEBS – Kenya Bureau of Standards

LAR - Legally Authorized Representative

MUST - Meru University of Science & Technology

MIRERC – Meru University of Science & Technology Institutional Research Ethics Review Committee

NACOSTI – National Commission for Science, Technology and Innovation

PI – Principal Investigator

SAE - Adverse and Serious Adverse Events

SOPs – Standard Operating Procedures

SUSAR - Suspected Unexpected Serious Adverse Reactions

VC – Vice-Chancellor

WHO – World Health Organization

WMA - World Medical Association

Acknowledgement

The development of these SOPs was informed by the CIOMS, ICH, NACOSTI and WHO ethical guidelines; and the SOPs of the Moi University and the University of Pretoria institutional research ethics committees SOPs. The MUST SOPs were developed by MIRERC members: Dr Elijah Walubuka, Professor Joses M. Kirigia, Ms MaryJoy Kaimuri Kaura, Mr Patrick Kubai, Ms Joy Nyawira Riungu, Ms Ruth Gibendi, Dr Njati Ibuathiu, Ms Lydia Thuranira, Dr Huka Guyo, Mr. Steve Mageto, Ms Anne Ntoiti, Ms Stella Kaburia and Mr Peter Biu. The inputs from Professor Gitonga N. Mburugu, Professor Robert M. Kei, and Professor Peter Masinde are also greatly appreciated.

1. Constitutive Terms

1.1 Research involving human participants includes any social science, biomedical, behavioural or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge; in which human beings:

1) Are exposed to manipulation, intervention, observation or other interaction with investigators, either directly or through alteration of their environment; or
2) Become individually identifiable through investigators' collection, preparation or use of biological material or medical or other records (WHO, 2009).

1.2 The Meru University of Science and Technology Institutional Research Ethics Review Committee (MIRERC) do, at the discretion of the Chairperson and Secretariat, accept review of research proposals/protocols submitted to it, by researchers from other institutions who are not MUST staff members, students or affiliates.

1.3 Guidelines which MIRERC adhere to

The MIRERC functions in compliance with, but not limited to the following documents and guidelines:

1.3.1 International Ethical Guidelines

The international guidelines that are applicable are inter alia the following:

- The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans (CIOMS, 2016).
- The World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (WMA, 2013).
- The Nuremberg Code (Nuremberg Code, 1949).
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) - Good Clinical Practice (ICH, 1997).
- The Belmont report ethical principles and guidelines for the protection of human subjects of research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

1.3.2 National Legislation

The following National Legislations are applicable:

1.3.2.1 Universities Act No. 42 Of 2012

According to the Universities Act of 2012, the objectives of university education shall include — "(a) advancement of knowledge through teaching, scholarly research and scientific investigation; (e). promotion of the highest standards in, and quality of, teaching and research; dissemination of the outcomes of the research conducted by the university to the general community" (The Republic of Kenya, 2012). The National Council of Science and Technology guidelines for ethical conduct of biomedical research involving human subjects in Kenya provide a systematic and coherent framework for determining whether research is ethical (National Council of Science and Technology, 2004).

1.3.2.2 The Constitution of Kenya

According to Chapter One of the constitution of Kenya, Article 1, all sovereign power belongs to the people of Kenya and the people may exercise their sovereign power either directly or through their democratically elected representatives (The Republic of Kenya, 2010).

According to Constitution Chapter 6, Article 73(1), authority assigned to a State officer — (a) is a public trust to be exercised in a manner that—(ii) demonstrates respect for the people (The Republic of Kenya, 2010).

1.3.2.3 Science, Technology and Innovation Act

Article 14 of the Kenya Science, Technology and Innovation Act No. 28 of 2013 stipulates that any person issued with a research licence shall adhere to such procedures, standards, code of ethics and guidelines as may be prescribed by regulations made under this Act (The Republic of Kenya, 2014). Those guidelines include the Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (National Council for Science and Technology, 2004).

2. The Role of MIRERC

The MIRERC and membership was proposed by the Research Committee in accordance with the MUST research policy. The Vice-Chancellor approved establishment of MIRERC and appointed its membership. The role of MIRERC in reviewing research projects undertaken by members of staff, registered students and affiliates of the University, is to contribute to safeguarding the dignity, rights, safety, health and well-being of all actual or potential human research participants. MMIRERC will strive to provide independent (devoid of political, institutional, professional, and market influences), competent, and timely review of the ethics of proposed studies.

Four fundamental ethical principles provide a framework for ethical decision-making in research involving human participants (WHO, 2000, 2009):

- ***Respect for the dignity of persons:*** This refers to individuals' autonomy, i.e. ability to make decisions for oneself, including the decision of whether to participate in research or not voluntarily. For those individuals with diminished capabilities – such as children or those with mental disabilities – extra protection must be granted to protect the individuals from any risk of harm.
- ***Beneficence:*** the obligation to "do good" for others.
- ***Non-maleficence:*** the obligation to avoid causing harm to others.
- ***Justice:*** Requiring that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture, and ethnic considerations. For example, prisoners should not be unfairly excluded or included in research without valid scientific and ethical justification.

MIRERC will review and approve ethical aspects of research proposals on behalf of the National Commission for Science, Technology and Innovation (NACOSTI), which is the legal entity authorized to review and approve research in Kenya under Cap 250 of the Laws of Kenya (The Republic of Kenya, 2014).

3. The General Attitude of MIRERC

In line with the international ethics standards for health research as well as the commitment of MUST to ensuring ethically sound research, MIRERC highlights the following points that are pertinent to MUST community fulfilling its role diligently and accountably:

- MIRERC upholds the principle that the primary responsibility for ethically sound research practice resides with researchers.
- The role of MIRERC is to support and guide researchers towards better/best ethical research practice. In this way MIRERC is a resource for the University research community.
- MIRERC approaches ethical review of proposals in a collaborative spirit in order to arrive at decision making that involves researchers.
- The main purpose of questions MIRERC members ask is to clarify or better understand researchers' intentions.
- The comments made and questions asked by any one member of MIRERC are important to the deliberations of the Committee as a whole (University of Pretoria, 2016).

4. Research Evaluation Policy

MIRERC reviews all research involving human and animal research subjects. No retrospective (post ex facto) ethics approval can or will be granted.

All postgraduate students, staff and other researchers affiliated to the University must apply to MIRERC for the approval of their research proposals before research is undertaken. Researchers not affiliated to MUST can also apply for MIRERC ethical clearance at a fee determined from time to time.

5. Independence of MIRERC

MIRERC is an independent functioning body. This means:

a) Its decisions and resolutions are made independently;
b) No pressure from outside the MIRERC may be exerted on the Committee or its members to influence its decision;
c) MIRERC decisions may not be overturned or overruled by the University leadership or any other party but complaints/objections should be subjected to the appeals procedure with potential recourse to NACOSTI.

6. Membership

The Committee shall be composed of 13 members, with 1/3 of the total being of either gender, having core members from various disciplines including Biomedical, Clinical and Social Sciences, Biostatistics, Law and a lay person(s).

6.1. Co-option

The Committee may co-opt member(s) at any one time for independent expertise as and when required. The Committee shall determine the duration of the co-option.

6.2. Appointments

The Committee members shall be appointed by the Vice-Chancellor (VC) hereinafter referred to as the Appointing Authority.

6.3 Tenure and conditions of appointment

6.3.1 MIRERC shall have a Chair, Vice Chair, and Secretary, Deputy Secretary, Administrator and other members.

6.3.2 Members shall be selected in their personal capacities, based on their interest, ethical and/or scientific knowledge, and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the Committee's work.

6.3.3 Members shall be appointed initially for a period of three (3) years, renewable once.

6.3.4 To maintain continuity in the operations of the Committee, at least 1/3 of the membership shall be retained.

6.3.5 The outgoing Chairperson shall be an ex-officio member in the incoming Committee for one term.

6.3.6 At appointment:

6.3.6.1 Members shall sign a confidentiality agreement at the start of the term and abide by the confidential agreement regarding meeting deliberations, applications, protocol submissions, information on research participants and related matters; which they have had privilege to as a result of being members of the Committee (University of Pretoria, 2016; Moi University, 2016). The confidentiality protects all the privacy and confidentiality of all parties whose information may be disclosed to the Committee in the course of its work.

6.3.6.2 Members shall provide their updated CV's to MIRERC's administrative office at the beginning of their term; and be willing to publicize their identity, i.e. name, profession and affiliation to the Committee.

6.3.6.3 A member is obliged to declare in writing any potential and/or conflicting interests (financial, professional or otherwise) pertaining to any study, project or proposal under consideration by MIRERC.

6.3.7 Any member who has vested interest in a proposal submitted to the Committee shall not participate in the deliberations of the protocol.

6.4 Resignation, disqualification, and replacement of members

6.4.1 Members may resign from their post by giving a letter of resignation, at least one month in advance, to the appointing authorities through the Chairperson.

6.4.2 Members may also be disqualified from continuance should the appointing authority provide written arguments to the other members and there is unanimous agreement.

6.4.3 The Committee shall request for replacement of any members under the following circumstances

6.4.3.1 Protracted illness of a member, which does not permit him/her to participate in the deliberations of the Committee.

6.4.3.2 Persistent absenteeism of a member for more than three consecutive meetings.

6.4.3.3 Voluntary withdrawal of a member.

6.4.3.4 Ethical/professional misconduct.

6.5 Allowances

6.5.1 Allowances for MIRERC membership shall be considered by the appointing authority on recommendation of the Committee (University of Pretoria, 2016).

6.5.2 The community representative shall be paid a sitting and travel allowance which shall be determined by the Committee from time to time.

6.6 Review fees

The Committee shall charge a fee to cover administrative costs of research proposal review. These fees shall vary from time to time as determined by the Committee (University of Pretoria, 2016; Moi University, 2016).

6.7 Contact Information for MIRERC

MIRERC shall have a designated physical address, telephone contact, Website and E-mail address (mirerc@must.ac.ke). The MIRERC Administrator shall be the contact person.

7. Terms of Reference (TOR)

Broad Terms of Reference for the Committee are as follows:

7.1 Review and Approvals of Research Proposals

The Committee shall provide independent, competent and ethical review of research proposals.

7.1.1 The Committee shall provide independent ethical review of new research proposals, amendments and requests for continuing approval submitted to it within a reasonable time specified in section 10.0 and document its views in writing to the applicant(s).

7.1.2 The Committee shall safeguard the dignity, rights, safety, and wellbeing of all study participants and communities paying special attention to investigations that may involve vulnerable participants.

7.1.3 The Committee shall require the investigator(s) to explain any aspect of the study that may require personal appearance at its Committee meeting.

7.1.4 The Committee shall make available standard format for submissions of research proposals for ethical review (Appendix 1: MIRERC Application Form for Ethical Review).

7.1.5 The Committee shall obtain relevant documents including but not limited to the following:

7.1.5.1 Where research is for academic purposes, it would be best that the relevant School-based Post-Graduate Committees reviews the proposal first to assure scientific rigor and veracity before submitting to MIRERC. Therefore, the PI should submit a memorandum from the relevant School certifying approval for submission to MIRERC for ethical review.

7.1.5.2 Abstract of proposal.

- A short summary should accompany the research proposal (Appendix 2: MIRERC Abstract Form).

7.1.5.3 Detailed study protocol(s) and /or amendment(s)

A protocol of the proposed study should address the following:

- Background and relevance of the proposed research study
- Problem statement (Literature references as evidence of existence of a knowledge gap)
- Research questions / Hypothesis
- Objectives
- Methodology
    - Study area
    - Research design
    - Study population
    - Participants exclusion criteria / inclusion criteria
    - Sampling procedures: sample size and sampling methods
    - Data collection tools and procedures
    - Quality assurance of specific tools to be used (validity and reliability)
    - Data management and analysis
- Ethical considerations, e.g. anonymising of data and participants. Assurance of data anonymity must be given. Details on how this will be done, must be written in the protocol under "Ethics." Any such study using data only, must be approved by the Ethics Committee.
- References: use American Psychological Association style (American Psychological Association, 2010).

Please refer to Appendi**x 3A on Funding protocol/proposal format and Appendix BB on the MSc/MPHIL/PHD proposal format**.

7.1.5.4 Written informed consent form(s) and research tools that the investigator proposes for use in the study. (Participant's information and consent document (PICD) (Appendix 4: Participants Information and Consent Form). These tools may need to be translated into local language(s). Please refer to section 13.3.

7.1.5.5 Available safety information and products manufactured under established Good Manufacturing Practice and certified by competent authorities (KEBS approved) (where applicable).

7.1.5.6 Budget details

7.1.5.7 Any other relevant documents that may be required.

7.1.5.8 Declaration of conflict of any interest.

7.1.6 The Committee shall consider the suitability of the investigator(s) for the proposed study with respect to relevant qualification, training and experience, as documented by current curriculum vitae and/or by any other relevant documentation.

7.1.7 The Committee shall review both the value and type of benefit to study participants to ensure that neither presents ethical problems (such as coercion or undue influence) on the study participants.

7.1.8 Submitted proposals that have already been reviewed and approved by NACOSTI accredited institutional ethics review bodies shall be considered and ratified.

7.1.9 The Committee may conduct site visits to approved research projects for purposes of monitoring.

7.1.10 The SOPs are subject to review from time to time to incorporate emerging issues and reflect the global changes in higher education quality management systems and international ethical standards. The review should not be later than 3 years. Any member of the University community may submit a request for SOPs revision to Chairman of MIRERC.

7.2 Continuous professional development in research ethics

7.2.1 All newly appointed members will undergo an orientation training session.

7.2.2 NACOSTI accredited research ethics lectures, workshops, conferences and seminars will be identified and members can attend. Requests to attend such courses can be submitted to the Chairman.

7.2.3 All members will receive the following guidelines:

- World Health Organization (WHO) Operational guidelines for Ethics Committees that review biomedical research (WHO, 2000).
- CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMs, 2016).
- Republic of Kenya Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004).
- American Psychological Association (APA) Guidelines for Ethical Conduct in the Care and Use of Nonhuman Animals in Research (American Psychological Association, 2012).

7.2.4 All members will receive the following human rights and research ethics review-related articles on Africa:

- Readiness of ethics review systems for a changing public health landscape in the WHO African Region (Motari, Ota, & Kirigia, 2016).'
- Health-related biotechnology transfers to Africa: principal-agency relationship issues (Kirigia, Kirigia, & Muthuri, 2007.
- Realizing the Right to Health in the WHO African Region: Issues, Challenges and the Way Forward (Motari, & Kirigia, 2016).
- Status of national research bioethics committees in the WHO African Region (Kirigia, Wambebe, & Baba-Moussa, 2005).
- Research ethics policies and practices in health research institutions in sub-Saharan African countries: results of a questionnaire-based survey (Zielinski, Kebede, Mbondji, Sanou, Kouvividila, & Lusamba-Dikasssa).
- Mapping research ethics committees in Africa: evidence of the growth of ethics review of health research in Africa (Mokgatla, Ijsselmuiden, Wassenaar, & Kasule, 2017).

7.3 Provide Leadership in Research Ethics

Through:

7.2.1 Sharing of international research ethics guidelines with Schools and other interested parties.

7.2.2 Providing research ethics review guidelines and forms.

7.2.3 Developing and maintaining an institutional research ethics database.

7.2.4 Providing training on research proposal ethics review guidelines.

7.2.5 Monitoring of ethical aspects of implementation of approved protocols.

8. The Secretariat

The MIRERC Secretariat shall consist of the Secretary, Deputy Secretary, an Administrator and support staff.

9. Functions and Responsibilities

9.1 Chair:

The Chair shall:

9.1.1 Conduct meetings in accordance with the regulations

9.1.2 Facilitate induction and training of new Committee members

9.1.3 Facilitate continuing education for members

9.1.4 Oversee the functions and activities of the Secretariat

9.1.5 Assign responsibilities and duties to any member of the Committee

9.1.6 Sign the minutes of the Committee meetings

9.1.7 Sign approval letters for research proposals on the recommendation of the Committee

9.1.8 Shall coordinate logistical support to the Secretariat to ensure prompt execution of MIRERC mandate

9.1.9 Liaise with NACOSTI and other Institutional Research Ethics Review Committees or Boards.

9.2 Vice-Chair

The Vice-Chair shall:

9.2.1 Perform all the functions and duties of the chair whenever the chair is absent.

9.2.2 Perform any other duties as assigned the chair

9.2.3 Oversee monitoring activities.

9.3 Committee Secretary

The Committee Secretary shall:

9.3.1 Be responsible for the safety of Committee documents, records and archives

9.3.2 Call meetings in consultation with the Chair

9.3.3 Identify suitable reviewers in collaboration with the Committee

9.3.4 Dispatch proposals to reviewers for ethical review

9.3.5 Receive reviewed proposals and monitor the review process of proposals to ascertain comments from reviewers are received within the stipulated period.

9.3.6 Prepare proposal review documents for discussion at regular Committee meetings.

9.3.7 Design templates (forms) for approval by the Committee, including research protocols, informed consent materials, ethical review guidelines, etc.

9.3.8 Oversee the functions and activities of the Administrator and the support staff

9.3.9 Record, process and circulate the minutes of the MIRERC meetings

9.3.10 Shall archive the official documents of MIRERC.

9.3.11 Organize ethical review meetings, and distribution of SOPs and guidelines.

9.3.12 Perform any other duties as assigned by the Committee or the Chair.

9.4 Deputy Committee Secretary

9.4.1 To officially deputize the Committee Secretary

9.4.2 Perform any other duties assigned by the Committee Secretary

9.5 Administrator

The Administrator shall:

9.5.1 Perform day to day running of the MIRERC secretariat including financial management with approval of the Committee

9.5.2 Perform a pre-review of each protocol to ensure compliance with administrative submission requirements

9.5.3 Manage and maintain copies of all correspondences

9.5.4 Attend Committee meetings and assist in taking of minutes

9.5.5 Assist the Secretary in drawing the agenda

9.5.6 Circulate research proposals and minutes to Committee members

9.5.7 Assist in preparation and submission of annual work plans and budget in consultation with the Chair.

9.5.8 Design and maintain a system for collecting and filing all Committee documents.

9.5.9 Maintain inventory of all office equipment

9.5.10 Undertake all other administrative duties as assigned by the secretary.

9.6 Committee Members

Committee members shall:

9.6.1 Review, discuss and consider ALL proposals submitted for evaluation to safeguard the rights and wellbeing of study participants

9.6.2 Ratifications of the considerations taken by the chairman on behalf of the Committee

9.6.3 Maintain confidentiality of documents and deliberations of the Committee meetings.

9.6.4 Declare conflict of interest whenever applicable: COI may arise when a MIRERC member has financial, material, institutional, or social ties to the research.

9.6.5 Participate in continuing education activities in research ethics

9.6.6 Attend Committee meetings regularly and contribute constructively to the deliberations

9.6.9 Provide technical support to uphold the integrity of MIRERC

10. Regular MIRERC Meetings

10.1 Frequency

The Committee shall convene a meeting once every last Wednesday of the month at 9.00 am.

10.2 Quorum

Quorum shall be constituted of over (1/2) of MIRERC members including apologies. The quorum shall be achieved only when they are over 1/3 members physically present.

11. Conduct of MIRERC Meetings

11.1 MIRERC Meeting Schedule and Distribution of Agenda

11.1.1 The Committee Secretary shall notify and circulate the agenda for the next meeting to all Committee members at least one week in advance.

11.1.2 The Committee Secretary shall notify all Committee members of any changes of the meeting time, date or agenda within 24 hours

11.2 Meeting Procedure

11.2.1 The Chair shall call the meeting to order

11.2.2 The Chair shall request for adoption of the agenda

11.2.3 The Standard agenda shall be as follows:

11.2.3.1 Prayers

11.2.3.2 Apologies

11.2.3.3 Communication from the chair

11.2.3.4 ISO 9001: 2015

11.2.3.5 Performance Contracting

11.2.3.6 Declaration of Conflict of Interest.

11.2.3.7 Confirmation of minutes

11.2.3.8 Matters arising from previous minutes

11.2.3.9 Consideration of actions taken by the Chair on behalf of the Committee

11.2.3.10 Receive and Consider Research Proposals

11.2.3.11 Receive and Adopt Sub-Committee Reports

11.2.4 Committee members with conflict of interests in any research proposal shall declare, record the same and shall leave the meeting for the duration of the deliberations on the proposal.

11.2.5 MIRERC may where necessary invite the Principal Investigator to the meeting to clarify certain issues relating to their proposal.

11.2.6 Decision making of the Committee shall be by consensus.

11.3 Minutes of meetings

11.3.1 The Chair shall review the minutes for accuracy and completeness then sign/approve for circulation.

11.3.2 The minutes of each meeting shall be distributed to members within a period of not more than one week after every meeting

11.3.3 The minutes shall be confirmed at the next meeting

11.3.4 The confirmed minutes shall be distributed to the Deputy Vice-Chancellor Academic, Research and Student Affairs.

12. Special Meetings

12.1 Special meetings shall be called as deemed necessary

12.2 Specific agenda shall be circulated in the meeting notice. Only specified agenda items shall be discussed.

13. The Participant Informed Consent Document and The Consent Process

(Refer to section 3.5.4 Patient / Participant's Information and Consent Document)

13.1 Language of Informed Consent Documents:

(a). We acknowledge that Kenya is a multi-lingual society. We underscore that informed consent to participation in research is a process that is distinct from its affirmation in an informed consent document. Consequently, the language in which informed consent process is conducted may not always be the language in which the informed consent document is written. The flexibility to use the language that is most effective in communication or even more than one language to obtain consent and its written affirmation is considered congruent to and required in a multilingual society, and should be seen and deployed as providing added value rather than being a compromise (as it may appear when judged from a unilingual context).

(b). If research participants by virtue of research selection, all speak the same language at home, we strongly advise that the informed consent document be in that language. However, we appreciate that most studies are not restricted to people who all speak the same language, hence we acknowledge that English and Kiswahili as the lingua franca in Kenya is usually the most practically appropriate language in which an informed consent document will be written, reflecting the local realities as expressed in point (a) above.

(c). We encourage that (but do not insist upon) informed consent documents be made available in English, Kiswahili and Local Languages (as appropriate) from which a specific research participant may choose. Note that translations of informed consent documents from English must be accurate.

(d). In case an informed consent document is available in more than one language, we underscore that research participants may choose to use an informed consent document in a language that is different from their home language.

13.2 General requirements

Researchers need to obtain informed consent from participants or from the participant's legally authorized representatives, before any research related procedure is undertaken.

Where necessary the MIRERC may waive the need to obtain informed consent, if motivated by the researcher and deliberated by the Committee.

The information that is given to the participants needs to be presented in a language that promotes their understanding of the proposed research study. Translated Informed Consent Form or Translators can be used.

Researchers need to **obtain written, valid and voluntary informed consent** from prospective participants and/or from their representatives and need to give them sufficient time to consider whether or not to participate in the research.

If the participant is **unable to read or write** an independent witness needs to verify in writing that the informed consent process was valid and in accordance with the requirements of this SOP document.

The process of recruitment, the study population and the documentation of how informed consent will be obtained from participants, needs to be described in detail in the study protocol.

Once the participant has agreed to participate, the Informed Consent Form must be kept at the study site. The participants must also get a copy of the Informed Consent Form.

13.3 The Elements of Informed Consent

13.3.1 Basic Elements of Informed Consent

The following ***basic elements of informed consent*** information needs to be provided to each participant when seeking informed consent (CIOMS, 2016):

- Title of research, researchers involved, and research timeframe;
- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the participant's participation;
- A description of the research procedures to be followed;
- A disclosure of appropriate alternative procedures or treatments, that are available as standard care of treatment;
- A disclosure of any conflict of interests;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participants themselves or to the community;
- A statement that participation is voluntary and that refusal to participate will not involve any penalty or loss of benefits or of care to which the participant is otherwise entitled to;
- Information and data to be collected, how long the data will be kept, how it will be stored, who can access it, and that participants can withdrawal their data (refer to CIOMS Guideline 11);
- A statement regarding the confidentiality of the participants' information;
- A statement that the participants will be reimbursed for any out of pocket expenses related to the research (where applicable);
- Researchers' names and 24 hour phone numbers must be provided on the Informed Consent Form (ICF) for any questions about the research; and
- A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- declarative statement of understanding that the potential participant agrees to and signs.

14. Submission of a Research Protocol / Proposal

14.1 The principal investigator shall submit Four (4) hard copies and a soft copy of their study proposal that conform to the Committee guidelines.

14.2 These copies shall be distributed as follows:

14.2.1 Two (2) to reviewers

14.2.2 One (1) to circulate among the Committee members

14.2.3 One (1) to be archived

14.2.4 Soft copy and subsequent revised copies to be saved into MIRERC database.

14.3 The Principal Investigator shall submit a Curriculum Vitae (CV) including copies for Co-investigators when making first application to the MIRERC.

15. Types of Review

There shall be five (5) types of review, namely;

15.1 Expedited Review

15.2 Full Review

15.3 Continuing Review

15.4 Exempt Review

15.5 Review of Amendments to a previously approved Proposal.

15.1 Expedited Review

15.1.1 An expedited review shall be conducted jointly by the Committee Secretary and two other reviewers designated by the Chair.

15.1.1 The following categories of research proposal shall qualify for an expedited review and approval:

15.1.1.1 Research investigations that present no more than minimal risk to the study participants.

15.1.1.2 Minor amendment in previously approved research during the period for which approval was granted.

15.1.2 Definitions of “minimal risk” and “minor amendment” will be based upon accepted guidelines/categories as defined in national and international guidelines.

15.2 Full Review

15.2.1 All other research proposals submitted for review and which do not meet the criteria for expedited and exempt review shall undergo the process of a full review.

15.2.2 The administrator shall circulate copies of the proposal abstracts to MIRERC Members and assign the proposal to two MIRERC members for ethical review.

15.2.3 The administrator shall provide each assigned reviewer a copy of the proposal, reviewers checklist (Appendix 5B: MIRERC Checklist for Reviewers) and a reviewer’s comments form (Appendix 5A: MIRERC Ethics Reviewer’s Comments Form) to assist them in reporting their review findings.

15.2.4 The reviewer shall return the reviewer form, the proposal and any other comments to the administrator within 2 weeks.

15.2.5 If after 4 weeks there is no response from the reviewer, the proposal shall be withdrawn and assigned to another member to review.

15.2.6 There shall be a MIRERC review meeting to adopt the reviewers reports on various proposals.

15.2.7 The administrator communicates the comments from MIRERC to the principle investigator (PI).

15.2.8 The PI is required to address the concerns within a period of 2 weeks from receipt, after which a copy of the amended proposal shall be returned to the Administrator for re-review by one of the original reviewers.

15.2.9 Once satisfied, the reviewer shall communicate the recommendation in writing to the Committee Secretary.

15.2.10 The Committee Secretary will draft an approval letter for the Chairman's signature.

15.3 Continuing Review

15.3.1 All approvals shall be valid for a period of One (1) year.

15.3.2 Studies that last for more than 1 year shall apply for a continuing approval annually, using a standardized application format (Appendix 6: Continuing Review Form).

15.3.3 For all research studies that are likely to run for more than a year, the MIRERC administrator shall send all PIs an alert notice reminding them to apply for continuing review two months before the expiry of the MIRERC approval for their study. The alert notice shall be accompanied by the standard form for application for Continuing Review.

15.3.4 A copy of the application form for Continuing Review submitted by the PI shall be circulated to all MIRERC members and will be discussed at the next regular MIRERC meeting.

15.4 Exempt review

15.4.1 Unless otherwise defined by the Committee and other relevant regulations, research activities in which the involvement of human and animal subjects will be in one or more of the following categories are exempt from these SOPs:

15.4.2 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

15.4.2.1 Research on regular and special education instructional strategies, or

15.4.2.2 Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

15.4.3 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour, unless:

15.4.3.1 Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the subjects; and

15.4.3.2 Any disclosure of the human participants' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

15.4.4 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviour that is not exempt under paragraph 14.4.3 of this section, if:

15.4.4.1 The human subjects are elected or appointed public officials or candidates for public office; or

15.4.4.2 Any laws / regulations require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

15.4.5 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers that are linked to the subjects.

15.4.6 Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine the following;

15.4.6.1 Public benefit or service programs;

15.4.6.2 Procedures for obtaining benefits or services under those programs;

15.4.6.3 Possible changes in or alternatives to those programs or procedures; or

15.4.6.4 Possible changes in methods or levels of payment for benefits or services under those programs.

15.4.7 Taste and food quality evaluation and consumer acceptance studies such as:

15.4.7.1 If wholesome foods without additives are consumed or

15.4.7.2 If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the any local or international regulatory body.

15.5 Review of Undergraduate Research Proposals

15.5.1 The undergraduate proposals shall be duly signed by Departmental supervisors certifying that the they have undergone scientific review. The School shall present to MIRERC selected undergraduate proposals which have ethical implications.

15.5.2 Each proposal will be allocated one MIRERC reviewer. The MIRERC Chair shall sign approvals on behalf of the Committee for proposals which have received approvals from the reviewers. These proposals shall be presented before the full Committee for ratification on advise by the MIRERC reviewer at the next regular meeting.

16. Post Approval Protocol / Proposal Amendments and Continued Review

So as to ensure ongoing communication between the Ethics Committee and researchers, the following should be taken into consideration:

16.1 Proposal/protocol Amendments

Amendments are defined as any changes to a research protocol/proposal initiated by the Principal Investigator (PI) after ethical clearance by MIRERC.

16.1.1 An "Application for Approval of Amendment" form (Appendix 7: MIRERC Amendment Request Form) must be completed for all amendments to the study proposal.

16.1.2 The PI should submit to MIRERC two printed copies of the **Amendment plus an updated protocol/proposal**. In addition, the PI should send an electronic copy to MIRERC Office.

16.1.3 The PI must explain the rationale for the amendment on the specific form and also clearly mark the amended sections, as indicated on the form. This ensures that MIRERC members can easily identify the changes as well as the rationale of the amendment.

16.1.4 Protocol Amendments cannot be implemented until MIRERC has reviewed and approved it at the monthly meeting.

16.1.5 Should an Amendment need expedited approval, as human research subject safety is at stake, it can be submitted as such to the secretariat. Provisional approval can be granted, which then needs to be ratified at the next formal MIRERC meeting.

16.1.6 In the case of minor modifications (which do not have an impact on the safety of the participant and the protocol methodology) or administrative activities changes only, modification can be considered a minor notification, and these do not require formal approval. This can be submitted as a notification to MIRERC office and will be approved as such.

16.1.7 All amendments on methodology shall undergo full review process, if possible, by the original primary reviewers.

16.2 Adverse and Serious Adverse Events (SAE) and Suspected Unexpected Serious Adverse Reactions (SUSAR Reports)

This section is mainly applicable to researchers conducting clinical and randomized controlled trials. Serious Adverse Event or Serious Adverse Drug Reaction refer to any untoward medical occurrence that results in death, is life-threatening, requires patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect (WHO, 2000; University of Pretoria, 2016).

Medical and scientific judgement should be exercised when deciding if other situations are serious. Such instances could include medical events that may not be immediately life threatening or result in death or hospitalisation, but which may jeopardise the patient or may require intervention to prevent one of the outcomes listed in the definition above. Examples include blood dyscrasias (disease) or convulsions not resulting in hospitalisation, or development of drug dependency or drug abuse.

16.2.1 The PI needs to interpret and complete the required "Reporting of Serious Adverse Event" form (Appendix 8: MIRERC Unanticipated Events Prompt Reporting Form) available from MIRERC Office or its website.

16.2.2 On this form, it is important that the PI interprets the SAE and comments as to how the MIRERC should construe it.

Note: The Research Ethics Committee is guided solely by the content of this form as completed by the Principal Investigator.

- Serious Adverse Events (SAE) from the local approved site must be submitted and will be noted per study, per site.
- One hard and electronic copy of SAEs must be submitted by PI.
- A MIRERC member with a clinical background (who is not involved in the study) will review the SAE and it will be put on the Agenda of the main Ethics Committee's meeting for discussion.

16.2.3 Suspected Unexpected Serious Adverse Reactions (SUSAR Reports) and Global Safety letters can be submitted to the Ethics Committee as a notification. One to six months' submissions are acceptable.

17. Communication of Review Decisions

17.1 The Chair shall communicate within 2 weeks of the date of the decision to the Principal Investigator all review decisions.

17.2 Communications shall be in writing through standard MIRERC documents bearing the signature of the MIRERC Chairman, secretary or a designated officer appointed by the Chairman to do so.

17.3 The review decision shall be in the following format:

- Formal Approval
- Not Approved.

When the decision is Not Approved, the reasons shall be given to the Principal Investigator in writing.

17.4 The approvals shall be valid for one-year period, renewable on application for Continuing Ethical Approval.

18. Follow-Up

18.1 Progress Reports

- Annual Progress Reports (using relevant form) (Appendix 9) for projects beyond one year must be submitted in a typed format, pertaining to the progress of the envisioned research.

18.2 Protocol deviations and protocol violations

- All protocol violations (instances where the selection criteria of the protocol was not adhered to) must be reported to MIRERC as soon as the researcher becomes aware of the violation; and
- Protocol deviations (all other deviations from the protocol) and violations must be reported to the Committee as part of the application for re-approval or on the progress report form.

18.3 Premature Suspension/Termination of a research study

The PI must immediately notify the Ethics Committee of premature suspension/termination of a research study. A summary must be communicated regarding the reasons of the suspension or termination, if before the anticipated date of completion.

18.4 Completion of the study

The PI must notify the Ethics Committee using a study completion form (Appendix 10: Close Project Report Form) when the study has been completed.

18.5 Dissemination of Research Results

The PI must state in the protocol how the results (positive or negative) will be disseminated for example:

- Publication (Article/Abstract);
- Conference Oral Presentation / Posters; and
- How the community will be informed (if applicable).

Note: All research results must be put into the public domain. The publications from staff, researchers and students affiliated with MUST should be emailed to MIRERC Office (email: MIRERC@must.ac.ke).

19. Monitoring of Research

According to the Declaration of Helsinki, paragraph 23, Research Ethics Committees have the right and need to monitor research.

19.1 MIRERC shall constitute a Sub-Committee on Monitoring and Evaluation (SME) to monitor progress of approved research.

19.1.1 The SME may follow up studies seeking amendments that are likely to affect the rights, safety, and/or wellbeing of the participants or the conduct of the study.

19.1.2 The SME shall be expected to make a follow-up on serious and unexpected adverse events related to the conduct of the study or study product and the response taken by the investigators, sponsors and regulatory agencies. Should it be necessary an external auditor may be appointed to do an audit.

19.1.3 The SME shall be further expected to follow up any event or new information that may affect the benefit/risk-ratio of the study. Active monitoring becomes likely when research misconduct and/or complaints are received by the MIRERC.

19.1.4 Follow up decisions will be communicated in writing to the PI indicating either of the following decisions:

- Approval of amendment
- Suspension of study processes
- Termination of study

19.1.5 Passive monitoring is done by evaluating Progress Reports and Annual Review applications.

20. Appeal Against Committee Decision

20.1 An investigator who feels dissatisfied with a review decision has a right of appeal.

20.2 The aggrieved investigator shall be expected to lodge their appeal with MIRERC Chair within 14 days of receiving the review decision.

20.3 The MIRERC Chair shall then constitute an Appeals Sub-Committee of four, consisting of the MIRERC secretary, the Principal Investigator, a member of MIRERC with expertise in the subject matter or is content expert in the area of the research proposal under review and non –MIRERC content expert in the subject matter of the proposal under review but who should not have reviewed the proposal before the appeal.

20.4 The non-MIRERC member shall be the convenor and the chair of the Appeals Sub-Committee.

20.5 The MIRERC Chair shall ensure the Appeals Sub-Committee has access to the proposal in dispute and request them to meet once to consider the appeals merits and present their report at the next regular MIRERC meeting usually within one month of the appeal being lodged with the MIRERC chair.

20.6 The Committee shall consider the recommendations of the Appeals Sub-Committee and MIRERCs decision at this point shall be final.

20.7 If the appellant is dissatisfied with the decision of Committee, they have a right to appeal to NACOSTI and if allowed; then it will be acceptable.

21. Responsibility of The Principal Investigator in The Review Process

The Principal Investigator shall be responsible for prompt response to reviewers' comments, usually within one month of receiving the comments.

21.1 The administrator shall remind the PI to respond to the reviewer comments after the month grace period elapses.

21.2 If after being reminded, the PI does not respond to the reviewer comments within a further period of one month, the review shall be considered to have lapsed and the PI shall be required to make a fresh submission for MIRERC review.

21.3 The Principal Investigator shall submit a completed close of project form (Appendix 10); in hard and soft copies.

22. Documentation and Archiving

22.1 MIRERC shall document and archive the following documents:

- MIRERC standard operating procedures
- Duly signed confidentiality agreement forms
- Curriculum vitae of members
- One copy of all materials submitted by applicants
- Correspondence by MIRERC members with investigators in regard to application decisions and follow up
- All correspondence and other materials received during follow-up
- A list of MIRERC members
- Records of MIRERC income and expenditure
- Agenda of meetings
- Minutes of MIRERC meetings
- Notification of completion, premature suspension or premature termination of a study
- Completed MIRERC close of project form. (Appendix 10)

22.2 Ethics Committee: All documentations regarding protocols, Agendas and Minutes will be kept in the MIRERC office for 5 years after completion of a study. Thereafter, all files will be Archived for another 10 years.

22.3 Researcher's duties: Investigators must also indicate where they will store their data and documentation for 15 years after their research protocol has been completed. Supervisors are responsible to store their student's documentation.

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