TOM MBOYA UNIVERSITY

KNOWLEDGE FOR SUSTAINABLE INNOVATION ENTERPRISE

STANDARD OPERATING PROCEDURES (SOPS)

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1. Acronyms and Abbreviations

ACUC: Animal Care and Use Committee

CV: Curriculum Vitae

IGA: Income Generating Activity

IRBs: Institutional Review Boards

ISERCs: Institutional Scientific and Ethical Review Committees

Ksh: Kenyan Shilling

MPESA: Mobile Payment Service (M-PESA)

PI: Principal Investigator

PhD: Doctor of Philosophy

SERC: Scientific and Ethical Review Committee

SOPs: Standard Operating Procedures

TMU: Tom Mboya University

USD: United States Dollar

2. Introduction to Tom Mboya University-SERC Standard Operating Procedures (SOPs)

Scientific and ethical review of research involving human participants, animals, or sensitive data is essential to ensure that research is conducted responsibly, safely, and with integrity. The review process helps safeguard the rights, dignity, safety, and well-being of research participants while ensuring that studies meet acceptable scientific standards.

The Standard Operating Procedures (SOPs) presented in this document provide a structured framework for the submission, review, approval, and monitoring of research proposals by the Scientific and Ethical Review Committee (SERC) as well as the operation of the SERC. The document outlines the roles and responsibilities of committee members, investigators, research participants and administrative staff involved in the review process.

The SOPs are designed to promote transparency, consistency, accountability, and efficiency in the evaluation of research proposals and their implementation. They ensure that all submitted studies comply with national regulations, institutional policies, and internationally recognized ethical guidelines such as the principles of respect for persons, beneficence, and justice.

By adhering to these procedures, the committee aims to facilitate high-quality scientific research while maintaining the highest ethical standards and protecting research participants and communities involved in the studies.

3. Objectives of the TMU-SERC SOPs

The objectives of these Standard Operating Procedures (SOPs) are to:

i. Provide a clear and standardized framework for the scientific and ethical review of research proposals,
ii. Ensure that all research involving human participants, animals, biological materials, or sensitive data meet acceptable scientific and ethical standards,
iii. Protect the rights, dignity, safety, and well-being of research participants,
iv. Promote transparency, consistency, and accountability in the review and approval of research proposals,
v. Ensure compliance with institutional policies, national regulations, and internationally recognized ethical guidelines,
vi. Facilitate timely and efficient review of research proposals submitted to the Scientific and Ethical Review Committee (SERC), and
vii. Guide researchers and committee members on the procedures for submission, review, approval, monitoring, and reporting of research activities.

4. Scope of the SOPs

These SOPs apply to all research proposals submitted for scientific and ethical review to the TMU-SERC. They cover:

i. Research involving human participants, including clinical, social, behavioral, and public health studies,
ii. Research involving biological samples, medical records, or personal data,
iii. Research involving animals, where applicable,

iv. Research involving plants,
v. Research on the environment and natural resources,
vi. Studies conducted by institutional researchers, students, collaborators, or external investigators seeking approval from the committee,

The SOPs outline procedures for proposal submission, review, decision-making, communication of decisions, monitoring of approved studies, and handling of amendments, adverse events, and final reports.

5. Roles and Responsibilities of the TMU-SERC

4.1 Scientific and Ethical Review Committee (SERC)

The committee shall be appointed by the Vice Chancellor. The committee is responsible for ensuring that research proposals meet acceptable scientific and ethical standards before approval. Its responsibilities include:

i. Reviewing submitted research proposals for scientific validity and ethical compliance,
ii. Ensuring that risks to participants are minimized and justified by potential benefits,
iii. Protecting the rights, safety, and welfare of research participants,
iv. Approving, recommending modifications, deferring, or rejecting research proposals,
v. Monitoring approved research to ensure continued compliance with ethical standards,
vi. Reviewing proposal amendments, adverse event reports, and progress reports,
vii. Offering guidance on handling deviation and non-compliance.

4.2 Chairperson

4.2.1 The committee will be led by a Chairperson deputized by a vice chair. The Chairperson is responsible for:

i. Providing leadership and oversight of the committee's activities,
ii. Presiding over committee meetings,
iii. Ensuring that reviews are conducted in a fair, transparent, and timely manner,
iv. Confirming that decisions are properly documented and communicated in time.

4.2.2 In the absence of the Chairperson, the deputy will assume the responsibilities of the Chairperson.

4.3 Committee Members

Committee members are responsible for:

i. Implementation of TMU-SERC SOPs,
ii. Reviewing assigned research proposals,
iii. Providing objective and constructive feedback on reviewed proposals,
iv. Declaring any conflicts of interest and recusing themselves where necessary,
v. Participating actively in committee meetings and discussions,
vi. Ensuring confidentiality of submitted research documents.

4.4 Secretariat/Administrative Staff

The Secretariat is responsible for:

i. Receiving and logging research proposal submissions,
ii. Conducting preliminary administrative checks for completeness,
iii. Coordinating the review process and scheduling meetings,
iv. Communicating committee decisions to investigators,
v. Maintaining records and documentation of all reviews and approvals.

6. Standard Operating Procedures (SOPs)

SOP1 Procedure for Submission of Application for Ethical Review

6.1 Application Requirements

6.1.1 An application for ethical review of a research study shall be made by the Principal Investigator (PI)

6.1.2 All applications shall be submitted to TOM MBOYA UNIVERSITY-SERC by the

date determined by the Committee

6.1.3 The Secretariat shall check the applications for completeness as required

6.1.4 Only completed applications shall be processed

6.1.5 One application for each research proposal shall be made to the SERC for review

6.1.6 All the relevant required documentations outlined in 1.2 below shall be submitted

1.1.7 All complete application shall be reviewed within six (6) weeks of receipt by the SERC

1.2 Documents Required

Documents for ethical review of the proposed research shall include (but not limited to):

1.2.1 Duly filled TOM MBOYA UNIVERSITY-SERC application form

1.2.2 The proposal with a version number and date

1.2.3 Relevant attachments such as interview guides, questionnaires, diaries, advertisements and promotional materials, focus group discussion guidelines, maps and diagrams, clearance from relevant institutions

1.2.4 Study instruments translated into a language understandable to the proposed study community

1.2.5 The curriculum vitae of investigators on the study

1.2.6 Informed consent, including patient information sheet (where applicable) and informed consent/assent form, translated to local language(s) and a certificate of translation

1.2.7 Relevant toxicology and pharmacology data and information on the planned treatment period, where the research involves clinical drugs trials. Specification for any medical device to be used in investigation must be provided. In addition, the registration and imports of the investigational drugs or medical devices must be received from the Pharmacy and Poisons Board after ethical clearance is granted by the TOM MBOYA UNIVERSITY- SERC

1.2.8 A signed agreement to comply with the relevant national and universally acceptable ethics guidelines and rules

1.2.9 A statement describing any compensation for the study participants including expense and access to medical care to be offered to research participants

1.2.10 A description of the arrangements for indemnity in case of study-related injuries, where applicable

1.2.11 A description of the arrangements for insurance coverage for research participants, where applicable

1.2.12 A statement on conflicts of interest if any

1.2.13 Evidence of payment of review fee (as per attached payment schedule) payable to TOM MBOYA UNIVERSITY with the following details:

Account Name : Tom Mboya University IGA
Account Number : 1198213183
Bank : Kenya Commercial Bank Ltd
Branch : HOMA BAY
Bank Code: 01230
Swift Code : KCBLKENX

OR

MPESA PAYBILL: 522522
Account Number : 1198213183
Bank : Kenya Commercial Bank Ltd]

1.3 Scientific Evaluation

The TOM MBOYA UNIVERSITY-SERC shall evaluate the proposal based on:

1.3.1 The research problem, background analysis, question(s) and/or hypothesis

1.3.2 The innovativeness, relevant literature and study objectives

1.3.3 The methodology

1.3.4 The budget and budget justification

1.3.5 The work plan

1.3.6 The roles and responsibilities of all investigators in the study

1.3.7 The plans for capacity building /dissemination of findings/technology transfer

1.3.8 The agreement on intellectual property

1.4 Ethical Considerations

Ethical considerations in the proposal shall include a description of:

1.4.1 The recruitment plan

1.4.2 Identification and mode used to contact potential study participants

1.4.3 Screening process

1.4.4 Incentives/inducements for participation in the research study

1.4.5 Special considerations related to research conducted among vulnerable populations or captive populations such as prisons and mental institutions. Where data is to be obtained from vulnerable groups using individuals other than the PI, the PI shall be required to explain why this is necessary and a copy of the statement submitted with the application

1.4.6 The potential benefit to participants, community or society

1.4.7 The potential harm to participants and others and how these will be mitigated against

1.4.8 The adequacy of provisions to protect confidentiality of data

1.4.9 Alternative treatments or procedures available in place of study procedures

1.4.10 If the research involves clinical trials, the adequacy of the clinical research facilities

1.4.11 The adequacy of information used to obtain informed consent or assent

1.4.12 Plans for dissemination or publication of results

1.4.13 Significant previous decisions by other research regulatory authorities concerning the proposal and an indication of the modification(s) made on that account

1.4.14 Data safety and monitoring plan which should include but not limited to plans for:

i. Compliance assurance with requirements for reporting adverse events
ii. Monitoring of the progress of clinical trials and safety of research Participants
iii. Data accuracy and protocol compliance

iv. Communication and exchange of information among multi-centre study sites.

1.4.15 Data protection and security. The PI must comply with the requirements of the Data Protection Act and any other laws governing data and research samples

SOP 2 Procedure for the Preparation of Tom Mboya University-SERC Meeting

2.1. The Secretary shall prepare the agenda for each scheduled meeting;

2.2. All applications received will be assigned to the agenda for consideration at the next scheduled meeting

2.3. At the first meeting to consider the applications, the SERC members shall designate the primary reviewers for each application

2.4. The primary reviewers shall be required to declare conflict of interest in the study. To be a primary reviewer:

2.4.1. He/she should not be named as an investigator or have supervisory or advisory role

2.4.2. He/she should not be involved in the research or in research that competes with the proposal or application under review

2.4.3. He/she should not have a financial interest in the sponsor or the outcome of the research

2.5. The TOM MBOYA UNIVERSITY-SERC members shall use their discretion for expedited reviews and inclusion of other documents including revised protocols received after the deadline for submission

2.6. The following agenda format shall be followed:

2.6.1. Attendance/apologies
2.6.2. Declaration of conflict of interest
2.6.3. Confirmation of minutes of the previous meeting
2.6.4. Matters arising from the previous minutes
2.6.5. Consideration of new proposals/applications
2.6.6. Consideration of the previously reviewed proposals/applications
2.6.7. Review of amended protocols/proposals
2.6.8. Review of study status reports
2.6.9. Review of final study reports
2.6.10. Review of safety reports
2.6.11. Protocol deviation/protocol violation notification
2.6.12. Expedited review reports
2.6.13. Any other business

2.6.14. Date of the next SERC meeting

2.7. For each new application, reviewers will be required to complete the review and return within 14 days. For expedited applications, reviewers will be required to complete the review within 7 days.

2.8. The outcome of the review will be communicated to the PI within 30 days of submission and 14 days for expedited reviews

2.9 There shall be special meetings for expedited reviews and any other emerging issues.

SOP 3:Procedure for the Regulations of Meeting

3.1 TOM MBOYA UNIVERSITY-SERC shall hold monthly regular meetings

3.2 The meeting schedule shall be prepared in advance and a copy given to members at the beginning of each calendar year

3.3 The schedule for the SERC meetings shall set the dates, times, venues and the closing date for new applications

3.4 In case of urgency, the Chairperson may convene special ad-hoc meetings giving a notice of not less that 3 working days to address emerging issues

3.5 The signed minutes of each meeting shall be recorded and confirmed at the next regular meeting

3.6 The PI may be invited to a SERC meeting to present their proposal or to elaborate on specific issues or offer clarification

3.7 An independent consultant may be invited to a meeting or requested to provide written confidential comments upon review of an application

3.8 An observer or observers may be invited to attend SERC meetings, subject to written invitation setting out the terms under which observer status is permitted

3.9 The chairperson shall verbally inform any investigator who attends the meeting whenever an observer is present. The PI shall have the opportunity to object to or approve the presence of any observer. In the event of objection, the observer shall be requested to leave the meeting room

3.10 No meeting shall be held or proceed without a quorum constituting 50% of core SERC members and one officer from the Secretariat

3.11 If quorum is lost during the meeting, the SERC shall not take a vote or make a decision on a research proposal or application until the quorum is restored. If quorum cannot be re-established, the meeting shall be re-scheduled

3.12 A member shall be required to attend at least 2/3 of the scheduled meetings each calendar year, failure to which the said appointment **may be** terminated.

SOP 4 Procedure for Recording of Minutes of the Meeting

4.1 The Secretariat shall be responsible for preparing and maintaining detailed minutes of each meeting;

4.2 The minutes of the meeting shall include the following items:

4.2.1 Members present, apologies and absent

4.2.2 Quorum (number and composition)

4.2.3 The approval of previous meeting minutes after corrections or clarification

4.2.4 The resolution of action items from the previous meeting

4.2.5 Proceedings for proposal review; discussion and decision taken

4.2.6 Details on the ethical issues identified and discussed:

i. A discussion on any dissenting issues and their resolution

ii. The number of SERC members voting for, against, abstaining or absent from the SERC's action

iii. The approval period for initial or continuing review

iv. The names of investigators or applicants who attended the meeting

v. The date and signature of the chairperson

vi. The time meeting was initiated and closed.

4.3 The minutes shall be produced within 5 working days and be verified by the chairperson and/or secretary

4.4 The minutes shall be circulated to all SERC members as an agenda item within 5 days

SOP 5 Procedure for Review of a Research Proposal

5.1 The SERC Secretariat shall table new research proposals or applications at its next meeting provided that the same are received by the secretariat on or before the closing date

5.2 The proposals or applications shall be reviewed by at least two (2) experts. If no reviewer is available, SERC will outsource from among identified reviewers

5.3 Reviewers shall complete proposal review and return written comments

within 14 days from the date of receipt

5.4 The SERC shall only make ethical evaluation on complete research proposals or applications

5.5 Each research proposal or application requiring initial review shall be individually presented, discussed and acted upon in a convened meeting

5.6 The SERC shall provide an assessment on:

5.6.1 The scientific validity of the research question

5.6.2 The relevance of the proposed study to the needs of the study community

5.6.3 The potential risks and how they will be mitigated

5.6.4 Protection rights and welfare of vulnerable participants

5.6.5 Obtaining informed consent/assent from research participants

5.6.6 The use of identifiable or potentially identifiable information

5.6.7 Plans for collection, storage and protection of research data and biological samples

5.6.8 Provisions for compensation of research participants where applicable

5.6.9 Provision for member checking or participants validation to confirm accuracy

5.7 For external proposal or application presented to TOM MBOYA UNIVERSITY-SERC, the committee may seek views held by other duly constituted ISERCs or IRBs

5.8 Following the deliberations on a given research proposal or application, the SERC will

make one of the following decisions at the meeting:

5.8.1 Approve application as submitted if all of the following conditions are satisfied:

i. The risks to research participants are reasonable in relation to anticipated benefits

ii. The knowledge that is expected to result is of importance to the public and for the advancement of the discipline of research

iii. The selection of research participants is rationalized and equitable

iv. Informed consent/assent will be adequately documented, unless waiver is granted

iv. The research plans provide for monitoring of data collected

v. There are adequate provisions to maintain the confidentiality of research data

vi. There are adequate safeguards to protect the rights and welfare of research participants.

5.8.2 Grant approval upon clarification of information or incorporation of recommended changes

5.8.3 Defer until the reasons for the deferment have been addressed

5.8.4 Defer until specialist advice or opinion has been received, where applicable

5.8.5 Request for a re-submission if substantive revisions are required

5.8.6 Not recommend ethical clearance if any of the following conditions apply

i. Excessive risks to research participants; or

ii. Flawed study design without generalized knowledge of scientific merit; or

iii. Negligible value of study results; or

iv. Significant risks and addresses issues already answered in earlier research; or

v. Insufficient safety data on a given investigational product or device to warrant further testing

5.9 The SERC may at its discretion appoint an ad-hoc sub-committee to undertake further review of a disapproved application

5.10 Members of the sub-committee to include at least 2 experts in the field of research presented

5.11 The ad-hoc sub-committee shall be provided with all necessary documents

5.12 The review report obtained from the sub-committee shall be used in making a final decision on the proposed research study

5.13 The SERC shall make a decision based on the ad-hoc committee's recommendations;

5.14 The SERC may delegate to its Secretary the authority to approve research proposals

administratively

5.15 The authority for administrative approval shall be ratified at the next meeting

5.16 Any research proposal or application under SERC review shall remain on the agenda for a maximum of 90 days only (3 consecutive scheduled SERC meetings)

5.17 Following approval of a study for a term of twelve (12) months, the PI shall be advised to submit an annual study report and application for renewal 4 weeks prior to the date of expiry of the current approval.

SOP 6 Procedure for Obtaining Informed Consent

6.1 TOM MBOYA UNIVERSITY-SERC shall require investigators to obtain informed consent from each study participant. Consent shall be sought from adults eighteen (18) years of age and above and assent from parents/guardians of children involved in the study.

6.2 The following documents relating to procedures for obtaining informed consent shall be required for ethical clearance:

i. A full description of the process for obtaining informed consent including the identification of those responsible for obtaining consent shall be disclosed

ii. A comprehensively written information to be given to participants and their legally authorized representatives

iii. A clear justification for the plan to include individuals who cannot

consent and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.

6.3 Consent notes shall also include:

i. Provisions that research participants will receive information that becomes available during the course of the study

ii. Provisions that receiving and responding to enquiries, concerns or complaints from research participants or their representatives during the course of a research study shall be made available to the participants and guardians

6.4 The SERC shall waive all or part of the requirements for documentation of informed consent, if the research meets the following criteria:

i. If the waiver is justifiable
ii. Oral consent is obtained
iii. The proposed plan for the protection of privacy is adequate
iv. The waiver will not affect the rights and welfare of the research participants
v. The research participants will be given additional pertinent information after their participation
vi. The research presents no more than the minimum required and involves procedures for which consent would not normally be obtained outside the research context.

6.5 Translation of all consent documents into Kiswahili and/or relevant local dialects shall be mandatory

SOP 7 Procedure for Obtaining Informed Assent

Where a proposed participant is a minor aged between thirteen (13) and seventeen (17) years and who possesses sufficient understanding to grant informed consent but is precluded from granting such consent solely on the grounds of age, the PI may obtain a written assent in addition to permission from a parent or guardian.

7.1 TOM MBOYA UNIVERSITY-SERC shall consider the following elements in its review of the assent process:

i. Procedure put in place for obtaining parental or guardian permission (consent) to have his/her child/children participate in the research; If the minors are aged between fourteen (13) to seventeen (17) years, the language and syntax of the assent form may be written in a similar fashion as the parental or guardian permission manner

ii. If the research proposed is expected to present greater than minimal risks and there is no direct benefit to an individual study participants, then both parents or a guardian shall be required to give permission unless one parent is deceased , unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child

7.2 The parental permission and child assent be in writing unless the SERC grants a waiver of documentation

7.3 The table below is a guide in deciding whether or not to enroll a child, aged between 13-17 years in research:

If Parent/ Guardian say (YES/NO)	**If Child says (YES/NO) to participate**	**Can Child participate?**
YES	YES	YES
YES	NO	NO
NO	NO	NO
NO	YES	YES

7.4 In all cases the ethical standards required in obtaining informed consent shall apply to assent

7.5 The SERC shall waive the requirement for obtaining assent from a child if any of the following conditions apply in which case, consent from the parents (s) is sufficient:

i. The intervention stands to directly benefit the health and welfare of the child and is available only in the research setting

ii. The child is unable to provide assent due to age (12 years and below);

iii. The research meets the same conditions for a waiver of informed consent in research involving adults

SOP 8 Procedure for Obtaining Consent from a Mature Minor

Mature minor is any individual less than eighteen (18) years of age, who is married, pregnant, a mother, a father or a household head.

8.1 A mature minor is permitted to give consent for himself or herself and for their child/children but not allowed to consent on behalf of a sibling

SOP 9 Procedures for Obtaining Consent from Special Population

TOM MBOYA UNIVERSITY-SERC shall give special consideration by protecting the welfare of vulnerable groups such as children, pregnant women, neonate, fetuses, homeless persons, mentally and physically impaired persons, internally displaced persons, economically or educationally disadvantaged persons, marginalized social groups or individuals with terminal illness or prisoners.

The SERC shall determine on a protocol-by-protocol basis the specific requirements for obtaining and documenting consent whenever any vulnerable groups are involved in research studies.

SOP 10 Procedures for Involvement of Community

During the evaluation of research proposal or application, the SERC shall consider the following:

10.1 Possible impact and relevance of the research to the study community

10.2 Community consultation during the research process

10.3 Community engagement process (public barazas and participation)

10.4 Social-economic and health benefits and extend to which the research contributes to the community's capacity

10.5 The community feedback mechanism

10.6 Cultural practices consideration and sensitivity

SOP 11 Procedure for Documentation of Consent

TOM MBOYA UNIVERSITY-SERC shall require that informed consent be documented unless a waiver is given.

11.1 The consent form must be signed and dated by the research participant or his/her legally authorized representative

11.2 A copy of the signed and dated consent form shall be given to the person(s) signing

11.3 When verbal consent is obtained from the research participant or his/her legally authorized representative, the SERC shall require the presence of a witness to the oral presentation

11.4 The SERC shall review and approve the written summary of what is to be presented

SOP 12 Procedure for the Review of Amended Proposals

12.1 Any changes to the originally approved design of the research project are considered amendment. These include:

i. Changes in the sample size, methods of recruitment, materials for recruitment, selection of sample participants

ii. Changes in research personnel - PI, Co-PI, students or research coordinators or other investigators on the study

iii. Changes in research sponsor of funding agency

iv. Changes in study site(s), study design, study procedures, equipment, intervention or follow-up procedures

v. Changes in the privacy of information or confidentiality

vi. Changes in data collection, storage, custody or destruction procedures

vii. Changes in informed consent/assent forms, procedures, new or additional information

viii. Changes in terms of compensation

ix. Changes in conflicts of interests

12.3 All PIs shall be required to submit any proposed changes to TOM MBOYA UNIVERSITY-SERC for review prior to initiation. Exception to this rule shall specifically be where the change is necessary to eliminate immediate dangers/risk to the research participants. In such a case, the PI shall submit a report to the SERC explaining the protocol deviation

12.3 The PI shall be required to submit the amended protocol, a cover letter, justification for the change and an evaluation of any ethical consequence arising from the proposed amendment

12.4 SERC members assigned to review an amended proposal shall further require:

i. A duly signed explanatory cover letter from the PI;
ii. The modified soft copy of the study proposal highlighting the changes ('tracked changes'); and
iii. A copy of the same version of the document with incorporated (accepted) changes;
iv. Any additional documents to support the request.

12.5 The amendment request shall be discussed at the next available SERC meeting provided that the request has been received by the deadline for submission

12.6 The SERC shall determine whether the amendment is approved as submitted or if further information, clarification or change is required for the evaluation

12.7 The SERC Secretary shall communicate to the PI, in writing, the outcome of its deliberations on the request within five (5) working days of the meeting at which the amendment was considered

SOP 13 Procedure for the Expedited Review

13.1 In the event that an expedited review is desired, the PI or applicant shall be required to submit 3 copies of the application, one of which shall have an original signature

13.2 The SERC shall evaluate each application for its eligibility for expedited review

13.3 Only applications which meet the following criteria shall qualify for expedited review:
i. Full payment of the prescribed fee for expedited review;
ii. Fulfilling the criteria as outlined in SOP 1 for the new applications;
iii. Considered to have a minimal risk to the participants; and
iv. Having the PI's written explanation giving reasons for the requested expedited review

13.4 The chairperson shall nominate 3 SERC members to undertake the expedited review

13.5 Should the application fulfil the SERC requirements, the Chairperson shall grant provisional approval which will be communicated to the PI within 5 working days from the date of review

13.6 Provisional approval granted by the Chairperson shall be subjected to ratification by the full SERC at the next scheduled meeting

13.7 Applications under expedited review that require additional information, clarification or change shall not be processed any further under the terms of expedition

13.8 The SERC Secretary shall communicate to the PI or applicant, in writing, within 3 working days of receipt of the evaluation comments clearly explain the reasons for the deferment to full committee review

13.9 Expedited review process shall take no longer than fourteen (14) days.

SOP 14 Procedure for Annual Project Reporting

14.1 TOM MBOYA UNIVERSITY-SERC shall require all approved projects to submit annual reports for review and subsequent renewal

14.2 Where necessary (e.g. by the level of risk), the project shall require frequent reviews

14.3 The request for renewal shall include a duly signed cover letter, status report and one copy of the expiring approval study documents

14.4 All active or open studies require renewal. Such studies include:

i. Those that are close to finish but research participants are in the follow-up phase

ii. Those in which direct contact with study participants is complete but data analysis and report writing are on-going activities

iii. Studies that were proposed but have not been initiated within twelve (12) months from the date of ethical approval provided that valid reasons for not undertaking the research in the initial approval period have been provided.

14.5 Study reports shall be reviewed at the next available SERC meeting provided that the request has been received by the deadline for submission

14.6 Continuing studies shall be reviewed using the same criteria as for the initial review

14.7 If the continuing review does not take place within the time frame set by the SERC, the study approval shall automatically expire and the PI notified, in writing within 14 days of the expiration

14.8 The PI shall be required to immediately submit a list of research participants for whom the postponement of research would cause harm. The chairperson in consultation with the SERC members shall issue an appropriate course of action

14.9 The PI may resume the study once continuing review and approval by the SERC has taken place

14.10 Any given study will be renewed at least once every twelve (12) months

14. 11 A final study report shall be submitted to the SERC and notice of closure shall be issued to the PI on or before the expiry date of the approval

SOP 15 Procedure for Studies Involving Animals

15.1 TOM MBOYA UNIVERSITY-SERC shall review research proposals or applications involving animals

15.2 Any application for research involving animals shall include:

i. The study protocol and supporting documents
ii. A copy of an Animal Care and Use Committee (ACUC) approval letter
iii. Evidence of prior scientific review and approval by ethics review board
iv. CVs of veterinary experts, animal care staff and of all affiliated investigators of the study

15.3 In its review, the SERC shall make an assessment of:

i. The justification for the use of the animal
ii. The arguments in support of the chosen animal species or model
iii. The training and expertise of veterinarians and animal care staff on the duty
iv. The biosafety measures instituted in all aspects of the study
v. The potential benefits and injuries and the possibility of minimizing pain and injuries

vi. Any amendment to an approved study shall be considered by the SERC only upon receipt of evidence of prior scientific review and approval of the suggested amendment by similar review bodies.

15.4 The SERC Secretary shall communicate to the PI, in writing, the outcome of its deliberations on the proposed animal study within 7 days of the meeting in which the research proposal or application was discussed.

SOP 16 Procedure for Research on Traditional Medicine and Alternative Therapy

16.1 TOM MBOYA UNIVERSITY-SERC shall review applications involving herbal and alternative medicines

16.2 Any application for research involving herbal products must include:

i. A duly signed explanatory cover letter
ii. The study protocol and any supporting documents
iii. CVs of the PI and all affiliated investigators in the study

16.3 All applications involving the use of herbal products shall be subjected to the same requirements for the assessment of scientific clinical research

16.4 The SERC shall also make an assessment of the following:

i. Study personnel (who should comprise of at least one clinician and one toxicologist)

ii. Plans for preserving indigenous knowledge of the community or any traditional health practitioners consulted

iii. Agreement(s) on intellectual property rights

iv. Evidence that the herbal product has been subjected to stringent toxicological testing

v. Safety profile of the product and not reliance on anecdotal Observations

vi. Plans for benefit sharing in the event of the production of commercial

Products

vii. Process of patent in the form of technology transfer, medical benefits or a share in the intellectual property rights

vii. Data safety and monitoring plan

viii.

ix. Process for obtaining and documenting consent

16.5 SERC's decisions shall be communicated to the PI or applicant in writing within five (5) working days of the meeting at which the research proposal or application is discussed.

SOP 17 Procedure for Handling Protocol Deviation and Violation

17.1 Protocol deviation is any failure to adhere to the defined procedures outlined in the protocol version approved by the SERC

17.2 Protocol violation is any planned or inadvertent changes that may or may not affect the integrity of study impact on safety of study participants and affect the willingness of study participants to participate in a study already approved by the SERC.

17.3 Should any of the above occur;

i. Reporting should be made in writing, addressed to the SERC Chairperson, and must be received by the SERC secretariat within 14 days of the deviation or violation notification

ii. The SERC shall review the deviation or violation report at its next scheduled meeting

iii. Appropriate course of action will be made including noting if the remedial measures taken by the PI are satisfactory

iv. The SERC Secretary shall communicate to the PI, in writing, the decision of the SERC within five (5) working days after the meeting.

SOP 18 Procedure for Suspension or Cancellation of Ethical Approval

18.1 The SERC shall have the authority to suspend ethical approval for any research not conducted in accordance with provisions of the approved protocol

18.2 The SERC may also suspend the ethical approval of a research not complying with applicable regulatory requirements

18.3 Where applicable, the Chairperson shall communicate in writing for immediate temporary suspension of enrolment of new study participants pending review of the situation by the next scheduled SERC meeting

18.4 The SERC shall review the suspension report and may:

i. Request for minor or major changes in the research procedures and/or consent documents or process

ii. Modify current approval period

iii. Request for monitoring of the research process including monitoring of the consent/assent process

iv. Suspend enrolment of new study participants

v. Request that enrolled participants be notified when emerging information may influence their willingness to continue participating in an ongoing research

vi. Terminate the research if it presents excessive risks to research participants.

18.5 The SERC shall give reasons for its action and advise the PI and study sponsor, in writing, of such suspension/termination and the necessary steps to be taken

18.6 The suspension/termination shall occur within 5 working days of the date of the SERC making the determination

18.7 In the case of resumption of a previously terminated research, the PI shall not resume study without ethical approval from the SERC

SOP 19 Procedures for Requesting of Shipment of Biological Samples

All shipment applications shall be submitted by the PI to the SERC Secretariat.

19.1 A complete application shall include the following items:

i. A duly signed explanatory cover letter of why the specimens are being exported/imported, specific contact details of the recipient person/institution/organization and country

ii. Detailed description of the quantity and type of sample/specimen to be shipped (e.g.

number of vials each containing x mls of serum or any other specimen etc.)

iii. A copy of the initial and current SERC approval letter for the study

iv. A copy of the study protocol and consent/assent documents specifying that the samples in question would be shipped to a particular destination and the projected timelines.

19.2 The SERC secretariat shall review the application to ensure all the details included are accurate and recommend the application for further approval by relevant entities

19.3 The approved application shall allow for the shipment of the specified samples only

19.4 If the approval expires before the actual shipment is done, the PI shall be required to renew approval and attached the expired copy

19.5 The final authority to ship biological samples or specimens for research purposes shall be obtained from the relevant agencies and conventions where applicable.

SOP 20 Procedure for Maintaining Confidentiality of the SERC

20.1 The SERC shall strictly adhere to confidentiality of records and decisions made on the basis of voting by SERC members

20.2 Members and staff of SERC Secretariat shall be required to sign a confidentiality agreement upon appointment (Confidentiality Agreement Form)

20.3 All SERC documents shall be delivered to the respective SERC members' office by the SERC Secretariat staff; at the end of each ERC meeting, all members shall be

required to return their meeting files to the SERC Secretariat and submit their evaluation reports

20.4 If a SERC member retains or makes a copy of any document in digital or any other format, he/she shall be considered to be in breach of the confidentiality agreement

20.5 All SERC documents shall be disposed of in a safe manner such as shredding and/or incinerating

ANNEX 1: Tom Mboya University-SERC Review Fee

Applicants	Category	Kenyan(Ksh)	Non-Kenya (USD)
Students	PhD Degree Applicants	5,000	US$100
	Masters Degree Applicants	3,000	US$100
	Undergraduate Degree Applicants	500	US$100
Scientists/ Researchers	Tom Mboya University Applicants	7,000	-
	Other Applicants	20,000	US$ 1000
Institutions/ Companies	Kenyan Scientists/Researchers as PIs	30,000	-
	Non-Kenyan Scientist/ Researchers as PIs	-	US$ 1000
Consultants	Kenyan Scientists/Researchers as PIs	40,000	
	Non-Kenyan Scientist/ Researchers as PIs	-	US$ 1000

PROF. ELYJOY MUTHON MICHENI

CHAIR, TOM MBOYA UNIVERSITY-SERC