KAMUZU UNIVERSITY
OF HEALTH SCIENCES

KAMUZU UNIVERSITY OF HEALTH SCIENCES RESEARCH AND ETHICS COMMITTEE (KUREC)

GUIDELINES

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Approval:

Director, Institute of Postgraduate Studies and Research:

_____	_____	_____
Name	**Date**	**Signature**

Vice Chancellor:

_____	_____	_____
Name	**Date**	**Signature**

Director General, National Commission for Science and Technology:

_____	_____	_____
Name	**Date**	**Signature**

Contents

Appendices

1.0 INTRODUCTION

The core functions of the Kamuzu University of Health Sciences (KUHeS) include: teaching, service, research, community and policy engagement. Research conducted in KUHeS include those that require the participation of humans and animals. All such research requires ethical review and approval. KUHeS established the Kamuzu University of Health Sciences Research and Ethics Committee (KUREC) to perform ethical review functions. KUREC is constituted as an independent scientific and ethics committee with delegated powers from the National Commission for Science and Technology (NCST). KUREC functions are informed by international and national research ethics guidelines. The international guidelines include the Declaration of Helsinki (WMA),[2] the International Ethical Guidelines for Biomedical Research Involving Human Participants (CIOMS, WHO),[3] Guidelines for Good Clinical Practice (GCP).[4] The national guidelines developed by the NCST[5], which are based on international guidelines. Compliance with these guidelines helps to ensure that the dignity, rights, safety, and well-being of the research participants are promoted and that the results of the investigations are credible and valid.

Kamuzu University of Health Sciences Requirements on Research

KUHeS requires that:

1. Reviewers provide independent decisions from political, institutional, professional and market influences.
2. All research conducted meets these national and international ethical andscientific guidelines.
3. The reviewers should consider the interests and needs of the researchers and have due regard to the national regulatory agencies and applicable laws.
4. Approvals should be granted before the commencement of the research.
5. Researchers act in the full interest of research participants or concerned communities.

2.0 PURPOSE OF GUIDELINES

These guidelines are intended to facilitate and support scientific and ethical reviews of research involving human participants and animals carried out in KUHeS and its affiliates. The guidelines are not intended to supersede relevant national laws and regulations.

[1] Kamuzu University of Health Sciences Research and Consultancy Policy

[2]World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. 1964

[3]International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS; 2002.

[4]ICH-Guidelines for Good Clinical Practice, 1996

[5]Revised Policy Measures and Requirements for the Improvement of Health Research in Co-ordination in Malawi (November 2012)

3.0 KUREC FUNCTIONS, ORGANISATION AND ADMINISTRATION

3.1 Functions of KUREC

The core function of KUREC is to promote research ethics and integrity. This is achieved by:

i. Reviewing research protocols to ensure the proposed research is both scientifically and ethically sound.
ii. Monitoring data and safety of ongoing research.
iii. Safe storage of approved research protocols and essential documents.
iv. Ensuring dissemination of research findings to the public and community.

3.2 Membership of KUREC

3.2.1 Membership Requirements

KUREC shall have multidisciplinary membership to provide an adequate scientific and ethical review of research protocols submitted by researchers. The committee shall be sufficiently qualified through training, expertise, and experience of its members. The committee shall include at least two lay members who are not affiliated with the University. Overall, major competence categories shall include Biomedical Science, Health sciences, Research Methods (e.g., epidemiology and biostatistics), behavioral science and research ethics. Membership shall be based on the principle of unity in diversity which includes gender and community sensitivity.

3.2.2 Composition of KUREC

KUREC shall comprise thirty-three (33) voting members and one (1) ex-officio. Twenty-seven will be drawn from all KUHeS departments; two, from NHSRC; two from teaching hospital and two members as lay community members.

3.2.3 External Experts

KUREC shall establish a pool of independent experts, who may provide special expertise to the committee on proposed research protocols outside the expertise scope of the committee. In the event of emerging scientific and ethical issues, new expertise could be incorporated. Experts will be inducted in the scientific and ethical review process and standards. Experts will be provided with a copy of the guidelines before initiating their work.

3.3 Qualification Requirements and Appointment Procedures

3.3.1 Suitability for appointment

Appointments from KUHeS must be members of staff, ideally at a minimum grade of Senior Lecturer who preferably has peer-reviewed publications. Candidates should have experience in writing a scientific research proposal and conducted KUREC approved research or successfully published a peer-reviewed manuscript. The selection of the office bearers shall consider the following:

- Competency and experience in scientific and ethical disciplines
- Professionalism

3.3.2 Appointment Procedures

The Executive Deans shall nominate the members to serve in KUREC who will be duly appointed by the Vice Chancellor. The appointment of a new committee shall ensure an overlap system, retaining some old members of the committee to allow forcontinuity, the development and maintenance of expertise within KUREC, and the regular input of fresh ideas and approaches. Therefore, a new committee shall be constituted 3 months before the end of the academic year to allow for training of the incoming KUREC members and to ensure a smooth and effective handover of KUREC. KUREC members shall nominate and propose names to be appointed as lay members.

3.3.3 Terms of Appointment

The appointment of KUREC members from KUHeS shall be on the same terms as other KUHeS standing committees. There shall therefore be no extra financial or monetary payment for membership for KUHeS academic staff serving on KUREC. However, KUREC members shall be provided with honoraria. All members shall be reimbursed for any expenses they incur on KUREC activities including subsistence allowances when they have to spend a night outside the duty station. The duration of the appointment for the committee shall be three (3) years. A member may be reappointed to serve another 3-year term. A member may be allowed to resign upon giving valid reasons. A member shall be removed for incompetency or inefficiency or misconduct, or when they cease to be a member of KUHeS.

Vacant Position: A position that falls vacant before the end of the term of a committee shall be filled within three months following the procedures of appointment articulated in section 3.3.2. The appointed member shall serve up to the end of the remaining term of the committee and for reappointment shall be regarded as having served a full term.

3.4 Offices

The leadership of KUREC shall have the following offices: The Chairperson and Vice Chairperson. Only KUHeS academic members of staff are eligible for these positions. Members of KUREC shall elect Chairperson and Vice

The election of these office bearers shall be ratified by the Vice Chancellor. Ex-officio members shall not hold any office.[6]

3.4.1 The Chairperson

The chairperson shall provide the overall direction for the efficient functioning of KUREC and therefore shall among other duties:

- **Chair all KUREC meetings, directing discussions, leading reviews, and voting on research proposals.**
- **Take an active role in establishing and reviewing KUREC guidelines and procedures.**
- **Chair sub-committees of KUREC, where applicable.**
- **May conduct expedited reviews with a subset of the full KUREC committee.**
- **Liaise with the Senior KUREC Administrator on ethical issues affecting research.**
- **Resolve any issues arising during the work of the committee or refer unresolved issues to DREGO.**
- **Represent the KUREC in communicating with other constituencies within and without the institution, including researchers and government regulators.**

3.4.2 Vice Chairperson

The Vice Chairperson shall have delegated powers from the chair to execute equivalent duties.

3.4.3 Head of Department of Research Ethics and Governance (DREGO)/ Senior KUREC Administrator

KUREC shall have the following administrative support staff located in the Department of Research Ethics and Governance (DREGO). DREGO will serve as a Secretariat of KUREC. The Senior REC Administrator is Head of DREGO. The Senior REC administrator is responsible for the day to day administration and operations of a REC. He/she shall be responsible for co-ordinating research protocol submissions and review. The He/She shall provide technical assistance as well as advisory services to investigators and REC members so as to be in compliance with the NCST's approved REC Guidelines and SOPs, and applicable national and international policies, regulatory requirements and laws. The Administrator shall provide recommendations for improving the REC review processes, if necessary. Without derogation from the generality of the responsibilities, the REC Administrator shall perform the following specific duties;

- Ensure assessments and audits are conducted as required by the institution and KUREC Guidelines; and
- Ensure the membership and proceedings of KUREC fundamentally comply with government policies, directives, and regulations.
- Ensure that KUREC discharges its duties in accordance with the KUHES Research Policy.
- Act as a liaison officer between the KUREC, the Chairperson, Investigators, Department of Research and Innovation, and other relevant Institutional Committees.
- Ensuring that Investigators conduct research following the protocol as approved by the ethics committee and following local regulations as well as international ethical guidelines.
- Ensuring the protection of the rights, safety, and wellbeing of research participants.
- Training of KUREC members in Good Clinical Practice (GCP) and Research Ethics.

- Inspecting on-going studies.
- **Submission of research proposal/protocol application package**
- Assist investigators, where necessary, with the application submission process as per REC guidelines and SOPs
- Interpret and advise investigators on applicable national regulatory requirements, policies, procedures, guidelines and other compliance related requirements
- Answer various questions and provide needed guidance to investigators through given processes.

- **b. Screening of the application package for research ethics review by members**

- Screen for completeness and accuracy of application packages for ethics and scientific review by the committee
- Liaise with the Accounts Office for verification of payments of applicable fees by applicants
- Assign protocol reference numbers to the complete and accepted protocols on register
- In liaison with the Chair, assign reviewers for each protocol
- Determine whether the studies meet the established review criteria defined in the approved standard operating procedures and guidelines
- Screen applications to REC to ensure that protocols and consent forms and other associated appendices receive appropriate review and are in accordance with national regulatory requirements.
- Screen applications for determining national interest studies and advise applicant as per regulatory requirements.
- Manage and screen revised applications and re-submissions in readiness for review by committee members
- Manage and screen review changes, and if acceptable, forward to REC Chairperson and assigned members for final approval.

- **c. General Administration**

- Establish and maintain a database of incoming and approved research proposals/protocols.
- Distribute application packages to REC assigned members for review.
- Distribute all relevant correspondence to Investigators and REC members
- Co-ordinate with Principal Investigators for preparation of material for committee meetings.
- Generate required correspondence
- Stamp approved consent forms appropriately.
- Prepare and submit REC annual review reports to REC members and institution management
- Prepare annual budget estimates for the activities of REC

- **d. Co-ordinating Protocol Review Process**

- Act as a liaison between the REC, the Chairperson and Investigators
- Advise REC members on any applicable national regulatory requirements and policies to be adhered to

- Be responsible for following up with investigators and REC members on issues required by REC.

- **e. Co-ordinating REC Meetings**

- Prepare schedules of REC meetings for review of protocols.
- Formulate agenda of the review meetings
- Prepare all documentation required by members in advance of the scheduled review meeting
- Organise meetings for review of protocols
- Ensure that a quorum has been reached according to REC approved guidelines and SOPs.
- Ensure approved REC procedures are followed.
- Take minutes, prepare written draft and timely circulate the draft minutes to all members before writing feedback letters to the applicants and before the next meeting
- Write and dispatch REC feedback letters based on deliberations at the meeting
- Present and seek ratification of the approval of minutes at the following meeting.

- **f. Monitoring and Evaluation**

- Periodically monitor and evaluate the review process and shall make recommendations deemed necessary for the efficiency and effectiveness of REC. Such evaluation shall not be limited to REC review process; revision of guidelines, Standard Operating Procedures, applications and consent forms, investigator notification, prior categorization and assignment of applications submitted for review.

g. **Obligation to National Commission for Science and Technology**

- Submit progress report to the Commission periodically on number of protocols reviewed and inspected as well as report on general performance of a REC
- Obtain regulatory approvals on any REC SOPs and Guidelines before their implementation
- Seek regulatory guidance from NCST on issues requiring regulatory governing and policy
- Provide any information as may be required by NCST from time to time

- **KUREC Grants Applications.** Seeks and spearheads grant applications for effective functioning of the committee.

3.4.5 KUREC Administrator

The KUREC Administrator **have delegated powers from the Senior KUREC Administrator to execute equivalent duties. He/She** provides scientific and ethical technical support to the Committee. Provides technical assistance to investigators involved in human participants research. Provides recommendations for improving the KUREC review process. These functions include:

- **Submission Assistance.** Assists investigators with the application submission process. Interprets and advises investigators on applicable policies, procedures, guidelines, national regulations, and other compliance related requirements. Answers various questions and may guide investigators through some processes.

- **Scientific and ethical screening process**: Screens research study applications to determine completeness and accuracy. Determines if studies meet review criteria for "exempt", "expedited", or full board by reviewing the KUREC application, protocol and consent forms, ensuring they receive appropriate review according to national regulations. Screens applications for determining national interest studies and advises the applicant to submit such applications to the National Health Sciences Research Committee as per 2005 Government Policy Measures for the improvement of Health Research Co-ordination in Malawi. Screens revised applications and resubmissions, reviews changes, and if acceptable, forwards for review.

- **Review Coordination**. Responsible for following up with investigators to ensure they are aware of time limits anddeadlines. Coordinates and schedules monthly reviews and annual review reports with theKUREC.

- **Meeting Coordination**. Coordinates meetings for the KUREC. Creates agenda, and ensures there is an appropriate composition of members to make quorum according to national regulations. Ensures proper procedures are followed. Takes minutes, prepares written draft and distributes to the Chairperson as required.

- **Process Improvement.** Makes recommendations for streamlining the KUREC review process such as the revision of guidelines, SOPs, applications and consent forms, investigator notification, prior categorization and assignment of application submitted for review. Ensure that operations research is done to improve the process of the committee.

3.4.6 Senior KUREC Compliance Officer

The Senior Compliance Officer works closely with the chairperson of the ethics committee, members of the committee and the KUREC Administrators to improve the operations of the ethics committee by assessing whether research approved by KUREC is being conducted in accordance with KUREC guidelines and other relevant national and international standards. These functions include:

1. Ensuring that Investigators conduct research following the protocol as approved by the ethics committee and following local regulations as well as international ethical guidelines.
2. Ensuring the protection of the rights, safety, and wellbeing of research participants.
3. Training of KUREC members in Good Clinical Practice (GCP) and Research Ethics.
4. Inspecting on-going studies.
5. Preparing site inspection visit reports for the ethics committees.
6. Updating KUREC webpage/website content in liaison with the ICT department.
7. Ensuring that serious adverse events, violations, and deviations are properly documented and reported.
8. Ensuring that all Material Transfer Agreement and Data Transfer Agreement forms are completed appropriately.
9. Assisting the IRB Administrators in taking minutes at the KUREC monthly review meetings-

10. Further developing skills required for conducting clinical trial inspections and training of KUREC on study inspections.
11. Working closely with Principal Investigators, Clinical Trial Coordinators and Officers from the Research Support Centre, National Health Sciences Research Committee (NHSRC), and Pharmacy, Medicines Regulatory Authority (PMRA)
12. Deputizes the IRB Administrator in their absence.
13. Ensuring that investigators conduct research following the protocol as approved by REC and in accordance with national regulatory requirements and policies
14. Inspect on-going studies through conducting inspection visits with at least a member of REC
15. Preparing reports of site and protocol inspection visits for REC
16. Take part in the training of REC members and investigators in research ethics and standards
17. Provide advisory services to REC members and investigators on good research practice
18. Ensure the protection of the rights, safety and wellbeing of research participants
19. Assist/deputize REC Administrator in discharge of duties including screening of application packages (i.e., protocols) in line with REC Guidelines and SOPs, and national regulatory requirements.
20. Assisting the REC administrator in taking minutes at the REC review meetings
21. Ensure that serious adverse events are properly documented and reported to REC and relevant national regulatory bodies
22. Ensure that all Material Transfer Agreement forms are completed appropriately
23. Ensure that all annual progress reports/continuing review applications are completed
24. Ensure filling and maintenance of study files
25.

3.4.7 KUREC Compliance Officer

The Compliance Officer reports to the Senior Compliance Officer and works with the Co-chairperson, members of the committee and the KUREC Administrator to improve the operations of the ethics committee. The Officer assesses whether approved research is being conducted in accordance with KUREC guidelines and other relevant national and international standards. These functions include:

1. Ensuring that Investigators conduct research following the protocol as approved by the ethics committee and following local regulations as well as international ethical guidelines.
2. Ensuring the protection of the rights, safety, and wellbeing of research participants
3. Training of committee members on Good Clinical Practice and Research Ethics.
4. Inspections of on-going studies.
5. Preparing site inspection visit reports for the safety committee.
6. Ensuring that all Annual Progress Reports/Continuing Review applications are done on time and that reminders are sent to investigators 3, months prior to the expiration.
7. Notification to investigators of expiration of their studies if one month has lapsed.
8. Ensuring filing and maintenance of study files in the ethics committee Office
9. Ensuring the research inspection database are kept up to date.
10.
11. Assisting the KUREC Administration in taking minutes at the KUREC monthly review meetings-
12. Further developing skills required for conducting clinical trial inspections and training of KUREC on study inspections.
13. Deputies the senior compliance officer.

3.4.8 KUREC Research Data Management Officer

The KUREC Research Data Management Officer assists in the proper functioning of the KUREC office by assisting the Administrative Assistants with their work. KUREC Research Data Management Officer:

1. Establishes record of incoming mail into KUREC database.
2. Ensures that the RIEMS is up to date and functioning.
3. Filing copies of all research proposals reviewed, scientific evaluations, consent documents, progress reports, reports of injuries to participants and other unanticipated problems.
4. Preserving and storing SOPs in electronic or other media forms and making themaccessible for audit purposes.
5. Ensuring the confidentiality of researchers' and research participants' data.
6. Ensuring data security to all software updates and patches being applied.
7. Ensuring that data collected, transmitted, and stored employ appropriate methods and standards.
8. Coding data stored with the corresponding de-identified data.
9. Developing encryption methods to be used on all portable devices (laptops, mobile devices, and removable storage).
10. Developing a data security plan to describe how the research data will be protected during collection, storage, transmission, and destruction.
11. Administering KUREC research data repository taking responsibility for uploading datasets, creating high quality metadata, and developing sound processes for adding, structuring, and hosting inputs.
12. Supporting technical developments, liaising with the repository hosting organization and implementing improvements to meet emerging requirements.
13. Archiving research data using KUREC institutional repository infrastructure, ensuring long term preservation and integrity of datasets, and developing processes and infrastructure.
14. Engaging the research community to promote best practices in research data management, encourage compliance with policies and funding body requirements, maximize deposit of research data and raise awareness of the support available for researchers.
15. Supporting the creation of data management plans, adherence to funding body requirements and promoting the deposit of data.
16. Contributing to the development of policies and procedures for the management of research data at KUREC.
17. Keeping up to date with developments in research data protection, management, establishing future requirements and making recommendations to improve and develop the services offered to KUHES researchers.
18. Producing reports as required.

3.4.9 Administrative Assistant

The Administrative Assistant assists in the proper functioning of the KUREC secretariat office by providing administrative support to the Senior KUREC Administrators and the Chairperson and shall be responsible for:

- Assist in the filing of all documents, correspondence and protocols
- Assist in photocopying and collating proposals and other important documents in readiness for review

- Assist in the dispatch of mail and documents to REC members and any addressees.
- Assist the REC Administrator with administration of the review process, including assignment of reviewers and compiling reviewers' comments.
- Assist the REC Administrator with preparation of agenda and minutes of meetings of REC
- Assist the REC Administrator and Compliance Officer with preparatory processes aimed at the review of guidelines and Standard Operating Procedures as and when necessary.
- Perform any other REC related duties as assigned by REC Administrator
- Maintaining files (electronic and hard copies)
- Scheduling appointments
- Acting as a receptionist
- Typing
-
- Conducting correspondence
- Distributing information
- Data entry
- Coordinating activities
- Distributing exempt and expedited studies to KUREC Chairperson for review
- Coordinating with principal investigators for preparation of material for board meetings
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- Stamping consent forms appropriately
- Distributing correspondence to Investigators
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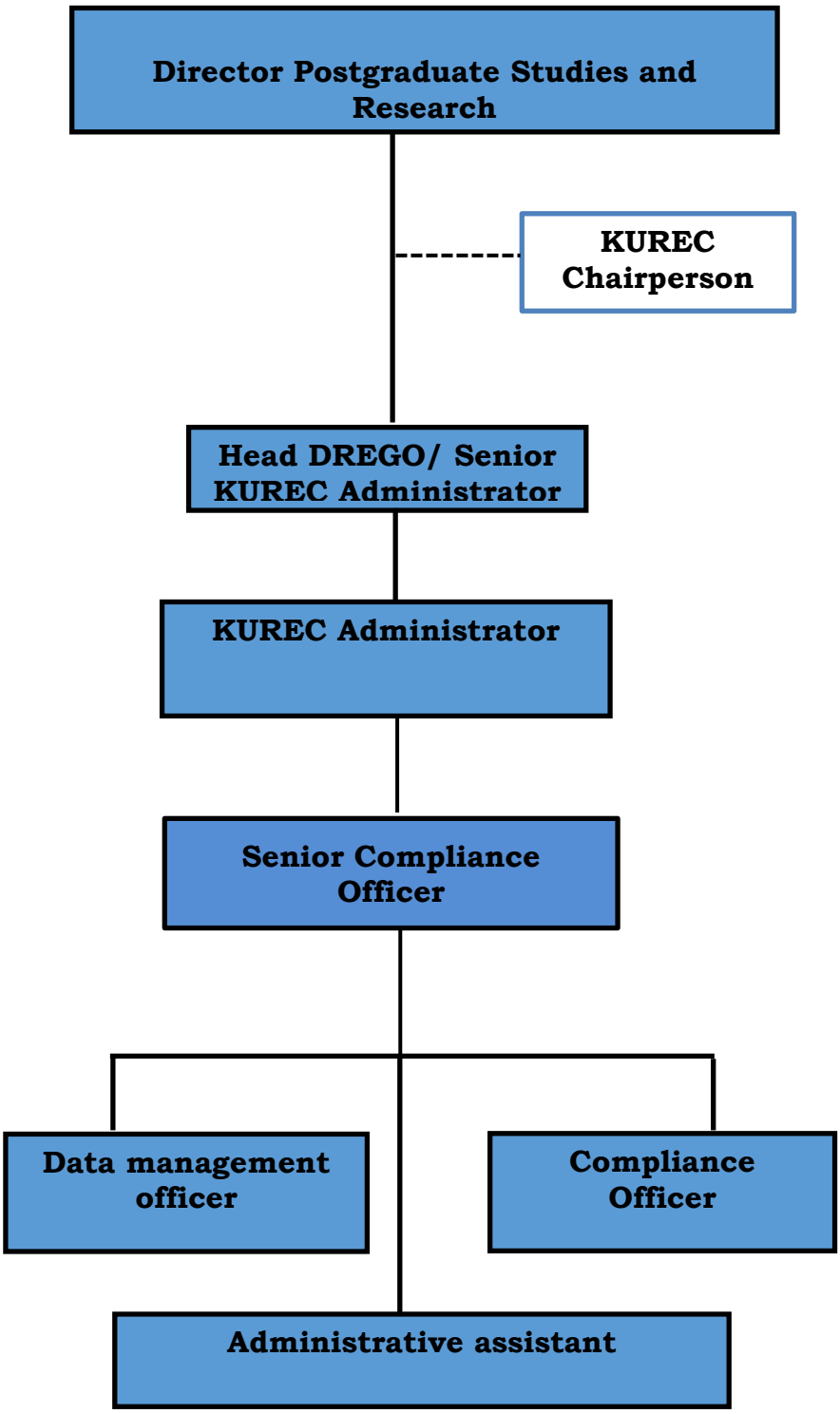

KUREC Organogram

Figure 1: KUREC Secretariat

3.5 Code of Conduct

All members are expected to adhere to a high degree of conduct in order to maintain the good image and reputation of the Committee and the expected respect of the Committee by the community it serves.

3.6 Confidentiality Agreement

Members including external experts serving on KUREC shall maintain confidentiality relating to KUREC official documents and research participants. Therefore, upon appointment, all members shall sign a confidentiality statement.

3.7 Conflict of Interest

There is always a potential for direct or indirect conflict of interest for academic members of staff in the University who are serving on the committee. KUREC, therefore, has put in place mechanisms to minimize this. For example, a KUREC member who is an investigator on or is linked to a research protocol under consideration by the committee, although they may participate in the discussions (open) session shall recuse themselves from the voting (closed) session. Other examples of conflict of interest include:

- A member who holds a significant financial interest in a sponsor or product under study.
- A member whose spouse or close relative has research under review by the committee.
- A member who has any other special form of relationship with the investigator or sponsor of the research under consideration if such a relationship is likely to influence the decision of the committee.

3.8 Attendance

Members are expected to attend all meetings of the Committee. Members who, for valid reasons, are unable to attend regular meetings of the Committee should where possible inform the secretariat at least three days before the scheduled meeting. Absenteeism and inconsistent attendance reduce the respect of the committee. Failing to attend three consecutive meetings shall form a basis for a member being withdrawn from the committee.

3.9 Training of Committee Members

Members of KUREC shall be trained in human participant protection, International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guideline , research ethics and science of research. KUREC members shall be required to attend KUREC continuous professional development training (CPD).

3.10 Finances

All resources required to run activities of KUREC shall be funded by the University budget. KUREC shall submit an annual budget to the Director of Finance and Investment. To cover the cost of protocol

review, the University shall charge a processing fee for each new protocol submission when resubmitting for the fourth time. To cover ongoing administrative costs incurred by the University for human participants' research protections the University levies 10% of the research budget. KUHeS undergraduate students are exempted from paying the levy. However, postgraduate students are required to pay the processing fee and the 10% levy.

4.0 MEETINGS OF KUREC

4.1 Scheduling of Meetings

KUREC shall meet at least twice every month. The secretariat shall make available the calendar schedule of its meetings at the beginning of each year to all relevant stakeholders. The committee shall convene extraordinary meetings, when necessary, provided that the stipulated quorum requirements are met. Meetings should be planned in accordance with the needs of the workload. The agenda shall generally be on a first-come-first-served basis. The secretariat shall compile all the relevant documents and materials required for review and shall be circulated to the members at least 7 days before the date of the scheduled meeting. The materials include the complete proposal package submitted for review and any other relevant documentation.

4.2 Quorum

A quorum of any meeting shall be achieved when 50 + 1 % of the members attend. If the quorum cannot be achieved the meeting must be rescheduled within 2 weeks of the failed meeting. If the subsequent meeting does not achieve quorum, then the Chairperson shall decide based on the expertise and number of members present.

4.3 Agenda

The annual calendar of meetings shall be released by November each year and made available to all departments and all other stakeholders. The agenda for the first meeting of the year will include the following:

- KUREC annual report and financial report,
- The annual calendar,
- Review of protocols,

The last review meeting of the year shall take place in November.

5.0 SUBMISSION OF APPLICATIONS FOR KUREC REVIEW

5.1 Eligible applicants

All applicants must fulfil the following requirements:

- Full-time member of staff KUHeS, affiliates and collaborators
- Honorary members of staff of KUHeS.
- Students of KUHeS

A complete submission of a new study must include the following:

- A covering letter from the Principal investigator
- Signed and dated KUREC application form
- The protocol of the proposed research
- Data collection tools e.g., case report forms, questionnaires etc. intended for research participants.
- Investigator(s) curriculum vitae (updated, signed, and dated).
- Material to be used (including advertisements) for the recruitment of potential research participants (posters, flyers, appointment cards, etc.)
- Informed consent form including both English and the local language(s)
- Itemized Budget and justified
- Investigator's brochure or Product Insert
- Letter of support from KUHeS Head of department
- Letter of support from the gatekeepers

All protocols shall be submitted using the online platform known as the Research Ethics Information Management Systems (RIEMS). Protocols will be assigned a reference number for identification. This numbershould be quoted in all correspondence relating to that protocol.

5.2 Review Process

The committee shall ensure complete proposals are submitted and timely reviewed.

5.3 Elements of the Review

The primary focus of the review and approval process shall be on the science and ethics of the proposed research. Therefore, the elements to be considered shall be as in protocol assessment form. 1:

- Project title
- Sponsor and sponsorship amount
- Names of investigators and qualifications (CVs should be appended)
- Institution of affiliation (local or international)
- Proposed sector
- Executive Summary
- Introduction/literature review
- Justification/problem statement
- Broad Objective and specific objectives
- Methodology/materials and methods
- Ethical considerations
    - Social value
    - Meaningful collaborative partner
    - Scientific validity
    - Consent form

    - Risk-Benefit analysis
    - Respect for participants (privacy and confidentiality)
    - Fair selection of participants
- Work plan (roles and responsibilities, monitoring, and evaluation tools
- Expected outcomes
- Strategies of dissemination of results
- References
- Budget
- Source of funding (proposed)

5.4 Expedited Review

Expedited Review refers to a review process that does not require the full seating of the committee. In this instance, the committee, upon deciding on an expedited review for a re-submission, shall appoint at least 3 members who will review the response and corrections made by the applicant. The review period shall not exceed 14 days from the day of re-submission. In the event that this deadline cannot be met, the secretariat shall communicate the decision to the applicant by the fastest possible means and follow up with written communication. The decision of the expedited review shall be ratified and reflected in the minutes of the next full committee meeting.
Expedited review may apply to the following:

- Proposals/protocols that have previously been reviewed by a fully convened committee and require the PI to address minor issues.
- Undergraduate students' proposal for dissertation.
- Continuing review of research previously approved by committee where the research has completed enrolment of participants and all participants have completed all research-related interventions.
- Studies that are non-intrusive, minimum or less risk could qualify under the discretion of the Chair of KUREC, for exemption or expedited review.

5.5 Amendments and Modifications

Amendments and modifications are changes to the originally approved protocol. Any proposed changes to a previously approved protocol must be submitted for review and approval by KUREC irrespective of the magnitude of perceived risks that may come with the changes. KUREC shall set out the procedures to determine whether such submission require expedited review or a full committee meeting.

5.6 Continuing Review

All KUREC approvals of new applications are valid for one year. Therefore, all approved studies running for more than one year are subject to continuing review annually. The application for continuing review shall be made at least three months before the expiry of the previous approval. The application should be made on a KUREC continuing review form and should include a progress report detailing progress with enrolment and problems encountered. The review shall consider the following:

- Progress with enrolment
- Safety of participants
- New knowledge

- Changes in procedures

KUREC shall send reminders to investigators at least three months before the expiry of approval. Studies shall be considered lapsed and inactive if continuing review application is not received one month after the expiry of the previous approval. In such instances, KUREC shall send an order to immediately cease all study-related operations except those that are necessary for the welfare of participants. The lapsed protocol can be resubmitted and will be reviewed as a new protocol.

5.7 Review by external experts

The committee shall provide the terms of reference for the external experts. KUREC shall establish appropriate procedures of how comments or recommendations from external experts are incorporated into the review process.

5.8 Exemption from Review

KUREC Chairperson will decide whether a proposal can be exempted from review by the full committee. Exemption from the review may be considered under the following conditions:

- Research involving the collection of existing data, documents, records, programme evaluation, pathological specimens, or diagnostic specimens, only if the sources are publicly available or if the information is recorded by the investigator in such a manner that individuals/participants cannot be identified directly or through identifiers linked toparticipants.

The Chairperson shall review the application for exemption and determine whether to grant the exemption or defer to a full committee seating. Where the Chairperson has granted an exemption at his/her discretion, a full report shall be made at the next full committee meeting.

5.9 Review of Studies of 'National Interest'[1]

- Most health research being done in Malawi is generally of national interest. However, some studies deserve particular attention because of their sensitive, political, and safety implications. Studies covering the following areas are to be regarded as examples of National Interest Studies prescribed in the guidance set forth in the Policy Measures for the Improvement of Health Research Coordination in Malawi.

All studies of "national interest" regardless of the origin of the protocol should be reviewed by the NHSRC. Considering that biomedical research is evolving, KUREC secretariat shall seek guidance from NCST on any emerging research designs that may be presumed to be protocols of studies of national interest. Upon consultation and approval by NCST, NCST shall promulgate the said study or studies and have them appear on the NCST regulatory register as study or studies of national interest.

[1] Revised Policy Measures for the Improvement of Health Research Co-ordination in Malawi (November 2012)

5.10 Decision-Making

In making decisions on the applications for ethical review, the committee shall consider the following:

- A member shall withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest.
- The conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- A decision shall only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, except for KUREC staff.
- Decisions shall only be made at meetings where a quorum is present.
- The documents required for a full review of the application should be complete and the relevant elements mentioned above should be considered before a decision is made.
- Only members who participate in the review shall participate in the decision.
- The final decision will be arrived at through a consensus. If this cannot be achieved a decision will be taken through a majority vote.
- Non-binding advice may be appended to the decision.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed shall be specified.
- A negative decision on an application should be supported by clearly stated reasons.
- Non-scientific and non-ethical issues (e.g., politics) shall not be used to deny a protocol approval provided approval decision is made within the confines of applicable national guidelines, laws and regulations.

5.11 Communicating a Decision

A decision shall be communicated in writing to the applicant according to KUREC procedures, within two weeks of the meeting at which the decision was made. The communication of the decision should include, but is not limited to the following:

- The exact title of the research proposal which was reviewed.
- Clear identification of the protocol of the proposed research or amendment, date, and version number (if applicable) on which the decision is based.
- Names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential research participant information sheet/material and informed consent form.
- Name and title of the applicant.
- Name of the study site(s).
- Date and place of the decision.
- A clear statement of the decision reached.
- Any advice by the committee.
- In the case of a conditional decision, any requirements by the committee, including suggestions for revision and the procedure for having the application re-reviewed.
- In the case of a positive decision, a statement of the responsibilities of the applicant, e.g., the need to notify KUREC in the case of amendments to the recruitment material, or the informed consent form; the need to report serious and unexpected adverse events related to the conduct of the study etc.

- In the case of a negative decision, clearly stated reason(s) for the negative decision.
- Signature (dated) of the chairperson (or another authorized person) of KUREC.

6.0 Compliance Inspection

To promote compliance with good ethical practice, KUREC shall follow the progress of studies for which a positive decision has been reached, from the time the decision was taken until the termination of the research. The committee shall establish a safety sub-committee that will be responsible for monitoring ongoing studies. However, each protocol should undergo a follow-up review at least once a year. The follow-up procedure should consider the following:

- The follow-up review intervals should be determined by the nature and the events of research projects,
- The following instances or events require the extra-ordinary follow-up of a study:
    - Any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study.
    - Serious and unexpected adverse events related to the conduct of the study or study product, and the response taken by investigators, sponsors, and regulatory agencies.
    - Any event or new information that may affect the benefit/ risk ratio of the study.
- In the case of the premature suspension/termination of a study, the applicant should notify KUREC of the reasons for suspension/termination; a summary of results obtained in a study prematurely suspended/terminated should be communicated to the committee.
- KUREC should receive notification from the applicant at the time of the completion of a study.
- KUREC should receive a copy of the final summary or final report of a study.

The monitoring process will take the following forms:

- Submission of annual progress report 3 months before the expiry of annual approval. KUREC approval certificate is valid for 12 months and this should be renewed annually.
- Submission of social harms and serious adverse events reports to KUREC.
- Inspection visits to study sites as required.

6.1 Sanctions

KUREC may suspend, withdraw, and terminate ethical approval of a research project if judged necessary. KUREC shall refer such cases to NCST if there is non-compliance.

7.0 SUSPENSION OR TERMINATION OF KUREC APPROVAL OF RESEARCH[8]

KUREC shall inform KUHeS management about suspension, withdrawal and termination of research approval that is not being conducted in accordance with the guidelines or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the committee's action and shall be reported promptly to the investigator, appropriate institutional officials, Director of Postgraduate Studies and Research and the Deputy Vice Chancellor. KUREC shall send a report of suspended or terminated studies with the reasons contained therein to the NCST and the PMRA or any other government agency responsible for research policy matters.

8.0 DOCUMENTATION AND ARCHIVING

All documentation and communication of KUREC shall be dated, filed, and archived according to written procedures. KUREC shall define the access and retrieval procedure (including authorized persons) for the various documents, files, and archives. Documents shall be archived for a minimum period of 10 years following the completion of a study. Documents that should be filed and archived include, but are not limited to:

- The terms of reference, written SOPs, and reports.
- The curriculum vitae of all committee members.
- A record of all income and expenses of the committee, including allowances and reimbursements made to the secretariat and committee members.
- The published guidelines for submission established by the committee.
- The agenda of the committee meetings.
- The minutes of the committee meetings.
- The correspondence by committee members with applicants or concerned parties regarding the application, decision, and follow-up.
- Decisions and any advice or requirements sent to an applicant.
- all written documentation received during the follow-up.
- The notification of the completion, premature suspension, or premature termination of a study.
- The final summary or final report of the study and publications.
- Electronic documents should also be archived in two separate places.

[8]World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. 1964

9.0 INDEMNITY FUND

Research involving human participants carries a risk of injury. The University shall establish a fund to ensure researchers and participants are protected. Each KUHeS funded protocol will contribute to thefund at a rate to be determined by KUHeS Management.[9] In the event that a participant is injured, oran investigator faces liability claims, the University will use the fund to compensate.

The Fund will apply to KUHeS sponsored research studies only. For all other studies which are NOT sponsored by KUHeS, but KUHeS is a host site or a member of KUHeS or an individual of KUHeS' affiliate institution is a site investigator for such studies, the provision for insurance and indemnity cover for participants and researchers in such studies remain the responsibility of the Sponsor of suchstudies if so, requested by any of the ethics committee and any applicable regulatory authority. Specific legal representation and arrangements shall be sought by KUHeS for research participants to enter any arrangements aimed at benefiting from such a Fund when requested by either of the ethicscommittees before implementation of studies that have attracted an insurance cover for participants. KUHeS shall ensure that any legal representation and arrangements for participants to benefit from this Fund or sponsor insurance cover are verified by the requesting ethics committee and endorsed by the NCST. Any insurance cover for clinical trial participants shall be obtained and provided in accordance with the National Policy Requirement and Guidance for the Provision of Insurance Cover for Research Participant in Clinical Trials in Malawi as issued by NCST in 2012.

NOTE:

•According to international law and ethical guidance as stipulated in the ICH-GCP and the Geneva Convention echoed in the CIOMS, it is the responsibility of the Sponsor of a study/clinical trial to provide compensation/insurance or indemnity for participants and researchers, respectively. This must remain a standard of care.

• If NHSRC or KUREC asks for insurance and indemnity cover for such internationally sponsored studies, a site investigator, through KUHeS as a site/host institution, must be obliged to inform the Sponsor of the study to provide for such a cover.

•Please NOTE the **definition**[10] of a Sponsor as provided for in the ICH-GCP to avoid confusing it with astudy Funder. A clinical trial sponsor is not necessarily a funder. Take note of the ethical distinction inthe definition.

[9] KUHeS Research Policy, 2024

[10]Sponsor of a multicentre clinical trial is not necessarily a funder but refers to an individual, company, institution or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial (ICH-GCP, 1.53):

•An Investigator is a person responsible for the conduct of the clinical trial at a trial site (ICH-GCP, 1.34)

•If required by the applicable regulatory requirement(s), the Sponsor should provide insurance or should indemnify (legaland financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence (ICH-GCP, 5.8.1)

•The Sponsor's policies and procedures should address the costs of treatment for trial subjects in the event of trial-related injuries in accordance with applicable regulatory requirements (ICH-GCP, 5.8.2)

•When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirements (ICH-GCP, 5.8.3)

•The financial aspects of the trial should be documented in an agreement between the Sponsor and theinvestigator/institution (ICH-GCP, 5.9)

NATIONAL POLICY MEASURES AND REQUIREMENTS FOR THE IMPROVEMENT OF HEALTH RESEARCH CO-ORDINATION IN MALAWI

[Sections 18 & 48 of the S&T Act No.16 of 2003]

National Commission for Science and Technology

Revised Edition

November, 2012

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The 2012 revised edition of the ***Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi*** builds on the edition of 2005. In pursuance of its legal mandate, the development of this revised set of measures and requirements was undertaken by the National Commission for Science and Technology (NCST). Throughout the development process, the NCST workedjointly with a cross-section of stakeholders including the Ministry of Health and other relevant institutions. The NCST would like to acknowledge the efforts of all experts and stakeholders, all of whom so numerous to mention, that were engaged at different stages of the development process. While it may not be possible to individually mention all manner of people that contributed to the development process, I would like to pay special tribute to the following groups and individuals;

- **The Taskforce** under the chairmanship of Dr Charles C V Mwansambo (Ministry of Health)**.** His expert leadership, guidance and zeal throughout the process have been inspiring to all members of the Taskforce in drafting the revised set of measures and requirements. The taskforce members, who were in themselves a force to be reckoned with, demonstrated outstanding commitment to the development process. Other members of the Taskforce were Mrs Gertrude Hiwa (Law Commission); Prof J M Mfutso-Bengo (College of Medicine); Mr Wycliffe Masoo (Malawi Human Rights Commission); Dr Damson D Kathyola (Ministry of Health); Mr Mike G Kachedwa (National Commission for Science and Technology); and Mr Andrew M Mpesi (National Commission for Science and Technology). The Taskforce had done extensive co-ordinatory and regulatory critical reviews besides stakeholders' consultations and use of a wide range of source materials in order to inform the proper drafting of this revised set of measures and requirements. The taskforce also served as an editorial team.

- **National Committee on Bioethics (NACOB) and National Health Sciences Research Committee (NHSRC) i**n line with their specific terms of reference as functional technical committees of NCST were structures through which the NCST provided overall policy and regulatory oversight, quality assurance and technical back-up services at each and every stage of the development process.

- **All stakeholders** who provided their inputs and constructively critiqued and reshaped the document.

All stakeholders are, therefore, called upon to adhere to this revised set of policy measures and requirements.

Dr H M Chimoyo

DIRECTOR GENERAL
NATIONAL COMMISSION FOR SCIENCE AND TECHNOLOGY

Table of Contents

1.0 INTRODUCTION

The 2005 Policy Measures for the Improvement of Health Research Co-ordination in Malawi has been in use for over seven years. As a first edition, it performed generally well as a co-ordinatory tool. However, during the period of its performance, a number of co-ordinatory and regulatory complexities, challenges and difficulties in the co- ordination, review and conduct of health research evolved which could no longer be adequately managed and addressed by the 2005 set of policy measures. Therefore, this revised edition which is the second edition entitled ***"Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi"*** has been developed to build on the first edition with the aim of objectively managing and addressing the co-ordinatory and regulatory complexities, challenges and difficulties that have evolved over the years for the benefits of the research participants, researchers and other stakeholders planning to conduct health/biomedical research in Malawi.

This revised edition describes a thematic set of measures and requirements at a national level that are required to be adhered to by all stakeholders without let or hindrance. The specific measures and requirements are in the following thematic sections: Structural Relationship of the National Commission for Science and Technology, National Health Sciences Research Committee (NHSRC) and College of Medicine Research and Ethics Committee (COMREC) while clearly describing the respective revised jurisdictions of NHSRC and COMREC; Membership for NHSRC and COMREC; Management of Conflict of Interest; Review and Approval of National Interest Studies; Review and Approval of Multi-Centre Studies; Submission of Protocol for Review by the Drug Regulatory Authority; Validity of the Ethical and Regulatory Approval; and Regulating the Operations of Research Projects, Units and Institutions Established in Malawi.

These measures and requirements apply to all researchers, sponsors and stakeholders who are planning to conduct health/biomedical research involving humans in Malawi. They, however, represent the minimum standards in the co-ordinatory and regulatory governance framework, which stakeholders are required to adhere to. These policy measures and requirements are lawfully made under and enforced by **Sections 18 (1) and 48 of the Science and Technology Act No.16 of 2003.**

2.0 STRUCTURAL RELATIONSHIP OF NCST, NHSRC AND COMREC

The National Commission for Science and Technology (NCST) has a central co-ordinatory and regulatory oversight role over all research, science and technologyrelated activities in Malawi. It continues to oversee the National Health Sciences Research Committee (NHSRC) and College of Medicine Research and Ethics Committee (COMREC) through, among others, its *ex-officio* membership on these committees; reviewing and approving the committees' specific guidelines and standard operating procedures; and monitoring the committees' performance and adherence to the relevant national policies, laws, regulations and guidelines. Cross-representation is the primary requirement for fostering the relationship between the research ethicscommittees and the NCST. The following specific requirements and measures shall be adhered to;

2.1 Secretarial representation (from NHSRC and COMREC) which already exists should continue. This should facilitate the transfer of information from one committee to the other. Secretarial representatives shall not vote.

2.2 One voting representative from the NCST shall sit on both committees.

2.3 Two voting members from NHSRC shall sit on COMREC and vice versa.

2.4 The agenda of each committee shall have as a regular and standing item an update of the events of the other committee.

2.5 There are only two research ethics review committees in Malawi that are authorized by NCST to review and approve health/biomedical research involving human beings, namely; NHSRC and COMREC. These committees have their own specific jurisdictions as described below.

2.6 Within the scope of its terms of reference as established under **section 11 of the S&T Act**, the NHSRC shall have the sole jurisdiction to review and approve the following classes of studies;

- **National Interest Studies as fully defined under section 6.0 irrespective of the origin of the studies;**
- **Multi-centre studies[1] as fully defined and required under section 7.0 irrespective of the origin of the studies; and**

[1] **For purposes of this policy and in the context of Malawi, a multi-centre study is a study, whether from within or outside Malawi, planned to be conducted/implemented in Malawi at different centres/contract research organisations by different investigators according to the same/single protocol. Such studies are typically conducted at different centres/contract research organisations and at different sites by different investigators in Malawi.**

- **All studies originating from researchers who are <u>not</u> <u>faculty members; nor affiliates; nor collaborators/co-investigators; nor students</u> of College of Medicine or Kamuzu College of Nursing**

2.7 Within the scope of authority delegated by NCST to COMREC as an independent institutional research and ethics committee, COMREC shall have the jurisdiction to review and approve only the following classes of studies;

- **Studies involving and/or originating from faculty members of the College of Medicine (COM) and/or Kamuzu College of Nursing (KCN) and their collaborators/co-investigators/affiliates (*except national interest and multi-centre studies that shall be reviewed by NHSRC);***

- **Single-centre studies involving or originating from faculty members of COM and/or KCN and their collaborators/co-investigators/affiliates with either one or more sites[2] *(except national interest studies that shall be reviewed by NHSRC)***

- **Studies originating from students of College of Medicine and/or Kamuzu College of Nursing** (***except national interest and multi-centre studies)***

2.8 In the event that COMREC is circumstantially not functional at any particular period of time, NHSRC shall take over the review of protocols of studies that are classified to be reviewed by COMREC as defined in <u>section 2.7</u>

2.9 Where ever applicable, the NHSRC and COMREC shall allow for an open and closed session on review of a protocol.[3]

2.10 Both the NHSRC and COMREC **are required to have an operational secretariat office comprising at the minimum the following officers; Committee Administrator, Compliance Officer and Secretary and any other relevant and suitably qualified personnel.**

2.11 The NCST remains the overall national authority for advisory, co-ordinatory and

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[2] For purposes of this policy and in the context of Malawi, a single-centre study is a study, whether from within or outside Malawi, that is to be conducted in Malawi at only <u>one</u> <u>centre/contract research organization</u> by one Principal Investigator at that centre/contractresearch organization. A single-centre study <u>may have one or more sites</u> under the supervision of one Principal Investigator.

[3] **This measure allows NHSRC and COMREC to call a researcher to attend a particular session of a committee meeting at which a researcher's protocol will be reviewed. The purpose of attendance is to allow the researcher to provide any additional information that may be requested by a particular committee. The NHSRC and COMREC will pass a decision on a protocol discussed in an open session during a closed session (i. e when a researcher has left the meeting room).**

regulatory affairs for all research, science and technology activities in Malawi as empowered by the Science and Technology Act No.16 of 2003.

3.0 MEMBERSHIP OF THE NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

The following shall be the NHSRC membership;

3.1 Membership of NHSRC shall be based on **relevant specialty and expertise** and not necessarily on the basis of institution or geographical location. **Subject to the provisions of the S&T Act, members of the NHSRC may be appointed in their own right or from any institution in Malawi, provided that such appointment is on the basis of relevant specialty and expertise**.

3.2 Membership shall also include representatives of the lay public (1), social scientist (1) and a legal representative (1).

3.3 One voting representative from the NCST as a member ***ex-officio***

3.4 In addition, membership of NHSRC shall include **two voting representatives of COMREC** as specified in **section 2.3** as members ***ex-officio***, and **a representative of the Drug Regulatory Authority in Malawi.**

3.5 The NHSRC shall establish and develop strong sub-committees including an inspection and monitoring sub-committee for effective management of its affairs.

3.6 NHSRC shall make a provision for co-opting individuals outside NHSRC into its committee or sub-committees for specific and time limited assignments.

3.7 Membership of NHSRC shall exclude research project directors, trustees and owners of research institutions or projects.

4.0 MEMBERSHIP OF THE COLLEGE OF MEDICINE RESEARCH AND ETHICS COMMITTEE

Membership of COMREC shall generally comprise the following;

4.1 College of Medicine (COM) **full time members of faculty with relevant expertise and competencies.** Thus, appointment of members to COMREC from within COM **shall be on the basis of relevant specialty and expertise and not necessarily on the basis of COM departmental representation.**

4.2 At least two representatives from Kamuzu College of Nursing **appointed on the basis of relevant specialty and expertise.**

4.3 One NCST voting representative as described in **section 2.2** as member ***ex- officio***

4.4 Two NHSRC voting representatives as described in **section 2.3** as members ***ex-officio***

4.5 One Lay Public

4.6 Membership of COMREC **shall exclude directors, trustees/owners of research projects/affiliates, institutions or organizations**. However, **individuals working full time** in a department of the College of Medicine who may be involved in a time limited research project on which their names appear can sit on COMREC, **provided that such individuals posses the relevant expertise and competence that is required for the business of COMREC**. They must howeverdeclare their interest in any proposal and recuse themselves from the review of that proposal. Both the declaration of interest and the recusal process must be properly documented. This aspect of the requirement and measure is fully expanded under the section of minimization and management of conflict of interestin **section 5.0** below.

4.7 COMREC shall establish and develop strong sub-committees including an inspection and monitoring sub-committee for effective management of its affairs.

5.0 MANAGEMENT OF CONFLICT OF INTEREST

Individuals who themselves generate research protocols and carry out research may sometimes find themselves sitting on research committees. There is need for transparency, accountability and professionalism in handling research protocols in order for research and ethics committees to gain public trust and respect locally and internationally. The National Commission for Science and Technology is aware that there is a school of thought that holds that in research there is always a conflict of interest. The issue, therefore, is how to manage the real or perceived conflict of interest.It is with this consideration in mind that the NCST directs the NHSRC, COMREC and any other research review committees on the minimization and management of conflict of interest through the following measures and requirements;

5.1 Membership of research and ethics committees should exclude research project directors, trustees or owners of research institutions or projects or affiliates.

5.2 Members of NHSRC and COMREC must declare their interest in a research study whose protocol is under review, if any, and must recuse themselves from any discussion and voting on that proposal/protocol.

5.3 NHSRC and COMREC must have Conflict of Interest (COI) Declaration Forms which shall be duly completed by any member who has declared a conflict of interest.

5.4 Duly completed COI Declaration Forms shall be retained and properly filed by the committee for future reference.

5.5 The recusal should be documented and properly reflected in the minutes of the meeting

5.6 Where more than one member of the committee appears on a research proposal/protocol under review with their interest in that study, the issue of the quorum should be reviewed so that the quorum is not in favour of members with direct interest in that study. In that event, the meeting may even consider deferring discussion of the proposal/protocol or referring it to a sister committee which could be either COMREC or NHSRC.

6.0 NATIONAL INTEREST STUDIES

Most health research being conducted in Malawi is generally of national interest. However, there are some studies that deserve particular attention because of their sensitive, political and safety implications. Studies covering the following areas are to be regarded as examples of "National Interest Studies":

- ***All vaccine trials;***
- ***All drug trials where patent issues are involved and/or where safety issues remain fully unknown;***
- ***All human genetic studies;***
- ***Stem cell research;***
- ***Cloning research; and***
- ***National health surveys***

6.1 All studies of "national interest" regardless of the origin of the study protocol shall be reviewed by the NHSRC or an ad hoc committee which may be formed by the NHSRC for that specific project composed of members to be drawn on the basis of their expertise rather than which committee they come from. If an ad hoc committee is formed, such a committee shall monitor the research study/project through to its conclusion. The study may be carried out in any geographical location as the committee sees fit. This *ad hoc* committee shall include a representative each from MOH, NCST, NHSRC and COMREC.

6.2 The ad hoc committee referred to in **section 6.1** shall be responsible to the NHSRC.

7.0 MULTI-CENTRE STUDIES

Externally sponsored multi-centre research studies[4] command special ethical and regulatory complexities that vary from country to country. These studies potentially exhibit different trans-boundary/transnational ethical and regulatory implications across the host countries. Similarly, the multi-centre studies that originate from within Malawi have their own ethical and regulatory implications. These implications are quite challenging. Hence, the multi-centre studies, irrespective of their origin, require special national consistency and uniform ethical and regulatory equipoise in the approach for their review, in order to not only enhance the safety and welfare of the research participants but also to safeguard national interests and serve researchers better. **In keeping up with the consistent and uniform ethical and regulatory equipoise in review, and in avoiding differentials, duplicative tendencies and inconsistencies in the review environment for the benefit of both participants and researchers, theNHSRC is lawfully designated and mandated to be the ethics committee that shall review, approve, inspect and monitor such studies irrespective of the local affiliation of the PI or co-investigator or collaborator who has filed an application for review of such a multi-centre study** as described in **section 2.6 and as defined in the footnote of the same section.** Therefore, the following policy requirement, measure and procedure shall be adhered to by sponsors, PIs and all that are concernedwith the conduct of studies of this type;

7.1 Pre-Clinical Trial Submission and Authorisation Meeting

Sponsors and PIs of clinical trials may at their own choice and cost plan to hold a meeting with the NHSRC. **This meeting is not a must** but its purpose is to give sponsors and PIs a chance to inform the committee of the impending trial and to give the sponsors/PIs a deliberate opportunity to **familiarise themselves with the specific applicable national requirements and procedures in advance of submitting aformal application for review, thereby minimising irritants and consequent delays in the review process.**

[4] The term externally sponsored research refers to research undertaken in a host country but sponsored, financed, and sometimes wholly or partly carried out by an external international or national organization or pharmaceutical company with the collaboration or agreement of the appropriate authorities, institutions, and personnel of the host country (CIOMS: Guideline 3, 2002).

As this is not a must, **a sponsor/PI who has not opted for this meeting is directly permitted to submit a formal application for review as described in section 7.2 below.** A sponsor/PI who has opted for the pre-clinical trial submission and authorisation (Pre-CTA) meeting is required to abide by the following procedure;

7.1.1 Sponsor/PI shall write the secretariat of the review committee requesting the arrangement of the (Pre-CTA) meeting **at least four weeks in advance of the suggested date of the meeting** in order to allow secretariat to have adequate time for liaison with the committee chairman and to facilitate communication to committee members.

7.1.2 The sponsor/PI shall submit copies of the protocol of the impending trial to all the members of the review committee when the date of the meeting has been agreed with the secretariat. This submission shall include the full address (i. e physical and e-mail addresses) and name of sponsor and PI.

7.1.3 The sponsor/PI shall liaise with the secretariat on the venue, time and standard costing of any arranged pre-CTA meeting.

7.1.4 After the pre-CTA meeting, the sponsor/PI may eventually decide whether to submit an application for review or not. If decided to submit, the submission shall be in accordance with the specific requirement and procedure described in **section 7.2 below**.

NOTE: ***Though this section is about multi-centre studies, COMREC may at its own discretion allow a pre-CTA procedure, where applicable, at the request and cost of the sponsor.***

7.2 Specific Requirement and Procedure in Submitting a Formal Application

7.2.1 Protocols of these studies shall be submitted in a format required by NHSRC and be reviewed according to the specific requirements, procedures and guidelines of this committee. The NHSRC reserves the right to develop a specific standard operating procedure on the review and monitor of such studies.

7.2.2 The sponsor/PI is required to provide full address of the sponsor and PI including the e-mail addresses in the submission of an application for review.

7.2.3 Sponsor and PI are required to first ensure that multi-centre studies adhere to all national regulatory requirements and laws before submission for review. The design of such studies must take into account local realities which must be well integrated into the design. **Local investigators must always critically evaluate the protocols of such studies before submission for review to ensure that**

all aspects of local realities and national regulatory requirements are addressed within the protocol.

7.2.4 Multi-centre studies in conflict with the relevant national policies, laws and regulatory requirements shall not be allowed in Malawi. **The NHSRC shall pay special attention to identify and prohibit any elements of bio-terrorism and illicit traffic in human organs, tissues, samples or genetic materials.**

7.2.5 The sponsor/PI is required **to first obtain an ethical approval from an ethics review committee of a country of the sponsor** before submitting an application to the NHSRC (in the case of all multi-centre studies originating from outside Malawi). Thus, an external sponsor and the individual investigators shall first be required to submit the research protocol for ethical and scientific review in the country of the sponsor. **The NHSRC shall require such an ethical approval to accompany the submission of an application to NHSRC, although such an approval is <u>not</u> a pre-liquisite/guarantee for obtaining the approval of the NHSRC** but it only serves as an indication and a regulatory requirement that the study had been reviewed and approved by the independent ethics committee in the country of the external sponsor as stipulated by CIOMS (2002).

NOTE: The requirement to first obtain an ethical approval from an ethics review committee of a country of the sponsor also applies for single-centre studies originating from outside Malawi. Therefore, COMREC is empowered to demand such an approval in reviewing single centre studies originating from outside Malawi.

7.2.6 The sponsor and the PI are required to provide a sound justification for wanting to conduct the multi-centre study in Malawi as a host country rather than in a country of the external sponsor or in another country. **Thus, the sponsor/PI is required to adequately demonstrate that the proposed research study is responsive to the health needs and research priorities of Malawi as a host country.**

7.2.7 The requirement for submitting an application for review of a protocol of a multi-centre study involving or originating from faculty members of a university college or affiliate or a subsidiary of such a university college in Malawi shall be as follows:

(a) Only full time faculty members who are PIs are allowed to submit an application for review. The submission is required to be through the academic department of which the PI is a member.

(b) Non full time faculty members are not allowed to submit an application in their own right but are required to collaborate with full time faculty members. It is this full time faculty member as a collaborator/co- investigator who will then have the responsibility to submit for review an application of a protocol in which the non full time member is participating, provided that the submission is through the academic department of which the collaborator/co-investigator is a member.

(c) Only full time members of the university research affiliates/subsidiaries who are PIs are allowed to submit an application for review. The submission is required to be through the academic department which is nesting the affiliate/subsidiary (and of which the PI is a member).

(d) Non full time members of research affiliates/subsidiaries are required to collaborate with full time members. It is this full time member as a collaborator/co-investigator who will have the responsibility to submit an application of a protocol, provided that the submission is through the academic department which is nesting the affiliate/subsidiary (and of which such a collaborator/co-investigator is a member).

7.2.8 The application for the review submitted by PIs, collaborators or co-investigators who are full time faculty members of a university college or who are full time members of any university research affiliate/subsidiary and where such a university college is a host institution of such an affiliate/subsidiary or is a host institution of such a multi-centre study, **shall be accompanied with a letter of institutional endorsement issued by a designated official of a research co-ordinating office at that university college or institution. Such an endorsement shall clearly indicate that the study had been declared into registry of the institutional research co-ordinating office.** Such an institutional office shall be the office such as any of the following: Director of a Research Support Centre; Dean of Research; Controlling Officer of an institution or any equivalent officially designated office for research co-ordination at that institution.

7.2.9 The outcome of the initial review and on-going annual review shall be communicated by NHSRC to the PI with **a copy to the Sponsor of the study/trial.**

7.2.10 The required application/processing fee shall be paid directly to NHSRC Secretariat **on submission of the protocol for review**. In addition to the application/processing fee, **Sponsor/PI is required to pay a research capacity building and administrative overhead fee, as determined from time to time,** as follows;

(a) Where a study application for review is filed by a PI or Co-investigator from a research affiliate of any public or private university college where such a college is a host institution of such an affiliate or research study and that such astudy is registered by the research co-ordinating office at that host institution, **this fee shall be payable to the host institution** when ethical approval for theconduct of such a study has been granted. In this regard, a research budget forsuch a study shall be expected to have duly incorporated the cost item of the required fee. The incorporation of such a cost item shall constitute an elementof review by the NHSRC besides other ethical and regulatory elements as specified in the guidelines of the committee. **Documented evidence obtained from the designated official of the institutional research co-ordinating office shall be required by NHSRC as proof of having registered the study at the institution and as proof of having paid such a fee to the institution**.

(b) Where an application is filed by any other PI or co-investigator of an institution other than in the case as specified in **sections 7.2.7, 7.2.8 and 7.2.10 above**, this fee shall be payable to the **Ministry of Health** when ethical approval has been granted. In this regard, research budgets for such studies shall be expected to have duly incorporated the cost item of the required fee. The incorporation of such a cost item shall constitute an element of review besides other ethical and regulatory elements as specified in the guidelines of the NHSRC.

7.2.11 Inspection and monitoring arrangements of approved studies: For those studies whose research capacity building and administrative overhead fee has been made payable to the host institution as fully described under **section 7.2.10(a)** above, the cost of inspection and monitoring that shall be commissioned by NHSRC shall be borne by that host institution **without let or hindrance**. The NHSRC shall file a budgetary requisition to the host institution in advance in order for the host institution to facilitate the undertaking of the commissioned inspection and monitoring. For the inspection and monitoring of studies whose research capacity building and administrative overhead fee has been made payable to the Ministry of Health as fully described in **section**

7.2.10(b) above, the cost of such inspection and monitoring shall be borne **directly by the Ministry of Health**.

NOTE:

- Money realised from the research capacity building and administrative overhead fee is for paying the cost of the following items: ***Meetings of NHSRC; inspection and monitoring of research studies; continuing education for members of the NHSRC; research dissemination conferences; administrative overheads***; ***etc.***

- ***COMREC is also mandated to charge the capacity building and administrative overhead fee for each of the research study it reviews. Money realised from this fee is for paying thecost of the same items as above***.

7.2.12 The NHSRC shall make full initial review of the same protocols of multi-centre studies submitted by different local investigators, **provided that such protocols have been submitted to NHSRC concurrently/simultaneously. Concurrent/simultaneous submissions of the same protocols by different investigators shall be treated as submissions independent of each other and shall be specific to the particular centre while specifying the number of participants to be enrolled at each of the site in Malawi**. Such applications and any annual subsequent applications for continued study implementation shallbe required to fulfil all the applicable regulatory requirements.

7.2.13 Protocols of the same multi-centre study planned to be implemented at different centres by different local investigators may also be merged/fused as one protocol which can be treated by NHSRC as a joint submission for review. In which case, such a fused/merged protocol must clearly indicate that it is a joint protocol submission **while clearly indicating the total number of participants to be enrolled in the whole study and specifying number of participants at each centre**. In this case, the merged/fused protocol must clearly indicate the **overall contact principal investigator** who would be in-charge of the entire study and responsible for managing the affairs of the study at all the participating centres. This PI shall be the one who will be responsible for correspondence with the NHSRC and whose institution or office shall be entered on NHSRC's file as one implementing the study. Names of all the personnel involved in the implementation of the study shall be required to be provided by the overall contact PI.

7.2.14 The NHSRC shall not accept any **new** application (**i e which is not a concurrent/simultaneous submission**) of a protocol of the same multi-centre study that is made by another/different investigator to be conducted at a different centre in Malawi other than the centre for which it was originally and initially approved, when such an application is made during the period when this original and initial approval of the protocol was already issued and/or when the study is already running. **The PI at the centre to whom the original or initial approval was already granted for such a study is, however, allowed to file an application for review and approval of the intention to extend to any new site, provided that adequate justification for consideration by the NHSRC has been submitted.**

7.2.15 Any withdrawals or suspensions of the approvals by NHSRC or the Drug Regulatory Authority shall be communicated to sponsor and PI of a given study.

7.3 Sponsor's Confirmation of Review and Approval of the Protocol

7.3.1 The sponsor must verify any documented approval of a particular protocol obtained from the NHSRC and the Drug Regulatory Authority as specified in **section 8.0** below by enquiring at the secretariat.

7.3.2 If the NHSRC conditions its approval upon change(s) in any aspect of the multi-centre study, such as modification(s) of the protocol, written informed consent form and any other written information to be provided to participants, and/or other procedures **the sponsor must obtain from the principal investigator or a contract research organisation a copy of the modifications made and the date that the approval was given by NHSRC/Drug Regulatory Authority.**

7.3.3 The sponsor must obtain from the PI documentation and dates of any NHSRC annual re-approvals/re-evaluations.

8.0 SUBMITTING AN APPLICATION TO THE NATIONAL DRUG REGULATORY AUTHORITY

All trials involving pharmaceutical products are subjected to the secondary review and approval by the Clinical Trial Review Committee at the National Drug Regulatory Authority. The sponsors and PIs are required to adhere to the following general policy requirement and procedure in submitting an application to the National Drug Regulatory Authority;

8.1 Sponsors/PIs **must first obtain a full ethical approval** from either NHSRC or COMREC. PIs and sponsors must note the respective jurisdictions of these ethics committees in seeking ethical approval as defined in **sections 2.6** and **2.7** above.

8.2 Parallel/concurrent/simultaneous submissions of application to the ethics committee and the Drug Regulatory Authority are prohibited. Submission to the Drug Regulatory Authority **shall only be done after having first obtained a written ethical approval from a particular ethics committee that is authorized to review and approve a given study as classified in section 2.6 above.** ***The onus is on the PI and sponsor to adhere to all the applicable national regulatory requirements including the provision of all the required documentation at each level of application in order to avoid unnecessary delays in obtaining the required approval.***

8.3 A written approval of the ethics committee shall be required to always accompany an application to the Drug Regulatory Authority. Submitting an application to the Drug Regulatory Authority without the attachment of the written ethical approval of the ethics committee shall be a violation of these lawfully instituted policy measures and requirements which is an offence under the S&T Act.

8.4 Any amendments to the originally approved study protocol **shall first be reviewed and approved** by the ethics committee that had initially approved it before submitting the amendments for the approval of the Drug Regulatory Authority. Submission of application for review of amendments by the Drug Regulatory Authority shall also be accompanied with a written approval of the ethics committee. Amendments shall not be implemented before the approval of the ethics committee and the Drug Regulatory Authority.

8.5 PIs and sponsors shall be required to access specific guidelines of the Drug Regulatory Authority to aid them in submitting a complete application to the Drug Regulatory Authority.

8.6 The study shall be implemented **only when** approvals from both the ethics committee and the Drug Regulatory Authority have been granted.

9.0 VALIDITY OF APPROVAL OF A STUDY

Approval of a study is valid for the period of the study as described in the protocol which is effective from the date of approval as indicated in the approval letter, subject to the following;

9.1 Sponsors/PIs shall be applying for annual continuing review and approval for studies that take longer than one year, **provided that such studies have been implemented within one year after the issuance of the approval.**

9.2 Continuing annual review of studies that have not been implemented within one year of approval is not permitted. **Such studies will be recorded by secretariat as closed.**

9.3 Approval shall automatically lapse and be withdrawn for all studies that have not been implemented within one year of the approval.

9.4 Approval period shall be considered for extension on written application with clear justification by the PI, provided that the application for extension is for a study that had been implemented within one year of the approval.

10.0 REGULATING THE OPERATIONS OF RESEARCH PROJECTS, UNITS AND INSTITUTIONS ESTABLISHED IN MALAWI

Foreign based research projects have existed in Malawi since the 1970s. The number of these projects has increased over the past seventeen years or so and the volume of research undertaken and the complexity thereof has also increased. As part of local capacity building, some of these projects have funded post graduate training to various levels of doctors, laboratory technicians, nurses and non clinical staff. Some of the projects have put up the infrastructure including laboratories and offices. There hasbeen some support for clinical work in some hospitals in the form of laboratory investigations and nursing time on the wards. **The NCST requires that foreign based research projects be affiliated to a local institution**. This affiliation has, for example, resulted in the Memoranda of Understanding being signed between the parties while the infrastructure has appeared on the land of the Government Ministry. For example, some infrastructure has appeared on the premises/land of the Ministry of Health. Such memoranda have occurred without a national guidance framework on mutual usage and ownership of the infrastructure during and after the business of the project. Recently, there have also been efforts by local Malawians towards establishing privately owned

research related projects, institutions or organizations. Irrespective of the ownership status of the established research project/organization/institution, all such institutions/organizations are required to abide by the stipulated national co-ordinatory and regulatory requirements for the conduct of research in Malawi. Therefore, the following specific policy measures and requirements are lawfully made under the S&T Act to be adhered to by all parties and stakeholders;

10.1 All Research projects, institutions and organizations operating in Malawi are required to operate in accordance with Malawi laws, regulatory requirements, policies, procedures and guidelines that govern the conduct of research in Malawi and any other such applicable laws and policies existent in Malawi as shall be issued from time to time.

10.2 Any foreign based research project, institution or organization intending to operate in Malawi shall have to first **be affiliated to a local Malawian institutionthat is recognized by NCST before starting any operations in Malawi, provided that such a local institution is relevant to the research business of such a project/institution/organisation**. All NCST-recognized local research related institutions are published periodically by NCST in a directory of science and technology institutions. **Government sectoral ministries and departments are naturally recognized by NCST**. Affiliating institutions shall have institution-specific affiliation guidelines, policies or requirements that shall be in tandem with the policy measures and requirements contained herein.

10.3 For a research project, institution and organization to be accepted to affiliate, establish and operate in Malawi, **it must demonstrate commitment that its research business and activities are geared towards addressing and responding to the needs and priorities of Malawi as a host country. Similarly, it must clearly define the benefits that it would bring to the affiliating institution and to Malawi as a whole, and a strategy of realizing such benefits**.

10.4 Any foreign based research project, institution and organization affiliated, established and operating in Malawi is required to undertake activities aimed at promoting local capacity building, transfer of knowledge and skills.

10.5 To foster the spirit of collaboration, capacity building, solidarity and co-operation, both the affiliate and the affiliating institution shall enjoy the mutual access and usage of the research infrastructure and facilities brought about by a research project, institution or organization during the life span of the business of such a project, institution or organization. ***Research infrastructure and facilities shall include research laboratory and the associated pieces of equipment and machines; buildings; and all other non human assets brought about by the research project/institution/organization***.

10.6 The infrastructure and facilities of a research project, institution or organization established and affiliated to any local institution shall be the property of the local affiliating institution at the end of the business of such a project/organization, **when the affiliating institution is neither the Government Ministry nor its department or its facility and when such infrastructure does not have its occupancy on the land/premises of the Government Ministry (i.e it is not established on the land/premises of a Government Ministry).**

10.7 The infrastructure and facilities of a research project, institution or organization established and affiliated to any local institution shall be the property of the Government of Malawi as represented by the Government Ministry at the end of the business, **when the affiliating institution is the Government Ministry or its department or its facility**.

10.8 The infrastructure and facilities of a research project, institution or organization established and affiliated to any local institution shall be the property of the Government of Malawi as represented by the relevant Government Ministry at the end of the business, **when the affiliating institution is a parastatal/statutory corporation and when the research project, institution or organization (or its infrastructure, either in part or in whole) is occupied on the land/premises of that Government Ministry.** However, **that Government Ministry and the affiliating parastatal would mutually agree on how to put the infrastructure and facilities to best use.**

10.9 All research projects, institutions or organizations established and operating in Malawi are required to locally release and disseminate their research results through local dissemination conferences and/or publication in locally renowned journals. In addition, research projects/institutions/organizations are required to submit copies of their research reports to the NCST which would consequently compile a national research database. The NHSRC and COMREC shall have this particular aspect in their standard operating procedures as element of ethical and regulatory review.

10.10 **Any foreign research project/institution/organization** or **any locally owned project/institution/organization to affiliate or wishing to partner**, respectively, for its operations in Malawi in accordance with the aforementioned measures and requirements must enter into a **Memorandum of Understanding or an Agreement** (as the case may be) which shall be mutually agreed and signed by both parties before the start of any operations of such a project/institution/organization.

10.11 Any foreign research project contemplating to establish/affiliate to a parastatal organization in Malawi whose infrastructure (either in part or in whole) occupies the land/premises of the Government Ministry/Department/Facility is required to enter into a Memorandum of Understanding/Agreement with both the Government Ministry owning the said land/premises and the affiliating parastatal

organisation.

10.12 The aforementioned measures and requirements shall constitute minimum basic elements, terms and conditions of any Memorandum of Understanding (MOU) or Agreement which shall form the basis of NCST review or inspection (of such an MOU/Agreement). **The affiliating institution shall ensure that these basic elements are duly incorporated into the MOU/Agreement before signing**. Any research related MOU/Agreement falling short of these basic elements shall be declared null and void by NCST, and consequently the intended operations of the research project/institution/organization shall be halted by NCST until suchan MOU/Agreement is rectified and compliant with these basic elements.

10.13 The affiliating institution is required to submit a copy of any signed MOU/Agreement to NCST. Upon receipt of this copy, **the NCST shall make a review and issue a letter of contentedness or otherwise, besides making a regulatory catalogue of research projects/organizations operating with an MOU/Agreement**.

10.14 NCST shall periodically monitor the performance of the signed MOUs/Agreements.

10.15 Research projects/institutions/organisations that have not yet signed MOUs/ Agreements and were already operating in Malawi **before date** of this set of policy measures and requirements must immediately liaise with their local affiliating institutions to start preparing their respective MOUs/Agreements. Such projects/institutions/organization are granted **hundred and twenty days (120) days being grace period effective from 1st March, 2013 during which period they will have prepared their MOUs/Agreements**. Those that already have the MOUs/Agreements that have not yet expired shall proceed as per running MOU/Agreement until the expiry date after which a renewed MOU/Agreement, if need be, would be prepared in a manner and in accordance with the aforementioned measures and requirements. The institution/department which offered affiliation arrangements is required to act towards aiding the preparation of the required MOU/Agreement.

10.16 The validity, construction and performance of the MOU/Agreement will be governed by the Malawi Law and all the applicable regulatory requirements.

10.0 CONCLUSION

In conclusion, stakeholders are called upon to adhere to the policy measures and requirements contained herein for the collective benefit of the research participants,

researchers and the country as a whole. The NCST shall ensure that these measures and requirements are adhered to without let or hindrance.

11.0 REFERENCE/SOURCE MATERIALS

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POLICY REQUIREMENTS, PROCEDURES AND GUIDELINES FOR THE CONDUCT AND REVIEW OF HUMAN GENETIC RESEARCH IN MALAWI

[Sections 18 & 48 of the S&T Act No.16 of 2003]

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September, 2012

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- **National Health Sciences Research Committee and its Leadership** which spearheaded the development process of the Policy Requirements, Procedures and Guidelines in line with one of its terms of reference. As a technical committee of the NCST, this was a structure through which the NCST provided policy oversight, quality assurance and technical back-up services at each and every stage of the development process.

- **The Drafting Panel** under the chairmanship of Dr Charles C V Mwansambo (Ministry of Health)**.** His expert leadership, guidance and zeal throughout the process have been inspiring to all members of the drafting panel. The panel members, who were in themselves a force to be reckoned with, demonstrated outstanding commitment to the development process that ranged fromundertaking critical and analytical reviews of literature on genetics research ethics and regulatory requirements to undertaking stakeholder consultations in order to come up with a framework of requirements and guidelines that isethically, politically and religiously responsive to the Malawi context. Other members of the drafting panel were Prof J Mfutso-Bengo (College of Medicine, University of Malawi), Mr Mike G Kachedwa (National Commission for Science and Technology), Dr Damson D Kathyola (Ministry of Health), Mr Andrew M Mpesi (National Commission for Science and Technology) and Mr Francis Masiye (College of Medicine, University of Malawi). The Panel used a wide range of source materials to inform proper drafting of the document. The Panel also served as an editorial team.

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Dr H M Chimoyo

DIRECTOR GENERAL

NATIONAL COMMISSION FOR SCIENCE AND TECHNOLOGY

Table of Contents

1.0 INTRODUCTION

The benefits of human genetics research in promoting the health of mankind cannot be over-emphasised. For example, genetics research enhances the understanding of how genes and environmental factors interact to influence the health of individuals and communities. Gene localization and identification studies would be helpful in identifying genes in individuals or communities that cause or contribute to a disease/disorder or a trait. These types of studies including genetic screening and diagnostic studies have both the public health and therapeutic advantages to the participating individuals and communities. Thus, research in genetics has the potential to generate scientific knowledge that could improve the health of individuals and communities.

However, research in human genetics is internationally recognized as an area in biomedical research that poses greater concern for ethical, political, religious and cultural sensitivities and controversies than any other area in biomedical research involving humans. While genetic science and technology offers some benefits, it also has potential for risks of various harms not only for the individuals or communities that are participating in a genetic study but also families, populations and a country as a whole. Ethically and politically, genetic information (more than any other health information) could have harmful social consequences for individuals and countries whenused in contexts such as employment, insurance and immigration. For example, cases have been reported of people with asymptomatic genetic predisposition who wereexcluded from employment or insurance and denied immigration status (Emanuel, EJ *etal*., 2003). Other risks of harm associated with genetics research include potential for stigmatisation and discrimination of certain individuals, families, tribes and societies besides psychosocial impacts all arising from use and careless disclosure of genetic information. As genetic research also involves family members, some family members may prefer not to be given genetic information that might provide knowledge of future health or health risks. In addition, other family members who are not blood relatives, such as partners and spouses, may have an interest in the genetic information because

of concerns about the health of the offspring. While potential risks of harm arising from genetic research could be several, the Government of Malawi does not prohibit the conduct of genetic research but requires concerned researchers and stakeholders to not only clearly articulate sound rationale/justification for the conduct of such studies but also to properly define steps and strategies of how they would obviate the risks of harm. It is important to note that Government of Malawi through "*The Government Policy Measures for the Improvement of Health Research Co-ordination in Malawi (2005)"* designated genetics research as one of the areas under studies of national interest because of the greater magnitude of the ethical, safety and political implications associated with such studies.

In establishing these requirements, great effort was carefully taken to critically review peer- reviewed and published literature on genetics research ethics and regulatory requirement. The application of such review was analytically contextualized into the Malawi setting. In addition, a number of relevant international conventions and declarations on the conduct of health research including the 2005 Universal Declaration on Bioethics and Human Rights as well as the Government of Malawi 2005 Policy Measures on the Improvement of Health Research Co-ordination and the 2003 Government of Malawi Communiqué to the UN on Malawi's Position on Human Cloning provided an integrated national framework in benchmarking the policy requirements, procedures and guidelines contained herein. These requirements apply to allresearchers and stakeholders involved in human genetics related research to be conducted in Malawi. They, however, represent the minimum standards in the ethical and regulatory governance of genetics research in Malawi, and stakeholders are, therefore, required to adhere to them. These policy requirements, procedures andguidelines are lawfully made and enforced by **Sections 18 (1) and 48 of the Science and Technology Act No.16 of 2003.**

2.0 GENETIC RESEARCH GOVERNANCE STRUCTURE

2.1 Review Structure

The 2005 Government Policy Measures for the Improvement of Health Research Co-ordination in Malawi stipulates that any genetic research proposed for implementation in Malawi shall be reviewed by the National Health Sciences Research Committee (NHSRC) irrespective of the affiliation of the principal investigators (PIs) and collaborators for the said research. The NHSRC shall have the discretion of either, by itself reviewing the submitted genetic research protocol, or appointing a special *ad hoc* committee to conduct the review on its behalf. Such an *ad hoc* committee shall be responsible to the NHSRC. In the case of a review done by the *ad hoc* committee, feedback of decision to the applicant/PI shall be done by the Secretariat of the NHSRC. The appointment of such an ad hoc committee shall be done by the chairman of the NHSRC. Relevance of expertise, policy and regulatory experience and key stakeholder representation shall be the most important considerations. At a minimum, the ad hoc committee shall include **Chairman of the NHSRC; representative of the National Commission for Science and Technology; Ministry of Health; National Health Sciences Research Committee; College of Medicine Research and Ethics Committee; and any individual(s) with special expertise in the area of the proposed research**. This *ad hoc* committee shall monitor the study through to its conclusion.

2.2 Secretariat of the *Ad Hoc* Committee

Any *ad hoc* committee appointed for the purpose described in 2.1 shall be serviced by the Secretariat of the NHSRC.

2.3 Format and Submission of Protocols

All protocols shall be prepared in the required format of the NHSRC which is contained in the Procedures and Guidelines for the Conduct of Health Research in Malawi (2007) and shall be submitted for review in accordance with the application procedures which are available at the secretariat. **However, investigators shall be required to clearly state in their protocols the permissible category (or a combination thereof) under**

which a particular study is falling. The permissible categories appear in section 3.2 below.

3.0 SCOPE AND CATEGORISATION OF PERMISSIBLE AREAS OF GENETIC RESEARCH IN MALAWI

3.1 Scope

While medical genetics concerns the clinical decision made by a medical doctor to use genetic technology for the benefit of his or her patient, public health genetics is concerned with the systematic application of human genetic technologies to identify, prevent or ameliorate genetic conditions in whole populations or communities. Genetic testing, therefore, involves the decision to test an individual patient, while genetic screening involves a decision to systematically test a discrete population. While being cognisant of the on-going international debate and controversies in human genetics research, Malawi, while carefully informed by a series of stakeholder consultations at a national level, adopted her own policy and regulatory position on human geneticsresearch that fits her own context. The policy and regulatory position is to promote only human genetics research which serves a clear medical and/or public health goal and utility. Only scientifically and ethically sound genetics research studies with clearly defined therapeutic and public health value shall be permissible for review, approvaland implementation in Malawi, provided that all the minimum requirements for safeguards and considerations as set under section **4.0 below** are adhered to. As is thecase in any health related research involving humans, ethical principles of *respect for persons; beneficence and justice* shall be the framework of principles within which researchers are expected to conduct their proposed genetics research. Review and approval of such studies by the NHSRC shall occur within this framework. Protocols of these studies shall be reviewed against all the important considerations and elements specific to research in genetics as described in sections **4.0 and 5.0 below**. Genetics studies that smack of elements akin to eugenic activities are not allowed in Malawi and must be avoided. In addition, the NHSRC shall expect researchers to design studies in the permissible areas that are in tandem with the National Health Research Agenda in Malawi.

3.2. Categories of Genetic Research

Research in human genetics is generally classified into three main categories, namely: gene localization and identification studies; genetic screening and diagnostic studies; and gene therapy studies. Because of differences in these categories, protocols of studies under each of them attract specific elements of review. These categories are briefly outlined below.

3.2.1 **Gene Localization and Identification Studies:** The intention of these studies is to identify genes that cause or contribute to a disease or trait. Done typically by first finding the approximate chromosomal position of the gene (termed gene-mapping), and then by determining the identity of the gene.

3.2.2 **Genetic Screening and Diagnostic Studies:** These studies include population based genetic research studies and protocols aimed at identification, among apparently healthy individuals, of those who are sufficiently at risk of a specific disorder or of those who are at risk of being a carrier of a gene that causes a genetic disease/disorder to justify a subsequent diagnostic test or procedure. These studies are also concerned with genetic testing protocols on individuals at different levels that would include clinical phenotyping; chromosomal analyses; metabolite level analyses; polypeptide or protein level analyses; and DNA level analyses for genetic mutations, susceptibilities and disorders.

3.2.3 **Gene Therapy Studies:** These include studies aimed at introducing genetic material into patients to treat a genetically inherited or acquired disorder.

3.3 Permissible Areas and Forms

Permissible areas and forms of genetic research studies are those with **a clear therapeutic and/or public health value** that fall under any of the three categories of research in genetics or a combination thereof which have satisfied the requirements, procedures and guidelines as well as specific elements of review as described in **sections 4.0 and 5.0.** These shall also include areas and forms **not** mentioned as

examples under the section of non-permissible areas and those that the NHSRC has not determined as being non permissible at any given time.

3.4 Non Permissible Areas and Forms

The following non permissible areas/forms of genetics research only serve as examples. The NHSRC has the ultimate authority to determine from time to time other non permissible areas and forms besides the ones listed hereunder.

3.4.1 Research in Human reproductive cloning
3.4.2 Any research related to human germ line genetic engineering
3.4.3 Research involving the creation of human embryos for research or therapeutic purposes
3.4.4 Human genetic enhancement studies aimed at promoting socially desirable personal characteristics
3.4.5 Genetic screening and testing for genetic disorders/diseases that manifest later in life
3.4.6 Genetic screening and testing for conditions/diseases for which there is no possible and suitable interventions
3.4.7 All forms of studies and testing aimed at collecting and storing human biological samples for future unspecified genetic research/analyses including any scientific retrospective genetic analyses
3.4.8 Plans, attempts and requests for obtaining human biological/genetic material for future research
3.4.9 Any studies or scientific intentions that do not serve the therapeutic and public health goal for the people of Malawi

4.0 REQUIREMENTS, PROCEDURES AND GUIDELINES

The scientific and ethical design of any research in human genetics serving a clearly defined therapeutic and/or public health goal that has been proposed for implementation in Malawi shall incorporate the following requirements, procedures and guidelines in relation to a specific study in the defined categories and permissible areas and forms as outlined above;

4.1 Consent in Genetic Research

The traditional paradigm for research ethics requires an autonomous individual to make an informed choice/consent about participation in research. However, genetics

research and genetic information are by nature about families. For ethical reasons and success of the study, where a protocol calls for family members to inform relatives about the study, the researchers must undertake to obtain an informed written permission from the family members. However, each individual participant has the right to make an informed written consent to participate or not. To make an informed and educated consent, the consent form or information sheet must include statements on what is being studied and why; details about study procedures, known risks, discomforts, and benefits; and alternatives to participation besides what is specifically described in the tables of schema of NHSRC review as applicable to each permissible category of genetic research.

4.2 Genetic Counseling

On recruitment, potential participants should be counseled about the possible consequences, implications and psychosocial impacts for the proposed research and disclosure of tests results. The research protocol must provide for counseling and support services to the participants before enrolment begins and when contemplating to disclose research results to the participants. Counseling and disclosure of tests results must be provided by health professionals who have appropriate training, skills and experience. Researchers shall adhere to the related requirement as further described under **section 4.6.**

4.3 Genetic Testing and the Availability of Therapy or Prevention Strategies

Where safe and effective therapy or prevention strategies exist that have been accepted as standard of care and standard practice, providing the information necessary for patients or participants to make appropriate choices is in the best interests of the participants. Where there is no therapy, and prevention strategies are unknown or unproven, **genetic testing is unethical and is herein prohibited as such research cannot offer a therapeutic and/or public health value.**

4.4 Validity of the Protocol

A research design that leads to false conclusions is unethical because actions based upon those conclusions may have adverse consequences. Research that lacks validity also raises ethical issues of justice, if scarce resources are wasted. Researchers, should, therefore, ensure that the design of the study has taken into consideration all factors avoid those that would render the study invalid. Such design elements include (among others): appropriate inclusion criteria, sample size to give a proper statistical power, appropriateness of the study design in relation to the title and objectives of the study. Proper justification for including narrow group of potential subjects like in pedigree studies must also be given.

4.5 Sensitivity and Specificity of the Test and the Uncertainty of Clinical Prediction

Receiving accurate information on the anticipated predictive value of a testing or screening protocol is important for the NHSRC for a number of reasons. The accuracy of the results and their consequent usefulness to participants will be a determining factor in the investigator's and NHSRC consideration of whether individual tests results should be disclosed to the participants. In undertaking the risk-benefit analysis, the NHSRC shall weigh the scientific, clinical and public health usefulness of the test or screen. **The predictive value shall be cardinal in making these considerations. Thus, the NHSRC expects the researcher to indicate how frequently a result is expected to be falsely negative or falsely positive and the impact that this will have on the participant receiving the results**. Higher reliability and accuracy of the screening and diagnostic tests and any associated confirmatory tests in terms ofproviding the positive and negative predictive values is extremely paramount in genetic research. Therefore, researchers are expected to include in their protocols, the acceptable cut-offs of the values of the tests against those of any gold standard, to show the reliability of the tests and confidence that the NHSRC may place in such testsand their results as such would minimize potential for making erroneous and harmful disclosure of test results to the participants.

The NHSRC, therefore, expects and requires the researcher to thoroughly explore in the protocol the role of false positives and false negatives in the context of the importance of the results and the existence of confirmatory testingas such would provide further relevance on:

- how results should be handled (i.e.; what steps should be taken with a positive test result; what steps should be taken with a negative test result; and what steps should be taken when the result is equivocal)
- deciding to repeat the test if there is an additional diagnostic tool that can be employed in order to confirm **the accuracy** of the testing process.

4.6 Obligation to Disclose or not to Disclose Results

The principle of respect of persons is often tempered by the principle of beneficence: the decision to disclose test results must involve a consideration of the risks and benefits of disclosure. The NHSRC takes a middle view of these principles where investigator's obligation to disclose the test results to participants is regarded as a mechanism for realizing and promoting the therapeutic and public health advantage of the research study. However, the participant has a right and choice to consent to the disclosure of the results while taking into consideration requirements as described under sections on genetic counseling; protocol validity; sensitivity and specificity of the tests; and the uncertainty of clinical prediction**.** The NHSRC shall require a protocol to properly take into account all these requirements in meeting the obligation to disclose or not to disclose.

4.7 Privacy and Confidentiality

Genetic information about individuals is highly sensitive and requires that investigators take great care in handling it. The NHSRC or its *ad hoc* committee expects the investigator and/or the sponsor of the study to describe in detail how the privacy of participating individuals, communities, tribes will be protected and how the confidentiality of obtained information will be maintained. Thus, the consent form or information sheet shall be required to include explicit descriptions of the type and

scope of genetic information that will be collected and used in the proposed research study as well as whether, when and how participants will be informed of the results of the genetic analysis including outcomes not currently contemplated that may have implications for an individual participant.

In order to properly achieve the therapeutic and/or public health value and depending on the nature of the research study, a protocol must specify whether genetic information or genetic material, and any other information derived from studying the genetic material will be stored in code-identified or anonymous form.

4.8 Stigma and Discrimination

Genetic information, more than any other health information, has harmful social consequences for individuals and families when used in contexts such as employment, insurance and immigration. As cited earlier, cases have been reported elsewhere of people with asymptomatic genetic predisposition who were excluded from employment or insurance. The NHSRC, therefore, requires the researcher to demonstrate how best the protection of confidentiality of genetic data of these individuals or families will be maintained in a manner that does not lead to divulsion into the public domain and consequently lead to the adoption of discriminatory and exclusionary practices.

4.9 Risks and Safety Concerns and Strategies for Obviating Risks

Genetic research studies in all the categories outlined above have specific risks which researchers are required to fully describe in a protocol and provide strategies forobviating them. The specific risks vary with categories and proposed methods or techniques of genetic research. The risks which must be described are not limited to thefollowing ones;

4.9.1 Gene therapy studies require a clear and detailed description of any strategies for delivering genes to cells. The genes are delivered through what is termed gene delivery vehicles or vectors. Whatever the gene delivery strategies and gene delivery vehicles/vectors, there are risks and safety concerns that are associated

with each of the chosen strategy and vector. The NHSRC shall require the investigator to honestly describe all the potential risks and safety concerns associated with the chosen gene delivery strategy and vector and as a whole risks and safety issues of the proposed gene therapy study (i.e. risks to the individual orto society).

4.9.2 Having described such risks, the NHSRC shall require the investigator to provide precautionary measures that will be taken to obviate and mitigate such risks.

4.9.3 There is no single set of risks associated with or applicable to gene therapy studies. The risks vary with the technique used to transfer the genetic material into the research participant's body. For example, the following risks are possible risks that are associated with gene therapy studies: *contamination during vector preparation; certain delivery systems triggering a significant immune response that would in turn disrupt or interfere with treatment efficacy; potential for some viral vectors including retrovirus and adeno-associated virus permanently incorporating into the research subject's genetic material which in turn may disrupt important host gene or may activate oncogenes.*

4.9.4 Gene localization and identification studies as well as screening and diagnostic studies have their own risks of harm too. Some of which are summed up in the NHSRC schema for protocol review. The NHSRC shall require protocols under all these categories to contain a detailed description of all possible risks and strategies for obviating them.

4.10 Capacity Building, Collaboration and Affiliation

4.10.1 As a strict and fundamental requirement, all foreign based researchers intending to conduct genetics research in Malawi are required to:

- be affiliated to local research related institutions/departments. The affiliating institutions' roles shall be to aide such researchers to conduct research in Malawi according to the applicable regulatory requirements

and to foster meaningful local capacity building arrangements. In considering affiliation, appropriate fees and memoranda of understanding shall be required depending on procedures and policies of the affiliating local institutions.

- enter into meaningful collaborative arrangements with investigators/researchers of a local research related institution to which they shall have been affiliated. In particular, NHSRC shall require the participation of local collaborators/co-investigators of the affiliating/collaborating institution that have requisite qualifications that are commensurate with the nature of the proposed study.

4.10.2 The NHSRC shall require evidence of such affiliation arrangements. The NHSRC shall also require a protocol that clearly describes **meaningful collaborative and capacity building activities with roles of every collaborator clearly defined**. Testing and analysis shall primarily be required to be done in Malawi. Researchers, collaborators and the affiliating institution shall ensure that the research project has the appropriate technology for testing and analysis. All the technology that shall have been transferred into Malawi to fulfill the objectives of a research study shall be the property of the local affiliating institution. The requirement and guidance under **section 4.12** applies to only very exceptional circumstance. Such a circumstance shall, however, be reviewed and approved by the NHSRC.

4.11 Statement on the Therapeutic and Public Health Value of the Research

In line with the Malawi policy position on genetics research as outlined above, the NHSRC shall require the protocol to have a clear statement that defines the scope of the envisaged therapeutic and/or public health value of the proposed research. Depending on the nature and category under which the proposed research falls, such astatement shall include a description of the proven and acceptable standard of care and practice and/or prevention strategies planned to be administered to the participants in tandem with the requirement as defined in **section 4.3**.

4.12 Material Transfer Agreement and Ownership of Genetic Material

4.12.1 While it is a strictest requirement that genetic analyses must be done locally, there may be restricted circumstances and reasons (for example, to expedite a timely therapeutic cause) where there might be a justifiable need to do such analyses/tests beyond the Malawi borders. Such circumstances would necessitate the transfer/exportation of biological/genetic material, subject to the provisions of any national relevant law. In which case, the researcher shall be required to apply for such a transfer under a material transfer agreement that shall be reviewed, approved and signed for by the NHSRC, provided that the researcher shall provide satisfactory description of how privacy and confidentiality of the individuals and communities as well as safety of suchmaterials will be maintained. Storage period of such materials shall not exceed initial period of five years.

4.12.2 A researcher must not transfer genetic material and related information to another research group locally and internationally unless:

- The researcher and the other research group are collaborating on a research study that has been approved by the NHSRC; and

- The genetic material and information is provided in a form that ensures that participants can not be identified, and that the research group must undertake to hold the material and related information in such a manner that there is no reduction in the protection of the privacy of the participants or of the confidentiality of the information, subject to the guidance provided in sections **4.12.1; 4.12.3; 4.12.4; 4.12.5 and 4.12.6**.

4.12.3 The quality of the technology/equipment or laboratory facilities and personnel where the diagnostic or confirmatory genetic tests will be performed is so

fundamental in providing the credibility of the results. Tests results are only as good as the equipment and the personnel involved. Participants in genetic research and the NHSRC must know whether those results are in any way limited or compromised. Thus, for ethical and quality assurance reasons, the NHSRC shall require the investigator to provide a certificate of accreditationand good laboratory practice for a laboratory providing genetic test results to which the genetic material has been transferred/exported to for the purpose defined under section **4.12.1**.

4.12.4 Any human biological/genetic material that may have been transferred/exported as specified under section **4.12.1** is the property of the Ministry of Health of the Government of Malawi represented by a local affiliating and collaborating institution. The Government of Malawi through the Ministry of Health requires investigators to send back such samples after analysis and the cost of shipment back to Malawi shall be borne by the research group/institution that initially requested the transfer/exportation. All such materials on return shall be accessioned into the **National Public Health Reference Laboratory** in Malawi or any other laboratory that shall be designated in advance by the Ministry of Health.

4.12.5 The National Commission for Science and Technology shall subsequently charge a fee on any approved study in respect of the collection and transfer/exportation of biological samples including the genetic material beyond the Malawi borders in accordance with the regulations of the Science and Technology Fund. The investigator shall make payment of this fee directly to theCommission.

4.12.6 In accessing, collecting and transferring human biological samples/tissues for research purposes, the NHSRC shall require researchers to satisfy the provisions of any relevant national statute including the **Penal Code, Anatomy Act, Health Act and Public Health Act.**

4.13 Disclosure of Interest

The investigator, sponsor and all collaborators are required to provide a statement of disclosure of interest in the research study.

4.14 Prohibition of Commercial Exploitation of Human Biological/Genetic Materials

Any form of commercial exploitation of human biological/genetic materials collected in Malawi **is strictly prohibited**.

5.0 SCHEMA/ELEMENTS OF REVIEW OF GENETIC RESEARCH

The NHSRC will take into consideration all the requirements and guidelines as outlined above in reviewing protocols. In addition, the NHSRC shall review the protocols in terms of the specific elements that are applicable to each type of the three categories of research in genetics. These elements are presented in form of specific questions under each of the sections of a protocol format. These questions are summed up as a schema for the NHSRC review of a protocol. In reviewing protocols falling under Gene Localisation and Identification Studies, the NHSRC will use the schema presented in **Table 1** while **Table 2** schema will be used in reviewing protocols falling under Genetic Screening and Diagnostic Studies. In reviewing protocols that fall under Gene Therapy Studies, the schema in **Table 3** will be used. The NHSRC may use a combination of theschemas or parts thereof in reviewing a protocol, should a protocol be of a study that falls under a combination of the pre-classified categories of genetics research. The investigator is, therefore, expected to address the requirements, procedures and guidelines as well as the specific elements for review contained herein in light of their applicability to the proposed study under a given permissible area of research in genetics. These tables appear in appendix **one.**

6.0 SOURCE DOCUMENTS/REFERENCES

A number of source materials were used in drafting these guidelines. The full list of all source materials appears in **appendix two**.

APPENDIX ONE: SCHEMA FOR REVIEW OF PROTOCOLS ACCORDING TO CATEGORY OF RESEARCH IN GENETICS

Table 1: Schema of review of gene localization and identification studies

{Questions marked with an asterisk refer to issues of particular relevance in genetics protocols}

BACKGROUND AND JUSTIFICATION

What questions does the research address? Has the investigator demonstrated that the research has scientific and medical/therapeutic or public health value? How does the proposed study relate to previous work, if any? Does it provide a rational continuation of this work?

RESEARCH DESIGN

Is the scientific method to be employed valid? Has it been used previously, and if so, how has it been assessed? What quality controls are built into the method?

Is the planned statistical analysis appropriate (i.e., is it likely to provide valid and unbiased answers to the study question)?

*If a full genome scan is planned,
Does the sample size provide sufficient power to identify one or more loci with a reasonable degree of certainty?
Are population-specific allele frequencies already known? If not, how will they be determined?

*If the trait to be mapped is complex, will robust nonparametric methods of analysis (which do not necessarily require a Mendelian model) be used first? If not, is there good justification for this?

*If the study is a case-control study, are the cases and controls carefully matched for ethnicity?

*Is there adequate consideration and/or statistical correction for multiple comparisons (which may number in the hundreds for genome scans), and is the procedure to be used described clearly?

PROCEDURES

What procedures are involved in the study (e.g., medical examinations, blood draws, tissue/tumor donation, questionnaires, interviews, etc.)?How often? How much time will they take?

Are all of the procedures in this study required to answer the research question? Can any be eliminated?

Will the data/DNA be destroyed at any point according to the requirement on the initial storage period? Will identifiers be maintained with the stored data/DNA for the initial allowable storage period?

*Will subjects be asked to allow investigators to contact them in the future for more information about “nonparticipating “family members, if need be)?
*Are the procedures for maintaining confidentiality of data/records/database information specified clearly (e.g., encryption, use of unique identifiers, sequestering of records, security measures)?

SUBJECT SELECTION

How is the study population defined? Does it include affected and/or unaffected individuals, related or unrelated? Are healthy controls included?

Have the eligibility criteria been justified? Do they strike a defensible balance between scientific validity and generalizability (i.e., is the study population sufficiently restricted to yield interpretable results without being unduly restrictive)?

How are subjects to be recruited? Will they be reasonably compensated?

If so, in what form will be the compensation? Is the nature of the compensation or reimbursement reasonably appropriate?

*If the study involves families, how will family members be recruited? By the proband? By the health worker? By investigators directly?
*Will the proposed recruitment process place undue pressure on other members to participate?
*Might recruitment itself “inflict” unwanted information about risk status on family members?

Are adequate procedures in place to protect the interests of these people?

*Does the protocol involve “nonparticipating” family members about whom subjects will provide personal/medical information?

*Does the protocol include incompetent subjects (young children or incompetent adults) Is there a valid alternative to their participation in this protocol?
If not, have provisions been made for assent and/or proxy consent?
*Does the protocol involve other vulnerable populations (e.g., patients with Alzheimer disease or psychosis who have periods of fluctuating competence)? Have their special needs been taken into account?

RISKS AND BENEFITS

Is the importance of the research question sufficient to justify risks associated with the procedures specific to the proposed research?
Have risks been minimized to the extent possible?

*Will participation in the protocol result in any benefit to subjects? Will the results have any predictive value for subjects in terms of life or health choices (e.g., marriage, reproductive choices, choice of employment, medical treatment, disease prevention)?
*Are instances of nonpaternity or incest likely to be uncovered by the research? How will these be handled (e.g., disclosure of the possibility in consent materials, withdrawal of the samples from the research)?
*Will the knowledge gained by the subjects about their current or future health or their carrier status pose additional risks to them, such as risks to insurability, employability, immigration, paternity suits, or social stigma? Have adequate provisions been made for privacy and confidentiality of subject information, including for “nonparticipating subjects”?
*Could the research result in stereotyping or stigmatizing a particular community or cultural group?

Have investigators taken steps to approach the group involved and solicit comments where appropriate?

*Will a family pedigree be published? Will the method or occasions of publication or presentation of findings contain the potential for identifying family members?
If so, how will the confidentiality be maintained?

INFORMATION TO SUBJECTS

Does the information to be provided to prospective subjects adequately inform them of what is being studied and why, details about study procedures, known risks and benefits as well as uncertainties about risks and benefits, and alternatives to participation?

*If there is no individual benefit to subjects, has this been disclosed?

*Have subjects been told of their right to withdraw from the research without penalty or loss of benefits to which they are otherwise entitled? Have they been advised of any consequences of withdrawal?

Are there any limitations on the ability of subjects to withdraw their data or DNAsamples?

If so, has this been adequately disclosed?

*Is it clear to subjects what information will be revealed to whom and under what circumstances (e.g., participants may learn about other family members risk status)?
*Will subjects be informed of any special risks associated with the study (e.g., changes in family relationships, risks to privacy, confidentiality, insurability, employability, immigration status, paternity suits, and educational opportunities)?
*Will the general study results be made available to subjects?
*If no immediately useful or interpretable information of relevance to subjects is likely to result from the study, has this been adequately explained?
*If information that is clinically relevant to subjects is likely to result, will counseling by an experienced health worker or genetic counselors be made available?
*Have subjects been given the option of individually choosing not to receive their study results?
*Could other clinically relevant information be uncovered during the study? If so, how will it be disclosed to subjects? Who will disclose it (e.g., investigators, experienced health worker or genetic counselors, the family physician)?

Will there be any costs associated with participating (including the cost of genetic counseling or psycho/social counseling) that are not covered by the investigator or the institution? If so, has this been disclosed?

Table 2: Schema for Review of Diagnostic and Screening Protocols

{Questions marked with an asterisk refer to issues of particular relevance in genetics protocols}.

BACKGROUND AND JUSTIFICATION

What questions does the research address? Has the investigator demonstrated that the research has scientific and medical/therapeutic or public health value?

How does the proposed study relate to previous work, if any? Have any innovative aspects been adequately justified?

*If the study concerns a diagnostic test, in what (clinical or other) situations will this test be helpful?

RESEARCH DESIGN

Is the scientific method to be employed valid? Has it been used previously? And if so, how has it been assessed? What quality controls are built into the method?

Is the planned statistical analysis appropriate (i.e., is it likely to provide valid answers to the study questions)?

*For diagnostic studies, how is the condition (or risk thereof) currently diagnosed? Will the new diagnostic strategy be compared with the best available standard test/gold standard?

*What is known about the nature and frequency of genetic polymorphisms related to the study condition?
If the study is a diagnostic protocol: How does the existence of polymorphisms affect the ability to define risk thresholds (cut-offs)?

If the study is a screening protocol: How does the frequency of polymorphisms affect the feasibility of population screening?

*Is it likely that other genes are required for full trait expression?
*If subjects will be informed of the test results, does the study design provide for an adequate assessment of the psychosocial impact of genetic testing?

PROCEDURES

What research-specific procedures are involved in the study (e.g. physical examinations, blood tests, tissue/tumor donation, questionnaires, interviews, etc)? Howmany? How often? How much time will they take? Are they all required to answer the research question?

*If long-term follow up is required, over what period of time will this take place?
*What are the procedures for maintaining privacy and confidentiality of information on data/DNA? (e.g., use of identifiers, limitation on access, duration of storage not exceeding initial required period of five years?

*Are adequate procedures in place for maintaining security and confidentiality of data/records/database information specified clearly (e.g., encryption, use of unique identifiers, sequestering of records)?

SUBJECT SELECTION

*How is the study population defined?
If the study is a diagnostic protocol: Does it include affected and/or unaffected individuals, related or unrelated?

If the study is a screening protocol: How is the population at risk defined and why was it chosen? (General population? Targeted population – prenatal, newborns, young children, adolescents, adults, at-risk population?)

Have the eligibility criteria been justified? Do they strike a defensible balance between scientific validity and generalizability (i.e., is the study population sufficiently, but not unduly, restricted so as to yield interpretable results)?

How are subjects to be recruited? If compensation/remuneration is provided, is the amount or nature appropriate?

*Does the protocol target members of an indigenous or other identifiable community? Have appropriate measures been included to take account of this fact (e.g., approaching community leaders, soliciting collaboration where appropriate)?

*Does the protocol include or target newborns or other young children? If so, is the study condition one that manifests or requires initiation of preventive measures inchildhood? Have provisions been made for children's assent, where appropriate, and consent of the parents/guardians?

*Does the protocol include or target adolescent subjects? If so, is the study condition one which has implications for health at this age? For reproductive planning? Have provisions been made for counseling taking account of any special needs of subjects in this age group?

*Does the protocol include incompetent adults? Is there a valid alternative to their participation? If not, have provisions been made for assent, where appropriate, and/or proxy consent?

If children or incompetent adults are included in the protocol, is there any conflict of interest between the research subjects and the parent/guardian giving consent? If so, how will the subjects' interests be protected?

*Does the protocol involve other vulnerable populations (e.g., patients with Alzheimer disease or psychosis who have periods of fluctuating competence)? Have their special needs been taken into account?

RISKS AND BENEFITS

Is the importance of the research question sufficient to justify the research-specific risks? Have risks to subjects been minimized?

*Will participation in the study result in any benefit to subjects? Will the results be informative for participants in terms of life or health choices?

*Will knowledge gained by the subjects about their current or future health or their carrier status pose additional risks to them, such as risks to insurability, employability, immigration, paternity suits, educational opportunities, or social stigma? Have adequate provisions been made for privacy and confidentiality of subject information?

*Could the research result in stereotyping or stigmatizing a particular community or cultural group? What steps will be taken to obviate this?

Have investigators taken steps to approach the group involved and solicit comments where appropriate?

*Is psychological support required for those determined to be at risk? How will it be provided?

INFORMATION TO SUBJECTS

Does the information to be provided to prospective subjects adequately inform them of what is being studied and why; details about study procedures, known risks, discomforts, and benefits; and alternatives to participation?

*Will subjects be adequately informed if the study objective is to assess unknown risks?

*Will subjects be adequately informed of any limitations of the test/screen results as a predictor of clinical risk?

*Will subjects be informed of any special risks associated with the study (e.g., risks to privacy, confidentiality, insurability, immigration status, paternity suits, educational opportunities, or social stigma)?

*If no immediately useful or interpretable information of relevance to subjects is likely to result from the study, will this be disclosed adequately to subjects in advance of their participation?

*Will subjects be told of their right to withdraw from the research without penalty or loss of benefits? Will they be advised of any consequences of, or limitations on, withdrawal, including withdrawal of data or DNA samples?

Will the general study results be made available to subjects?

*Could other clinically relevant information be uncovered during the study? Who will disclose it (investigator, experienced health worker or genetic counselor?)

*Will genetic counselors or experienced health worker be available to transmit relevant information to subjects?

*Will subjects be given the opportunity not to receive their test results?

*Will there be any monetary costs to the subject associated with participation (including the cost of counseling)?

Table 3: Schema of Review of Gene Therapy Studies/Gene Transfer

BACKGROUND AND JUSTIFICATION

- Why is this disease a good candidate for gene transfer or gene therapy?
- What previous work has been done, including studies of animals and cultured cell models? Does the work demonstrate effective gene delivery? How does the proposed study relate to previous work?
- Is the disease course sufficiently predictable to allow for meaningful assessment of the results of the treatment proposed?
- What level of gene expression is presumed to be required to achieve the desired effect?
- Given responses to the above questions, is there a sufficient justification for the investigator to proceed at this point to a clinical trial?

RESEARCH DESIGN

- What are the objectives of the proposed study (e.g., establishing feasibility or relative safety of the gene transfer, determining a safe dose range, demonstrating proof of principle, etc.)?
- Is the goal of the study to ameliorate or cure disease?
- What is the target tissue for gene transfer (e.g., bone marrow cells, skeletal muscle cells, respiratory epithelial cells, central nervous system tissue, etc.)?
- What method(s) (e.g., direct injection, inhalation, *ex vivo genetic modification with injection of modified cells) and reagent(s) - e.g* vectors based on retroviruses, adeno-associated viruses, herpes viruses) will be employed forgene delivery? What is the rationale for their use? Are other methods or reagents known that are more appropriate with regard to efficacy, safety, and stability?

- How will the investigator determine the proportion of cells that acquires and expresses the added DNA?
- How will the investigator determine if the product is biologically active?
- Is the planned statistical treatment appropriate (i.e., is it likely to provide valid answers to the study question)?
- Is it reasonable to expect that the research design proposed will meet the investigator's objectives?

PROCEDURES

- What research-specific procedures and research-specific investigations are required by the study over and above those that would be required for patients receiving standard clinical care (e.g., physical examinations, venous or arterial blood tests, collection of target cells, imaging procedures, irradiation, chemotherapy, direct injection of vector, reinjection of genetically modified cells, organ or tissue transplantation, surgery, tissue/tumor donation, questionnaires, interviews)?

- Is long term follow-up appropriate or essential for this protocol? If long term follow-up is proposed, is there justification for the number of visits and the length of time required? Is such follow-up feasible in the case of this protocol (e.g., have provisions been made for subjects who are mobile or move to other geographical areas, is adequate funding available for such follow-up)?

- Are all of the research-specific procedures necessary? In combination with data collected in the course of clinical care, is it reasonable to expect that the information produced by this study will be sufficient to answer the research question?

CONFIDENTIALITY

- Are the practical steps for maintaining confidentiality of data /records/ database information clearly specified and adequate (e.g., encryption, use of unique identifiers, sequestering of records, security measures)?

SUBJECT SELECTION

- How has the study population been defined?

- Has an adequate rationale been provided for each eligibility criterion (e.g., safety considerations, definition of disease, avoidance of additional concurrent therapies, administrative considerations)? Do they strike a defensible balance between scientific validity and generalizability (i.e., is the study population sufficiently, but not unduly, restricted so as to yield interpretable results)?

- How will the subjects be recruited? If a cohort of eligible patients exists, how will selection be made amongst them? If several trials exist for which the same patients are eligible, how will this be presented to prospective subjects?

- Does the definition of the research population reflect appropriate scientific, clinical, and ethical norms? In recruiting and negotiating with potential subjects, have the norms of nondiscrimination been respected?

RISKS, DISCOMFORTS, AND BENEFITS

- What risks and discomforts are associated with the research-specific procedures and investigations (e.g., surgery, chemotherapy, radiation, bone marrow transplantation)? Have they been minimized?

- If a virus-mediated gene transfer is proposed, what is the potential for the presence of a replication-competent or pathological virus or other form of contaminants? How sensitive are the tests to detect such viruses or contaminants? What level of viral presence or other form of contamination would be tolerable in this protocol?

- Has the possibility of vertical transmission (i.e., gene insertion into germ cells or a fetus) or horizontal transmission (e.g., to family members or health care staff) been considered? What measures have been taken to minimize the risks of this transmission? Are other measures possible? If transmission were to occur, what would be the consequences?

- What are the risks for the vector to activate an oncogene or to inactivate a tumor suppressor gene leading to vector-related malignancy?

- Are the risks and discomforts of the study justified given the potential benefit to subjects and the scientific importance of the research?

INFORMATION TO SUBJECTS

Have prospective participants been adequately informed of the following?

- What is being studied and why, given details about study procedures, known or potential risks, discomforts and benefits, and alternatives to participation;

- Their rights: (a) to information on an ongoing basis, confidentiality with regard to their participation and handling of their data, and the right to consult with others before making a decision whether to participate; and (b) to withdraw from the study without penalty or loss of benefits, as well as of any health consequences of withdrawal for themselves or their immediate contacts, or limitations on withdrawal, ifany;

- Any special issues related to this gene therapy trial, such as uncertainty associated with short and long term risks and benefits; and

- Disclosure of investigator’s or sponsor’s interest in the research.

Have prospective participants been provided this information in simple language, using translation where necessary, with answers to their questions, referral to other sources of information, and adequate time to make up their minds whether to participate?

If there is no individual benefit from participation in the research, has this been appropriately disclosed?

Will the general study results be made available to subjects?

Do all the elements of the consent process combine to allow subjects a full opportunity to make an informed choice?

APPENDIX TWO: SOURCE MATERIALS

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National Commission for Science and Technology

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National Commission for Science and Technology

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TABLE OF CONTENTS

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The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi was drafted through a specially appointed taskforce that worked with all the dedication under my direction. The taskforce was ably chaired by Prof. Wiseman Chijere Chirwa (Faculty of Social Science, Chancellor College, University of Malawi). Other members of the taskforce were: Dr. Peter Mvula (Centre for Social Research, Chancellor College, University of Malawi), Mr Japhet Bakuwa (Philosophy Department, Faculty of Humanities, Chancellor College, University of Malawi), and Mr Chrispin Mphande (History Department, Faculty of Education, Mzuzu University), and Messrs Mike Kachedwa, Hambani Gausi and Andrew Mpesi from the NCST.

The National Commission for Science and Technology remains indebted to a cross-section of stakeholders who discussed and vetted this Framework at various stages of development including all those who participated at the national stakeholders' consultative meeting on 30th May, 2011. The NCST gratefully acknowledges the use of and reference made to various guidelines and codes of ethics of other local and international institutions as listed in the section on source materials. Lastly, I declare with gratitude that funding for the development of this Framework was provided by the Government of Malawi under the stewardship of the NCST Board.

Dr H M Chimoyo
DIRECTOR GENERAL

1.0 INTRODUCTION

Researchers in the fields of social sciences and humanities work within a variety of economic, cultural, legal and political settings that influence the emphasis of their disciplines involving their own techniques, procedures and ethical approaches. Even within the same setting and discipline, individuals may have different moral precepts that guide their work. No declaration could successfully impose a rigid set of rules to which social and humanities researchers everywhere should be expected to adhere. For this reason this document is referred to as *The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi*, herein referred to as the *framework*.

The framework contains a preamble; value of research in the social sciences and humanities; ethical principles and obligations; and sections on autonomous implementation of the framework; research communication; appropriate research environment; monitoring system; application; affiliation and clearance, and acknowledgements.

The purpose of the framework is to provide individuals and institutions with guidelines for making ethical choices in the conduct of social sciences and humanities research in Malawi. Its aim is to enable the social and humanities researchers make individual ethical judgments and decisions informed by shared ethics, principles, values and experiences that are not imposed by their professions. This is a mere framework given that the specific disciplines in the social sciences and humanities can present researchers with many and different complex situations. It shall be adapted by researchers according to the situations they encounter.

The framework is designed to be informative and descriptive rather than being authoritarian or rigidly prescriptive, and is applicable as far as possible to different disciplines in the social sciences and humanities. Its informative and descriptive nature, however, reflects the minimum standards and requirements that should be followed by stakeholders. Its provisions are fairly broadly drawn. However, it will require periodic updating and amendment as deemed necessary by the National Commission for Science and Technology (NCST).

2.0 PREAMBLE

Noting the steady growth of social sciences and humanities research in Malawi, the NCST developed this framework to guide the conduct of research in the Social Sciences and Humanities in conformity with national policies, laws and international standards.

Most research in the social sciences and humanities has direct impact on individuals' privacy and security. Without ethical commitment and guidelines, the credibility and quality of the research work being done, the autonomy and rights of the research participants, the integrity of researchers, and public confidence in research are adversely affected. This framework shall therefore guide the co-ordination, procedure, and ethical conduct of research in the social sciences and humanities in Malawi.

The National Committee on Research in the Social Sciences and Humanities and any NCST approved and registered institutional research and ethics committee shall be key structures to facilitate observance and to promote adherence to what has been provided in this framework. The National Committee on Research in the Social Sciences and Humanities in Malawi is a technical committee established within the institutional set up of the NCST as provided for in Part III, Section 11, Sub-section 1-3 of the Science and Technology Act No. 16 of 2003.

3.0 VALUE OF RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES

The ultimate goal of research in the social sciences and humanities is to improve human life in the physical, material, moral, emotional and intellectual forms. The collection and use of research data in the various disciplines that fall in the categories of the social sciences and humanities, therefore, have direct bearings on people. Data are collected from human research participants, for use by individuals or groups of individuals, to meet individual or collective needs.

Researchers in the social sciences and humanities, therefore, have obligations to: their sources of research data, those whose lives will be

affected by the research findings, other interested parties and end-users of the research data, as well as themselves and their colleagues. Such obligations raise issues related to values, ethics, professional conduct, and moral commitment.

The framework provided herein is premised on the values of:

i. service and benefit to humanity,
ii. respect for the rights, worth and dignity of research participants.
iii. promotion of innovation and creativity in research,
iv. excellence and professionalism,
v. collegiality,
vi. continuous transfer of skills and knowledge,
vii. encouragement of collective participation in matters of human development, and
viii. transparency and accountability at all levels of the research continuum.

4.0 ETHICAL PRINCIPLES AND OBLIGATIONS

This framework forms the basis for the ethical design and conduct of research in the social sciences and humanities.

4.1. Informed Consent

All persons have the right to individual autonomy and self determination. Some of them are vulnerable in the sense that they havea compromised autonomy related to decisions about research participation to a degree that would violate the principle of respect for persons. Therefore, any individual who is invited to participate in a research study shall be given an adequate description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process is designed to provide potential participants with readily understandable information in an amount and timing appropriate to achieve the participant's understanding. Consent shall be obtained from each research participant who is legally, mentally and physically able. For those that are not, including minors, permission shall be sought from parents or legal guardians or any of their legally authorized representatives as the situation may apply. The following are examples of the exceptional

circumstances under which research can be approved by a research ethics committee without parental permission;

i. If the research ethics committee determines that a research protocol is designed for conditions or for a subject population for which permission is not a reasonable requirement to protect the researchparticipants (for example, neglected or abused children), provided an appropriate mechanism for protecting the children who will participate in the research is adequately substituted, and provided further that the waiver **is not inconsistent** with any of the relevant local laws.

ii. Research on adolescents involving their access to contraceptives; or research on adolescents that aims at describing sexually transmitted diseases treatment seeking behaviours, provided the waiver **is not inconsistent** with any of the relevant local laws.

4.1.1. Written Consent

Consent shall be in writing unless an NCST -recognized research ethics review committee finds that written documentation of informed consent may be waived. Consent forms and other informational documents like information sheets shall be written in simple language so as to be easily understood by potential participants and any persons without technical background in the field. The standard consent form and/or information sheet must include the following elements which are considered the most important information to be given out to the research participants;

- ***Research purpose and procedures***: a statement that the study involves research, an explanation of the purposes of the research and the expected duration of participation, a description of procedures to be followed, and identification of any procedures which are experimental;
- ***Risks and discomforts of the research study***: a description of any reasonably foreseeable risks or discomforts to the research participants;

- ***Potential benefit of the research study***: a description of any benefits to the research subjects or to others or to the country as a whole that may reasonably be expected from the research;
- ***Alternative procedures***: a disclosure of appropriate alternative procedures, if any, that might be advantageous to the research participants;
- ***Provisions for confidentiality***: a statement describing the extent to which confidentiality of records identifying the research participant will be maintained;
- ***Research related injury***: for research involving more than minimal risk, an explanation as to whether any compensation is available and if so, what it consists of and how it will be provided;
- ***Voluntariness in participation and the right to discontinue participation without penalty***: a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- ***Contacts for additional information***: an explanation of whom to contact for answers to pertinent questions about the research and research participants rights, and whom to contact in the event of the research related injury (i.e. contacts of the principal investigator and the chair of the research and ethics committee reviewing and approving a particular study for additional information on the research and rights of participants, respectively);

4.1.2. Oral or Verbal Consent

Any NCST-recognized research ethics review committee may allow an oral or verbal consent in the case of all those that do not read or write or do not understand the language of the written consent form. However, the script or information sheet to be read to the potential participants must be approved by the NCST-recognized research ethics review committee and be signed for by their parents or legal guardians or any

of the legally authorized representatives. The consent form or information sheet to be read out shall, however, contain the elements described in **4.1.1**.

4.1.3 Consent for protected sites

For research related to intangible cultural heritage (as per definition contained in the convention for the safeguarding of the intangible cultural heritage), heritage sites and graveyards/cemetery, consent/permission (be of entry) shall be obtained from the relevant custodians and/or offices or legal representatives.

4.1.4 Use of Language

No consent form or information sheet, whether written or oral, shall include intimidatory, threatening, or deceptive language through whichthe subject or the subject's authorized representative is made to lose or waive any of the subject's legal rights, or releases or appears to release the investigator or sponsor from liability for negligence or any harmful consequences originating from participating in the research.

4.1.5 Requirement

The standard requirement is that all participants shall sign in person a consent document or form or information sheet containing adequate elements of a consent document. Those who cannot sign, due to illiteracy, will provide a thumb print under a witness who shall also sign for witnessing. For those who cannot legally, mentally and physically give consent, their parents or legal guardians or authorized legal representatives will be required to sign or thumbprint.

4.1.6 Assent

Researchers shall obtain assent from minors who are capable of assenting. In determining whether children are capable of assenting, an ethics review committee and the researchers shall take into account the ages, maturity and psychological state of the children involved. However, minors must assent in tandem with parental permission. An

assent needs to be tailored to the level of comprehension of the prospective participants. A research ethics review committee is granted wide discretion in determining whether a child is capable of assenting and can waive the requirement for child assent under the following circumstances;

- If a child is not capable of assent
- If the research offers a prospect of direct benefit not available outside of the research(thus falling under the scope of parental authority in overriding a child's desires)
- Or given the same conditions under which parental permission can be waived (as stated above in 4.1)

4.1.7 Consent from Emancipated Minors

Emancipated minors may include those that society may regard as mature minors by law, those legally married, or students under a defined Malawian adult age. Assent from such minors may be regarded as an informed consent.

4.1.8 Protection for Vulnerable Populations

Vulnerable persons are those who have a compromised autonomy related to decisions about research participation to a degree that would violate the principle of respect for persons. Researchers to involve such persons shall be required to obtain extra protections or safeguards for their safety and welfare. Examples of vulnerable populations include pregnant women, prisoners, orphans, people living with HIV and AIDS, refugees, persons with mental disabilities, the illiterate, and women and men who, in some settings, may have to ask their spouses before consenting to participate in a research. .

4.2 Privacy and Confidentiality

i. Researchers shall be required to take precautionary measures to ensure that sensitive research information is not attributed to specific individuals that provided it and is collected in a manner that does not invade the privacy of the participants.
ii. Researchers shall respect individuals' right to privacy.
iii. Researchers shall ensure that sensitive, identifiable information is collected for research purposes and access to such

information is limited to a well defined group such as the research team, the research ethics committee or the research regulatory authority.

4.3 Rights of Participants

i. Research participants have the right to know the benefits andrisks of their participation in a research study
ii. Research participants have the right to withdraw from participating in a research study without any penalty for their voluntary withdraw.
iii. Research participants or communities from which research participants come have the right to feedback from researchers.

4.4 Accountability and Transparency

Researchers shall be committed to research that is fair, honest and transparent. They shall be accountable to their profession, research participants, and the wider society, and shall make arrangements to have their research data preserved for a reasonable period of time for posterity.

4.5 Obligations to others

Researchers shall promote social relations based on the principle of non-exploitation, collaboration, and mentorship. They shall strive to establish working relationships that benefit other researchers and participants, and have primary ethical obligations to the people they study. They shall respect the dignity and well-being of all people involved in their research. Their research shall not unnecessarily consume the time of participants or make them incur undue loss of property and income. Research shall not expose research participants to risks due to their participation in the research.

4.6 Responsibility to the public

Social and humanities research shall be done to benefit society and groups and individuals within it by making the research appropriately available to sponsors, students, decision makers, other researchers and research participants. Above all, researchers shall conduct their work responsibly and in light of the moral and legal order of the society in which they practice. They shall be truthful and be responsible for the

factual content of their statements and must consider the wider implications of the information that they disseminate. They shall make sure that the information presented is well understood, properly contextualized and responsibly utilized.

4.7 Responsibility to colleagues and fellow researchers

Social and humanities researchers shall maintain standards andappropriate professional behaviour that are shared amongst the professional research community. Without compromising obligations to funders, employers, subjects or society at large, this requires methods, procedures and findings to be open to collegial review and dissemination of findings to the scientific and scholarly community.

Where junior researchers work with their senior colleagues the aims shall be to: transfer professional skills, mentor, and build capacity in them.

4.8 Responsibility to students and trainees

Where researchers use students, the following guidelines shall apply:

i. Research and teaching shall be conducted in such a way that does not discriminate on the basis of gender, marital status, race, social class, political convictions, religion, ethnicity, nationality, age or any other criterion irrelevant to academic performance;
ii. Ensure improvement in teaching and training techniques, and being available to the needs and interests of the students;
iii. Impress on students the ethical challenges involved in stages of social and humanities research;
iv. Teachers shall publicly acknowledge student assistance in research and preparation of their work; and
v. Wherever students are used in the research the aim shall be to transfer professional skills and to build capacity in them.

4.9 Non-discrimination

Researchers shall avoid discrimination against others on the basis of sex, race, religion, ethnicity, culture, or other social and human categories that are not related to their scientific competence and integrity.

4.10 Avoidance of conflict of interest

Researchers and members serving on research ethics review committees shall avoid conflict of interests. In this case, conflict of interests shall include but not limited to:

i. researchers and members of any research ethics review committee who serve as an investigator on research under consideration by the same committee;
ii. researchers and members who hold a significant financial interest in a body that funds or sponsors research or promotes products or services on which the research is being done;
iii. a member whose spouse or close relative has a research under review by the committee;
iv. researchers and members who have any special form of relationship with the sponsor of the research under consideration if such relationship is likely to influence decision of the committee;
v. any person who receives a bribe or inducement to do research that compromises objectivity.

Insider dealing shall not be allowed in the research review process, and award of research grants. In a case where conflict of interest is likely to occur, a member of the committee or researcher shall be required to declare the nature of the conflict of interest and provide relevant information. Such a member shall not participate in the review of a particular protocol in which such a member has a conflict of interest. Such a member shall recuse oneself and move out of the meeting room to allow the committee freely deliberates on the protocol in which a member has declared conflict of interest. Such a member shall only be recalled into the meeting room after decision on that protocol had been made. The declaration and recusal shall have to be properly reflected in the minutes of that meeting.

4.11 Objectivity

Researchers shall strive to avoid bias or deception in the design of methods, data analysis, and data interpretation of their research. They shall serve rather than threaten the interests of society in which they

operate. For this reason they shall be aware of the fact that their assumptions may have an impact upon society. Hence, their duty is, on the one hand, to keep an unbiased attitude as far as possible, while, on the other hand, to acknowledge the tentative and relative character of the results of their research and not to conceal their own ideological position(s). No social sciences and humanities assumptions shall be presented as indisputable truths. Researchers shall need to clear misconceptions and misinterpretations about their research.

4.12 Integrity

Social science and humanities researchers bear responsibility for the integrity and reputation of their disciplines of scholarship and of science in general. Researchers shall not deceive or knowingly misrepresent (i.e. fabricate evidence or results, falsify, plagiarize), or attempt to prevent reporting of misconduct in any way, or obstruct the scientific or scholarly research of others. Researchers shall also allow others to have access to their research data and other research materials for purposes of their own work.

4.13 Coercion and Undue Influence

Coercion and undue influence shall not be allowed. Coercion refers to a situation in which a person to some degree is forced, or at least strongly pushed, to do something that is not good for him or her to do. Its interchangeable term is undue influence. If individuals are put in a position where there is undue influence to participate in research, then their ability to control their own destiny has been compromised. It shall be noted that undue influence and inducement amount to coercion.

5.0 AUTONOMOUS IMPLEMENTATION OF THE FRAMEWORK

This framework is of a general application, but academic and other institutions are encouraged to develop their own frameworks in line with it. Such institutional frameworks/guidelines shall, however, be required to be endorsed by the NCST.

6.0 RESEARCH COMMUNICATION

Research communication entails popularization of research results. Researchers in the social sciences and humanities shall ensure that

scientific knowledge is communicated to a wider audience beyond the research community. Reporting of research and its results shall be the responsibility of every researcher and the research institution. The responsibility may be delegated to either the sponsor or any individual upon mutual agreement and expressed commitment to publish or disseminate the results within a specified period.

6.1. Authorship

As a rule, research results shall be published whether they support or contradict the expected outcome. When publishing, the following authorship guidelines shall apply:

i. Authorship shall be based on the level of contribution made in terms of ideas, conceptualization, and actual performance of the research, analysis and writing of the report or any other publications based on the research.
ii. Co-authorship and its sequence should not be based on the status of an individual in the institution or elsewhere.
iii. All other persons not meeting the criteria for authorship but contributed to the conduct and completion of research or publication shall be properly acknowledged.
iv. Students shall be listed as principal authors on any multiple authored publications that considerably originate from their dissertations.
v. Appropriate acknowledgment shall be given where data or information from other studies or publication is quoted or otherwise included.

6.2. Research Dissemination

Researchers bear a special responsibility to convey research results in a comprehensive and responsible manner. Researchers may disseminate preliminary results of their research before being peer-reviewed or published in recognized journals. When such results are being disseminated through the popular media, great care shall be taken to ensure that the media people, not specifically trained in social science and humanities issues and research, are able to understand the limitations and implications of research results to avoid distortions.

It is incumbent upon research institutions to promote multifaceted and comprehensive research communication, characterized by high quality and relevance. Institutions conducting social science and humanities research shall establish committees responsible for dissemination of research results to ensure that the results reach end-users. The committees shall also be charged with the responsibility of publishing circulars and organizing events for specific dissemination of results.

All funded research shall have a component on dissemination of results. Institutions shall be required to establish budget lines for dissemination of research results and organize theme specific conferences orsymposia.

Institutions shall establish research data banks and repositories from which they shall develop research indicators in the social sciences and humanities and compile annual inventories of research and to facilitate availability and access by other users.

7.0 APPROPRIATE RESEARCH ENVIRONMENTS

Researchers shall establish and maintain sound and appropriate research environments in which research can be conducted. Researchers shall actively participate in the initiatives and efforts to improve the quality of research environments in their communities and institutions, and to promote public involvement in these.

8.0 AFFILIATION AND RESEARCH CLEARANCE

As a matter of policy, it remains a fundamental requirement that all foreign based researchers intending to conduct research in Malawi should be affiliated to local research related institutions and government departments. The affiliating institutions' role shall be to aide such researchers to conduct research in Malawi according to the applicable regulatory requirements.

In considering affiliation, fees and MoUs may be required depending on procedures and policies of the affiliating local institutions.

Researchers in Civil Society Organisations/NGOs and other related institutions shall be required of their research to be reviewed and approved by an NCST authorized research and ethics review committee.

9.0 FORMAT FOR RESEARCH PROPOSALS

Research proposals/protocols shall be prepared according to the following general or specific format;

9.1 General Format

This format shall apply where a research and ethics review committee has not specified a format.

i. Proposal title
ii. Names of investigator(s) and qualifications (their CVs should be appended)
iii. Institution of affiliation (local and/or international)
iv. Summary
v. Introduction/literature review
vi. Problem Statement/Justification
vii. Main and specific objectives
viii. Methodology/Materials and methods
    - This should include a description of details of the study design and methods to be used. The description should include study site(s)/location(s); study participants; sampling

methods; sample size; data collection instruments; and data management and analysis methods.

- Data collection instruments, where appropriate, must be translated into the appropriate local language and should be attached in the annex and be appropriately referred to.

ix. Ethics

- This should include a description of strategies and/or processes that will be followed to guarantee the protection of the rights and welfare of the research subjects/communities as required and described under **section 4.0,** while taking into cognizance of the nature and design of a particular study.
- Consent/assent forms or information sheets in English and in an appropriately translated local language should be attached in the annex and be appropriately referred to.

x. Work plan (where appropriate, roles and responsibilities of collaborators, should be stated clearly)

xi. Expected outcomes of the study

xii. Strategies of dissemination of research results

xiii. Budget

xiv. Declaration of source of funding (if already available or proposed)

xv. Reference

9.2 Specific Format

i. Some funding agencies may have different requirements which researchers shall be required to follow in soliciting funding.

ii. In submitting for research and ethical review to the **National Committee on Research in the Social Sciences and Humanities** as mentioned **under section 10,** researchers shall be **generally** required to;

- follow the format that is defined in **section 9.1;**
- submit both **an <u>electronic copy</u> and <u>two</u> hard copies** of the research proposal/protocol

- follow the required checklist for submission of a protocol;and to
- enquire from the secretariat on the other specific requirements and standard operating procedures including requirement for the payment of any lawfully required fee(s) for processing, review and/or approval of a research protocol by this committee which are not described herein but shall be specifically stipulated as requirements in the standard operating procedures of the National Committee on Research in the Social Sciences and Humanities.

iii. Institutional research and ethics committees shall specify their own formats that shall, however, be modeled on the general format.

10.0 MONITORING SYSTEM

Once misconduct during research has been reported, a proper process of investigation shall be set up. All relevant facts for investigation shall be gathered without taking sides and the findings shall be made public for purposes of preserving the integrity of the research community. The regulatory research authority shall impose strict measures in the case of fabrication, falsification, fraud, or plagiarism or any form of serious violation of this framework. All those that report any forms of misconduct shall be protected.

All records of research approved by institutional research ethics review committees shall be submitted to the NCST for record keeping and for creating research data base of all research taking place in the country. **In the event that there are no institutional research and ethics review committees, researchers shall be required to seek approval from the National Committee on Research in the Social Sciences and Humanities which was lawfully established in terms of section 11 of the Science and Technology Act No.16 of 2003, and whose secretariat is at the NCST**.

11.0 APPLICATION OF THE FRAMEWORK

The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi shall apply to all researchers and research institutions in the social sciences and humanities doing research in Malawi. The requirements and guidelines give due consideration to prevent research activity from becoming unduly constricted, and

limiting of academic or scientific freedom but placing emphasis that such freedom should occur within the framework of ethical principles set forth in this document as minimum standards. Nonetheless, all institutional and subject or discipline specific guidelines are subject to this framework and other relevant laws and national policies for conducting research in Malawi.

12.0 SOURCE MATERIALS

The International Sociological Association Code of Ethics (2001), United Kingdom
Republic of Malawi Constitution (1995)
The Social Sciences and Humanities Research Ethics Board (SSH REB) (2005), United Kingdom
The Science Council of Japan Code of Conduct for Scientists (2006), Japan
National Committee for Research Ethics, Guidelines for Research Ethics in the Social Sciences, Law and the Humanities (2006), Norway
Human Sciences Research Council Code of Research Ethics, South Africa
National Research Council of Malawi, *Procedures and Guidelines for the Conduct of Research in Malawi* (2002), Malawi
Ethical Guidelines for Social Sciences Research in Health, India
The National Health Sciences Research Committee*, National Guidelines for the Conduct of Health Research in Malawi (2007),* Malawi
The American Anthropological Association Code of Ethics, USA
Social Research Association Ethical Guidelines, (2003), (UK)
HIV/AIDS Research Strategy for Malawi (2005-2007), Malawi
Institutional Review Board Member Handbook (2003) by Robert Amdur
Government of Malawi, (2003), Science and Technology Act No. 16 of 2003
National Advisory Board on Research Ethics (2009) Helsinki
Economic and Social Research Council Research Ethics Framework

KAMUZU UNIVERSITY OF HEALTH SCIENCES

Research and consultancy policy

Policy Name	Research and Consultancy Policy
Policy No.	
Effective Date	
Last Review	
Next Review	
Council Proposal	
Council Approval Date of the Policy	
Stakeholders Subjected to this Policy	Faculty, students, and collaborators of the University
Responsible Officer(s)	Deputy Vice-Chancellor & University Registrar
Responsible Office(s):	Executive Deans, Heads of Department, Research Coordinators

TABLE OF CONTENTS

FOREWORD

Research and consultancies are important because they support the development of the country by providing solutions to problems, explaining phenomena, as well as opening up new opportunities. By being proactive through the development of research strategies that respond to national priorities, and by pursuing research that increases the stock of knowledge, the University places itself at the forefront of shaping the country's transformation in critical areas of development. In the University community, research is one of the strategic pillars and remains an essential part of academic life and advancement.

This KUHeS policy on research and consultancy provides guidance, sets best practices and regulates the conduct of research and consultancies within the university and among the stakeholders locally, regionally and internationally. The policy was developed by a team of experts from the KUHeS and the process benefited from a wide consultative process from the stakeholders. Various other documents from universities within Malawi, in the region, and internationally were consulted.

A policy document is a living document that should continually be updated. The KUHeS hopes that this document will play an important role in projecting an image of a vibrant university in research and consultancy.

Council Chairman

PREFACE

The Kamuzu University of Health Sciences was created by an Act of Parliament number 20 of 2019 through a restructuring process of the then University of Malawi. KUHeS is made up of what used to be called the College of Medicine and Kamuzu College of Nursing and comprises different schools which are headed by Executive Deans. Its administration system is headed by the Vice-Chancellor, assisted by the Deputy Vice- Chancellor and University Registrar. The KUHeS Research and Publications Committee (KRPC), a Senate committee, is the central body for strategic planning of the research enterprise at KUHeS. It is responsible for the development and implementation of the policy on research and consultancies in the University and it also supports and monitors all University-approved research, consultancy and related activities. There are several aspects that the Research and Consultancy Policy looks into and these include research proposal approvals for funding, determining priority research areas, types of research projects encouraged, time allowance for research, training in research, research budgets,dissemination of research results, peer review of research documents, research clearance and consultancies. The rapidly changing external environment, including the emergence of other tertiary institutions withcompeting needs, demands that the university must make itself more marketable, forge more linkages and collaborations both nationally and internationally, and regulate the inevitable but welcome proliferation of consultancy activities. Therefore the Research and Consultancy Policy will look into all issues to do with research and consultancy in the KamuzuUniversity of Health Sciences in line with other relevant University policies.

Vice-Chancellor

ACKNOWLEDGMENTS

This policy has benefitted tremendously from inputs from manyindividuals and offices. Firstly, we would like to acknowledge the supportof the Senior Leadership Team of the KUHeS towards the development of this policy. Secondly, all schools of the University made useful contributions, largely through Deans of Schools, Deans of Postgraduate Studies and Research to various aspects of the policy. This is fullyappreciated. Thirdly, the tireless efforts of the members of the task force which coordinated the work on the development of the policy is also hereby being acknowledged. It was their dedication and the long hours of hardwork which made it possible for the developed policy to take the present shape.

LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune-Deficiency Syndrome
DVC	Deputy Vice Chancellor
ED	Executive Dean
HIV	Human Immuno-Deficiency Syndrome
HoD	Head of Department
IRB	Institutional Review Board
IT	Information Technology
KRPC	KUHeS Research and Publications Committee
KUHeS	Kamuzu University of Health Sciences
MGDS	Malawi Growth and Development Strategy
NCST	National Commission for Science and Technology
RPC	Research and Publications Committee
URPC	University Research and Publications Committee
VC	Vice-Chancellor

1. BACKGROUND & SCOPE

The KUHeS Policy on Research and Consultancy (hereafter referred to as the Research and Consultancy Policy) aims at ensuring consistency across the University in establishing a common mechanism for planning, implementing and monitoring the research and consultancy processes. The policy is an instrument that ensures that high-quality research practices and outputs are achieved thereby attracting funding organisations. The policy shall apply to Schools, Departments, Centres, Units, Institutes and other entities within the University. Specifically, the policy shall apply to staff, students and other key stakeholders such as collaborators both inside Malawi and outside. It maps out the process of research needs identification and prioritisation and grants management. The Policy also aims at guiding procedures including remuneration governing the conduct of consultancies by staff members of the KUHeS. This policy shall also apply to key stakeholders including those who have commissioned the consultancy.

The Policy also maps out the process of proposal preparation and approval procedures, projects management, intellectual property rights, monitoring and evaluation and dissemination of research results from both research and consultancies.

2. THE RATIONALE FOR THE POLICY

Research supports the development of the country by providing solutions to problems, explaining phenomena, as well as opening up new opportunities. Through research, new technologies have developed that help to improve the quality of life of human beings. The University is in a unique position of having a concentration of highly trained individuals who can contribute to developing new knowledge for solving problems fromdifferent approaches by data gathering, analysis, synthesis, interpretation of results and informing policy. By being pro-active through the

development of research proposals that respond to national priorities, as detailed in the Malawi Growth and Development Strategy (MGDS), the National Commission for Science and Technology (NCST) Strategic Plan and other key sectoral strategies, the University can place itself in the forefront of shaping the country's transformation in critical areas such as health, education and engineering.

The KUHeS recognises that the conduct of consultancies;

a) provides opportunities for improving professional and academic competence for staff;
b) enhances linkages with external agencies;
c) provides opportunities for community engagement; and
d) generates additional income for staff and the University. This explains why there is a need to develop a comprehensive policy that will guide engagement in consultancies by staff.

3. KUHES VISION

To be a world-class, innovative university committed to scholarly and professional excellence in the provision of health education, research and services in Malawi and globally

4. KUHES MISSION

To provide high-quality student-centred and innovative health education informed by research that responds to policy, societal health and development needs in an efficient, sustainable and result-oriented manner, and to influence health policy and practice through the generation of new knowledge.

5. AIMS OF POLICY

To provide a coordination framework on the conduct of research and consultancies by staff, students and stakeholders (affiliates) of the Kamuzu University of Health Sciences.

6. OBJECTIVES OF POLICY

The objectives of the Research and Consultancy Policy are to:

a) Build capacity for conducting research and consultancies among staff and students of the University.
b) Develop and implement a framework through which resources for research, consultancies, teaching and learning can be effectively mobilised.
c) Provide a framework for establishing research partnerships by staff of the University.
d) Enhance the culture of community engagement within KUHeS through the promotion of research among staff and students.
e) Regulate the conduct of research and consultancy in the University.
f) Institutionalise the dissemination of research findings through local (including those arranged by the University) and regional and international conferences and publications.
g) Guide how research and consultancy funds should be distributed.
h) Strengthen institutional capacity in research management.

7. POLICY PRIORITY AREAS

7.1. Research priorities

KUHeS shall:

a) Facilitate the development of research priorities by Schools and Departments, Research Centres, Institutes and Research Units in the University in line with international, national and regional trends;
b) Facilitate and support Schools and Departments/ Research Centres, Institutes and Research Units to develop and implement their

research priorities in line with international, national and regional trends.

c) Compile an annual report which shall detail the research and consultancies (where necessary) which have been carried out in the year; and
d) Work with its Schools to mobilise sufficient resources for the full implementation of this policy.

7.2. The organisational structure of research and consultancy, planning and administration

a) The Deputy Vice-Chancellor shall coordinate the implementation of this policy and shall chair the University Committees responsible for Postgraduate Studies, Research and Publications.
b) The DVC shall also be responsible for consultancies in University.
c) The following offices shall be responsible for the operation of this policy: DVC, Head of RSC, Chair of IRB, School ResearchCoordinators.
d) The Research Support Centre shall play a crucial role in the implementation of the policy.

7.3. Research and consultancy functions of the DVC

DVC shall:

a) Strengthen the capacity of the Offices of ED with resource management units in the Schools whose sole function shall be to coordinate grants management.
b) Strengthen and support the University Research and Publications Committee;
c) Facilitate the creation of research entities as the need arises at each School of the University;

d) Enforce that all Research Centres and projects be affiliated to relevant Schools and departments and are run following University rules and regulations;
e) Facilitate the formulation and regular review of guidelines for the planning and administration of research in each school of the University;
f) Ensure that there is a representative of the Research Centres on the University Research and Publications Committee, and
g) Enforce that all affiliates to the University pay an affiliation fee to the host institution which shall only be waived depending on their contribution to the University.

7.4. Funding for research

KUHeS shall:

a) Collect information and maintain an inventory of funding agencies, including contact details and specific requirements with regard to accessing their funds;
b) Disseminate to researchers in the University information relating to funding opportunities and mode of accessing the funds from within and outside the University;
c) Actively participate in dialogue with the Government for increased allocation of financial resources for research in the national budget;
d) The University shall target financial resources equivalent to at least 2% of its annual budget from both subventions and own generated income to internal research activities which shall, among other things, be used to mentor young faculty and students to build research and consultancy capacity in Departments/Centres;
e) Explore ways of creating linkages with industry to promote industry-university partnerships for direct financing of research and development; and

f) Encourage collaboration with external researchers, including the establishment of research chairs, for purposes of mobilising financial resources.

7.5. Procedure for approval, control and monitoring of research and consultancies

KUHeS shall:

a) Support the enhancement of Institutional Review Boards (IRBs) in line with guidelines from the National Commission for Science and Technology.
b) Enforce that students, staff and affiliates submit their research proposals to their IRBs for ethical clearance;
c) Develop effective mechanisms for effective implementation of research projects which have been approved by recognised IRBs
d) Motivate researchers to submit their proposals through the Research Support Centre for value addition to increase chances of getting funding.
e) Sensitize faculty to declare all their consultancies. Evidence of declaration of consultancy shall be used during promotion application as bringing resources to the Universities.
f) Monitor budget compliance and delivery of research projects, and
g) Monitor the implementation of research through IRBs.

7.6. Capacity building

KUHeS shall:

a) Organise training in research ethics for faculty members who serve on IRBs;
b) Institute training programmes to improve research and consulting capabilities and skills of staff;
c) Effectively implement coordinated postdoctoral research programmes in its various Schools;

d) Institutionalise research internship programmes in its various Schools;
e) Create and sustain research pathways for staff;
f) Create and sustain Research Centres which shall be adequately staffed to effectively achieve their mandate;
g) Maintain Professors who are active in research and publications for purposes of advancing scholarship and mentoring young faculty;
h) Build capacity of research management staff;
i) Encourage collaboration with external researchers, includingthe establishment of research chairs, to promote capacity building.

7.7. Administrative costs

7.7.1. Administrative costs of research

KUHeS shall:

a) Require that administrative costs in respect of processing and implementation of research projects are built into projectproposals. At least 10% of the total research budget shall be allocated for institutional overheads.
b) Ensure that sharing of the contribution to administrative overheads is as follows: 5% will go to the immediate School/centre or section hosting the project; 1% will go to the University RPC;1% will go to RSC; 1% will go to the University Library; 1% to ICT and 1% shall go to University Central Administration Office. The University RPC will work out a mechanism with University Administration to have a transparent accounting system.
c) Ensure that it does not subsidise any externally funded research project or consultancy. If donor projects do not provide administrative fees, they shall be charged direct costs.

d) Ensure that all equipment purchased under research projects becomes property of the University.
e) If a staff member becomes unavailable because of a consultancy s/he is involved in, the proceeds from the consultancy shall cover the costs for his/her replacement.

7.7.2. Professional fees for consultancies

KUHeS shall:

a) Require that administrative costs in respect of processing and implementation of consultancies and services are built into project proposals;
b) Ensure that sharing of the professional fees from declared consultancies shall be as follows: 80% shall go to the individual(s) implementing the consultancy and 20% shall go to the University;
c) For consultancies procured by the University (i.e. Departments, Research Centres, Schools etc.), the sharing of professional fees shall be as follows: 50% to the individual(s) carrying out the consultancy; 25% to the executing agency and 25% to the School/University;
d) Work out mechanisms to have a transparent accounting system at the university level.
e) 10% of the total amount of consultancy will be charged to all clients to meet capital and infrastructure costs and for reinvestment.

7.7.3. Liabilities

The sharing of liabilities shall be as follows for declared, undeclared and University procured consultancies:

a) Own procured declared consultancies: The consultant will shoulder 80% of the liabilities in the event of unprofessional

conduct and poor quality products by the consultant and 20% shall be borne by the institution.

b) University procured consultancies: The liabilities will be shared in a 50-50 manner between the University and the consultant.

c) Undeclared consultancies: The consultant will be 100% responsible for all liabilities.

7.7.4. Sharing of resources including information

KUHeS shall:

a) Promote, facilitate and coordinate the sharing of research projects and consultancy resources among researchers to promote efficiency. This may involve utilisation of research project facilities such as vehicles, computers, digital cameras, photocopiers, and specialised equipment, for other research projects and tasks, especially where the resources are underutilised;

b) Encourage openness and transparency in the utilisation of institutional time and facilities for consultancies, and

c) Promote, facilitate and coordinate the sharing of information and information sources both in printed and electronic forms following the data sharing guidelines.

7.7.5. Staff motivation, incentives and research culture

KUHeS shall**:**

a) Support staff to enhance their IT skills and access to information technology;

b) Encourage each staff member to present at least one research-based seminar per year;

c) Give staff an allowance of one semester for research every three years. This shall require coordinated scheduling of classes/courses and will require making a provision for more members of staff so that classes do not suffer;

d) Develop a research assessment and merit scheme to ensure that staff who excel in research are well recognised and supported;

e) If the donor permits a researcher can supplement their salary from research funds depending on the FTE spent on the project. The salary supplementation shall depend on the grade of the researcher and time spent on the project. The salary supplementation schedule outlines the amounts allocated to each grade per FTE spent.

f) Ensure that research projects are budgeting for the research management to incentivize the staff.

g) Provide a monetary incentive of US$100 per article published in a refereed non-predatory journal. The incentive for each published article shall only be claimed once by one author in that calendar year. These funds will only be used to supportthe authors' research and related activities. The introduction of such an incentive shall encourage non-performers to be more involved in research and publication and, therefore, write articles that are needed for their career growth and advancement ;

h) Introduce regular in-service research methodology and management courses for academic staff;

i) Develop strong training programmes in research at postgraduate level and induct senior undergraduate students in research skills;

j) Strengthen administrative infrastructure to ensure that staff improve their publication records;

k) Build staff capacity in consultancies, research and research management.

l) Encourage staff to spend 30% of their time on research, 50% on teaching and 20% on consultancies.

7.7.6. Dissemination of research results

KUHeS shall:

a) Fund academic journals and conference proceedings in which research results are published;
b) Encourage and reward the publication of research results locally, while ensuring that the quality of the local journals is of international standard;
c) Support the promotion and dissemination of research outputs such as books, patents and other intellectual property;
d) Ensure that Schools organise annual field days in different study areas;
e) Ensure that the University organises an annual research dissemination workshop where research results are presented and discussed. The University shall budget for the annual workshop/conference;
f) Encourage researchers to incorporate in their project proposals the dissemination of results to end-users;
g) Ensure that all research reports are peer-reviewed using set guidelines before dissemination;
h) Digitise the research results and create digital repositories in all University libraries including at departmental/centre level, and all postgraduate students' theses; and
i) Compile annual inventories of research abstracts, research reports and activities of staff members for dissemination to policymakers.

7.7.7. Ownership of results/outputs, data and equipment

KUHeS shall:

a) Stipulate to all researchers that copyright ownership of all research results/outputs from research funded by the University rests with the University;

b) Use the criteria for sharing of copyright ownership for research output as stipulated in the Intellectual Property Policy if research is financed either partially or wholly from external sources;
c) Allow copies of all raw data to be submitted to national collaborating researchers while observing restrictions on distribution to foreign collaborators;
d) Own all data from KUHeS funded research;
e) Ensure that at the close of any University or donor-funded research project, researcher/s should make available for shared use equipment and buildings which must be handed over to the researcher's department/centre/School as the property of the University (to be marked as such) and that preferential use of the equipment such as computers/vehicles should be given to the researcher as long as s/he is still a member of the University/department/centre and that this should apply whether or not the donor agency stipulates this.

8. GUIDING PRINCIPLES FOR IMPLEMENTATION

a) The Deputy Vice-Chancellor shall oversee the implementation of the Policy.
b) The Executive Deans shall be responsible for the implementation of the policy at the school level.
c) The University RPC shall develop implementation strategies that will be compatible with this policy.
d) The Deputy Vice-Chancellor shall monitor the development of guidelines for the implementation of the policy on research and consultancies.

9. MONITORING AND EVALUATION

The Office of the Deputy Vice-Chancellor shall be responsible for monitoring and evaluating the implementation of this Policy. The policy shall be reviewed every two years.

10. FINANCIAL IMPLICATIONS

For this policy to be operationalised, there is a need to set aside funds for the development of the implementation plan of the policy. Funds should also be set aside for rewarding researchers who publish in peer-reviewed journals.

Malawi

Marriage Act

Chapter 25:01

Legislation as at 31 December 2014

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Marriage Act
Contents

Malawi

Marriage Act

Chapter 25:01

Commenced on 1 February 1903

[Up to date as at 31 December 2017]

[Note: This version of the Act was revised and consolidated in the Fourth Revised Edition of the Laws of Malawi (L.R.O. 1/2015), by the Solicitor General and Secretary for Justice under the authority of the Revision of the Laws Act.]

An Act to make Provision for Marriages

1. Short title

This Act may be cited as the Marriage Act.

2. Interpretation

In this Act, unless the context otherwise requires—

"**district**" means a marriage district constituted under this Act;

"**Registrar**" means a Registrar of Marriages, and includes a Deputy Registrar.

3. Constitution of marriage districts

The Minister shall, by order published in the *Gazette*, divide Malawi into districts for the purposes of this Act and may, from time to time, by like order, alter the marriage districts either by alteration of boundaries or by union or subdivision of districts, or by the formation of new districts.

4. Appointment of Registrars and Deputy Registrars

(1) The Minister shall from time to time appoint a fit and proper person to be the Registrar for each district, and may also from time to time appoint a Deputy Registrar for any district.

(2) The Minister may revoke any appointment made under subsection (1).

5. Officers of Registrars

Every Registrar shall have an office at such place in his district as the Minister shall from time to time direct.

6. Places of worship to be licensed for celebration of marriages

The Minister may license any place of public worship to be a place for the celebration of marriages, and may at any time cancel such license; in either case he shall give notice thereof in the *Gazette*.

Preliminaries to marriage

7. Notice of marriage

Whenever, after the commencement of this Act, any persons desire to marry, one of the parties to the intended marriage shall sign and give to the Registrar of the district in which such party resides a notice in the Form A in the First Schedule.

Should the party giving the said notice desire the marriage to be celebrated in a district other than that in which he resides he shall so inform the Registrar.

8. Signature of notice by person unable to write or to understand the English language

If the person giving such notice is unable to write or is insufficiently acquainted with the English language, or both, then it shall be sufficient if he places his mark or cross thereto in the presence of some literate person who shall attest the same, which attestation shall be in the Form B in the First Schedule.

9. Registrars to supply forms of notice

Every Registrar shall supply forms of notice gratuitously to any persons applying for the same.

10. Notice to be entered in Marriage Notice Book and published

Upon receipt of such notice the Registrar shall cause the same to be entered in a book to be called the "Marriage Notice Book", which may be inspected during office hours without fee. He shall also publish such notice by causing a copy of the same to be affixed on the outer door of his office, and to be kept exposed there until he grants his certificate as hereinafter mentioned, or until three months shall have elapsed.

If the marriage is intended to be celebrated in another district he shall forward a copy of the said notice to the Registrar of such other district who shall immediately on receipt thereof cause it to be affixed to the outer door of his office.

11. Registrar's certificate

The Registrar of the district in which the person giving the said notice of marriage resides, at any time after the expiration of twenty-one days and before the expiration of three months from the date of the notice and upon payment of the prescribed fee, shall thereupon issue his certificate in the Form C in the First Schedule:

Provided always that he shall not issue such certificate until he has been satisfied by affidavit—

(a) that one of the parties has been resident within his district for at least fifteen days preceding the granting of the certificate; and

(b) that eacbh of the parties to the intended marriage (not being a widower or widow) is 21 years old, or that if he or she is under that age, the consent hereinafter made requisite has been obtained in writing and is annexed to such affidavit; and

(c) that there is not any impediment of kindred or affinity, or any other lawful hindrance to the marriage; and

(d) that neither of the parties to the intended marriage is married by customary law to any person other than the person with whom such marriage is proposed to be contracted.

Such affidavit may be sworn before the Registrar, or before a magistrate.

Explanations to be given

The Registrar or magistrate taking such affidavit shall explain to the person making the same what are the prohibited degrees of kindred and affinity and the penalties which may be incurred under this Act.

12. Facilities for marriages between Commonwealth citizens resident in Malawi and Commonwealth citizens resident in the United Kingdom

(1) Where a marriage is intended to be solemnized or contracted in Malawi between a Commonwealth citizen resident in Malawi and a Commonwealth citizen resident in the United Kingdom, a certificate for marriage issued by a Superintendent Registrar in England and a certificate for marriage issued by a Registrar, and a certificate of proclamation of banns in Scotland, and a certificate for marriage issued by a Registrar in Ireland shall have the same effect as a certificate for marriage issued under section 11.

(2) Where a marriage is intended to be solemnized or contracted in England, Scotland or Ireland between a Commonwealth citizen resident in England, Scotland or Ireland and a Commonwealth citizen resident in Malawi the Registrar may issue the certificate set forth in section 11 in the like manner as if the marriage was to be solemnized or contracted under circumstances requiring the issue of such a certificate, and as if both such Commonwealth citizens were resident in Malawi.

13. Marriage to take place within three months after date of notice

If the marriage shall not take place within three months after the date of the notice, the notice and all proceedings consequent thereupon shall be void, and fresh notice must be given before the parties can lawfully marry.

14. Power of Minister to grant licence to marry

The Minister, upon proof being made to him by affidavit that there is no lawful impediment to the proposed marriage, and that the necessary consent (if any) to such marriage has been obtained, may, in his discretion, dispense with the giving of notice, and with the issue of the certificate of the Registrar, and may grant a special licence, which shall be according to the Form D in the First Schedule authorizing the celebration of a marriage between the parties named in such licence by a Registrar, or by a recognized minister of some religious denomination or body.

15. Issue of certificate may be forbidden

Any person whose consent to a marriage is hereby required, or who may know of any just cause why the marriage should not take place, may enter a caveat against the issue of the Registrar's certificate, by writing at any time before the issue thereof the word "Forbidden;", opposite to the entry of the notice in the Marriage Notice Book, and appending thereto his name and place of abode, and the grounds upon or by reason of which he claims to forbid the issue of the certificate, and the Registrar shall not issue his certificate until such caveat shall be removed as hereinafter is provided.

16. Caveat to be referred to Court

Whenever a caveat is entered against the issue of a certificate, the Registrar shall refer the matter to the High Court, and that Court shall thereupon summon the parties to the intended marriage, and the person by whom the caveat is entered, and shall require, the person by whom the caveat is entered to show cause why the Registrar should not issue his certificate, and shall hear and determine the case in a summary way, and the decision of the High Court shall be final.

17. Removal of caveat

If the High Court decides that the certificate ought to be issued, the judge shall remove the caveat by cancelling the word "Forbidden" in the Marriage Notice Book in ink, and writing in such Marriage Notice Book, immediately below such entry and cancellation, the words "Cancelled by order of the High Court;", and signing his name thereto. The Registrar shall then issue his certificate and the marriage may proceed as if the caveat had not been entered, but the time that has elapsed between the entering and the removal of the caveat shall not be computed in the period of three months specified in section 11.

18. Compensation and costs

The High Court may award compensation and costs to the party injured, if it appears that a caveat was entered on insufficient grounds.

Consent to marriage in certain cases necessary

19. Consent to marriage of minors

If either party to an intended marriage, not being a widower, widow or divorced person, is not over eighteen years of age, the written consent of the father or mother, or if both be dead or of unsound mind or absent from Malawi, of the guardian of such party, must be produced annexed to such affidavit as aforesaid, before a licence can be granted or a certificate issued.

[29 of 1997]

20. Signature of consent by person unable to write or to understand English language

(1) If the person required to sign such consent is unable to write, or is insufficiently acquainted with the English language, or both, then he shall sign such consent by placing his mark or cross thereto in the presence of one of the following persons—

Any judge, District Commissioner, magistrate, Registrar of the High Court, Registrar, medical officer or minister of religion.

(2) Such signature shall be attested by such person in the Form B in the First Schedule.

21. Consent where no parent or guardian capable of consenting

If there be no parent or guardian of such party residing in Malawi and capable of consenting to the marriage, then any of the following persons may consent to such marriage in writing, upon being satisfied after due inquiry that the marriage is a proper one; that is to say, the Minister, a Judge of the High Court, a District Commissioner, and such consent shall be as effectual as if the father or mother had consented.

Celebration of marriage

22. Marriage in licensed place of worship by recognized minister

Between hours of 8 a.m. and 6 p.m.

Witnesses

Marriages may be celebrated in any licensed place of worship by any recognized minister of the Church denomination or body to which such place of worship belongs, and according to the rites or usages of marriage observed in such Church, denomination or body, provided that the marriage be celebrated with

open doors between the hours of 8 o'clock in the forenoon and 6 o'clock in the afternoon, and in the presence of two or more witnesses besides the officiating minister.

23. Minister not to celebrate marriage if impediment nor without license, etc.

A minister shall not celebrate any marriage if he knows of any just impediment to such marriage, nor until the parties deliver to him the Registrar's certificate or the Minister's licence.

24. Where minister may celebrate marriage

A minister shall not celebrate any marriage except in a building which has been duly licensed by the Minister, or in such place as a special licence may direct.

25. Registrars, etc., to be provided with books of certificates

The Minister shall cause to be printed and delivered to the several Registrars, and to the recognized ministers of licensed places of worship, books of marriage certificates in duplicate and with counterfoils in the Form E in the First Schedule. Such books shall be kept by the several Registrars and the recognized ministers for the time being of such places of worship, under lock and key, and be in custody of such Registrars and ministers respectively.

26. Entries to be made in marriage certificate

Immediately after the celebration of any marriage by a minister, the officiating minister shall fill up in duplicate a marriage certificate with the particulars required by the said Form E, and state also and enter in the counterfoil the number of the certificate, the date of the marriage, names of the parties, and the names of the witnesses.

27. Signature of certificate

Duplicate certificate to be sent to Registrar

The certificate shall then be signed in duplicate by the officiating minister, by the parties and by two or more witnesses to the marriage. The minister having also signed his name to the counterfoil, he shall sever the duplicate certificate therefrom, and he shall deliver one certificate to the parties, and shall within seven days thereafter transmit the other to the Registrar for the district in which the marriage takes place, who shall file the same in his office.

28. Marriage in a Registrar's office

After the issue of a certificate under section 11 or 17, or of a licence under section 14, the parties may, if they think fit, contract a marriage before a Registrar, in the presence of two witnesses in his office, with open doors, between the hours of 10 o'clock in the forenoon and 4 o'clock in the afternoon, and in the following manner—

Form to be observed

The Registrar, after production to him of the certificate or licence, shall, either directly or through an interpreter, address the parties thus—

"Do I understand that you A B, and you C D, come here for the purpose of becoming man and wife?"

If the parties answer in the affirmative, he shall proceed thus—

"Know ye that by the public taking of each other as man and wife in my presence, and in the presence of the persons now here, and by the subsequent attestation thereof by signing your names to that effect you become legally married to each other, although no other rite of a civil or religious nature shall take place,

and that this marriage cannot be dissolved during your lifetime, except by a valid judgment of divorce; and if either of you before the death of the other shall contract another marriage while this remains undissolved, you will be thereby guilty of bigamy, and liable to punishment for that offence."

Each of the parties shall then say to the other, "I call upon all persons here present to witness that I, A B, do take thee, C D, to be my lawful wife (or husband)".

29. Marriage certificate to be signed

The Registrar shall then fill up, and he and the parties and witnesses shall sign the certificate of the marriage in duplicate, and the Registrar shall then fill up and sign the counterfoil as hereinbefore prescribed in the case of a marriage by a minister, and shall deliver one certificate to the parties and shall file the other in his office.

30. Marriage under special licence

Whenever a special licence authorizes the celebration of marriage at a place other than a licensed place of worship, or the office of a Registrar, the Registrar of the district in which such marriage is intended to take place, upon the production of such licence, shall deliver to the person producing the same, a blank certificate of marriage in duplicate, and the minister or Registrar celebrating such marriage shall fill up such certificate, and observe strictly all the formalities hereinbefore prescribed as to marriages in a licensed place of worship, or Registrar's office, as the case may be.

Registry and evidence of marriages

31. Marriage certificate to be registered

(1) The Registrar in each district shall forthwith register in a book to be kept in his office for such purpose, and to be called "The Marriage Register Book", every certificate of marriage, which shall be filed in his office, according to the Form F in the First Schedule; and every such entry shall be made in the order of date from the beginning to the end of the book, and every entry so made shall be dated on the day on which it is so entered, and shall be signed by the Registrar, and such book shall be indexed in such manner as is best suited for easy reference thereto.

(2) The Registrar shall at all reasonable times allow searches to be made in the Marriage Register Book, and shall give certified copies therefom upon payment of the prescribed fee.

(3) Within ten days after the last day of each month, every Registrar shall send to the Registrar General a certified copy of all entries made by him during the preceding month in the Marriage Register Book in his district, and the Registrar General shall file the same in his office.

32. Correction of clerical errors in marriage certificates

Any Registrar, when authorized by the Registrar General, may correct any clerical error in any certificate of marriage filed in his office, upon production to him of the certificate delivered to the parties, and shall authenticate every such correction by his signature and the date of such correction.

33. Evidence of marriage

Every certificate of marriage which shall have been filed in the office of the Registrar of any district, or a copy thereof purporting to be signed and certified as a true copy by the Registrar of such district for the time being, and every entry in a Marriage Register Book or copy thereof certified as aforesaid, shall be admissible as evidence of the marriage to which it relates, in any Court of Justice or before any person now or hereafter having by law or consent of parties authority to hear, receive, and examine evidence.

Invalid marriages

34. Marriage with deceased wife's sister or niece lawful

(1) A marriage may be lawfully celebrated under this Act between a man and the sister or niece of his deceased wife, but, save as aforesaid, no marriage in Malawi shall be valid, which, if celebrated in England, would be null and void on the ground of kindred or affinity, or where either of the parties thereto at the time of the celebration of such marriage is married by customary law to any person other than the person with whom such marriage is had.

(2) Certain marriages null and void

A marriage shall be null and void if both parties knowingly and wilfully acquiesce in its celebration (a) in any place other than the office of a Registrar or a licensed place of worship (except where authorized by a special licence); or (b) under a false name or names; or (c) without the Registrar's certificate of notice or a special licence duly issued; or (d) by a person not being a recognized minister of some religious denomination or body, or a Registrar of Marriages.

(3) But no marriage shall after celebration, be deemed invalid by reason that any provision of this Act other than the foregoing has not been complied with.

35. Marriages under this Act valid

All marriages celebrated under this Act shall be good and valid in law to all intents and purposes.

36. Marriages under customary law

Any person who is married under this Act, or whose marriage is declared by this Act to be valid, shall be incapable, during the continuance of such marriage, of contracting a valid marriage under any customary law, but save as aforesaid, nothing in this Act contained shall affect the validity of any marriage contracted under or in accordance with any customary law, or in any manner apply to marriages so contracted.

Marriages already celebrated

37. Certain existing marriages validated

Every marriage celebrated in Malawi before the commencement of this Act by any minister of any religious denomination or body, according to the rites in use by such religious denomination or body, shall be, and shall be deemed to have been from the time of the celebration thereof, a legal and valid marriage:

Provided that nothing herein contained shall legalize any marriage which has before the commencement of this Act been declared invalid by any competent Court, nor any marriage, either party to which had at the time of its celebration a lawful wife or husband living, nor any marriage which was void by reason of kindred or affinity, or fraud, or incapacity to contract marriage; nor any marriage otherwise invalid, either party to which shall before the commencement of this Act, and in the lifetime of the other party thereto, have intermarried with any other person.

38. Existing registers of marriages to be transmitted to Registrar General

Every minister of religion or other person in Malawi who has in his custody or control any register, record, or paper purporting to be such, of marriages heretofore celebrated in Malawi shall deliver or

transmit to the Registrar General the said register or official record, or a copy thereof, omitting, if desired, any matter of a private nature, with a certificate appended thereto in the following form—

"I, A B, of *[here describe place of abode and position]*, do certify that the annexed written pages contain the true record (excepting matters of a confidential nature) of the marriages heretofore celebrated in [here *name church*].

Dated the_____day of_____20 _____

[*Signed "A B".*]"

39. Certain expenses to be defrayed from moneys provided by Parliament

The Minister may defray out of moneys provided by Parliament all proper expenses connected with the transmission or delivery of the said registers, or which may otherwise become necessary to be incurred in carrying out this Act.

Fees

40. Fees

(1) The fees specified in the Second Schedule shall be paid to Registrars for the several matters to which they are applicable, and shall be paid by them into the Consolidated Fund.

[17 of 1997]

(2) The Minister may, by Order published in the *Gazette*, amend the Second Schedule.

41. Power to remit fees on ground of poverty

The Minister may, when he is satisfied of the poverty of the parties, reduce the amount of the said fees, or remit them altogether; and, if they have been paid into the Consolidated Fund, order their refund.

42. Marriage may receive customary fees

This Act shall not preclude a minister from receiving the fees ordinarily paid to a minister of his denomination for the celebration of marriage.

Offences and penalties

43. Bigamy

Whoever is guilty of bigamy shall be liable to imprisonment for five years.

44. Marriage with person previously married

Whoever, being unmarried, goes through the ceremony of marriage with a person whom he or she knows to be married to another person, shall be liable to imprisonment for five years.

45. Making false declarations, etc., for marriage

Whoever in any declaration, certificate, licence, document, or statement by law to be made or issued for the purposes of a marriage, declares, enters, certifies, or states any material matter which is false, shall, if he does so without having taken reasonable means to ascertain the truth or falsity of such matter, be

liable to imprisonment for one year, or shall, if he does so knowing that such matter is false, be liable to imprisonment for five years.

46. False presence of impediment to marriage

Whoever endeavours to prevent a marriage by pretence that his consent thereto is required by law, or that any person whose consent is so required does not consent, or that there is any legal impediment to the performing of such marriage, shall, if he does so knowing that such pretence is false or without having reason to believe that it is true, be liable to imprisonment for two years.

47. Registrar unlawfully performing ceremony

Any Registrar who performs the ceremony of marriage knowing that any of the matters required by law for the validity of such marriage has not happened or been performed, so that the marriage is void or unlawful on any grounds shall be liable upon conviction thereof before the High Court to a fine of K200 and to imprisonment for five years.

48. Minister unlawfully performing ceremony

Any minister who—

(a) celebrates a marriage without the certificate of the Registrar or a special licence or elsewhere than in a licensed place of public worship or the place named in the licence; or

(b) wilfully celebrates a marriage contrary to any provision hereof or knowing that any provision of this Act has not been complied with,

shall be liable upon conviction thereof before the High Court to a fine of K200 and to imprisonment for five years.

49. Unlawful performance of ceremony by person not legally competent

Any person who shall knowingly and wilfully celebrate or pretend to celebrate any marriage not being legally competent so to do, shall, upon conviction thereof before the High Court, be liable to a fine of K200 and to imprisonment for five years.

50. Wilful neglect of duty to fill up or transmit certificate of marriage

Whoever, being under a duty to fill up the certificate of a marriage celebrated by him, or the counterfoil thereof, or to transmit the same to the Registrar, wilfully fails to perform such duty, shall be liable to imprisonment for two years.

51. Personation in marriage

Whoever personates any other person in marriage, or marries under a false name or description, with intent to deceive the other party to the marriage, shall be liable to imprisonment for five years.

52. Fictitious marriage

Whoever goes through the ceremony of marriage, or any ceremony which he or she represents to be a ceremony of marriage, knowing that the marriage is void on any ground, and that the other person believes it to be valid, shall be liable to imprisonment for five years.

53. Contracting marriage under this Act when already married by customary law

Whoever contracts a marriage under this Act, or any modification or re-enactment thereof, being at the time married in accordance with customary law to any person other than the person with whom such marriage is contracted, shall be liable to imprisonment for five years.

54. Contracting marriage by customary law when already married under this Act

Whoever, having contracted marriage under this Act, or any modification or re-enactment thereof, during the continuance of such marriage contracts a marriage in accordance with customary law, shall be liable to imprisonment for five years.

55. Reservation of jurisdiction

Jurisdiction under this Act shall be reserved to the High Court.

Forms

56. Forms in Schedule may be used

(1) The forms contained in the First Schedule may be used in the cases to which they are applicable, with such alterations as may be necessary.

(2) Validation of certain marriages

In order to remove all doubts as to the validity of marriages celebrated under the Marriage Act by assistant district commissioners, all such marriages are hereby declared to be as from their celebration as valid as if in the case of each such marriage the assistant district commissioner was a Registrar of Marriages and empowered to issue the certificate required in connexion with the marriage by the Marriage Act and to celebrate the marriage, and as if his office was a place in which the marriage could legally be celebrated.

[Cap 25:01]

(3) Evidence of such marriages

The certificates of the marriages referred to in section 2 and entries relating to the same in any marriage register book or copies of such certificates or entries shall be received in all courts as evidence of such marriages in the same manner as similar certificates, entries, or copies in the case of marriages duly celebrated under the Marriage Act are by law receivable in evidence.

[Cap 25:01]

First Schedule

Form A

Notice of marriage

To the Registrar of Marriages for the_____District of Malawi.

I HEREBY give you notice that a marriage is intended to be had within three months from the date hereof between me, the undersigned, and the other party herein named at_____.

Name	Condition	Occupation, Rank, or Profession	Age	Dwelling or Place of Abode	Consent, if any, and by whom given
Bridegroom	Bachelor or Widow	Farmer, etc. (as case may be)	23	Zomba	_
Bride	Spinster or Widower	Laundress, etc. (as case may be)	18	Blantyre	Father

Witness my hand this_____day of_____, 19_____

_____

Signature

Form B (Sections 8 and 20)

Form of attestation

Signed by the said_____, at_____, on the_____day of_____, 19_____, this notice having been first read over to him [*her*] [*or*, *read over and truly interpreted to him her in the language*] by_____He [*she*] seemed to understand the same and made his [*her*] mark thereto in my presence.

_____

Signed

Form C (Section 11)

Registrar's certificate

I,_____Registrar of Marriages in the_____District in Malawi, do hereby certify that on the_____day of_____, notice was duly entered in the Marriage Notice Book of this district of the marriage intended between the parties herein named and described, such notice being delivered under the hand of_____one of the parties, that is to say—

Name	Condition	Occupation, Rank, or Profession	Age	Consent	Dwelling	Length of residence
A.B.	Bachelor	Cultivator (as case may be)	19 (as case may be)	E.F, the father (as case may be)	Blantyre (as case may be)	
C.D.	Spinster	Laundress (as case may be)	16 (as case may be)	G.H., the mother (as case may be)	Zomba (as case may be)	

Date of notice entered_____day of_____19_____

Place of intended marriage as set out in the Notice of Marriage.

Date of certificate given,_____day of_____, 19_____

No caveat has been entered against the issue of this certificate: or

A caveat was entered against the issue of this certificate on the_____day of_____,19_____, but it has been cancelled.

Witness my hand, this day of_____, 19_____

_____

Signed, *A.B.*

*Registrar of Marriages*_____*District*

NOTE—This certificate will be void unless the marriage is solemnized on or before the_____day of_____, 19_____

A.B.

Form D (Section 14)

Special licence

Whereas A.B. and C.D. desire to intermarry, and sufficient cause has been shown to me why the preliminaries required by the Marriage Act should be dispensed with:

Now, therefore, in pursuance of the said Act, I do dispense with the giving of notice and the issue of the certificate thereby prescribed, and do hereby authorize any Registrar of Marriages, or recognized Minister of some religious denomination or body to celebrate marriage between the said *A.B.* and *C.D.* at [place of celebration}, within_____days from the date hereof.

Such marriage may be celebrated by a Registrar of Marriages between the hours of 10 o'clock in the forenoon and 4 o'clock in the afternoon, or by such recognized Minister between the hours of 8 o'clock in the forenoon and 6 o'clock in the afternoon.

Given under my hand this_____day of_____, 19_____

*Signed*_____, *Minister*

Form E (Sections 25 and 26)

ss. 25 and 26 FORM E

MALAWI

The Marriage Act
Section 26
Marriages celebrated in the ..... at ..... in Malawi

CERTIFICATE OF MARRIAGE

No.

Date

19

	No.	When married	Names and surnames	Full age or minor	Condition	Rank or profession	Residence at time of Marriage	Father's name and surname	Occupation, rank, or profession of father
Name of husband									
Name of wife ..									
Witnesses									

Married at ..... by (*or before*) me
A.B.
Minister (*or Registrar*)
(*as the case may be*)

The marriage was celebrated between us *A.B* *C.D.* In the presence of us *E.F.* *G.H.*
Witnesses

MALAWI

The Marriage Act
Section 26
Marriages celebrated in the ..... at ..... in Malawi

CERTIFICATE OF MARRIAGE

No.

Date

19

	No.	When married	Names and surnames	Full age of minor	Condition	Rank or profession	Residence at time of Marriage	Father's name and surname	Occupation, rank, or profession of father
Name of husband									
Name of wife									
Witnesses									

Married at ..... by (*or before*) me
A.B.
Minister (*or Registrar*)
(*as the case may be*)

The marriage was celebrated between us *A.B* *C.D.* In the presence of us *E.F.* *G.H.*
Witnesses

Form F (Section 31)

When married	Names and surnames	Whether full age or minor	condition	Occupation	Residence	Father's name and occupation

Entered this_____day of_____,20 at the District

Registry of Marriages at_____

_____

Signed A.B., Registrar

Second Schedule

	K	t
Filing every notice and entering the same	250	00
Issuing each certificate or certified copy thereof or any certified copy of any extract therefrom	250	00
On each marriage in the Registrar's office	250	00
On issuance of a special licence	1,000	00

[5 of 1976]

[17 of 1997]

[G.N. 28/2005]

The Malawi Gazette supplement, dated 5th December, 2003, containing an Act (No. 4C)

MALAWI GOVERNMENT

(Published 5th December, 2003)

Act
No. 16 of 2003
I assent

BAKILI MULUZI
PRESIDENT

7th November, 2003

ARRANGEMENT OF SECTIONS

An Act to provide for the advancement of science and technology; to establish the National Commission for science and Technology and to provide for matters connected therewith and incidental thereto

ENACTED by the Parliament of Malawi as follows –

Short title and commencement

1. This Act may be cited as the science and Technology Act, 2003 and shall come into operation on such date as the Minister shall appoint by notice published in the Gazette.

Interpretation

2. In this act, unless the context otherwise requires -

"appeals committee" means an appeals committee appointed under section 44;

"Awards committee" means the Scientific Awards Committee established under section 34;

"Chairman" means Chairman of the commission;

"Commission" means the national commission for Science and Technology established under section 5;

"committee" means a committee of the Commission established under section 11 and includes the Scientific Awards Committee;

"Fund" means the Science and Technology Fund established under section 24;

"Member" means a member of the Commission;

"organism" means any biological entity, whether microscopic or not, capable of replication;

"Vice-Chairman" means the person elected as the Vice Chairman of the Commission under Section 6 (3)

PART 11 – ADVANCEMENT OF SCIENCE AND TECHNOLOGY IN MALAWI

Policy and Statement to rank paramount

3. Every public officer and any authority in Malawi exercising or performing powers, duties or functions in connection with or concerning the commitment of the Government in advancing science and technology in Malawi as declared in the National Science and Technology Policy (in this Act otherwise referred to as the "Policy") and in the statement of National Priorities in Science and Technology (in this Act otherwise referred to as the "Statement") shall, in the exercise of his powers or the performance of his duties or functions, consider and treat the Policy and the Statement as ranking paramount in the business of the Government and shall further consider it to be his paramount duty to act with all due diligence anddispatch in taking such action as is required or necessary to give effect to thePolicy and Statement.

Publication and revision of the Policy and the Statement

4. –(1) The Policy and the Statement shall be published respectively by the Minister and the Commission for general distribution and, in the case of the Statement, copies of its publication shall be made freely available and without charge in and outside Malawi to bodies connected with science and technology

(2) Following any change in the Policy or the Statement, or following any legislative or statutory action or other action having similar effect taken by the Government in pursuance or implementation of thePolicy or the Statement, the Minister shall publish in the Gazette the changes.

PART III – ESTABLISHMENT OF THE NATIONAL COMMISSION FOR SCIENCE AND TECHNOLOGY

Establishment of the National Commission for Science and Technology

5. There is hereby established a commission to be known as the National Commission for Science and Technology (in this Act otherwise referred to as the "Commission").

6. –(1) The Commission shall consist of –

Composition of the Commission

(a) the Chairman who shall be appointed by the Minister;
(b) nine persons, who shall be appointed by the Minister, atleast –
(i) six of whom shall be appointed from the industry academic, research and development institutions;
(ii) one of whom shall be appointed from the civil society and
(iii) one of whom shall be a gender expert; and

(c) the following *ex officio* members -

(i) the Secretary for Agriculture and Irrigation or his representative;
(ii) the Secretary for Education, Science and Technology or his representative;
(iii) the Secretary for Health and Population or his representative;
(iv) the Secretary for natural resources and Environmental Affairs or his representative;
(v) the Secretary for the National Economic Council or his representative.

(2)-(1) A representative of an *ex officio* member referred to in subsection (1) shall be designated by, or on behalf of, the ex officio member by a notice in writing to the Commission to attend the meetings of the Commission, and upon such designation such representative shall not attend to the business of the Commission by representation.

(3) The Vice-Chairman shall be elected by the Commission from among its members:

Provided that no member appointed under paragraph © of subsection (1) shall be elected as Vice-Chairman.

(4) The names of all members as first constituted and every change of membership shall be published in the Gazette.

(5) The persons to be appointed under subsection (1) *(b*) shall be chosen for their ability and experience in scientific disciplines, technology-related activities or their professional qualifications or their suitability otherwise for appointment

(6) A member shall not be in the employ of the Commission nor serve on a full time basis.

(7) The Director General shall be the secretary of the Commission.

Tenure of office and vacancies

7. –(1) A member, other than an *ex officio* member, shall hold office for a period of three years and shall be eligible for re-appointment for another three year term but the office of that member shall become vacant.

(a) if he resigns by giving one month notice in writing to the Commission;
(b) upon his death;
(c) if he is absent without valid excuse from three consecutive meetings of the Commission of which he has had notice;
(d) if he becomes an undischarged bankrupt;
(e) if he becomes of unsound mind; and
(f) if he participates, directly or indirectly, in an activity which is in contravention of this Act.

(2) On vacation of office by a member, the vacancy shall be filled by a person appointed in accordance with the relevant provisions of section 6 (1) (b) under which the former member was appointed:

Provided that if the remaining period is less than six months, the Minister may decide not to have the vacancy filled until the expiry of the period.

Allowances and expenses of members

8.-(1) Members or members of a committee of the Commission shall be paid such an allowance as the Minister shall determine.

(2) The Commission may make provision for reimbursement of any reasonable expense incurred by a member or a member of a committee of the Commission in connection with the business of the Commission or the committee.

Policy directions

9. The Commission may, where necessary, seek the general directions of the Minister on the manner in which it is to carry out its duties under this Act.

Proceedings of the commission

10. (1) Subject to the other provisions of this Act, the Commission may regulate its own procedure.

(2) The Commission shall meet for the transaction of business at least once every three months at such places and at such times as theChairman may determine.

(3) An extraordinary meeting of the Commission may be called by the Chairman upon written notice of not less than seven days received from any member and shall be called if at least four members so request in writing;

Provided that if the urgency of any particular matter does not permit the giving of such notice, an extraordinary meeting may be called upon giving a shorter notice.

(4) Half of the members shall form the quorum of any meeting of the Commission.

(5) There shall preside at any meeting of the Commission
(a) the Chairman
(b) in the absence of the Chairman, the Vice-Chairman; and
(c) in the absence of the Chairman and the Vice-Chairman, such member as the members present and forming a quorum may elect from among their number for the purpose of the meeting

(6) The decision of the commission on any matter before any meeting shall be that of the majority of the members present and voting at the meeting and, in the event of an equality of votes, the person presiding shall have a casting vote.

(7) No member shall attend to the business of his office by representation and where a member is unable to attend any meeting of the commission, he may request that his apologies for failure to attend be recorded.

Committees of the Commission

11. (1) In addition to the Awards Committee, the Commission may, for the purpose of performing its functions under this Act, establish other committees and delegate to any such committee such of its functionsas it considers necessary.

(2) The commission may appoint as members of a committee established under subsection (1) persons who are or are not members of the Commission and such persons shall hold office for such period as the Commission may determine.

(3) Subject to any specific or general directions of the Commission, a committee may regulate its own procedure.

Minutes of meetings

12. The Commission shall cause minutes to be kept of the proceedings of every meeting of the Commission and of every meeting of a committee of the Commission.

Disclosure of interest by members

13. (1) If any member is present at a meeting of the Commission or of any committee at which any matter which is the subject of consideration is a matter in which that person or his immediate family member or his professional or business partner is directly or indirectly in a private or professional capacity, he shall, as soon as is practicable after the commencement of the meeting, disclose such interest and, unless the Commission or the Committee otherwise directs, that person shall not take part in any consideration or discussion of, or vote on, any question touching on such matter.

(2) A disclosure of interest shall be recorded in the minutes of the meeting at which it is made.

Protection of members

14. No action, suit or other proceedings shall be brought or instituted personally against any member or a member of a committee in respect of any act done in good faith in the course of carrying out the provisions of this Act.

Invited persons

15. (1) The Commission may in its discretion at any time and for any period invite any person, and the Minister may in like manner nominate an officer in the public service, to attend any meeting of the Commission or of any of its committees and take part in the deliberations of the meeting, but such person or officer shall not be entitled to vote at the meeting.

(2) Section 14 shall apply, *mutatis mutandiis*, to a person or an officer attending a meeting of the Commission or committee pursuant to subsection (1).

Oath of secrecy

16. Every –

(a) member;
(b) member of a committee
(c) employee of the Commission; or
(d) consultant in the service of the Commission,

shall upon assumption of his office, take such oath of secrecy as may be approved by the Commission or as may otherwise be prescribed under this Act.

Prohibition of disclosure of information by unauthorized persons

17. (1) No person shall, without the consent in writing given by or on behalf of the Commission, publish or disclose to any person, otherwise than in the course of his duties, contents of any document, communication or information which relates to, and which has come to his knowledge in the course of, duties under this Act.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine of K1000,000 and to imprisonment for three years.

PART IV – FUNCTIONS AND POWERE OF THE COMMISSION

Functions of the Commission

18. (1) The functions of the Commission shall be to advise the Government and other stakeholders on all science and technology matters in order to achieve a science and technology-led development

(2) Without prejudice to the generality of subsection (1), the Commission shall –

(a) Create science and technology awareness at the political and other levels of society and thereby obtain their commitment towards the value of science and technology as integral parts of national development strategies;

(b) establish mechanisms to solicit support from the executive and legislative branches of Government, policy-makers and the private sector in order to promote the formulation and revision of policies, strategies, laws and regulations for science and technology and the monitoring of the implementation of science and technology development activities;

(c) source funding from within and outside Malawi to finance the national research and development effort and allocate the funds to research institutions based on set priorities;

(d) chart out national direction and establish national priorities in science and technology development in relation to socio-economic development needs;

(e) appraise, review, monitor and evaluate priority research and development programmes, plans and projects of research and development institutions and undertake independently or in collaboration with any appropriate person, body or institution surveys and research investigations considered necessary;

(f) promote and advocate for the development of science and technology human resources by building capacity in science and technology education and training programmes and providing assistance in the development of appropriate science and technology curricula of the various levels of the education systems;

(g) create a conducive working environment for science and technology personnel in order to retain them and attract those outside Malawi to return through, *inter alia*, providing appropriate science and technology infrastructures and facilities;

(h) encourage the use of local expertise in science and technology matters through use of a set of professional standards, ethics and guidelines and support professional science and technology associations;

(i) encourage the establishment and promote the coordination of research institutions that undertake research and development activities which promote national socio-economic development and other specialized research and development activities in a manner that enhances corporation and collaboration among national and international science and technology personnel and institutions;

(j) organise national science and technology fairs and open days so as to promote national science and technology awareness and culture, documentation, consolidation and dissemination of relevant science and technology information and generally promote the role of information technology;

(k) promote the transfer of technology through conventional methods including information exchange and training, purchase and licence agreements and joint venture agreements with foreign partners in which research and development is given prominent consideration and, in support of this, establish and maintain national capacity for negotiating, monitoring and regulating technology for negotiating, monitoring and regulating technology transfer agreements;

(l) promote and encourage the patenting and commercialisation ofresearch results to farmers, industrialists and entrepreneurs as end-users in a manner that enhances economic diversification, competitiveness and employment generation;

(m) promote sustainable socio-economic development through the general and application of environmental friendly technologies so as to protect and conserve natural resources;

(n) develop and synthesize science and technology indicators covering such aspects as research and development statistics, bibliometrics, technology balance of payments statistics, patent data, human resources and innovation data using internationally accepted procedures and standards;

(o) conduct an inquiry into any matter being investigated by the Commission;

(p) sponsor such national and international scientific conferences as it may consider appropriate;

(q) promote and maintain cooperation in science and technology with similar bodies in other countries and with international bodies connected with science and technology;

(r) prepare, every two years, a state of Science and Technology Report for presentation to the National Assembly; and

(s) perform any other function or activity related to science and technology.

Powers of the Commission

19. Subject to the directions of the Minister, whether general or special, the Commission shall have the power to do all such things as are incidental or conducive to the carrying out of its functions under this Act.

PART V – THE SECRETARIAT OF THE COMMISSION

Secretariat of the Commission

20. The Secretariat of the Commission shall consist of the Director General and such other suitably qualified officers as may be required for the proper administration of this Act.

Director General of the Commission

21. (1) The Minister, on the recommendation of the Commission, shall appoint, on such terms and conditions as he may determine, a Director General of the Commission who shall be the chief executive of the commission, and shall in addition perform such duties as the Commission shall assign to his office and ensure the effective administration and implementation of this Act.

(2) The Director General shall be appointed from within or without the civil service.

(3) Without derogation from the generality of the responsibilities and duties of the Director General conferred under subsection (1), the Director General shall be responsible for the day to day administration of the Commission

(4) The Director General, or such other officer of the Commission as the Director General may designate, shall attend meetings of the Commission and of any committee of the Commission and may address such meetings, but shall not vote on any matter:

Provided that the person presiding at any meeting may, for good cause, require the Director General or such other officer to withdraw from such meeting.

(5) Section 13 shall apply, *mutates mutandis*, to the Director General and such other officer referred to in this section.

Disclosure of interest by employee etc

22. (1) An employee of the Commission or a consultant to the Commission who, or whose immediate family member is directly or indirectly interested in a private or professional or official capacity in any matter being considered by the Commission, shall disclose such interest.

(2) A disclosure of interest made under this section shall be made to the Director General who shall take such decision as he considers appropriate in each case and submit a report to the Commission.

Functions of the Secretariat of the Commission

23. (1) The Secretariat of the Commission shall be responsible for implementing the programmes of the Commission.

(2) Without prejudice to the generality of subsection (1), the Secretariat of the commission shall-

(a) provide technical and administrative backup services to the meetings and other functions of the Commission;

(b) prepare and present to the Commission science and technology programmes for approval;

(c) manage and coordinate science and technology funds in accordance with general and specific directions of the Commission;

(d) maintain liaison with national and international agencies that provide financial and technical support for the implementation of the science and technology policy;

(e) coordinate all science and technology related issues in the country;

(f) prepare annual progress reports for consideration by the Commission; and

(g) perform such other functions as may be assigned to it by the Commission.

PART VI – SCIENCE AND TECHNOLOGY FUND

Establishment of the fund

24. (1) There is hereby established a fund to be known as the Science and Technology fund (in this Act otherwise referred to as the "Fund").

(2) The Fund shall consist of-

(a) such sums as shall be appropriated by Parliament for the purposes of the Fund;

(b) the levy imposed under section 32;

(c) advances made to the Fund under section 26;

(d) such sums or other assets as may be received for the purposes of the Fund by way of voluntary contributions or donations; and

(e) such sums as are paid as a result of services provided by the Commission.

The fund to vest in the Minister Cap.37:01

25. The fund shall be vested in the Minister and, subject to this Act, and the Finance and Audit Act, shall be administered in accordance with his directions

Advances to the Fund

26. If in any financial year the income of the fund together with any surplus income brought forward from a previous year is insufficient to meet the actual or estimated liabilities of the Fund, the Minister responsible for finance may make advances to the Fund in order to meet the deficiencyor any part thereof and such advances shall be made on such terms and conditions, whether as to repayment or otherwise, as the minister responsible for finance may determine.

Objects of the Fund

27. The objects of which the Fund is established shall be the advancement of science and technology in Malawi.

Application of the Fund

28. Without derogation from the generality of section 27, the fund may be applied for the purposes of-

(a) financing, by way of loan or grants, any research or study carried on, by or for the benefit of persons or organizations engaged in research matters relating to the development of science and technology;

(b) financing, by way of loans or grants, the training of citizens of Malawi for the benefit of organizations engaged in research in the development of science and technology;

(c) making awards to any person qualified for the grant to him of an award under this Act;

(d) providing support for scientific research and technology development and the application of the results in compliance with the national priorities determined by the Government upon advice by the Commission;

(e) Commissioning the carrying out of a project by any person for any specific research which is of special importance to the nation;

(f) Meeting any expenses arising from the establishment and maintenance of the Fund; and

(g) Any purpose which the Minister considers to be in the interest of the objects of the Fund.

Books and other records of accounts audit and reports of the Fund

29. (1) The Minister shall cause to be kept proper books and other records of account in respect of receipts and expenditure of the Fund.

(2) The accounts of the Fund shall be audited by the Auditor General, who shall have all the powers conferred upon him by the Finance and Audit Act.

(3) The Minister shall cause to be prepared, as soon as practicable, but not later than six months after the end of the financial year, an annual report on all the financial transactions of the Fund.

(4) The report under subsection (3) shall include a balance sheet, an income and expenditure account and the annual report of the Auditor General and shall be laid by the Minister before the National Assembly.

Holdings of the Fund

30. (1) All sums received for the purposes of the Fund shall be paid into a bank account and no amount shall be withdrawn there from except by means of cheques signed by such persons as are authorized in that behalf by the Minister.

(2) Any part of the fund not immediately required for the purposes of the Fund may, on the recommendation of the commission be invested in such manner as the minister may determine, after consulting with the Minister responsible for finance.

Financial year

31. The financial year of the fund shall be the period of twelve months ending on 30th June, in each year or on such other date as the Minister may specify by order published in the Gazettee:

Provided that the financial year of the fund may be a period shorter or longer that twelve months as the Minister shall determine, but in any case not longer than eighteen months

Levy

32. The commission may, from time to time, by order published in the Gazette, impose in levy.

PART VII – GRANTING OF AWARDS

Institutions of awards

33. The Commission shall, from time to time, institute awards for the purpose of promoting innovations in science and technology.

Awards Committee

34. (1) There is hereby established a Scientific and Awards Committee (in the Act otherwise referred to as the "Awards Committee") which shall consist of-

(a) a chairman, who shall be appointed by the Minister from among the members of the Commission;

(b) the director General who shall also be the Secretary of the Awards Committee; and

(c) six other members who shall be appointed by the Minister on the recommendation of the Commission.

(2) In appointing persons to the Awards Committee, the Minister shall give consideration to persons who have knowledge and experience of the application of science and technology.

(3) A member of the awards Committee shall, unless he sooner ceases to e a member, hold office for a period of three years from the date of his appointment, and shall be eligible for re-appointment.

(4) The Awards Committee may co-opt any person whose knowledge and experience in the application of science and technology may be of assistance to it in considering any application or proposal for the conferment of an award under this Act.

(5) The Awards Committee shall consider all applications or proposals for the conferment of awards under this Act and make appropriate recommendations to the board regarding the grant of an application or proposal.

(6) In deciding whether or not any application for the conferment of an award under this Act may be granted, the Awards Committee shall consider the importance of the invention or discovery in its application to the search for the solution of various social and economic problems obtaining in Malawi.

Malawi Award for Science and Technological Achievement

35. (1) There is hereby instituted an award to be known as Malawi Award for Science and Technological Achievement.

(2) The Malawi Award for Science and Technological Achievement may be conferred upon any person who within Malawi makes an invention or discovery which, in the opinion of the Awards Committee, is likely to promote and accelerate the social and economic progress of Malawi.

PART VIII – LICENCES AND PERMITS

Licensing authority

36. The Commission shall be the licensing authority responsible for the granting, renewal, variation, suspension and revocation of licence under this Act

Biotechnology consent

37. Subject to the provisions of this Act, no person shall engage in any matter related to biotechnology without prior consent of the Commission.

Classes of licences

38. The Commission may by order published in the Gazette prescribe activities, relating to science and technology, which shall not be carried out except under the authority of a licence issued by the Commission.

Exemptions

39. The provisions of section 38 shall not apply in such circumstances as may be specified by the Minister in a notice published in the Gazette.

Application for a licence

40. (1) Any application for a licence under this Act shall be made to the Commission in the prescribed form.

(2) Any application referred to in subsection (1) shall contain a description of activities or products to which the licence will relate.

Issues of licences

41. (1) If the Commission is satisfied that the applicant is a fit and proper person to engage in activities required to be done under a licence, the Commission may issue to the applicant the licence appropriate to suchactivity subject to such general or special conditions as the Commission mayconsider appropriate to impose.

(2) A licence issued under subsection (1) shall be in such form, and shall be for such duration, as may be prescribed.

(3) Where the Commission considers that the applicant is not a fit and proper person to whom a licence should be issued, it shall refuse to issue a licence.

Suspension and revocation of a licence

42. (1) Subject to this Part, the Commission may –

(a) suspend a licence for such period as it may determine;
(b) revoke a licence; or
(c) vary the provisions of a licence

(2) The suspension or revocation of a licence under this section may be limited to organisms or products thereof of one or more descriptions, or to any particular premises to a particular part of any premises.

Variation of a licence

43. Subject to section 40 the Commission may, on the application of the holder of a licence under this Act, vary the provisions of the licence, in accordance with any proposal contained in the application, if the Commission is satisfied that the variation will not adversely affect the safety, quality or efficacy of activities in respect of which the licence was granted.

PART IX – APPEALS

Appeals

44. 1 Any person who is aggrieved by-

(a) any refusal, suspension, revocation, or variation of a licence, permit or certificate issued under this act or

(b) any decision directly applicable to him taken by the Commission or any person exercising powers under this Act.

May within thirty days appeal in writing to the minister who shall appoint an appeal committee for purpose of hearing the appeal in question.

Appeals committee

45. (1) An appeals committee shall consist of five persons who, in the opinion of the Minister, have expert knowledge and who are otherwise suitable to determine the issues raised in the appeal.

(2) The minister shall designate one of the members of the appeals committee as chairperson of the committee.

(3) A member of the appeals committee shall excuse himself as a member of the appeals committee if he has any direct or indirect interest in the subject matter of the appeal or if for any reason there is likely to be conflict of interest as a result f his participation in the proceedings of the committee.

(4) There shall be paid to members of an appeals committee such remuneration or allowances as the Minister may determine.

Powers of appeals committee

46. (1) An appeals committee shall have, in relation to the hearing of any appeal, the power to –

(a) confirm, set aside, vary, alter, reverse or amend the decision which is the subject of the appeal;

(b) refer the relevant matter back to the Director General for the reconsideration by the commission;

(c) order persons to attend and give evidence or to produce or give discovery and inspection of documents in like manner as in proceedings in the High Court;

Provided that the appeals committee may in its absolute discretion admit evidence which would not be admissible in a court of law and may use evidence contained in any official record and may call evidence of its own motion;

(d) award costs of any proceedings before it and to direct that such costs shall be taxed upon such scale and in such manner as may be prescribed;

(e) make such order as it may deem fit; and

(f) do all things which it is required or empowered to do by or under this Act.

(2) The decision of the appeal committee on any appeal shall be-

(a) made in writing;

(b) sent to all the parties to the appeal and, where he was not a party, to the Minister; and

(c) made available for public inspection,

within thirty days thereof, apply to the High Court for judicial review of the decision of the appeals committee.

PART X – MISCELLANEOUS PROVISIONS

Secrecy to be observed

47. (1) A member or a member of a committee and every person employed under this Act shall not disclose to any person, except in the performance of his duties under this Act or when required to do so by any written law, any information which he may have acquired in the course of his duties in relation to the financial or business affairs of any person, undertaking or business.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine of K1,000,000 or to an amount equivalent to the financial gain generated by the offence, if such amount be greater and imprisonment for five years.

Offences

48. Any person who-

(a) contravenes or fails to comply with any provision of this Act or any regulations made hereunder, or any directive or order lawfully given, or any requirement lawfully imposed under this Act or any regulations made hereunder;

(b) omits or refuses -

(i) to furnish any information when required by the commission to do so; or

(ii) to produce any document when required to do so by a notice sent by the commissioner; or

(c) knowingly furnishes any false information to the Commission.

Penalty for offences

49. A person guilty of an offence under this Act for which no specific penalty is provided shall be liable to a fine of K100,000 or to an amount equivalent to the financial gain generated by the offence, if such amount be greater, an to imprisonment for three years.

Regulations

50. (1) The Minister may, on the advice of the Commission, make regulations for the better carrying into effect the purposes of this Act.

(2) Without prejudice to the generality of subsection (1), the regulations may provide for –

(a) anything required to be prescribed under, or for the purposes of, this Act;
(b) any forms required for the purposes of this Act;
(c) fees payable in respect of any service provided by the commission;
(d) the furnishing of reports to the Minister on science, technology, research and development; and
(e) the form of awards and certificates to be awarded by the commission.

Cap.1:01

(3) Any regulation made under this Act may, notwithstanding the provision of section 21 (e) of the General Interpretation Act, prescribe a fine of up to K20,000 and imprisonment for up to one year for an offence committed against any provision of such regulation

Passed in Parliament this fourth day of August, two thousand and three.

R.L. GONDWE
Clerk of Parliamen

MALAWI GOVERNMENT

(Published 9th February 2018)

Act

No. 9 of 2018

I assent

PROF. ARTHUR PETER MUTHARIKA
PRESIDENT
1st February, 2018

ARRANGEMENT OF SECTIONS

PART VI—PUBLIC HEALTH

SECTION

PART VII—INFORMATION

PART VIII—EMPLOYMENT

PART IX—EDUCATION

PART X—CONTROL OF HIV INFECTION

SECTION

PART XI—NATIONAL AIDS COMMISSION

PART XII—FINANCIAL PROVISIONS

PART XIII—MISCELLANEOUS

PART XIV—MISCELLANEOUS

An Act to make provision for the prevention and management of HIV and AIDS; to provide for the rights and obligations of persons living with HIV or affected by HIV and AIDS; to provide for the establishment of the National AIDS Commission; and to provide for matters incidental thereto or connected therewith

ENACTED by the Parliament of Malawi as follows—

PART I—PRELIMINARY

Short title

1.—(1) This Act may be cited as the HIV and AIDS (Prevention and Management) Act, 2017

(2) This Act shall come into force on a date the Minister may appoint by notice published in the *Gazette*.

Interpretation

2. In this Act, unless the context otherwise requires—

"AIDS" means Acquired Immuno Deficiency Syndrome;

"chairperson" means the chairperson of the Commission and includes any person acting in that capacity;

"Chief Executive Officer" means the Chief Executive Officer of the National AIDS Commission appointed pursuant to section 52;

"child" means any person below the age of eighteen years;

"Commission" means the National AIDS Commission established under section 40 of this Act;

"compulsory HIV testing" means HIV testing imposed upon a person characterized by the lack of informaed and voluntary consent;

"diagnostic testing" means HIV testing done on an individual who shows signs and symptoms that are consistent with HIV infection to aid clinical diagnosis and management;

"discrimination" includes any distinction, exclusion or restriction made on the basis of the actual or perceived HIV status of a person which has the effect or purpose of impairing or nullifying the recognition, enjoyment or exercise by that person or another individual associated with that person on a basis of equality with the other members of the community, of human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field;

"harmful practice" means any social, religious or cultural practice that—

(*a*) puts a person at risk of HIV infection or re-infection; or

(*b*) may catalyze progression of HIV infection to AIDS;

"health service provider" means—

(*c*) a medical practitioner, dentist, paramedical and allied health professional registered under the Medical Practitioners and Dentists Act; Cap. 36:01

(*d*) a nurse or midwife registered in any category of nurses and midwives registered under the Nurses and Midwives Act; Cap. 36:02

(*e*) a pharmacist, pharmacy technologist or pharmacy assistant registered under the Pharmacy, Medicines and Poisons Act; or Cap. 35:01

(*f*) where applicable, health service providers not registered under the Acts cited in this definition;

"HIV" means Human Immunodeficiency Virus, which causes AIDS;

"living with HIV" refers to the presence of HIV in a human body as documented by the presence of HIV or HIV antibodies in the human sample being tested;

"HIV testing" refers to any validated, medically recognized and viral sensitive test for determining the presence or absence of HIV in a person or blood, tissue or other bodily products of a person;

"immediate family member" includes a spouse, parent, grandparent, sibling, child, grandchild, aunt, uncle, niece and nephew of a person;

"post-test counseling" refers to the process of providing risk reduction information and psycho-social support to a person who submits to HIV testing at the time or after the result of the testing is released;

"pre-test counseling" means the process of providing an individual information on the biomedical aspects of HIV and AIDS and psycho-social support to the implications of undergoing HIV testing and the test result before he is subjected to a test;

"routine testing" means HIV testing offered in the course of providing other health services to a person;

"tissue" includes an organ or part of a human body, semen, breast milk and any other substance or secretion, other than

blood, extracted from the human body or from a part of the human body;

"VCT" means voluntary counselling and testing for HIV infection.

PART II—RESPONSIBILITY FOR PREVENTION AND MANAGEMENT OF HIV AND AIDS

Responsibilities of Minister

3. On matters of HIV and AIDS, the Minister shall be responsible for—

(*a*) formulation and review of national policies;

(*b*) leading the national response;

(*c*) commissioning research and innovation;

(*d*) monitoring and evaluating the national response;

(*e*) supervising sectoral policies relating to HIV and AIDS;

(*f*) overseeing the activities and finances of the Commission;

(*g*) facilitating mainstreaming of HIV and AIDS in all sectors of society; and

(*g*) the proper administration of this Act.

PART III—HARMFUL PRACTICES

Prohibition of harmful practices First Schedule

4.—(1) A harmful practice listed in the *First Schedule* is hereby prohibited.

(2) Any person who practices a harmful practice commits an offence and shall be liable, upon conviction to a fine of K5,000,000 and imprisonment for five years.

Subjecting another to a harmful practice

5. Any person who subjects, permits or encourages another person to indulge in a harmful practice commits an offence and shall be liable, upon conviction to a fine of K5,000,000 and imprisonment for five years.

PART IV—PROHIBITION OF DISCRIMINATION

Prohibition of HIV and AIDS discrimination

6.—(1) Discrimination on a basis related to HIV or AIDS is hereby prohibited.

(2) A person who discriminates contrary to subsection (1) commits an offence and shall be liable, upon conviction to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, a fine of K10,000,000.

Rights and duties of persons living with or vulnerable to contracting HIV

7.—(1) Subject to section 26, and in addition to any other rights conferred by any written law, a person who is living with HIV or vulnerable to contracting HIV, shall have the right to—

(*a*) dignity of his person, physical integrity, life and health;

(*b*) practice a profession of choice;

(*c*) compensation associated with the restriction of his enjoyment of his rights; and

(*d*) free medication, at a State medical institution, necessary for anti-retroviral therapy or treatment of an HIV related disease listed in the *Second Schedule*.

Second Schedule

(2) In addition to any other duties conferred by any written law, a person who is living with HIV shall have the duty to take medicine as provided in subsection (1) (*d*).

Rights of persons affected with HIV

8.—(1) In addition to any other rights conferred by any written law, a person related to or associated with another person who is living with HIV or who is vulnerable to contracting HIV has the right to—

(*a*) dignity, physical integrity, life and health; and

(*b*) compensation associated with the restriction of the enjoyment of his rights.

(2) A person who violates a right contrary to subsection (1) commits an offence and shall be liable, upon conviction to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, a fine of K10,000,000.

PART V—DISCLOSURE

Right to privacy and confidentiality

9.—(1) A person living with HIV has the right to privacy and confidentiality with regard to information concerning his status.

(2) It shall be the duty of every health service provider to strictly observe confidentiality in handling all medical information concerning a person living with HIV.

Disclosure by health service provider

10.—(1) A health service provider shall not disclose any information concerning a person's HIV status to another person, except—

(*a*) with the written all consent of the first person, his guardian, partner or parent, as the case may be;

(*b*) to a health service provider directly involved in providing health care to that person, where knowledge of the patient's diagnosis of HIV infection is necessary or relevant to making clinical decisions in the best interests of the person;

(*c*) for the purpose of an epidemiological study, where the release of information cannot be expected to identify the person to whom it relates; or

(*d*) upon an order of a court, where the information contained in the medical file is directly relevant to the proceedings before the court.

(2) A health care provider providing treatment, care or service to a person living with HIV may notify a sexual partner of the person living with HIV,—

(*a*) where the following circumstances exist—

(i) in the opinion of the health service provider, there is a significant risk of transmission of HIV by the person living with HIV to the sexual partner;

(ii) counseling of the person living with HIV has failed to achieve change in behaviour necessary to sufficiently reduce the risk of HIV transmission to the sexual partner;

(iii) the person living with HIV has refused to notify or consent to the notification of the sexual partner;

(iv) the health service provider gives the person living with HIV advance notice for a period that is reasonable in the circumstances;

(v) in the opinion of the health service provider, the person living with HIV is not at risk of serious harm as a consequence of any notification to the sexual partner;

(vi) the person living with HIV is dead, unconscious or otherwise unable to give consent to the notification; or

(vii) the person living with HIV is unlikely to regain consciousness or the ability to give consent; and

(*c*) in the opinion of the health service provider, there is or was a significant risk of transmission of HIV by the person living with HIV to the sexual partner.

Unlawful disclosure

11. A person who discloses the HIV status of another person otherwise than as provided for under this Act commits an offence and shall be liable, upon conviction, to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, to a fine of K10,000,000.

PART VI——PUBLIC HEALTH

HIV transmission and testing

12.—(1) In this Act, the recognized modes of transmission of HIV shall include transmission of HIV through—

(*a*) sexual activity;

(*b*) mother to child during pregnancy, labour, delivery or breastfeeding;

(*c*) transfusion of infected blood;

(*d*) transplant of an infected organ;

(*e*) contact of broken skin or mucus membrane with infected blood, blood products or tissue; and

(*f*) contact of broken skin or mucus membrane with contaminated wet objects.

(2) The modes of HIV testing shall include—

(*a*) VCT;

(*b*) routine testing;

(*c*) diagnostic testing;

(*d*) compulsory testing; and

(*e*) any other mode of HIV testing that the Minister may prescribe.

Age for accessing VCT without parental or guardian consent

13. A person who is at least thirteen years of age may access VCT without the consent of a parent or a legal guardian.

(2) Where a person below the age of thirteen years who does not have a parent or legal guardian seeks VCT, the health service provider whose services are requested in order to access VCT shall request a social welfare officer to apply to the magistrate court for the appointment of a legal guardian of the applicant.

Consent to HIV testing

14. A person shall not test another person for HIV infection except—

(*a*) with voluntary informed consent of the person to be tested;

(*b*) where the person to be tested is below the age of thirteen years, with the voluntary informed consent of a parent or legal guardian of that person; or

(*c*) where the person to be tested has a disability which in the opinion of the person providing the pre-test information, renders the person incapable of understanding the meaning and consequences of HIV testing, with the voluntary informed consent of one of the following persons, said consent to be sought from these persons in the order in which they are listed—

(i) his partner or spouse;

(ii) his legal guardian;

(iii) an immediate family member; or

(*d*) where a person is required to undergo HIV testing under the provisions of this Act or any other written law.

Testing donated body tissues

15.—(1) A person who offers to donate any tissue shall, immediately before the donation, undergo HIV testing.

(2) A health service provider shall not accept a donation of any tissue unless the donor has undergone HIV testing pursuant to subsection (1) and the result is HIV negative.

(3) Notwithstanding subsections (1) and (2), the proposed recipient of the donated tissue or his immediate family member shall have the right to demand further HIV testing on the donated tissue.

Testing of donated blood

16.—(1) A health service provider shall, as soon as practicable after donation, among other tests, subject donated blood to testing for transfusion transmissible HIV infection.

(2) Any blood tested under subsection (1) which is found to be infected with HIV shall immediately be disposed of in accordance with the prescribed guidelines on the disposal of medical waste.

Consent to be deemed

17. Consent to undergo HIV testing shall be deemed to have been given in the following circumstances where—

(*a*) a person offers to donate any tissue;

(*b*) a person offers to donate blood; or

(*c*) it is prudent for a health service provider responsible for the treatment of a person to undertake HIV testing in respect of that person and—

(i) the person is unconscious and unable to give consent; or

(ii) the health service provider reasonably believes that HIV testing is clinically necessary in the interest of that person.

Prohibition of compulsory testing

18.—(1) Compulsory testing for HIV infection is hereby prohibited.

(2) Notwithstanding subsection (1), compulsory testing for HIV infection shall be permissible under an order of the court, for any person who is convicted of a sexual offence.

(3) A person who contravenes the provisions of subsection (1) commits an offence and shall be liable, upon conviction, to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, to a fine of K10,000,000.

(4) In addition to the penalties imposed under subsection (3), a court may, upon conviction, order—

(*a*) in the case of a legal person, the revocation of any permit or licence; or

(*b*) in the case of an individual, the revocation of a licence to practice the person's profession.

Pre-test and post-test counseling

19.—(1) A health service provider who carries out an HIV test on any person shall be required to provide free pre-test and post-test counseling to the person.

(2) Notwithstanding subsection (1), a person who carries out HIV testing on any person for purposes of blood transfusion shall not be required to conduct pre-test and post-test counseling.

Duty to report HIV infection

20. A health service provider who carries out HIV testing has a duty to give monthly reports of the number of HIV tests conducted and the incidence of HIV infection to the District Health Officer, for statistical and epidemiological purposes only.

Prohibition of discrimination in health facility

21.—(1) A person shall not be denied access to health services or be charged a higher fee for any health services, at a health facility, on the grounds of actual or perceived HIV status of the person.

(2) Any person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, to a fine of K10,000,000.

(3) Notwithstanding the provisions of subsection (2), a court may, in addition to any penalty imposed on a person convicted, order—

(*a*) in the case of an individual, revocation of a licence to practice the person's profession; or

(*b*) in the case of a legal person, revocation of the business permit or licence in respect thereof.

PART VII——INFORMATION

Access to HIV and AIDS information

22.—(1) A person has the right to access information in connection with HIV and AIDS held by the State or any organ of the State, where the information is necessary for the exercise of his rights.

(2) A person who is in charge of information on HIV and AIDS has a duty to ensure that the information is relevant to the exercise of the rights of a person requesting the information.

Powers in relation to HIV and AIDS information

23. The Commission shall, in addition to the powers conferred on it by this Act, have the power to develop, co-ordinate and disseminate information on HIV and AIDS.

Accrediting authority

24.—(1) The Commission shall accredit any piece of information on HIV and AIDS before it is disseminated to the public.

(2) A person who develops information on HIV and AIDS shall submit the information to the Commission for screening and verification in order to establish its accuracy before dissemination.

(3) The Commission has a duty to ensure that information on HIV and AIDS is accurate and has been accredited by the Commission.

Publication of misleading information

25. A person who proclaims, utters, publishes misleading, false or inaccurate information concerning HIV and AIDS to any other person or the public commits an offence and shall be liable, upon conviction, to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, a fine of K10,000,000:

Provided that there shall be an aggravating circumstance of the offence if the misleading, false or inaccurate information was not accredited by the commission.

PART VIII—EMPLOYMENT

Prohibition of pre-recruitment testing

26. An employer shall not require any person to undergo HIV testing as a pre-condition for recruitment.

Prohibition of termination of employment on grounds of HIV or AIDS

27.—(1) An employer shall not terminate the employment of an employee solely on the ground that the employee is living with HIV or is perceived to be living with HIV:

Provided that where the capacity of an employee to discharge his duties is affected by reason of poor health, the general principles of employment law shall apply.

(2) A person who contravenes this subsection (1) commits an offence and shall be liable, upon conviction to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, to a fine of K10,000,000.

Prohibition of discrimination

28.—(1) An employee shall not be discriminated against or be subjected to unfair treatment solely on the ground that he is perceived to be or is living with HIV.

(2) Employers in consultation with the employee shall take measures to reasonably accommodate employees with HIV related illnesses provided the accommodation shall not cause undue hardship to the employer.

(3) A person who contravenes this subsection (1) commits an offence and shall be liable, upon conviction to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, to a fine of K10,000,000.

Procuring another to conduct HIV test for recruitment, etc

29. A person who procures another person to conduct HIV testing as a condition for recruitment, training, promotion, termination of employment or other matters arising out of an employment relationship commits an offence and shall be liable, upon conviction to—

(*a*) in the case of an individual, a fine of K2,500,000 and to imprisonment for three years; or

(*b*) in the case of a legal person, a fine of K5,000,000.

Aiding, abetting or concealing act of subjecting another to HIV test for recruitment

30. A person who aids, abets or assists another person to conduct HIV testing as a condition for recruitment, training, promotion, termination of employment or other matters arising out of an employment relationship commits an offence and shall be liable, upon conviction to—

(*a*) in the case of an individual, a fine of K5,000,000 and to imprisonment for five years; or

(*b*) in the case of a legal person, to a fine of K10,000,000.

Employer responsible for minimizing risk of infection at workplace

31.—(1) Where a person is employed in an occupation or is required to provide services where there may be a risk of transmitting or acquiring HIV, the employer shall provide appropriate training, protective equipment and clear and accurate information and guidelines on minimizing the risk of the spread of HIV.

(2) In the case of accidental exposure to HIV occurring in the workplace, the employer shall ensure free access to post-exposure prophylaxis and counseling for the employee in accordance with the law.

Workplace policy

32.—(1) The State shall ensure that employers adopt and implement an HIV and AIDS policy at the workplace.

(2) The design and content of the workplace policy shall be in accordance with the policy guidelines issued by the Minister.

Compensation

33.—(1) An employee who has been infected with HIV in the course of employment shall have the right to claim compensation in accordance with the Workers' Compensation Act.

Cap. 55:03

(2) An employee who is infected with HIV in the course of his employment is entitled to higher compensation, where he is able to show that his infection is due to non-compliance, by the employer, of section 31 or is otherwise due to negligence of the employer.

PART IX—EDUCATION

Prohibition of HIV testing for educational opportunities

34.—(1) A person shall not be required to undergo HIV testing as a condition for—

(*a*) entry into an education or training institution;

(*b*) an award of a scholarship, grant, bursary, benefit or other scholarly endowment; or

(*c*) remaining as a student or trainee in any education or training institution.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, a fine of K10,000,000.

Prohibition of discrimination in education and training institutions

35.—(1) An education or training institution shall not, solely on the grounds that the person is living with HIV or is perceived to be living with HIV,—

(*a*) refuse the person admission into the institution;

(*b*) expel a person from the institution;

(*c*) discriminate against the person;

(*d*) refuse the person participation in an event or activity; or

(*e*) deny any benefits or services to a person.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction to—

(*a*) in the case of an individual, a fine of K5,000,000 and imprisonment for five years; or

(*b*) in the case of a legal person, a fine of K10,000,000.

(3) Notwithstanding the provisions of subsection (2), a court may, in addition to any penalty imposed on a person convicted, order—

(*a*) in the case of an individual, revocation of the licence to practice his profession; or

(*b*) in the case of a private education or training institution, revocation of the business permit, licence or certificate.

HIV and AIDS materials in school curricula

36.—(1) The Minister shall, in consultation with the Minister responsible for Education, the Commission and other relevant authorities, ensure that materials on HIV and AIDS are integrated and mainstreamed into the school curricula for all education and training facilities at all levels.

(2) Pursuant to subsection (1), the Minister shall ensure that the materials on HIV and AIDS developed and integrated into the school curriculum are—

(*a*) appropriate for the level of education it is intended, having regard to the following factors—

(i) the age of learners;

(ii) the level of mental maturity of the learners; and

(iii) the objective of the materials used;

(*b*) free from all forms of stigmatization and discrimination against persons living with HIV;

(*c*) the content of the education is scientifically accurate and appropriate; and

(*d*) materials are available in key languages taking into account matters of disability and location.

Teachers and instructors to be trained on matters of HIV and AIDS

37. The Minister shall ensure that teachers and instructors are trained on matters of HIV and AIDS before commencing teaching or instruction on any subject related to HIV and AIDS.

HIV and AIDS information in non-formal education systems

38. The Minister shall ensure that official information on modes of transmission and ways of preventing HIV infection is progressively integrated in non-formal or indigenous learning systems.

PART X—PERSONAL CONDUCT AND RESPONSIBILITY

Person with HIV or AIDS to undergo counseling

39. A person diagnosed as having HIV infection shall be required to—

(*a*) undergo counseling by a health service provider; and

(*b*) comply with precautions and safety measures prescribed by a health service provider.

PART XI—NATIONAL AIDS COMMISSION

Establishment of National AIDS Commission

40.—(1) There is hereby established a body to be known as the National AIDS Commission (in this Act referred to as "the Commission").

(2) The Commission shall exercise its functions and powers independent of the direction or intereference of any other person or authority.

Function of the commission

41. The Commission shall, with respect to HIV and AIDS,—

(*a*) implement, co-ordinate and facilitate the national response;

(*b*) manage and co-ordinate the implementation of Government policies;

(*c*) provide technical support to Government in the formulation and review of HIV and AIDS policies;

(*d*) develop and maintain an up-to-date information system and establish suitable mechanisms of disseminating and utilizing the information;

(*e*) in liaison with the Secretary responsible for HIV and AIDS, monitor and evaluate progress and impact of the national response;

(*f*) mobilize and equitably disburse resources towards the national response;

(*g*) monitor distribution, and effective and efficient utilization of resources towards the national response;

(*h*) promote and commission research, information sharing and documentation;

(*i*) liaise with all Government Ministries, Departments and Agencies on matters relating to the national response and to ensure that there are no barriers to information;

(*j*) advocate for a strong, sustained and visible role of political, civil and traditional leaders;

(*k*) accredit information produced by any person before dissemination;

(*l*) develop and maintain profiles;

(*m*) provide technical guidance, capacity building and support to stakeholders;

(*n*) submit reports to the Minister on the implementation of the national response; and

(*o*) determine terms and conditions for the Chief Executive Officer and other members of staff of the Commission.

Powers of the Commission

42. The Commission shall have powers to—

(*a*) sponsor, support or organize conferences, seminars, workshops and meetings on any matter under its consideration or generally for the promotion of its functions and objects;

(*b*) receive and allocate donations of funds, materials and technical assistance for the furtherance of its work and ensure the effective utilization of those funds;

(*c*) engage persons having suitable qualifications and experience as consultants to the Commission;

(*d*) determine its own procedures for carrying out consultancies for the general conduct of its work;

(*e*) establish committees as it considers necessary for the performance of its functions and assign to the committees any of its functions without prejudice to the power of the Commission itself to perform those functions;

(*f*) co-opt any person to attend any of its meetings but that person shall not vote on any matter for decision by the Commission;

(*g*) reguest any information relating HIV and AIDS and not privileged from disclosure from any person or institution as part of its coordination function; and

(*h*) do and perform all other things or acts that are necessary or expedient for the implementation of this Act.

Composition of the Commission

43.—(1) Membership of the Commission shall not exceed seven commissioners and shall consists of—

(*a*) three commissioners, appointed by the Minister, one of whom—

(i) is professionally qualified in the medical sciences or a relevant social science field;

(ii) is a member of the civil society, representing people living with HIV;

(iii) is professionally qualified and practicing accountant;

(iv) represents the private sector;

(*b*) as *ex-officio* commissioners,—

(i) the Secretary responsible for HIV and AIDS;

(ii) the Secretary responsible for gender or children; and

(iii) the Secretary responsible for Local Government.

(2) The Minister shall place advertisements in at least two daily papers of widest circulation in Malawi in order to solicit names of persons for appointment to the Commission.

(3) An *ex-officio* commissioner or any person employed in the public service shall not be eligible to be elected chairperson of the Commission but shall have the right to vote on any matter at the meetings of the Commission.

(4) Non *ex-officio* commissioners shall not, by virtue of their appointment to the Commission, be deemed to be officers in the public service.

(5) The names of all commissioners, as first constituted and every change in the membership thereof shall be published in the *Gazette*.

Tenure of office

44.—(1) A commissioner, other than an *ex-officio* commissioner, shall hold office for a period of three years from the date of appointment and be eligible for re-appointment at the expiry of that period for one more term.

(2) When making appointments after the expiry of the three years, the Minister shall have regard to the need to maintain a reasonable degree of continuity in the membership of the Commission, so that at least half of the appointed commissioners shall be re-appointed for the next term of office.

(3) A vacancy in the office of an appointed commissioner shall occur, if the commissioner—

(*a*) dies;

(*b*) is adjudged bankrupt;

(*c*) is sentenced for an offence against any written law to any term of imprisonment;

(*d*) is absent, without the permission of the Commission, from three successive meetings of the Commission of which he has had notice;

(*e*) becomes incapacitated by reason of physical or mental disability; or

(*f*) resigns in accordance with subsection (4).

(4) An appointed commissioner may at any time resign his office by giving one month written notice to the Minister.

(5) A vacancy in the membership of the Commission shall be filled by the appointment of a new commissioner by the Minister.

(6) A person appointed to fill the vacancy shall serve for the remainder of the term of office but no person shall be so appointed where the remainder of the term of office is a period of less than six months.

Chairperson

45.—(1) There shall be a Chairperson of the Commission who shall be elected by the Commission from among the appointed commissioners at the first meeting of the Commission.

(2) Subject to subsection (3), the Chairperson shall hold office until the expiry of his term of office as member of the Commission.

(3) The chairperson may be removed from office as Chairperson by the Commission upon the unanimous decision of the rest of the members of the Commission for misconduct, incapacity or any other good cause.

Commission may establish committees

46.—(1) For the better carrying into effect of the provisions of this Act, the Commission may establish committees that the Commission shall deem appropriate, to perform any functions and responsibilities that the Commission shall determine subject to the directions of the Commission.

(2) The Commission shall appoint a chairperson for each committee from amongst the commissioners.

(3) The provisions of this Act relating to the meetings of the Commission shall apply *mutatis mutandis* to the meetings of the committees.

Commission may co-opt

47. The Commission may, in its discretion, at any time and for any length of period, co-opt any person on account of his special knowledge or expertize to attend any deliberations of the Commission, but the person shall not be entitled to vote on any matter at any meeting of the Commission.

Meetings of the Commission

48.—(1) The Commission shall meet as often as its business requires and in any event not less than once in every three months.

(2) Meetings of the Commission shall be held at a place and a time that the Commission shall determine.

(3) The chairperson shall convene the ordinary meetings of the Commission by giving commissioners at least fourteen days written notice.

(4) The chairperson may, in his discretion, or shall, at the written request of more than four commissioners and within seven days of the request, convene an extraordinary meeting of the Commission to be summoned at a place and time that he may appoint.

(5) A quorum for any meeting of the Commission shall be formed by the presence of more than half of the commissioners or members of a committee.

(6) In the absence of a chairperson, the commissioners present and forming a quorum shall elect one of their number to preside

over the meetings of the Commission, and the commissioner so elected shall exercise all the powers, duties and functions of the chairperson.

(7) Subject to the provisions of this Act, the Commission shall regulate its procedure.

(8) The Commission, and every committee of the Commission, shall record and keep minutes of its meetings.

Disclosure of interest

49. If a commissioner or a member of staff of the Commissioner acquires any pecuniary interest, direct or indirect, in any contract, proposed contract or other matter and is present at a meeting of the Commission at which the contract, proposed contract or the other matter is the subject of consideration by the Commission, he shall at the meeting, as soon as practicable after the commencement of the meeting, disclose the fact to the Commission, and shall not take part in the consideration or discussion of or vote on any question with respect to, the contract, proposed contract or the other matter.

Remuneration

50. Commissioners shall be paid reasonable remuneration for membership and allowances when discharging their duties determined by the Minister responsible for Finance.

Reporting

51. The Commission shall report to the Minister on the activities of the Commission.

Chief Executive Officer

52.—(1) There shall be the office of the Chief Executive Officer of the Commission which shall be a public office.

(2) The Chief Executive Officer shall be appointed by the Commission, on the recommendation of the Commission, on terms and conditions that the Commission determines.

(3) The office of the Chief Executive Officer shall be held by a person who has had experience and shown capacity in a profession or in activities devoted or relevant to HIV and AIDS.

(4) The Chief Executive Officer shall hold office for a period of three years, subject to renewal on account of satisfactory service.

Procedure for appointment of Chief Executive Officer

53.—(1) The chairperson shall sign and issue a public advertisement inviting applications, in writing and within thirty days, for the post of Chief Executive Officer.

(2) The Commission shall assess the applications received pursuant to subsection (1), and—

(*a*) may seek other or further information pertaining to an applicant, from the applicant or any other person or source;

(*b*) shall interview each eligible short listed applicant; and

Officer or any officer of the Commission designated to attend the meeting, the Commission or the committee, as the case may be, may exclude the Chief Executive Officer or the officer from the meeting.

PART XII—FINANCIAL PROVISIONS

Funding of the Commission

58.—(1) The funds of the Commission shall consist of—

(*a*) sums appropriated by Parliament for the purposes of the Commission;

(*b*) donation of funds, materials or any other resources for the purposes of its functions, powers and duties;

(*c*) funds that are derived from the sale of any property by or on behalf of the Commission; and

(*d*) other lawful sources of funding.

Cap. 37:01
Cap. 37:02
Cap. 37:03

(2) The Commission shall, at all times, comply with the provisions of the Public Audit Act, the Public Finance Management Act and the Public Procurement Act.

Accounts and audit

59.—(1) The Commission shall cause to be kept proper books and other records of accounts in respect of receipts and expenditures of the Commission in accordance with acceptable principles of accounting.

(2) The accounts of the Commission shall be audited annually by the Auditor General or by independent professional auditors appointed by the Commission in consultation with the Auditor General, and the expenses of the audit shall be paid out of the funds of the Commission.

(3) The Commission shall as soon as practicable, but not later than six months after the end of the financial year, submit to the National Assembly an annual report on all financial transactions of the Commission and on the work, activities and operations of the Commission.

(4) The report referred to in subsection (3) shall include a balance sheet and an income and expenditure account, shall be laid before the National Assembly in accordance with the provision of Public Audit Act.

PART XIII——MISCELLANEOUS

Powers of the Minister

60. The Minister may, by notice in the *Gazette*,—

(*a*) make regulations for the better carrying out of this Act;

(*b*) amend any schedule to this Act.

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(*a*) make regulations for the better carrying out of this Act;

(*b*) amend any schedule to this Act.

Agreements, licences, permits, etc

61.—(1) Any agreement, document or permission, made, granted or approved by the Registered Trustees of the National AIDS Commission shall, in so far as it is consistent with the provisions of this Act and except as otherwise expressly provided in this Act or in any other written law, continue and be deemed to have been made, granted or approved by the Commission or the Minister as the case may be, under the corresponding provisions of this Act.

(2) Any property and undertakings owned by the Registered Trustees of the National AIDS Commission and used by them, immediately before the commencement of this Act, for the functions which by this Act are transferred to or vested in the Registered Trustees of the National AIDS Commission shall, on the date aforesaid, by virtue of this Act be transferred to and vested in the Commission by the same title by which they were held immediately before the said date.

(3) Where, immediately before commencement of this Act, any legal proceedings are pending to which the Registered Trustees of the National AIDS Commission were entitled to be a party, the Commission shall, as from the date of commencement of this Act, continue in such proceedings, or shall be made a party thereto in like manner as the Commission could have become, and the proceedings shall not abate by reason of the substitution.

PART XIV——TRANSITION

Transfer of assets, funds, liabilities, etc

62.—(1) Property, assets, funds, liabilities, obligations, and other arrangements existing at the commencement of this Act and vested in, acquired, incurred or entered into by or on behalf of the Registered Trustees of the National AIDS Commission, shall, on the commencement of this Act, be deemed to have vested in, or to have been acquired, incurred or entered into by or on behalf of the Commission and shall become enforceable by, or against, the Commission to the same extent as they were enforceable by or against the Registered Trustees of the National AIDS Commission.

(2) Where the transfer of any property transferred to or vested in the Registered Trustees of the National AIDS Commission under subsection (1) is required by any written law to be registered, the Commission shall, within one year from the commencement of this Act, or within any other period as the written law may prescribe, apply to the appropriate registering authority for the registration of the transfer, and thereupon the registering authority shall, at no cost to the Commission or any person by way of registration fees, stamp or other duties—

(*a*) make such entries in the appropriate register as shall give effect to the transfer;

(*b*) where appropriate, issue to the Commission certificate of title or other statutory evidence of ownership of the property or make such amendments on such certificates or in the appropriate register as may be necessary; and

(*c*) make any necessary endorsement on such deeds or other documents as may be presented on such registering authority relating the title, right or obligation concerned.

Transfer of employees

63.—(1) All appointments of staff of the Registered Trustees of the National AIDS Commission made prior to the commencement of this Act and subsisting at the date of commencement of this Act shall be deemed to have been made in accordance with this Act.

(2) Any person who, immediately prior to the commencement of this Act is employed by the Registered Trustees of the National AIDS Commission shall be deemed to have been transferred to the employment of the Commission under his former terms and conditions of service, and, for the purpose of determining his rights thereunder, his service shall be regarded as continuous from the time he was appointed by the Registered Trustees of the National AIDS Commission.

FIRST SCHEDULE s.4

HARMFUL PRACTICES

1. *Chimwanamaye*
2. *Fisi*
3. *Hlazi*
4. *Chijura mphinga*
5. *Kuchotsa fumbi*
6. *Chiharo*
7. *Kuika mwana kumalo*
8. *Kujura nthowa*
9. *Kulowa or kupita kufa*
10. *Kulowa or kupita ngozi*
11. *Kupimbira*
12. *Kupondera guwa*
13. *Kusamala mlendo*

14. *Kutsuka mwana*
15. *Mbirigha*
16. *Gwamula*
17. *Mwana akule*
18. *Bulangete la mfumu*

SECOND SCHEDULE s.7

HIV RELATED DISEASES

1. Kaposi's sarcoma
2. Chronic and recurrent diarrhoea
3. Oral and oesophageal candidiasis
4. Herpes zoster
5. High Grade B cell malignant lymphoma
6. Cryptococcal and other fungal meningitis
7. Pneumocystic carini pneumonia
8. Pulmonary or disseminated tuberculosis

Passed in Parliament this twenty eigth day of November, two thousand and seventeen.

FIONA KALEMBA
Clerk of Parliament

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Malawi

Anatomy Act

Chapter 34:03

Legislation as at 31 December 2014

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Anatomy Act
Contents

Malawi

Anatomy Act

Chapter 34:03

Commenced on 1 April 1991

[Up to date as at 31 December 2017]

[Note: This version of the Act was revised and consolidated in the Fourth Revised Edition of the Laws of Malawi (L.R.O. 1/2015), by the Solicitor General and Secretary for Justice under the authority of the Revision of the Laws Act.]

An Act to make provision for the donation, examination and use of bodies, or parts of bodies, of deceased persons for educational, scientific, research, therapeutic, or diagnostic purposes; to re-enact the law dealing with human tissue and to provide for matters incidental thereto or connected therewith

Part 1 – Preliminary

1. Short title

This Act may be cited as the Anatomy Act.

2. Interpretation

In this Act, unless the context otherwise requires—

"**approved school of anatomy**" means any school, college, hospital or other institution authorized under this Act to receive, acquire, preserve, issue or use the bodies of deceased persons for educational, scientific, therapeutic or diagnostic purposes;

"**body**" means the human body;

"**dentist**" means a person registered as such under the Medical Practitioners and Dentists Act;

[Cap. 36:01]

"**examine anatomically**" includes dissection of a body;

"**medical practitioner**" means a person registered as such under the Medical Practitioners and Dentists Act;

[Cap. 36:01]

"**scientific purposes**" means—

(a) any medical or dental education or research; or

(b) the advancement of medical or dental science;

"**therapeutic purposes**", in relation to the use of tissue removed from the body of a person, means therapy of, including use in, the body of any other living person;

"**tissue**" means any human tissue including any human flesh, organ, bone, body fluid or derivative of any human tissue.

Part II – Authority for anatomical examination of the body of a deceased person

3. Authority for anatomical examination of the body of a deceased person

(1) If any person, either in writing signed by him at any time or orally in the presence of two or more witnesses during the illness from which he died—

(a) has directed or expressed the wish that his body after his death be examined anatomically; or

(b) has nominated any person to examine his body anatomically after his death,

the person lawfully in possession of that person's body after his death shall, if such direction, wish or nomination is made known to him before he has disposed of the body, in writing authorize that the body be examined anatomically or, in the case of nomination, shall in writing authorize the person nominated to examine the body anatomically, in either case, in an approved school of anatomy, unless the person lawfully in possession of the body has reason to believe that the direction or nomination was withdrawn by the deceased, or that the surviving spouse or a close relative of the deceased person objects to the body being examined anatomically.

(2) No authority shall be given under subsection (1) in respect of a body of a deceased person by a person lawfully in possession of the body for the purpose only of its cremation or interment.

4. Inquests, postmortems, etc.

Where a person has reason to believe that, in accordance with any written law—

(a) an inquest may be required to be held on a body of a deceased person; or

(b) a postmortem may be required to be carried out on a body of a deceased person; or

(c) a body of a deceased person or any part of the body may be required to be dealt with or disposed of in any other manner prescribed by or under such written law or any other written law,

he shall not give authority under section 3 in respect of that body or part thereof or act on such authority given by any other person.

5. Persons who may give authority in respect of bodies lying in hospitals, etc.

Where the body of a deceased person which is to be examined anatomically lies in a hospital, nursing home, prison or other institution, authority required to be given under section 3 may be given by the person having the control and management of that institution or by a person duly authorized to act on behalf of such person or by a medical practitioner serving at, or visiting, the institution.

6. Examination of bodies to be under supervision of a medical practitioner or a dentist

(1) No examination of the body of a deceased person or any part thereof required to be conducted in accordance with authority given under this Act, shall be carried out otherwise than by or in accordance with the instructions of, and under supervision by, a medical practitioner or dentist who shall first have satisfied himself by his own personal examination of the body that life is extinct.

(2) No removal of a part of the body of a deceased person in accordance with authority given under this Act shall be effected except by a medical practitioner or a dentist who shall first have satisfied himself by his own personal examination of the body that life is extinct.

7. Conditions to be complied with before a body is examined

(1) The body of a deceased person shall not be examined anatomically or removed for anatomical examination from the place where the person died unless—

(a) written notice of the intended anatomical examination has been given to the person who is in lawful possession of the body; and

(b) the person to examine the body many part thereof or the person to remove the body for anatomical examination, has first obtained a death certificate in accordance with subsection (2); and

(c) the person removing the body or any part thereof has first placed it in a decent coffin or in a manner acceptable under the culture or religion of the deceased person.

(2) The death certificate required for the purpose of subsection (1) (b) shall—

(a) state the cause of the death;

(b) be signed by the medical practitioner who was present at the death of the deceased or attended the deceased person during his last illness, not being the person referred to in subsection (1) (b); or

(c) where there is no such medical practitioner as is referred to in paragraph (b) be signed by a medical practitioner called in soon after the death of the deceased to view the body who shall state in the certificate the manner or cause of death according to the best of his knowledge and belief.

(3) Where the death certificate is obtained by the person who removes the body for anatomical examination, such person, on delivering the body for anatomical examination, shall deliver a copy of the certificate to the person who receives the body.

8. Disposal of body anatomically examined and notice thereof

(1) Any person who receives the body of a deceased person for anatomical examination shall, except as provided in subsection (3), make provision for such body, after having been examined anatomically, to be decently cremated or decently interred in consecrated ground or in some public burial ground devoted to persons of the deceased person's culture or religion, or in any other manner provided by law.

(2) After a body has been cremated or interred in accordance with subsection (1), the person who received the body for anatomical examination shall as soon as possible give written notice of such cremation or interment to the person who was in lawful possession of the body.

(3) Where a body which is examined anatomically is the body of a person who has been executed pursuant to death warrant, the person to whom the warrant was directed shall make provision for the body, after having been examined anatomically, to be disposed of in accordance with the directions contained in the warrant.

(4) A person who contravenes this section shall be guilty of an offence and liable to a fine of five hundred Kwacha and to imprisonment for a period of one year.

9. Illegal taking or removing of parts of a deceased person

(1) Where authority under this Act has been given for the body of a deceased person to be anatomically examined, no person shall—

(a) take or remove from that body any part thereof before the body is received into an approved school of anatomy;

(b) take or remove from an approved school of anatomy any part of the body except for cremation or burial or for educational, scientific, research, therapeutic or diagnostic purposes permissible under this Act;

(c) receive any part of the body taken or removed in contravention of paragraph (a) or (b).

(2) A person who contravenes subsection (1) shall be guilty of an offence and liable to a fine of two thousand Kwacha and to imprisonment for a period of one year.

10. Postmortem examination of a body

Any medical practitioner may, with the prior approval of a close relative of the deceased person or, in case where a close relative is not known, the police officer in charge of a police station, carry out a postmortem examination on the body of a deceased person before its burial or examination in order to establish the cause of death.

11. Removal of tissue from bodies of living persons

Any medical practitioner or any other authorized person may remove tissue from the body of a living person for educational, scientific, research, therapeutic or diagnostic purposes with the consent of—

(a) that person or his spouse or close relative;

(b) in the case of a minor or a mentally handicapped person, with the consent of a parent, guardian or close relative:

Provided that, in either case, the close relative is not himself a minor or a mentally handicapped person.

Part III – Conduct of anatomical examinations and approved schools of anatomy

12. Conduct of anatomical examination of bodies

(1) No anatomical examination in an approved school of anatomy shall be conducted, except by—

(a) a medical practitioner or dentist;

(b) a professor, lecturer or teacher of anatomy;

(c) a person registered as a student of any approved school of anatomy; or

(d) a person who practises a profession or calling allied to medicine and whose work is concerned closely with the prevention or treatment of physical or mental ailment in human beings:

Provided that in the case of a person referred to in paragraphs (c) and (d) he shall at all times act under the supervision of a person specified in paragraph (a) or (b).

(2) Authority given under this section shall, subject to this Act, entitle the person to whom it is given to conduct anatomical examination in an approved school of anatomy and to receive for the purpose of such examination, the body of a deceased person.

(3) A person who—

(a) not being qualified under this section to do so, examines anatomically or receives for the purpose of anatomical examination any body of a deceased person;

(b) whether or not qualified under this section,, examines anatomically the body of a deceased person at a place other than an approved school of anatomy; or

(c) practises anatomy in contravention, or not in accordance with the requirements, of this Act,

shall be guilty of an offence and liable to a fine of three thousand Kwacha and to imprisonment for a period of two years.

13. Designation of schools of anatomy

(1) The Minister may, by order published in the *Gazette*, designate any school, college, hospital or any other similar institution to be an approved school of anatomy and may in such order prescribe any conditions or requirements to be fulfilled by an institution so designated.

(2) A person—

(a) in charge of any premises which are not an approved school of anatomy, who permits anatomy to be practised at such premises; or

(b) in charge of an approved school of anatomy who permits anatomy to be practised at such premises by any person not authorized in accordance with this Act to practise anatomy,

shall be guilty of an offence and liable to a fine of five thousand Kwacha and to imprisonment for a period of three years.

Part IV – Miscellaneous provisions

14. Acquisition, preservation, receiving, use, etc., by authorized institutions

(1) The Minister may, by order published in the *Gazette*, authorize institutions specified in the order to receive, acquire, preserve, use or issue any tissue which has been lawfully removed from the body of a deceased person or a living person.

(2) An institution authorized under subsection (1) may at any time issue any tissue in its possession to an approved school of anatomy, a medical practitioner, a dentist or any person authorized under this Act for any educational, scientific, research, therapeutic or diagnostic purposes.

15. Control over the body or tissue

A person to whom the body of a deceased person or tissue is donated or who acquires any body or tissue under this Act shall, upon delivery of the body or tissue to him, be vested, subject to this Act, with the exclusive control over the body or tissue.

16. Prohibition of sale of body or tissue

A person who—

(a) sells or buys the body of a deceased person or a tissue removed from the body of a deceased or living person; or

(b) for gain or profit, supplies, to any person for educational, scientific, research, therapeutic or diagnostic purposes, or any other purpose whatsoever, tissue removed from the body of a deceased or living person,

shall be guilty of an offence and liable to a fine of fifteen thousand Kwacha and to imprisonment for a period of ten years.

17. Prohibition of publication of identity of donor or recipient of a body or tissue

(1) Subject to subsection (2), no person shall publish to any other person any fact whereby the identity of—

(a) the deceased person; or

(b) the donor of the body of a deceased person; or

(c) the donor of the tissue removed from the body of a deceased or living person; or

(d) the recipient of any tissue removed from the body of a deceased person or the body of a living person,

unless such donor, living person, recipient or, prior to his death, the deceased consented in writing to such publication:

Provided that where the recipient dies without giving consent or the deceased did not give consent but such recipient or deceased did not indicate that he would not be prepared to give consent, consent may be given in writing signed by a close relative who is himself not a minor or a mentally handicapped person.

(2) This section shall not apply in respect of any communication reasonably necessary in connexion with the removal, storage or use of the tissue or body.

18. Offences and penalties

(1) A person who—

(a) removes any tissue from the body of a deceased person or the body of a living person otherwise than in accordance with this Act or any other written law or, in pursuance of a profession or calling he lawfully practises; or

(b) conducts a postmortem on the body of a deceased person otherwise than in accordance with this Act or any other written law; or

(c) not being the person empowered to do so under this Act, purports to give authority for the body of a deceased person or for any tissue to be examined anatomically;

(d) being lawfully in possession of the body of a deceased person or of any tissue, delivers up such possession to another person knowing or having reason to believe that the body or tissue will be examined anatomically otherwise than in accordance with this Act; and

(e) receives for anatomical examination or examines anatomically, the body of a deceased person or any tissue in respect of which authority under this Act has not been given,

shall be guilty of an offence and liable to a fine of five thousand Kwacha and to imprisonment for a period of three years.

19. Documentation

(1) A person who sends to another person the body of a deceased person for anatomical examination under this Act shall, along with the body, send to such other person a copy of the death certificate referred to in section 7.

(2) A person who receives the body of a deceased person for anatomical examination under this Act shall enter or cause to be entered, in a book to be kept by him for that purpose, the following particulars—

(a) the day and hour he has received the body;

(b) the name and address of the person who delivered the body;

(c) the date and place of death;

(d) sex, name, age and last place of abode of the deceased person,

and shall send to the sender of the body a return showing all those particulars and shall forward a copy of the return to the Minister.

(3) Any person who contravenes this section shall be guilty of an offence and liable to a fine of five hundred Kwacha and to imprisonment for a period of one year.

20. Inspection

(1) A person authorized by the Minister in writing to do so, or any police officer of or above the rank of sub-inspector may—

(a) upon production of his proper identity, enter and inspect at any reasonable time any approved school of anatomy and inspect any body, of a deceased person, which has been received for anatomical examination and inspect any book which is required to be kept under section 19 (2);

(b) require any person who authorized the body of a deceased person to be examined anatomically or any person who received such body for the purpose of examining it anatomically, to give such information and produce any relevant documents as he may reasonably require for the purpose of ascertaining that the provisions of this Act are complied with.

(2) A person who resists, hinders or obstructs any person acting in pursuance of subsection (1) or who wilfully withholds any information or gives any information which he knows or has reason to believe that it is false or misleading, shall be guilty of an offence and liable to a fine of two thousand Kwacha and to imprisonment for a period of one year.

21. Dispatch of bodies or tissue between Malawi and other countries

(1) Where the Minister is satisfied that arrangements of a reciprocal nature or effect have been or are to be made by the competent authority in a foreign country, he may make arrangements with that authority—

(a) for the dispatch from Malawi to that country of a body of a deceased person or any tissue for anatomical examination in a school of anatomy established under the laws of that country; or

(b) for the receipt Malawi of the body of a deceased person or tissue dispatched from that country for anatomical examination in an approved school of anatomy in Malawi.

(2) Any arrangement made under subsection (1) shall include a requirement that—

(a) the person in charge of the school of anatomy where the body of a deceased person or tissue dispatched from Malawi be examined anatomically shall make provision that the body, after having been anatomically examined, be decently cremated or decently interred in consecrated ground or in some public burial ground in use for persons of the deceased person's culture or religion; and

(b) written confirmation of the cremation or interment of the body or disposal of tissue shall be transmitted to the Minister soon after the body has been cremated or after the tissue has been disposed of.

(3) Any person in lawful possession of the body of a deceased person may in writing authorize any other person to receive the body for the purpose of—

(a) dispatching it to a foreign country; or

(b) conveying it to an approved school of anatomy, pursuant to arrangements made under this section:

Provided that no body of a deceased person shall be dispatched or conveyed by the person so authorized, unless it is accompanied with a death certificate given under section 7 or under any relevant written law of the foreign country concerned.

22. Prohibition against unauthorized exportation of tissue

(1) No person shall dispatch to a person outside Malawi for histo-pathological examination any tissue removed from a person in Malawi except under the authority of a pathologist or of any person duly designated by a pathologist to act, in that respect, on his behalf.

(2) A person who contravenes subsection (1) shall be guilty of an offence and liable to a fine of five thousand Kwacha and to imprisonment for a period of three years.

23. Regulations

The Minister may make regulations generally for the better carrying out of the provisions and purposes of this Act, and without prejudice to the generality of the foregoing, such regulations may make provision for—

(a) the conduct, equipment, inspection and control of approved schools of anatomy;

(b) prescribing the form of application, authority, certificate and return to be used under this Act;

(c) prescribing the fees to be paid under this Act;

(d) relating to the receipt, preservation, use, possession, issue or disposal of any tissue removed from the body of a deceased person or a living person under this Act;

(e) prescribing the requirements with which an authorized institution shall comply; and

(f) any other matters required to be prescribed under this Act.

24. Repeal of Cap. 34:03

The Human Tissue Act is hereby repealed.

NATIONAL COMMISSION FOR SCIENCE & TECHNOLOGY

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What is the National Regulatory Requirement and Position on Accessing, Collection, Storage and Use of Human Biological Specimen for Research in Malawi?

- **Regulatory requirement and position**

  The Government of Malawi has been embracing a State practice and a national regulatory position on the accessing, collection, storage and use of human biological specimen for research from the time of the establishment and existence of the then National Research Council of Malawi in 1974 to the present time of the existence of the National Commission for Science and Technology that has the legal mandate to nationally promote, co-ordinate and regulate research, science and technology as empowered by the S&T Act No.16 of 2003. The national regulatory requirement and position of State practice is defined in a number of instruments. **Sections 3.4.7 and 3.4.8** of the National Policy Requirements, Procedures and Guidelines for the Conduct and Review of Human Genetic Research in Malawi (2012) stipulate non permissible areas and forms of research actions related to collection, storage and use of human biological specimens in Malawi. Specifically, section 3.4.7 states that *"all forms of studies and testing aimed at collecting and storing human biological samples for future unspecified genetic research/analyses including any scientific retrospective analyses"* is **non permissible.** Similarly, section 3.4.8 stipulates that *"plans, attempts and requests for obtaining human biological/genetic material for future research"* is also non permissible. Within the regulatory ambit of the national jurisdictional mandate of the NHSRC, it is specifically stipulated in section 10 of the General Guidelines on Health Research in Malawi (2007) that *"researchers should not collect biological specimens that are not required to address the study objectives; tests on biological specimens should only be as described in the approved proposal; and specimens collected for a particular purpose should not be used for other purposes"*

  The regulatory requirement on access, collection and use of human biological samples for research has a legislative anchorage as lawfully made under **sections 18 and 48** of the said S&T Act. Stakeholders including researchers are obliged to adhere to this regulatory requirement without let or hindrance.

- **Regulatory interpretation, application and guidance**

  The regulatory requirement stated above is self-explanatory. The regulatory requirement permits the access, collection, storage and use of biological samples **but only for a presently defined research study whose protocol clearly describes the study objectives, methodologies and other testing procedures after obtaining an informed consent. Thus, human biological samples/specimens are only allowed to be accessed, collected and used for tests/analyses necessary and required to answer objective(s) of a particular research study which has presently been approved. It is not permitted in Malawi to consent participants to collection, use and storage of specimens for future use, be it for future research or any other purposes.**

Similarly, specimens collected for one clearly defined and approved study are not allowed to be used for another research study nor for any other research purpose other than for tests/analyses required to answer objectives of a particular presently intended study for which initial approval is made. Thus, researchers are only **allowed** to administer consent to participants to collect specimens for purposes of only answering the study objectives of a presently intended study that has been clearly defined and for which approval is being sought. In the case of accessing and collecting cadaveric tissues/samples **for a presently clearly defined research study**, the relevant provisions contained in the Anatomy Act (1991) must be adhered to.

Any samples to which participants had been consented for future use remain **null and void** because an action to request potential participants to consent to storage for future use is a regulatory violation, and no committee must have approved such a consent form. Such samples are to be discarded and destroyed.

- **Period of storage**

Depending on the nature of the approved research study, samples can spontaneously be analysed or can be stored for analysis at a later date. Samples that can be stored for testing/analysis at a later date for purposes of answering study objectives of the presently approved study protocol can be kept for the maximum of the initial five year period during which all tests/analyses approved for that particular study should be concluded. In the case of certain studies that may require storage of samples longer than the initial five year period in order to perform the analyses/tests for which a particular study was authorised, approval from the ethics committee that originally approved that study shall be sought for renewal of storage for a further equal period, following a sound justification by the researcher that an ethics committee may consider, **otherwise specimens are required to be discarded and safely destroyed immediately after all the tests/analyses aimed at answering the objectives of a particular study are done.**

- **Material Transfer Agreement (MTA)**

Primarily, testing/analysis of samples in order to answer the objectives of a clearly and presently defined study for which the samples have been collected is required to be done locally within Malawi so as to promote local capacity building and transfer of technology. There are, however, restricted circumstances and reasons where there might be a justifiable need to perform analyses/tests beyond the Malawi borders. Such circumstances would necessitate the transfer/exportation of the samples, subject to the provisions of any national relevant law. In which case, the researcher shall be required to apply for such a transfer under a material transfer agreement that shall be reviewed and approved by the committee undertaking the review. Exportation of specimens is considered a last resort. Thus, it is permissible in exceptional circumstances to export specimens especially where there is no technology available in Malawi to conduct the desired tests and such technology can not be imported into Malawi, or where further tests to adequately answer the study objectives are necessary to confirm the results. Under any allowable circumstances, the researcher shall be required to provide an adequate justification for material transfer under a MTA Form that is available within the approved SOPs of COMREC.

NATIONAL POLICY REQUIREMENT AND GUIDANCE FOR THE PROVISION OF INSURANCE COVER FOR RESEARCH PARTICIPANTS IN CLINICAL TRIALS IN MALAWI

[Sections 18 & 48 of the S&T Act No.16 of 2003]

National Commission for Science and Technology

Revised 2nd Edition

December, 2012

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ACKNOWLEDGEMENT

The 2012 revised edition of the National ***Policy Requirement and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi*** builds on the first edition of 2008. In pursuance of its legal mandate as enshrined in sections 18 and 48 of the Science and Technology Act No 16 of 2003, the development of this revised edition was undertaken by the National Commission for Science and Technology (NCST). This edition is the product of the NCST's consultation of a cross-section of stakeholders. The NCST would like to gratefully acknowledge the efforts of all manner of people that were engaged at different stages of the development process. Specifically, I would like to pay special tribute to the following;

- **National Health Sciences Research Committee (NHSRC) and National Committee on Bioethics (NACOB)** which in line with their specific terms of reference as technical functional committees of NCST were structures through which this edition was developed. Members of the committees under the committed leadership and guidance of Dr Charles C V Mwansambo and Prof Joseph Mfutso-Bengo, respectively, worked tirelessly in collaboration with the secretariat to develop this revised edition;

- **Representatives of the Insurance Industry** who assisted a great deal in providing the much needed professional advice and information that has all been duly incorporated into this policy requirement;

- Prof Carl H. Coleman, Professor of Health Law and Director of Global Initiatives at the Centre for Health and Pharmaceutical Law and Policy at Seton Hall University in USA, and Consultant for World Health Organisation, who kindly contributed to the development of this edition by providing very constructive comments and insights; and

- **All stakeholders** who constructively critiqued the entire policy document by providing very useful comments.

Sponsors, researchers and all other stakeholders are, therefore, called upon to adhere to this revised policy requirement and guidance for the provision of insurance cover for research participants in clinical trials in Malawi. The adherence to this requirement will not only foster the desired protection for research participants but will also enhance speedy review and approval of clinical trials planned to be conducted in Malawi.

Dr H M Chimoyo
DIRECTOR GENERAL
NATIONAL COMMISSION FOR SCIENCE AND TECHNOLOGY

Table of Contents

1.0 INTRODUCTION

This 2012 revised edition of the "***National Policy Requirement and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi"*** includes extensive revisions to certain sections of the 2008 policy document. Such revisions aim at providing stakeholders further guidance and clarity on the policy elements. This revised and second edition has been developed to build on the first edition with the aim of objectively fostering the protection of the safety, rights, and welfare of persons taking part as research subjects in health/biomedical research in Malawi. Specifically, the policy requirement aims at protecting human participants in clinical trials. The requirement calls upon all sponsors and researchers of such trials, unless otherwise stated, to provide insurance cover for potential research participants tobe enrolled in clinical trials/studies in Malawi. Obtaining and submitting the required insurance as described in **section 2.0** is a requirement and pre-liquisite to obtaining ethical and regulatory approval of clinical trials, besides the fulfilment of other applicableethical and regulatory requirements that are existent in Malawi.

This policy requirement is made pursuant to the Principles of Bioethics and International Law as enshrined in CIOMS, ICH-GCP[1]**,** the Universal Declaration on Bioethics and Human Rights, and as enshrined in similar international law documents guiding the conduct of research involving human subjects. This policy requirement and guidance augments similar requirements, guidelines, standard operating procedures, regulations and relevant laws pertaining to the conduct of health research in Malawi.
This requirement applies to sponsors, researchers and other stakeholders intending to conduct clinical trials in Malawi to aid them in submitting adequate documentation in their application for the review and approval of their studies. The policy also applies to all health research review committees and applicable regulatory structures for enforcement as well as the insurance industry.

This policy requirement and guidance is lawfully made under and enforced by **Sections 18 and 48 of the Science and Technology Act No.16 of 2003.** Stakeholders are, therefore, called upon to adhere to the contents of this requirement without let or hindrance.

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[1] CIOMS: refers to the international ethical guidance on conducting research involving humans with specific guidelines appealing to the low income/developing countries. This ethical guidance was developed by the Council for International Organisations in Medical Sciences in collaboration with WHO (2002)

ICH-GCP: refers to the International Guideline for Good Clinical Practice in the Conduct of Clinical Trials involving pharmaceutical products as developed by the International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use

2.0 TYPE AND SCOPE OF THE REQUIRED INSURANCE COVER

2.1 Required Clinical Trials Insurance in Malawi

In line with **CIOMS** and similar sources of international ethical guidance documents (i.e. codes, declarations, conventions etc) that form part of international law; re-affirming that the rights, safety and well-being of the trial subjects are the most important consideration and should prevail over the interests of science and society[2]; and recognising the contextual vulnerabilities in Malawi, the required insurance for research participants/research subjects in Malawi is the ***Insurance Cover of No-Fault Type***.

2.2 Definition of the Insurance Cover of No-Fault Type

No-fault means "**proof of negligence or other wrongful conduct need not be established. However, the causal-connection between the trial and harm/bodily injury/death shall have to be established to trigger the obligation to make compensation payment.** Thus, the no-fault insurance cover is an insurance cover under which compensation for harm, bodily injury or death to research participants/research subjects arising from or attributable to participation in a clinical trialis given independent of proof of fault**, provided that causal-connection between harm, bodily injury or death and participation in the trial is established**. Whether a fault (i. e negligence or other wrongful conduct) is committed or not but a harm, injury or death attributable to participation in a given trial has occurred, monetary compensation shall be paid to the participants as determined by an insurance firm. This is a **claims- based insurance** cover that takes cognizance of the occurrence of harm, injury, death or any other harmful consequences.

2.3 Scope of Coverage

The scope of coverage includes all clinical trials **that have been classified** in this policy requirement or as can be determined specifically by the National Health Sciences Research Committee or College of Medicine Research and Ethics Committee (as the only independent research ethics review committees in health/biomedical research in Malawi) or by the Clinical Trial Review Committee at the National Drug Regulatory Authority. In making a determination, these committees shall take into consideration the relative safety of a particular trial on a case by case basis.

2.3.1 Studies Attracting Insurance Cover of No-Fault Type

Notwithstanding the generality of the statement provided in the scope of coverage in **section 2.3** above, the following classified clinical trials are examples that shall always attract the provision and enforcement of the required insurance coverage;

[2] ICH-GCP: The Principles of ICH-GCP, section 2.3

2.3.1.1 Vaccine or drug trials where safety issues remain fully unknown. This also includes all clinical trials for candidate vaccines and drugs at all phases of development.

2.3.1.2 Vaccine or drug trials involving vulnerable populations (e.g. pregnant women, neonates, children) and non vulnerable populations where such trials are of drug(s) already registered **but proposing new usage, dosage, combinations, and/or formulations other than the therapeutic usage, dosage, combinations and/or formulations for which the drug/vaccine wasoriginally prequalified by WHO and registered by a drug regulatory authority.**

2.3.1.3 Trial involving investigational/pharmaceutical product(s) which was already prequalified by WHO and registered by a drug regulatory authority for therapeutic usage and dosage in a specified route of administration **but the trial proposes changes to its originally approved route of therapeutic administration, dosage or usage**.

2.3.1.4 Any trial involving an investigational/pharmaceutical product in the formulation, combination, usage, dosage and with route of administration **not prequalified by WHO and registered by a Drug Regulatory Authority.**

2.3.1.5 Any trial involving any form of investigational product including a medical device that has not been prequalified by WHO and approved for usage.

2.3.1.6 Any gene therapy trials/studies aimed at introducing a genetic material into patients to treat a genetically inherited or acquired disorder.

2.4.2 **Other Possible Areas of Insurance Coverage**

The provision of insurance coverage for other forms of clinical trials/studies not specified in **section 2.3.1** above shall be subject to the discretion, determination and recommendation, on case by case basis, by the government authorized research review committee such as the ***National Health Sciences Research Committee (NHSRC); College of Medicine Research and Ethics Committee (COMREC); and/or the Clinical Trial Review Committee (CTRC) at the Drug Regulatory Authority.*** In making a determination, these committees shall take into consideration relative safety of such trials/studies.

3.0 PERIOD OF INSURANCE COVERAGE AND COMPENSATION

It is internationally recognized that a harm/bodily injury/death or any other harmful effects and consequences arising from participating in a given clinical trial may either occur or manifest during the running period of the trial or long after the trial is completed or closed thereby necessitating insurance coverage and compensation during and after trial is completed/closed. To allow ease of establishing causal-connection during and

after trial is completed or closed, this policy specifies the provision of the required insurance both during the running period of the trial and the period extending to only **five years** after trial is completed or closed. **The five year extension period of the initial insurance shall attract an additional proportion of the initial insurancepremium as shall be determined from time to time by the underwriting/insurance firm/broker**. Specifically, the following shall be adhered to;

3.1 Sponsors/researchers are required to arrange and provide the no-fault insurance coverage during the **running period** of the trial and **the future period covering five (5) years after the trial is completed or closed**, in order to provide compensation for harm/injury/death that may occur or manifest both during the running period of the trial and harm/injury/death that may occur/manifest **within fiveyears after the trial is closed.**

3.2 Sponsors/researchers are required to obtain **the insurance policy and certificate from their insurers that clearly and adequately provides for compensation for harm/injury/death or other harmful consequences that may occur or manifest both during the running period of the trial and that which may occur/manifest within five years after trial is completed or closed.**

3.3 The required insurance documents (i. e. insurance policy and its certificate) must be obtained in time from the insurers and be submitted as part of documentation in the application for ethical and regulatory review of a given trial protocol. **Protocols of trials that attract the insurance coverage as classified in section 2.2.1 above and those that may be determined to require insurance coverage as mentioned in section 2.2.2 will not be approved, if the required insurance coverage is not provided.**

4.0 OBTAINING THE INSURANCE COVER OF NO-FAULT TYPE

The required insurance cover for research participants in a specific clinical trial/study at a given site must be obtained **through a local insurance firm and broker that is registered and operating under law in Malawi**. The following is the possible way of obtaining the required insurance for research participants in a **specific** trial to be conducted in Malawi;

4.1 Direct Issuance of an Insurance Policy by the Insurance Firm

Any local insurance firm operating in Malawi which has the ability and potential to issue a policy for an insurance cover of the no-fault type from its menu of services can be approached by any sponsor/researcher wishing to conduct clinical trials that attract insurance cover as described above. **In the event that there is no local firm in Malawi that can directly issue this type of insurance cover from its menu of services at a given point in time**, sponsors/researchers shall follow the specific procedural requirement that is described in **section 4.2**.

4.2 Fronting Arrangement

This is where a local insurance firm registered and operating in Malawi issues an insurance policy on behalf of a firm registered and operating outside the Malawi borders but which has the ability and potential to provide the required insurance cover for the envisaged risk of a trial in Malawi. Under fronting arrangement:

4.2.1 Sponsors/principal investigators are required to contact local brokers in Malawi who have international presence who can source the product from internationally accredited insurers (i. e underwriting firms) and then arrange fronting with local insurers or alternatively;

4.2.2 Principal investigators in Malawi are required to contact their international sponsors or their head offices (for externally sponsored studies) who would, by themselves, source the required no-fault clinical trial insurance cover for the specific clinical trial to be conducted in Malawi and allow the local entity (i.e. local broker and insurer) arrange fronting.

4.2.3 **Once the required insurance policy is provided through fronting, the fronting insurance firm/insurance broker in Malawi shall submit anapplication to the Reserve Bank of Malawi for the approval of the fronting arrangement**.

5.0 AUNTHETICITY OF THE INSURANCE COVER DOCUMENTS

In tandem with the public notice and warning issued by the Insurance Association of Malawi, all copies of no-fault clinical trial insurance policy documents and certificates to be submitted for ethical and regulatory review shall have to be copies that had been **certified by a notary public in Malawi.**

6.0 GOVERNING POLICY AND LAW

Any fronted no-fault insurance policy for clinical trials to be conducted in Malawi shall be subject to the relevant Malawi laws, policies, ethical and regulatory requirements. Similarly, claim(s) and compensation arising directly or indirectly out of the conduct of the insured's business in Malawi shall be in accordance with and subject to the Malawi laws and applicable regulatory requirements.

7.0 ELEMENTS OF REVIEW OF SUBMITTED INSURANCE DOCUMENTS

To ensure uniformity in reviewing the submitted documentation of the required insurance, the following are elements of review which must be addressed in the insurance policy;

7.1 The insurance policy statement, certificate or statement of endorsement must bear a clearly written indication that the insurance cover obtained is the required no-fault type (i.e. no-fault compensation)

7.2 The required insurance must cover for participants **both during the running period of the trial and for five(5) years after trial is completed or closed**

7.3 Submitted insurance documents (i.e. policy, certificate or statement of endorsements etc) must be copies that had been certified by **a notary public** (e.g. commissioner for oath)

7.4 Insurance policy/statement of endorsement must contain a condition that describes that compensation shall be made **independent of proof of fault, provided that there is a causal-connection between harm/bodily injury/death and participation in the trial**

7.5 Insurance policy statement **must not** contain terms and conditions that appear to waive off the rights of the research participants (e. g denying a participant compensation as a result of participant's non-adherence to study procedures or as a result of participant's ignorance, illiteracy or lack of understanding etc)

7.6 Insurance policy statement must make reference to the requirement that claims for compensation and, terms and conditions of insurance shall be subject to and in accordance with the relevant Malawi Laws and applicable regulatory requirements

7.7 Each trial at a given site that attracts the required insurance must have its own specific insurance cover for participants in that trial at that site. A generic insurance cover for a trial sponsor or contract research organization **is not** allowed.

7.8 The required insurance policy for each of the specific trial at a given site must be obtained through and endorsed by the local insurance firm and broker registered and operating in Malawi as described in **section 4.0**

7.9 The insurance policy, certificate or statement of endorsement must clearly inform the regulatory authorities that participants can directly access the insurance benefits as compensation for harm/injury/death that may occur/manifest during

the trial period and within five years after trial is completed or closed by contacting the local insurance firm/broker through which the required insurance has been provided (***indicate name of the local insurance/broker firm***)

7.10 The insurance policy and certificate must indicate the following:

- Type of cover being no-fault insurance
- name of the insured;
- name of the clinical trial;
- retroactive/effective date and expiry dates of the policy
- period of insurance that includes a clear indication of the initial running period of the trial and **the five year period after completion/closure of the trial (Note: For clarity to the regulatory authorities, running period of the trial must be indicated distinct from the five year period after completion or closure of the trial, while the sum of both periods constitutes the period of insurance for a given trial as described in section 3.0).**
- Insurance policy number and issuance date
- Name of a local insurance broker

7.11 The required insurance must adhere to **policy exclusions** defined in **section 8.0 below.**

NOTE: **Sponsors and principal investigators must always critically evaluate the required insurance documentation against these elements before submission for review to ensure that all aspects of these elements are addressed. Doing a critical self-evaluation shall facilitate speedy review and approval.**

8.0 POLICY EXCLUSIONS FROM THIS REQUIREMENT

Study sponsors, principal investigators and review committees must note that this policy requirement excludes the professional indemnity/malpractice insurance. In no way must the required insurance for research participants in clinical trials be substituted for a professional indemnity or malpractice insurance because the professional indemnity or malpractice insurance is **not the required type of insurance cover for research participants in clinical trials as these apply to professional medical practice setting.** It must, thus, be remembered that professional indemnity or malpracticeinsurance is for coverage for harm, injury or death of any **patient** caused by or allegedto have been caused **by error, omission or negligence caused by a registered medical practitioner in the course of rendering professional services for which he/she was registered in Malawi**. Professional indemnity/malpractice insurance **excludes** coverage for **clinical trials as these are forms of insurance covered in fringe benefits of medical staff. All forms of insurance that are covered in fringe**

benefits (i.e. professional indemnity/malpractice or health insurance for medical staff) are excluded from this policy requirement.

9.0 CONCLUSION

In conclusion, stakeholders are called upon to adhere to this policy requirement and guidance on insurance for research participants/subjects in clinical trials/studies in Malawi. Speedy reviews and approvals of protocols will depend to a large extent on the co-operation and facilitation of sponsors and principal investigators in sourcing and providing the required insurance cover. Provision of the required insurance cover remains the responsibility of the sponsor of a given trial. Therefore, principal investigators in Malawi, as a host country for a given trial that would attract the provisionof the required insurance, are required to facilitate the process of obtaining the required insurance **without let or hindrance.** Regulatory authorities shall ensure the enforcement of this policy requirement in compliance with **sections 18 and 48 of the Science and Technology Act No.16 of 2003.**

Kamuzu University of Health Sciences Research Ethics Committee (KUREC)

Standard Operating Procedure for Distributing KUREC Documents

SOP #: 1

Place DO NOT COPY label here.

Version: 1.0

Author(s):

Approval: **Approved By** **Date**

22 June 2024

Prof Mac Mallewa - Vice Chancellor _____

Revision History:

Version	**Effective Date**	**Description**

Purpose

This SOP describes how to handle documents in order toprotect the confidentiality of the documents.

References

- Operational Guidelines for Ethics Committees that Review Biomedical Research,TDR/PRD/ETHICS/2016.1; WHO, 2000
- International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS2002. KUREC Guidelines, 2021

Scope

Documents: Protocols and related documents, data related to participants, correspondences to and from KUREC, minutes of meetings,

Chair/ Vice Chair

KUREC members

Secretariat Experts

Allowable Exceptions

None

Procedures

- New members, staff and Experts of KUREC sign a confidentiality agreement at the time of appointment.
- Members and staff of KUREC request for copies of documents
- Gadgets (laptop, tablet, desktop) containing KUREC documents shall be password protected.
- Documents submitted electronically shall have a password.

- .
-

Definition of Terms

Confidentiality: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

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

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for TRAINING AND CONTINUING PROFESSIONAL DEVELOPMENT OF KUREC MEMBERS AND STAFF

SOP #:	2
Version:	1.0
Author(s):	
Approval:	**Approved By**

Place DO NOT COPY label here.

–Prof Mac Mallewa Vice Chancellor

21 June 2024

Date

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this procedure is to inform KUREC secretariat and members what training is considered essential and how members can access the training.

KUREC recognizes the importance of continuing professional development and training of its members and secretariat in ethical and scientific review. New KUREC members and staff are required to undergo a training program immediately after joining KUREC. All members should be inducted to these guidelines;

- **National health research guidelines including**
  - KUREC
  - NHSRC
  - PMRA
  - NCST
  - Indemnity and insurance (in research)

- **International ethical guidelines including**
  - Declaration of Helsinki
  - WHO
  - CIOMS
  - Good Clinical Practice (ICH-GCP)/Federal Wide Assurance
  - UNESCO declaration of bioethics and human rights

Scope

KUREC members and secretariat.

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- All KUREC members and staff shall receive initial training at the start of the term of office on the following
    - Research ethics and integrity
    - Functions and operations of KUREC
    - Research guidelines (KUREC,)
    - How to conduct scientific and ethical review of protocols
    - Good research regulatory practice(GRRP), and GCP
    - Research methods
- Secretariat shall identify providers of trainers approved by the Director of Postgraduate and Research Institute.
- Secretariat continually provides information about relevant training courses, workshops,conferences.
- Members may identify an appropriate course and inform secretariat in writing
- Secretariat shall keep training records
- Members and secretariat will be encouraged to have continuous profession development training as defined by KUREC.

Definition of Terms

Conference: A meeting of individuals or representatives of various bodies for the purpose of discussing and/or acting on topics of common interest.

Good research practice: Internal standards of the way in which research is planned and conducted, results are recorded and reported, and the findings are disseminated, applied, and exploited

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

Workshop: A meeting at which a group of people engage in intensive discussion and activity on a particular subject or project.

Kamuzu University of Health Sciences Research Ethics Committee (KUREC)

Standard Operating Procedure for Managing a Protocol Submission

SOP #:	3	Place DO NOT COPY label here.
Version:	1.0	
Author(s):		
Approval:	**Approved By**	**Date**
	Prof Mac Mallewa - Vice Chancellor	21 June 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

To describe how a research protocol submitted by investigators is processed before the review by the committee.

References

- KUREC Guidelines 2024

Scope

This applies to protocol packages submitted for the first time to KUREC for review.

KUREC members

Investigators

Allowable Exceptions

This SOP is meant to be followed without deviation.

Procedures

- Check the received package against the check list.
- Secretariat conducts administrative review within 3 working days.
- Secretariat informs Investigator whether application package/e-mail was complete or incomplete within the 3 working days through RIEMS.
- If application package is incomplete Investigator provides missing documents/information within 2 working days.
- Secretariat assign review date for the protocol and inform investigator.

- Chairperson and the secretariat assign primary and secondary reviewers based on expertise of the subject area of study.

- Secretariat assign protocols in RIEMS to reviewers at least 7 days before the scheduled meeting

Definition of Terms

Protocol package: The set of documents that includes the protocol and other relevant documents submitted by investigator when applying for approval from KUREC. The package should comply with the submission requirements in the KUREC checklist.

Kamuzu University of Health Sciences Research and Ethics Committee(KUREC)

Standard Operating Procedure for PROTOCOL REVIEW PROCESS

SOP #: 4

Version: 1.0

Author(s):

Place DO NOT COPY label here.

Approval: **Approved By** **Date**

– Prof Mac Mallwa Vice Chancellor 22 June 2024

Revision History:

Version	**Effective Date**	**Description**

Purpose

This SOP describes how KUREC reviews and assesses the protocol submitted for approval of the study. The Protocol Assessment Form is designed to structure the protocol review process and to facilitate reporting recommendations and comments for the researchers.

References

- KUREC Guidelines 2024
- Protocol Assessment Form

Scope

This SOP applies to the assessment of all protocols submitted for review. The specific questions in the Protocol Assessment Form must be adequately addressed in the protocol itself and/or protocol-related documents under review

KUREC members, reviewers and secretariat.

Allowable Exceptions

This SOP is meant to be followed without deviation

- Reviewers complete the Protocol Assessment Form (KUREC form 08-01)
- Reviewers submit completed protocol assessment form (KUREC FORM 08-01) to KUREC secretariat at least 7 working days before the meeting
- Secretariat summarizes the comments on standard format for distribution at the meeting.
- Primary reviewer presents the protocol

- KUREC members discuss the protocol
- KUREC members will strive to reach consensus
- In the advent that consensus is not reached the members shall vote (50+1%)
- In case of a tie, chairperson will cast the deciding vote
- Maximum time for each protocol should not be more 30 minutes unless advised by the chair.
- Secretariat records the decision

Definition of Terms

Protocol Assessment Form: An official record that documents the protocol review process.

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Engaging External/Experts

SOP #: 5

Place DO NOT COPY label here.

Version: 10

Author(s):

Approval:	**Approved By**	**Date**
	Prof Mac Mallewa Vice Chancellor	21 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

To engage services of an independent expert in a specific area of expertise (e.g.ethics, law, specific diseases or methodologies, community representation, patients, special interest groups) not available among the Committee membership but is applicable to a submitted research protocol.

References

- Operational Guidelines for Ethics Committees that Review Biomedical Research. WHO and CIOMS
- KUREC Guidelines 2024

Scope

Chairperson of KUREC

KUREC members

Experts Allowable

Exceptions

None

Procedures

KUREC shall have a standard list of external reviewers. In addition, members may identify additional reviewers continually as need arises.

- The chairperson and secretariat identifies an expert
- Experts are approached in writing to serve in that capacity

- Those who are willing present their updated CVs to secretariat.
-
- Chair communicates to the appointed expert
- Each expert will sign a Confidentiality and Conflict of Interest Form (KUREC 021)
- Experts will serve in their capacity as long as the issue which they were called for still exist
- .
- Experts will be compensated the normal sitting allowance for KUREC.
- Experts t submits comments to secretariat and may be required to attend the meeting to discuss the protocol they review
- n expert is not voting member of a committee. During voting they will recuse themselves.
- The secretariat will keep records of all people who served as experts for KUREC. from the

Definition of Terms

Independent expert: An individual who gives independent expert advice, comment and recommendation upon review of the study protocols with no interest to the research protocol. Interest here means relational and financial.

Kamuzu University of Health Research and Ethics Committee (KUREC)

Standard Operating Procedure for Expedited Review

SOP #:	6	Place DO NOT COPY label here.
Version:	1.0	
Author(s):		
Approval:	**Approved By**	**Date**
	Prof Mac Mallewa - Vice Chancellor	21 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

To describe the process of approval of studies with minimal risk, changes or modifications required by KUREC or investigator initiated clarifications to an approved protocol and related documents so as to prevent unnecessary delays in reviewing minor changes or modifications to a previously reviewed or approved protocol.

References

- KUREC Guidelines 2024

Scope

Expedited review applies to protocols, Letter of clarification, Letter of Amendment, informed consent forms, and advertising material.

KUREC members especially, the secretariat, the Chairperson and appointed reviewers.

It is the responsibility of KUREC Secretariat to determine which requests and study protocols should be reviewed and approved through expedited process.

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- Secretariat and the Chairperson nominates 3 members to undertake the expedited review.
-
- .

- Secretariat communicates the decision to the investigator within 7 days of submission of application.
- Chairperson reports to the committee for noting at the next meeting

---

Definition of Terms

Expedited approval: KUREC approval granted by a Sub-committee headed by a Chairperson on behalf of a full committee. for minor changes to current KUREC approved research activities and for research which involves no more than minimal risk and other minor requests. Student protocols up to Masters level will also undergo expedited review

Minimal Risk: risk that is no more likely and not greater than that attached to routine medical or psychological examination – and if the procedures to be used are only those for which signed consent forms are not customarily required outside the research context.

Minor Modifications/Changes: *administrative revisions*, such as correction of typographic errors, addition or deletion of *non-procedural items*, such as the addition of study personnel names, laboratories, etc.

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Management of Protocol Amendments

SOP #:	7	Place DO NOT COPY label here.
Version:	1.0	
Author(s):		
Approval:	**Approved By**	**Date**
	Prof Mac Mallewa- Vice Chancellor	24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

This procedure describes how protocol amendments are managed and reviewed by KUREC.

References

- KUREC Guidelines 2024
- KUREC SOP# 6

Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval by KUREC. Amendments made to protocols may not be implemented until reviewed and approved by KUREC.

KUREC secretariat and members

Allowable Exceptions

This SOP is meant to be followed without deviation and violation

Procedures

- Secretariat receives the letter of amendment and the amended protocol
- Amended protocol goes through the standard review of the amended sections as per SOP#8.
- Secretariat and the Chairperson nominates 3 members to undertake the expedited review.
-
-
- Communicate decision to applicant no later than 7 days after the meeting

Definition of Terms

Protocol Amendment: A change to the protocol during the planning or course of the study. The amendment is a foreseen change to the study plan that requires formal approval by the sponsor/principal investigator.

KAMUZU UNIVERSITY OF HEALTH SCIENCES RESEARCH AND ETHICS COMMITTEE (KUREC)

KUREC FORM 103

Request for Amendment/Modification

Please complete the following:

KUREC REF. Number (KUREC will not process requests without this number.)	***Date of Request***
Principal Investigator Name Phone # Email	**Contact Person** (if other than PI) ***Phone #*** ***Email***
Title of Study	

1. **Description of proposed changes:** (Note: Changes may not be implemented before KUREC approval)
   Use attachments and additional pages, as needed.

2. **Reason for Amendment/Modification:**

3. **Changes to Consent Form:** Are changes required? No _____ Yes_____(If Yes, attach new consent form)

Signature of Principal Investigator Date

(1) Approval of Changes /Modifications by KUREC

KUREC Office Use only:
Approval
date:_____

Recommended :_____

Not recommended:_____

I. Signature

II. Chairperson Authorized Signatory

Date

KUREC form 103

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for ANNUAL CONTINUING REVIEW

SOP #:	8
Version:	1.0
Author(s):	
Approval:	**Approved By**

Place DO NOT COPY label here.

Date

01 December 2021

Prof Mac Mallewa –Vice Chancellor

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

This procedure describes how annual continuing reviews of protocols are managed by KUREC.

References

- KUREC Guidelines 2024, SOP# 3, SOP# 6

Scope

This SOP applies to the conducting of continuing review of study protocol involving human participants or animals at intervals appropriate to the degree of risk but not less than once per year. The purpose of annual continuing review is to review the progress of the entire study, not just changes in it in order to ensure the continued protection of the rights and welfare of research participants. Continuing review of a study will be done through expedited process.

Allowable Exceptions

This SOP is meant to be followed without deviation and violation

Procedures

- KUREC approval is valid for a maximum period of 12 months. Therefore, all approved protocols shall apply for continual review every 12 months.

Secretariat shall send reminders to investigators at least 3 months before the expiry

- All approved studies submit a progress report with the application for continuing review using the KUREC Continuing Review Form (FORM 102).
- Upon receipt of the application package, KUREC secretariat performs an administrative review (SOP#3).
- **A**pplications go through the expedited review process (SOP#3 and 4)

- The Chairperson of KUREC signs and datesthe Continuing Review Application Form after adecision has been reached.

- The completed Continuing Review Form is the official record of the decision reached by KUREC for the protocol.

- Communicate the decision to the investigator within 7 days by sending a copy of the approved progress report form and the protocol

Definition of Terms

Approved Protocols: Protocols that have been *approved without stipulations* or *approved with recommendations* by KUREC may proceed. Protocols that have been *approved with stipulations* by the KUREC may not proceed until the conditions set by the KUREC in the decision have been met. Protocols should be amended and submitted to the KUREC within *one* month for re-review.

KAMUZU UNIVERSITY
OF HEALTH SCIENCES

The Kamuzu University of Health Sciences Research and Ethics Committee
College of Medicine, Private Bag 360, Chichiri

Progress Report

1. Title of Study

2. KUREC PROTCOL #

3. KUREC Approval Date

D D M M Y Y Y Y

4. KUREC Expiration Date

D D M M Y Y Y Y

5. Anticipated End Date

D D M M Y Y Y Y

6. Principal Investigator

7. Co-Investigator(s)

8. Student Investigator(s)

9. Host Department

10. Phone No Email

11. Name of sponsor[1]

12. Name of funder[2]

13. Amount of total funding by funder/sponsor
(please indicate the currency)

14. Amount of KUHeS overhead fees KUHeS (10%) in the original approved budget *(please indicate the currency. Calculate this based on 13)*

15. Amount of overhead fees paid to KUHeS (10%) *(please indicate the currency and attach the proof of payment)*

16. Amount of KUHeS overhead fees outstanding (if any)
(please indicate the currency)

17. If KUHeS overhead fees are outstanding, provide an explanation why the fee is outstanding in the space below;

[1] A Spon
financin

[2] A fund ting
or mana

EXECUTIVE SUMMARY OF THE PROJECT

In the space below, provide a brief summary of the progress and results obtained to date (Please explain any changes made or are being planned for approval as indicated in C4).

A. Project Status: (Since last approval, check one category only.)

1. Enrollment Has Not Begun* ☐
2. Actively Enrolling Participants* ☐
3. Enrollment Completed, Contact with Participants Ongoing ☐
4. Contact with Participants Completed, Analyzing Identifiable Data Analysis Only ☐
5. Analyzing Identifiable Data (Samples or Data) Only ☐
6. Analyzing Unidentifiable Data; Data Do Not Contain Identifiers or Linkage to the Data if this is a Program Project, check here ☐
7. Complete Section E., sign the Progress Report and attach a ☐

completed List of Associated Projects ☐

If enrollment has not begun or you are actively enrolling participants, attach a copy of the consent document used or to be used.

B. Number of Participants enrolled, Records Reviewed or Samples Analyzed (if applicable):

What is the total sample size?

1. Since last renewal:

# of males		# of females	
# of adults		# of children	

2. Since original approval:

# of males		# of females	
# of adults		# of children	

C. (Answer Questions 1 through 7 based on information since last review. Attach a memo explaining "Yes" answers to questions 1 through 6.)

	Yes	**No**	**N/A**
1. Have any participants withdrawn voluntarily or been withdrawn from the study?	☐	☐	☐

2. Have any unexpected side effects, complications, or findings been noted that have not been reported to the Committee? ☐ ☐ ☐

Yes No N/A

3. Have there been any changes to the protocol (participant population, recruitment, study procedures, sample size or consent process) that have not been reviewed and approved by the Committee? ☐ ☐ ☐

4. Have there been any significant new findings which may relate to the participants' willingness to continue participation in the study? ☐ ☐ ☐

5. Has any new information appeared in the literature or been discovered from the study results that would affect the risk-benefit assessment of the project? ☐ ☐ ☐

6. Has a Data Safety and Monitoring Board been established for this project? If yes, provide a status report from the DSMB. ☐ ☐ ☐

7. Do any of the participating faculty (or their immediate family, staff or students) have a financial interest (royalty, equity or consulting) in the sponsor and/or products used in this project? ☐ ☐ ☐

Has this been reported to the KUREC previously? ☐ ☐

D. As Investigators indicate your assessment of the progress of this study

As expected ☐

Not as expected ☐

(Please explain)

Above expectation ☐

_____

_____

E. **Funding Status**: *(select one)*

Awarded ☐

Pending ☐

Project **not** funded ☐

If pending or not funded, please explain:

_____

_____

		D	D	M	M	Y	Y	Y	Y

Name and Signature of Principal Investigator Date

*****SEE BELOW FOR INVESTIGATOR RESPONSIBILITIES*****

Investigator is Responsible for:

- Making sure that changes, amendments, or addenda made to the protocol or the informed consent process must be submitted to KUREC for review and approval prior to initiating the change. This includes changes in investigator(s), sample size, population, research site, subject compensation, etc.
- Vulnerable groups shall not to be included in the study unless the study is approved by KUREC
- The KUREC protocol number shall be cited in all correspondence.
- Adverse events should be reported promptly to KUREC.
- Significant new information that may affect the risk: benefit ratio must be submitted promptly to KUREC.
- Only consent/assent documents with a valid approval date shall be presented to the participants.
- Signed consent forms for all participants enrolled in the study must be retained on file.
- All active research projects must be reviewed and re-approved by the KUREC prior to the project's expiration date.
- The Principal Investigator is responsible for submitting progress reports by the project's current submission date.
- The Principal Investigator is responsible for keeping the Co-Investigator(s) and Student Investigator(s) informed of the status of the project.

UPLOADTHIS FORM AND SUPPORTING DOCUMENT(S) IN REIMS

KUREC USE ONLY:

Project Re-approved for Period_____to _____

_____ _____

Chair/Co Chair KUREC **Date and Stamp**

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Serious Adverse Events Reports Review

KUREC SOP #: 9

Place DO NOT COPY label here.

Version: 1.0

Author(s):

Approval:

Approved By	**Date**
– Prof Mac Mallewa- Vice Chancellor	**24 JUNE 2024**

Revision History:	**Version**	**Effective**	**Date**	**Description**

Purpose

Studies are required to report adverse events (AEs) to KUREC to continually assess safety and protection of participants. This procedure describes which SAEs must be reported and how KUREC responds to the reports.

References

- Good Clinical Practice Regulations and Guidance Documents

Scope

AEs that must be reported include unexpected SAEs, Deaths, SAEs directly related to an investigational new product (INP).

Investigators

KUREC members

Allowable Exceptions

Adverse events that are non-serious and not related to study product, or related but anticipated

Procedures

- Investigator submits SAE report on a form approved for the study or a COMREC form
- Secretariat acknowledges receipt of SAE report and sends report to the COMREC Sub-committee on Research Participants' Safety.
- The COMREC Sub-committee on Research Participants' Safety shall make recommendations to the COMREC main Committee:
  - *Take no action and file the report away with an acknowledgement to the Investigator*
  - *Request further information from the investigator*
  - *Request the investigator for an amendment to the protocol*
  - *Suspend or terminate the study after informing the investigator promptly*
- The KUREC Sub-committee on Research Participants' Safety reports to full KUREC meeting
- KUREC makes decision on the recommendations and communicates decision to investigator

Definition of Terms

Adverse Event: Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for MANAGING NON-COMPLIANCE BY INVESTIGATORS

KUREC SOP #: 10

Version: 1.0

Author(s):

Place DO NOT COPY label here.

Approval: **Approved By** **Date**

Prof Mac Mallewa - Vice Chancellor 24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

This SOP provides instructions on how KUREC handles non-compliance by investigators and research team members who fail to comply with KUREC guidelines.

References

- KUREC Guidelines 2024

Scope

This SOP applies to all research approved by KUREC.

KUREC secretariat, members and investigators

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- Non-compliance can be identified through KUREC monitoring, reports, whistle-blowers
- When non- compliance is suspected, the secretariat conducts investigations to verify/clarify the non-compliance where necessary.
- Where non-compliance is confirmed, the Compliance Officer makesappropriate recommendations to investigator
- Compliance Officer reports to KUREC at next meeting.
- Meeting decides on course of action which may include
    - advising investigator on what action to take to address the non adherence.
    - depending on the gravity of the non-adherence KUREC suspend orterminate

approval of current studies
    - refuse subsequent applications from the investigators cited.
- Communicate decision to investigator (SOP#21)
- For decision to suspend or terminate clinical trials involving drugs, biologics and devices, send a copy of the notification to the PMRA, National Commission of Scienceand Technology (NCST), sponsor or the sponsor's representative [Contract Research Organization (CRO)] of the study.
- Follow up to verify whether the decision is being implemented

---

Definition of Terms

Compliance: Adherence to KUREC Guidelines and applicable national guidelines and regulatory requirements.

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Premature Termination of Protocols

KUREC SOP #:11

Place DO NOT COPY label here.

Version: 1.0

Author(s):

Approval:	**Approved By**	**Date**
	Prof Mac Mallewa – Vice Chancellor	24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

This procedure describes how protocol termination is managed by KUREC.

Protocols are usually terminated at the request of the Principal Investigator when subject enrolment and subject follow-up are discontinued or after a decision by KUREC.

References

- KUREC Guidelines 2024

Scope

This SOP applies to all studies approved by KUREC. Premature termination may be requested by the Investigator, recommended by KUREC or other regulatory agencies. Reasons for termination include ethical and scientific misconduct, safety, financial, new information/knowledge and efficacy (stopping rules).

Investigators, KUREC secretariat and members.

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- For KUREC or Investigator initiated premature termination, the investigator submits completed KUREC FORM 15-01.
- Secretariat reviews form for completeness of information and refer to chairperson.
- Chairperson reviews the request and makes recommendations regardingthe termination process.

- Secretariat communicates to investigator recommendations to be fulfilledto prematurely terminate the study.
- Secretariat must report the termination at next KUREC meeting.
- Premature termination for non-compliance shall be communicated to National Commission of Science and Technology and Pharmacy Medicines Regulatory Authority (PMRA) (For clinical trials).

Definition of Terms

Termination: The stopping of study. May be stopping as per protocol or premature as a decision of the KUREC.

KAMUZU UNIVERSITY
OF HEALTH SCIENCES

PROTOCOL TITLE:			
PROTOCOL NUMBER:			
PRINCIPAL INVESTIGATOR:			
MEDICAL ADVISOR (if applicable):			
KUREC APPROVAL DATE:		DATE OF LAST REPORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF SUBJECTS:		NO. ENROLLED:	
SUMMARY OF RESULTS			
REASON FOR TERMINATION:			
APPLICANT NAME:		DATE:	

The committee may request for additional information to support this request/notification.

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for **Standard Operating Procedure for Inspecting Approved Protocols**

KUREC SOP#	12	Place DO NOT COPY label here.
Version:	1.0	
Author(s):		
Approval:	**Approved By**	**Date**
	Prof Mac Mallewa – Vice Chancellor	24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

This procedure describes how monitoring of studies approved by KUREC will be conducted

References

- KUREC Guidelines 2024

Scope

Investigators, CRAs, Study Staff, Sponsors

KUREC secretariat and members

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- KUREC shall monitor research through the following mechanisms
    - Annual reports
    - Progress reports
    - Data and safety reports
    - Inspections
- Investigator submits annual, progress, data and safety reports whereapplicable
- KUREC reviews reports and make recommendations

- KUREC communicates recommendations to investigator

Definition of Terms

Inspection: An action that KUREC or its representatives visit study sites to assess how well the investigators and the sites are complying to the approved protocol, GCP and the applicable regulatory requirements. Normally inspection visit will be arranged in advance with the Principal Investigators but KUREC may also conduct unannounced visits.

A REPORT ON COMREC INSPECTION OF PROTOCOL #

STUDY TITLE	
ACRONYM	
PRINCIPAL INVESTIGATOR	
CO-INVESTIGATORS	
STUDY COORDINATOR	
SPONSOR	
INSTITUTION	
STUDY SITE (s)	
DATE OF VISIT	
DURATION OF THE INSPECTION	
NAME OF COMREC INSPECTOR	
DE- BRIEFING SESSION AFTER INSPECTION – PRESENT	

INSPECTION ACTIVITIES

1.0 REVIEW OF INVESTIGATOR'S SITE MASTER FILE DOCUMENTS

Queries on the Investigator's Site File Review

2.0 REVIEW OF SIGNED INFORMED CONSENT DOCUMENTS (ICDs)

QUERIES ON INFORMED CONSENT DOCUMENTS

3.0 REVIEW OF STANDARD OPERATING PROCEDURES (SOPs)

QUERIES ON STANDARD OPERATING PROCEDURES

4.0 CRF AND SOURCE DATA VERIFICATION (SDV)

Queries on CRF and Source Data Verification

5.0 PARTICIPANTS' INTERVIEW

Queries from the interview

6.0 SITE PHARMACY ASSESSMENT

Queries on Site Pharmacy

7.0 FACILITIES ASSESSMENT

Queries on Facility

N/A

8.0 RECOMMENDATIONS

COMREC CHECKLIST FOR A SITE INSPECTION

EC Protocol Ref :	Date of the Visit:
Study Title:	
Study Phase:	
Stage of study: Before commencement/ ongoing / complete	
Principal Investigator:	Phone:
Sub/Co-Investigators	
Institution:	
Reasons for doing this inspection:	
Study team members met included:	
Regulatory approval of protocol Version and Date:	
EC approval of protocol: Version and Date:	
Informed consent approval: Version and date:	
Amendment History: Version and Date:	
Total number of expected subjects:	Total subjects enrolled:
When was first participant enrolled	
Trial population (babies, women)	
How many participants withdrew? Comment/Reasons.	
Brief Update on the study	

progress	
Any unanticipated problems experienced	
Any adverse events recorded? Ask for AE files ☐ Yes ☐ No Were AEs and SAEs handled according to protocol and regulations (reported to EC and NRA in specified time)	
Any protocol non-compliance /violation? ☐ Yes ☐ No	Comment:
Are all EC & NRA & Sponsor correspondence Files up to date? ☐ Yes ☐ No	Comment: Are they filed in appropriate files?
SITE INSPECTION ACTIVITIES	
Reception area: Check on adequacy of size. Whether	•

accessible and labeled	
• Is receptionist trained to encounter participants? • Is receptionist trained in basic knowledge about study?	•
Assess other facilities in order to ensure that they are up to acceptable standards. • Consulting rooms spacious and appropriately designed, lockup cabinets for confidential documents. • Pharmacy including dispensary • Document storage rooms, security, lockable door, lockup cupboards • Counseling rooms re privacy • Specimen collection room with appropriate disposal equipment for sharps and other lab disposables appropriately staffed by a qualified nurse. • Toilets clean and accessible • Blood sampling area kept according to	• • - • • • • • •

infection control procedures? • Other facilities (specify) • General cleanliness of site and infection control,	
Trial specific equipment available and working and SOPs on equipment available	
Emergency • Emergency trolley available • Check on contents and validity • Are oxygen and accessories available, checked and signed • Staff trained in CPR • Staff trained in ALS • What action in event of emergency	
Informed consent Review Informed consent Documents and at least 25% of trial participants files to ensure the participants are signing the approved /correct informed consent documents. • Inspect binders containing consent forms • Informed consent documents in both Local language & English • Check on any irregularities in IC documents (no	

insurance, no treatment for trial related injuries, signature of PI, no date etc) • Patient information sheets were in both local language & English. • All participants sign the form prior to any study related procedures • All forms signed and dated • Thumb prints accompanied by witness. Check on witness. • Check all adverts and materials to ensure approved by EC	
Assess trial participants understanding of trial purpose and procedures. • How many study arms • What are they expected to do? • Duration of their participation • Awareness on randomization, randomization, placebo use • Awareness of their right to withdraw • Are there any problems that trial participants are facing that relate to their participation? • Check on compensation – How	

much is paid per visit including any other payments • Check on reimbursements • Any recommendations they have on the trial.	
Verify any issues regarding compensations and reimbursements with study coordinator.	
Document storage and data handling facilities Review to ensure they are up to acceptable standard • Trial record maintained in lockable cabinet • Record storage room secure • Record room locked at all times • Access to record storage room restricted • Staff have a system in place for tracking participant files. • How Clinic notes kept • Do all study files and records contain identifiers • Data handling during data entry satisfactory- • systematic quality checks, • computer software in use and double entry very important in reducing errors and omissions.	
Review study identification procedures as well as	

confidentiality maintenance strategies employed	
Observe the informed consent process if possible	
Check on the qualifications of staff to ensure that they are appropriately qualified. Professionals should be registered with appropriate bodies. • nurses, • clinicians, • counsellors • Pharmacists • Others (specify)	
Investigational products • Is pharmacy access controlled • Check on labeling • Check expiry dates on IPs • Is site only using approved IPs • Are IPs for different studies in separate cupboards and clearly identified? • Are IPs handled and transported as per requirements/cold chain etc • Are IPs prepared as per protocol • IS IP stored according to required conditions and humidity	

• Are temperature logs available • Does facility have power back up	
Study Procedures *(comment on appropriateness)* • Check on randomization • Check on double blinding • Check on placebo use	
Quality Assurance • Check on availability of QA system • Check on availability of SOPs • Check on protocol specific training • Check on SOP training • How ensure compliance with SOPs • Is study monitored by a CRO • When was last visit by CRO? • **Training of staff (Proof of training)** • GCP • Research Ethics	
Waste disposal • Is disposal of biological materials appropriate • Are there different containers for different wastes ○ Black-non infectious	

○ Red-infectious and blood waste ○ Yellow-for sharps	
Trial Insurance (where applicable) • Insurance valid for duration of trial • Check on indemnity document	
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:
Duration of visit: …….. hours	Starting from: Finish:
Name of IEC/IRB member/representatives and other officials:	
Completed by:	Date:

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Storage of Active Files

KUREC SOP #:13

Version: 1.0

Author(s):

Place DO NOT COPY label here.

Approval:	**Approved By**	**Date**
	Prof Mac Mallewa – Vice Chancellor	22 June 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

This SOP describes how documents of active protocols or studies approved by KUREC are stored

References

- KUREC Guidelines, 2024

Scope

Secretariat and KUREC members

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- File protocols and related documents for each approved active study in one file. The documents to be filed include:
  - Original application documents and any updates received during the study.
  - Investigator's brochure or similar documents
  - Approval letters and other correspondence sent to the investigator.
  - Approved documents (protocol, protocol amendments, informed consent, information provided to participants, advertising materials etc.)
  - Adverse events reports or safety report received
  - Continuing review reports
- Assign the active study files with unique identifiers.
- Maintain the study files in a secure place until the final report is reviewed and accepted by the Committee.

Definition of Terms

Active Study Files: Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by KUREC.

Administrative Documents: Documents include official minutes of Committee meetings as described in SOP Committee Meeting Minutes and Voting Records and the Standard Operating Procedures, both historical files and Master Files as described in SOP-SOP Distribution, Implementation and File Maintenance.

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for DECLARING CONFLICT OF INTEREST

KUREC SOP #:14

Version: 1.0

Author(s):

Place DO NOT COPY label here.

Approval:

Approved By	**Date**
Prof Mac Mallewa – Vice Chancellor	22 June 2024

Revision History:

Version	**Effective Date**	**Description**

Purpose

This procedure describes the process of declaring a conflict of interest by KUREC members, secretariat and external reviewers and guests

References

- KUREC Guidelines 2024

Scope

Conflict of interest are related to specific protocols

KUREC members, reviewers, and secretariat, guests.

Allowable Exceptions

This SOP is meant to be followed without deviation or violation

- KUREC shall inform and train members, secretariat, reviewers, and guests about potential conflicts of interest
- Members, secretariat, reviewers, guests shall sign a conflict of interest disclosureform
- In case of declared conflict of interest, one shall recuse oneself from deliberating and decision making for that protocol.
- A member who has declared a conflict of interest may be called upon to provide information or clarifications on the protocol if so required during the deliberations of thecommittee
- The declaration shall be minuted.

Definition of Terms

Conflict of Interest: A conflict of interest arises when a member (or members) of the ethics committee (EC) holds 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 focused on the protection of the research participants. Conflicts of interests may arise when an EC member has financial, material, institutional, or social ties to the research.

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Maintaining Confidentiality

Place DO NOT COPY label here.

KUREC SOP #: 15

Version: 1.0

Author(s):

Approval:	**Approved By**	**Date**
	Prof Mac Mallewa Vice Chancellor	24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

This procedure describes how confidentiality shall be maintained

References

- KUREC Guidelines 2024

Scope

KUREC members, reviewers, and secretariat, regulatory authorities.

Allowable Exceptions

This SOP is meant to be followed without deviation or violation.

Procedures

- All members, reviewers, secretariat, and guests sign a confidentiality agreement form (KUREC FORM #2).
- Members shall adhere to the following
    - not distribute KUREC documents to non-members
    - respect intellectual property
    - keep KUREC documents secure
    - maintain appropriate communication channels of the committee
- KUREC will recommend to the principal disciplinary action for members and secretariat who failadhere to the confidentiality agreement

Definition of Terms

Confidentiality: The non-occurrence of the unauthorized disclosure of information.

KUREC FORM2

Confidentiality and Non-Disclosure

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

If the Undersigned agrees with the terms and conditions set forth above, please sign and date this Agreement. The original will be kept on file in the custody of the KUREC Administrator. A copy will be provided for your records

I ..... have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Undersigned Signature Date

_____ _____

Senor KUREC Administrator Date

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for REVIEW OF GUIDELINES AND PROCEDURES

KUREC SOP #: 16

Version: 1.0

Author(s):

Approval: **Approved By** **Date**

Place DO NOT COPY label here.

p Prof Mac Mallewa – Vice Chancellor 24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

This procedure describes how to update guidelines and SOPs

References

- KUHeS
- KUREC Guidelines 2024

Scope

KUREC members and secretariat

KUHeS management and staff

Investigators

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- KUREC shall annually assess the need to review guidelines and SOPs.
- KUREC shall review SOPs annually.
- The review process shall be initiated at a full KUREC meeting.
- A sub-committee to conduct the review shall be appointed at the full meeting
- KUREC shall submit revised guidelines and SOPs to KUHeS management for endorsement
- KUREC shall ensure proper version control of guidelines and SOPs
    - Numbering of SOPs
    - Assignment of version numbers and effective dates
    - Minor changes will require changing the decimal in the version

- Major changes will require changing the version
- After change in version all old SOPs shall be retrieved from circulation. One master copy will be maintained on file
- Electronically circulated guidelines and SOPs shall be in PDF
- There shall be a hard copy version within 4 weeks of effective date
- After approval of SOP, the new version will be circulated based on a circulation list

Definition of Terms

Guideline: Any suggestion, rules, etc., intended as a guide for specific practice

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Audit and Inspection of KUREC

KURE	17	Place DO NOT COPY Tan here.
Version:	10	
Author(s):		

Approval:	**Approved By**	**Date**
	Prof Mac Mallewa – Vice Chancellor	22 June 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this procedure is to guide KUREC on how to prepare for an audit or inspection.

References

- KUREC Guidelines 2024

Scope

KUREC members and secretariat

KUHES management and

staff Investigators

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- Principal can initiate KUREC audit or inspection in writing to KUREC chairperson
- Principal can appoint individuals to conduct the audit and/or inspection of KUREC
- KUREC chairperson establishes contact with auditors to agree on programme for the audit
- Chairperson informs KUREC members and secretariat, and investigators where necessary
- Secretariat shall follow the preparatory procedures outlined in KUREC SOPs 1-22
- Secretariat must avail themselves for the meeting with auditors
- Secretariat must get a debrief from the auditors
- The auditors shall send a report to the Principal
- Principal shall discuss the report with KUREC chairperson and agree on course of action from recommendations of the report
- Chairperson informs secretariat and members of audit report

Definition of Terms

Audit: A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for CONVENING AN EMERGENCY MEETING

KUREC SOP #: 18

Place DO NOT COPY label here.

Version: 1.0

Author(s):

Approval:	**Approved By**	**Date**
	Prof Mac Mallewa- Vice Chancellor	22 June 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this procedure is to describe how KUREC convenes emergency meetings

References

- KUREC Guidelines 2024

Scope

Emergency meeting can be convened for the following reasons:

- Urgent issues, which if delayed will affect or have impact to the public benefit or national interest.
- Unusually high number of deaths reported from a study.
- Other appropriate reasons.
- Investigators request for an *adhoc* meeting to facilitate an initial review meeting for a proposal

KUREC secretariat and members

Allowable Exceptions

This SOP is meant to be followed without deviation

- The Investigator will cover all the expenses for the meetings
- Meeting will be conducted as per standard procedure for a regular meeting
- Decisions made at the emergency meeting may be effected immediately but shall be ratified at the next full meeting

Definition of Terms

Adhoc meeting: A council meeting that is scheduled outside of a normally scheduled council meeting to review study activities that require Full Committee review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion and voting portions of the meeting.

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)
Standard Operating Procedure for Risk Management

KUREC SOP #: 19

Version: 1.0

Author(s):

Place DO NOT COPY label here.

Approval: **Approved By** **Date**

Prof Mac Mallewa – Vice Chancellor 24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**
			This SOP was formally titled Handling participants complaints. Therefore the scope of this SOP will now include risk management of several participants' complaints and risk during study participation.

Purpose

This procedure describes how KUREC manages risks and complaints from study participants

References

- KUREC Guidelines 2024

Scope

Study Participants, Investigators, KUREC secretariat and members

Allowable Exceptions

This SOP is meant to be followed without deviation and violation

Procedures

- Investigator provides participants with contact information of KUREC in the information sheet.
- Investigator indicates in the protocol how risks and research related injuries are going to be managed.
- Participants may contact Chairperson of KUREC or investigator
- Investigator addresses the complaint with the participant within 48 hours. If necessary refer the matter to KUREC
- The Compliance Officer will recommend the matter to KUREC Chairperson.
- Chairperson may recommend further discussion with investigator and participant.
- If necessary chairperson will refer the matter to a full KUREC meeting
- Chairperson will give feedback to participant and investigator on outcome of KUREC meeting

- If the matter require further investigation, KUREC Compliance Officer will arrange for a monitoring visit to the study site

- A record of the complaint and resolution should be maintained in the appropriate file

Definition of Terms

Complaint: verbal and written communication from study participants to investigators, sponsors and IRB regarding the conduct of a study

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for MATERIAL & DATA TRANSFER AGREEMENT

KUREC SOP #:20

Version: 1.0

Author(s):

Place DO NOT COPY label here.

Approval:	**Approved By**	**Date**
	Prof Mac Mallewa –Vice Chancellor	24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this procedure is to describe how to facilitate material or data transfer agreementbetween Kamuzu University of Health Sciences and collaborating institutions

References

- KUREC Guidelines

Scope

KUHeS Management
Investigators
Collaborating Institutions
KUREC secretariat and members

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- Investigator indicates in protocols need for materials transfer
- Investigator completes materials transfer agreement form and submits together application package
- KUREC advises secretariat to sign the MTA /DTAform.
- Where an MTA/DTA form ist part of the application, KUREC advises investigator to submitcompleted form and secretariat to sign
- A copy of the signed MTA/DTA is sent to the Investigator
- A copy of signed MTADTA will be kept in appropriate

KUREC fil**eDefinition of Terms**

Material/DATA Transfer Agreement: A legal document defining the conditions under which researchor other materials can be transferred and used among research laboratories.

KAMUZU UNIVERSITY
OF HEALTH SCIENCES

Samples collected from Malawi for research purposes is the property of the Government of Malawi represented by the Kamuzu University of Health Sciences (KUHeS), under the authority of KUREC and such samples can be accessed or recalled by the Government of Malawi and KUHeS at any time without let or hindrance.

Shipment of samples outside the country without proper justified reasons is not allowed.

Investigators are encouraged to develop capacity to do all tests required in the country. In special cases where this may not be possible the investigators must justify in the proposal the reason for importation and exportation of samples.

In review process the following have to be considered:-

- There must be a justification for importation and exportation of samples.
- KUREC shall make sure that there is material transfer agreement between relevant institution in the context of exportation and importation of samples. The material transfer agreement shall include the following:-

    1. The intention of the importation and exportation
    2. The duration of storage
    3. Location of storage
    4. The appropriate informed consent authorizing the exportation and importation
    5. To whom it will be accessible
    6. Who will be the controlling officer of the samples.
    7. Ownership of samples
    8. Capacity Building

- For studies that requires shipping of samples should fill the Material Transfer Agreement (MTA) form at KUREC. In case there are issues of Intellectual Property Rights (IPR) the committee shall advise the concerned parties to have prior agreement of IPR which has to be signed by all stakeholders before KUREC approval.
- Samples collected in Malawi will not be sold.

- Initial authorization to store samples can last up to 5 years, if one wishes to use sample beyond 5 years, one must seek authorization from KUREC. This Authorization will last another 5 years before it is due for renewal.

KUREC MATERIAL TRANSFER AGREEMENT FORM
Protocol Number:
Title of protocol:
(a) **Intention and Justification of transfer**:
(b) Duration of storage: Indicate date, month or years
(b) Responsible Party:
(c) Location of stored samples:
(d) Transportation of samples:
(e) Ownership of samples:
(e) After all laboratory testing has been completed: Describe what will happen to the samples

(g) Appropriate informed consent authorizing the exportation and importation of samples
(h) To whom will the samples be accessible
(i) Who will be the controlling officers of the samples

- **Capacity building plan.**.
- **Please note exportation of samples should be considered as a last resort**. **Effort to build the local capacity and expertise should be a priority.**

Signed by

Name of the PI: **Name of Co – PI**

Name of Institution: **Name of Institution:**

Signature: **Signature:**

Date Signed: **Date Signed:**

KUREC APPROVAL

Name of the Chairperson: **Name of Senior KURECAdministrator**

Signature: **Signature:**

Date Signed: **Date Signed:**

KUREC STAMP OF APPROVAL:

DTA PAGE

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Decision Making

SOP #:	21	Place DO NOT COPY label here.
Version:	2.0	
Author(s):		
Approval:	**Approved By**	**Date**
	Prof Mac Mallewa – Vice Chancellor	24 JUNE 2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this procedure is to describe how KUREC will arrive at a decision to approve or not to approve a protocol

References

- KUREC Guidelines 2024
- KUREC SOP#3 and 4

Scope

Investigators

KUREC secretariat and members

External reviewers

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- KUREC shall demonstrate competence and efficiency in their work. Having allowed adequate discussion shall consider the following guidance in making a decision
  - Scientific merit of the protocol
  - Ethical soundness and safety of participants
- If all members agree on a decision, the protocol shall be deemed approvedby consensus
- If there is any disagreement, the chairperson shall call for a vote and decision shall be made based on a simple majority vote
- KUREC shall provide full details of the reasons for not approving a protocol
- KUREC shall not defer approval of a protocol for the following reasons

  - Non-payment of research overheads (KUHES 10%)
  - Funding agency proposal format different from KUREC proposal format
  - Minor administrative issues e.g., lack of covering letter from institution or department

Definition of Terms

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

Kamuzu University of Health Sciences Research and Ethics Committee (KUREC)

Standard Operating Procedure for Documentation of Meetings

Place DO NOT COPY label here.

SOP #:

Version: 1.0

Author(s):

Approval: ~~**Approved By**~~ **Date**

24 JUNE 2024

–Prof Mac Mallewa – Vice Chancellor

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

To describe the process of documentation, approval, circulation and archiving of minutes of KUREC meetings.

References

- KUREC Guidelines, SOP #3, SOP #4, SOP #5, SOP #6, SOP #7, SOP #8

Scope

Secretariat and KUREC members

Allowable Exceptions

This SOP is meant to be followed without deviation

Procedures

- Secretariat documents proceedings of meeting from beginning to end of meeting, recording the following:
  - Name and designation of person preparing the minutes
  - Location where the ***meeting is*** held (venue, city ordistrict)
  - Meeting date
  - Attending board members, consultants and guests
  - Agenda items
  - Individual serving as Chairman of the meeting
  - Determination of a duly constituted quorum by the Chairman to proceed with the meeting

- For each application being reviewed, record:
  - Sponsor name;
  - Protocol number/date/version of protocol
  - Investigator name;

- Name of board member presenting study materials;
- Discussion as deemed appropriate by the Chairperson, a including the concerns raised during reviewing;
- Number of members voting 'yes', 'no',
- Number of abstentions and the reason for the abstention;
- Reference to the investigator approval letter that lists all changes requested by the board;
- Determination of the next requested continuing review.

- For applications on expedited review, record:
  - Sponsor name;
  - Protocol number, if applicable;
  - Investigator name;
  - Lists of expedited approval requests and outcomes.
- For continuing review, record:
  - Sponsor name;
  - Protocol number, if applicable;
  - Investigator name;
  - Indication of the Board's determination to continue, terminate, or amend thestudy;
  - Lists of recommendations or actions to take with the investigator, if applicable.
- For review of Adverse Event notification and Final Report, record:
  - Sponsor name;
  - Protocol number, if applicable;
  - Investigator name;
  - Actions deemed appropriate by the Board's review.
- For Termination of Approval, record:
  - Sponsor name;
  - Protocol number, if applicable;
  - Investigator name; reason for termination
- Document decision and outcome
- Draft minutes and submit to Chairperson for approval
- Chairperson signifies approval by signature and date
- Circulate approved minutes to KUREC members as part of materials for next meeting.
- Adopt minutes at next meeting
- File minutes in appropriate file

-

Definition of Terms

Agenda: An official record of the business discussed and transacted at a meeting, conference, etc.

Minutes: A written record describing the events of a meeting or hearing.