



# **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**

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## ACKNOWLEDGEMENT

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 worked jointly 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)** in 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  
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## 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 technology related 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 ethics committees 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<sup>1</sup> as fully defined and required under section 7.0 irrespective of the origin of the studies; and**

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<sup>1</sup> 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 not faculty members; nor affiliates; nor collaborators/co-investigators; nor students 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<sup>2</sup> (*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 section 2.7

2.9 Where ever applicable, the NHSRC and COMREC shall allow for an open and closed session on review of a protocol.<sup>3</sup>

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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<sup>2</sup> 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 one centre/contract research organization by one Principal Investigator at that centre/contract research organization. A single-centre study may have one or more sites under the supervision of one Principal Investigator.

<sup>3</sup> 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 possess the relevant expertise and competence that is required for the business of COMREC.** They must however declare 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 interest in **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<sup>4</sup> 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, the NHSRC 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 concerned with 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 a formal application for review, thereby minimising irritants and consequent delays in the review process.**

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<sup>4</sup> 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 not 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 a study 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 the conduct of such a study has been granted. In this regard, a research budget for such 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 element of 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 the cost 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 shall be 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 has been 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 institution that 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 such an 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 1<sup>st</sup> 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.

## **11.0 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.

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## 12.0 REFERENCE/SOURCE MATERIALS

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