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

National Commission for Science and Technology
Lingadzi House, City Centre
Private Bag B303
LILONGWE 3, Malawi

Tel: 265 1771 550
Fax: 265 1772 431
E-mail: directorgeneral@ncst.mw
Website: www.ncst.mw

Secretariat Address for the Operations of the National Health Sciences Research Committee:

The Chairman
National Health Sciences Research Committee
C/O Ministry of Health
Research Unit
P.O. Box 30377
Capital City
LILONGWE 3
Malawi

Tel: 265 1 789 400,789 321
E-mail: doccentre@malawi.net

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 to be 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 applicable ethical 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.

---

[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 trial is 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 was originally 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 insurance premium 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 five years 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 an application 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 malpractice insurance is for coverage for harm, injury or death of any **patient** caused by or alleged to 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 provision of 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.**