GUIDELINES FOR THE PROVISION OF INSURANCE COVER FOR RESEARCH PARTICIPANTS IN CLINICAL TRIALS IN UGANDA

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These guidelines shall be cited as the *"Professional Guidelines on Provision Of Insurance Cover For Research Participants In Clinical Trials In Uganda, Doc. No. DPS/GDL/023, Revision No.:0".*

Adoption and approval of these professional guidelines

In EXERCISE of the powers conferred upon the Drug Authority by Section 5(i) of the National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition), the Drug Authority hereby ADOPTS and ISSUES these Professional **Guidelines on Provision Of Insurance Cover For Research Participants In Clinical Trials In Uganda,** Doc. No. PAR/GDL/023, Revision No.:0, made this **7th day of October 2019,** that take effect on **14th October 2019**.

Signature

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TABLE OF CONTENTS

1.0 INTRODUCTION....4
2.0 TYPE AND SCOPE OF THE REQUIRED INSURANCE COVER....5
2.1 REQUIREMENT FOR CLINICAL TRIALS INSURANCE IN UGANDA....5
2.2 DEFINITION OF THE INSURANCE COVER OF NO-FAULT TYPE....5
2.3 SCOPE OF COVERAGE....5
3.0 PERIOD OF INSURANCE COVERAGE AND COMPENSATION....7
4.0 OBTAINING THE INSURANCE COVER OF NO-FAULT TYPE....8
4.1 DIRECT ISSUANCE OF AN INSURANCE POLICY BY THE INSURANCE FIRM....8
4.2 FRONTING ARRANGEMENT....8
5.0 AUNTHETICITY OF THE INSURANCE COVER DOCUMENTS....9
6.0 GOVERNING POLICY AND LAW....9
7.0 REVIEW OF SUBMITTED INSURANCE DOCUMENTS....9
8.0 POLICY EXCLUSIONS FROM THIS REQUIREMENT....11
9.0 CONCLUSION....11
DOCUMENT REVISION HISTORY....12

1.0 INTRODUCTION

This guideline aims at providing stakeholders guidance and clarity on clinical trials insurance.

It has been developed 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 Uganda. Specifically, this guideline aims at protecting human participants in clinical trials and 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 Uganda.

Obtaining and submitting the required insurance as described in **regulation 20 of the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014** is a requirement and prerequisite to obtaining ethical and regulatory approval of clinical trials, besides the fulfillment of other applicable ethical and regulatory requirements that are existent in Uganda.

This guidance is made pursuant to the Principles of Bioethics and International Law as enshrined in the international ethical guidance on conducting research involving humans developed by the Council for International Organization of Medical Sciences (CIOMS), the International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use: Guidelines for Good Clinical Practice (ICH-GCP)**,** the World Medical Association's Declaration of Helsinki and the Universal Declaration on Bioethics & Human Rights, and in similar international law documents guiding the conduct of research involving human subjects.

This guidance augments similar requirements, guidelines, standard operating procedures, regulations and relevant laws pertaining to the conduct of health research in Uganda and applies to sponsors, researchers and other stakeholders intending to conduct clinical trials in Uganda to aid them in submitting adequate documentation in their application for the review and approval of their studies.

This guidance is lawfully made under and enforced by **Regulation 20 sub-regulations 1 and 2 of the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014. Statutory Instrument No.32.** Stakeholders are, therefore, called upon to adhere to the contents of this requirement without let or hindrance.

2.0 TYPE AND SCOPE OF THE REQUIRED INSURANCE COVER

2.1 Requirement for Clinical Trials Insurance in Uganda

In line with **CIOMS,** and other international ethical guidance documents (i.e. codes, declarations and conventions) 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; and in recognition of the contextual vulnerabilities in Uganda, the required insurance for research participants/research subjects 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 are to be conducted in Uganda** or as determined specifically by the Uganda National Council of Sciences and Technology (UNCST), the Research and Ethics Committee or by the National Drug Authority. In making a determination, these institutions shall take into consideration the relative risks of a particular trial on a case by case basis. Specifically with regard to the National Drug Authority, the scope refers to those applications seeking authorization in form of a clinical trial certificate.

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 are examples of clinical trials that attract the provision and enforcement of the required insurance coverage;

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 relevant institutions in the country mandated to review, authorize and give oversight of research involving human subjects**.** In making a determination, these institutions shall take into consideration the relative risks 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.

This guideline however is currently limited to provision of clinical trials insurance during the running period of the trial.

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 in order to provide compensation for harm/injury/death that may occur or manifest during the running period of the trial.

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 during the running period of the trial.

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 clinical trial application.

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 shall be obtained **from a local insurance company that is registered and operating under law in Uganda**.

4.1 Direct Issuance of an Insurance Policy by the Insurance Firm

Any local insurance firm operating in Uganda 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 insurance company in Uganda 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 Uganda issues an insurance policy on behalf of a firm registered and operating outside the Ugandan borders but which has the ability and potential to provide the required insurance cover for the envisaged risk of a trial in Uganda.

Under fronting arrangement:

4.2.1 Sponsors/principal investigators are required to contact local brokers or insurers in Uganda with international presence who can source the product from internationally accredited insurers (i. e underwriting firms) and then arrange fronting agreements through local insurers or alternatively;

4.2.2 Principal investigators who are resident in Uganda 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 Uganda 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 Uganda shall submit an application to the Insurance Regulatory Authority of Uganda (IRA) 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 Regulatory Authority of Uganda, 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 have been **certified by the Insurance Regulatory Authority of Uganda.**

6.0 GOVERNING POLICY AND LAW

Any fronted no-fault insurance policy for clinical trials to be conducted in Uganda shall be subject to the relevant laws, policies, ethical and regulatory requirements in Uganda. Similarly, claim(s) and compensations arising directly or indirectly out of the conduct of the insured's business in Uganda shall be in accordance with and subject to the laws and applicable regulatory requirements in Uganda.

7.0 REVIEW OF SUBMITTED INSURANCE DOCUMENTS

To ensure uniformity in the review of submitted documentation of the required insurance, the following elements shall 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 during the running period of the trial.

7.3 Submitted insurance documents (i.e. policy, certificate or statement of endorsements etc.) must be copies that have been certified by **the Insurance Regulatory Authority of Uganda.**

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 Uganda 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** acceptable.

7.8 The required insurance policy for each specified trial site must be obtained through and endorsed by the local insurance firm and broker registered and operating in Uganda 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 extension period 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:

a) Type of cover being no-fault insurance
b) Name of the insured;
c) Name of the clinical trial;
d) Number of insured participants
e) Effective date and expiry dates of the policy
f) Insurance policy number and issuance date
g) Name of the local insurance company
h) Period of insurance that includes a clear indication of the initial running

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 endorsement by the Insurance Regulatory Authority to ensure that all aspects of these elements are addressed.

8.0 POLICY EXCLUSIONS FROM THIS REQUIREMENT

Study sponsors, principal investigators and review committees must note that this guideline 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 settings. Therefore principal investigators are advised to obtain professional indemnity from sponsors as detailed in **Regulation 20 sub-regulation 2 of the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014.**

It must, thus, be remembered that professional indemnity or malpractice insurance is coverage against a negligence claim made for harm, bodily injury or death of any **human subject** caused by or alleged to have been caused **by errors and/or omissions made by registered health practitioners in the course of rendering professional services and/or professional advice for which he/she was registered in Uganda**.

This insurance coverage does not include criminal prosecution, nor all forms of legal liability under civil law but those specified in this policy.

9.0 CONCLUSION

In conclusion, stakeholders are called upon to adhere to this guidance on insurance for human participants in clinical trials being conducted in Uganda. Provision of the required insurance cover remains the responsibility of the sponsor of a given trial.

Therefore, principal investigators in Uganda are required to facilitate the process of obtaining the required insurance **without let or hindrance. National Drug Authority** shall ensure the enforcement of this guideline requirement in compliance with Regulation 20 sub-regulations 1 and 2 of the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014.

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
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