

TANZANIA FOOD AND DRUGS AUTHORITY



**GUIDELINES FOR INSURANCE AND INDEMNITY OF CLINICAL TRIALS IN
TANZANIA**

*(Made under Section 67 (b) of the Tanzania Food, Drugs and Cosmetics Act,
2003)*

First Edition

December 2010

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Acknowledgements

These guidelines have been developed to outline requirements for insurance and Indemnity for different parties involved in clinical trials intended to be conducted in Tanzania. The guidelines describe the legal responsibilities of different key players in clinical trials to ensure that proper arrangements are in place for insurance and compensation for study participants in case of injury and provision of indemnity in case of liability.

The process to develop the guidelines has been done with staff of Clinical trials control and Pharmacovigilance department and Legal counsel of TFDA who produced the first draft and the final document.

The drafting team relied on their experiences and knowledge on clinical trials, available literature, ICH-GCP guidelines, CIOMS guidelines, Insurance laws in Tanzania, Other countries guidelines eg. Australian guidelines on Insurance and Indemnity and country specific experiences on preparation of Insurance and Indemnity. I hereby thank all those who simplified our job by enabling us to refer to their documents.

I would like to express my profound gratitude to all those who contributed to the drafting and writing of the guidelines. Thanks are due to TFDA staff namely Mr. Henry Irunde, Ms. Alambo Mssusa, Dr. N.B Chukilizo, Mr. Meshack Shashi, Mr. Iskari Fute, Mr. Emanuel Alphonse, Dr. Alex Nkayamba and Ms. J. Mirambo.

I would also like to sincerely thank all other persons who participated in drafting these guidelines and made constructive comments and inputs to the guidelines including Dr. Rose Kingamkono (COSTECH), Mrs. Magareth Ikongo (Tanzania Insurance Regulatory Authority) Mrs. Joyce Ikingura from the National Institute for Medical Research (NIMR).

The valuable inputs received from Prof. Karim Manji, Dr. Doreen Mloka, and Dr. A. Kamuhabwa from Muhimbili University College of health and Allied Sciences (MUHAS) are also acknowledged.

The constructive remarks from the TFDA Management Team during approval of the guidelines are also greatly acknowledged.

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Abbreviations

ADRs	-	Adverse Drug Reactions
AEs	-	Adverse Events
API	-	Active Pharmaceutical Ingredient
CRF	-	Case Report Form
CRO	-	Contract Research Organization
ICH	-	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IMP	-	Investigational Medicinal Product
NEC	-	National Ethics Committee
NIMR	-	National Institute for Medical Research
PI	-	Principal Investigator
REC	-	Research Ethics Committees (Independent /Institutional)
SAE	-	Serious Adverse Event
SUSARs	-	Suspected Unexpected Serious Adverse Reactions
SOPs	-	Standard Operating Procedures
SPC	-	Summary of Product Characteristics
TFDA	-	Tanzania Food and Drugs Authority
WHO	-	World Health Organization
TIRA	-	Tanzania Insurance Regulatory Authority

Foreword

This is the first edition of the guidelines for insurance and indemnity of clinical trials in Tanzania which has been prepared by Tanzania Food and Drugs Authority (TFDA). The guidelines have been made under the provisions of Section 67 of the Tanzania Food, Drugs and Cosmetics Act, 2003.

The Authority has a legal responsibility of ensuring that all clinical trials obtain a written authorization from the TFDA prior to commencement and that all participants taking part in the trial are insured against any injury or risk of injury. It is therefore anticipated that all those who will be intending to conduct clinical trials in Tanzania will oblige with the aforementioned legal provisions and follow the procedures and requirements as set out in these guidelines.

The review process had evolved through drafting the guidelines and consultation with stakeholders from various institutions before final approval by TFDA Management.

The guidelines therefore provide an up-to-date guidance on insurance and indemnity requirements to be followed by all those who are involved in clinical trials in the country, to include research institutions, Institution Ethics Committee, Investigators, Contract Research Organizations (CROs), trial participants, trial applicants, Principal Investigators (PIs) and Sponsors alike.

It is the expectation of TFDA that the guidelines will enable consistent and uniform documentation of the procedures and documentation regarding Insurance and Indemnity and make it easier for the participants to be compensated based on clear and transparent criteria.

As clinical trials are complex in nature and since review of technical guidelines in any scientific spectrum is unavoidable in order to keep pace and benefit from developments in science and technology, the TFDA as always welcomes new ideas, opinions and suggestions in this context that will assist in improvement of the guidelines.

The Authority requests the sponsors, research ethics committees and research Institutions to adhere to these guidelines and abide to the law relating to Insurance and Indemnity while conducting clinical trials.

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Definition of terms

In the context of these guidelines the following words/phrases are defined as follows.

Act

The Tanzania Food, Drugs and Cosmetics Act, 2003 and all regulations relating to clinical trials made under the Act.

Adverse Drug Reactions (ADRs)

All noxious and unintended responses to a clinical trial medicinal product related to any dose or all unintended noxious responses to a registered medicinal product which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function.

Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation study participant administered a pharmaceutical product and which does not necessarily have a causal relationship with the treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of an investigational product (IP), whether or not related to the IMP.

Applicant

A person applying to conduct a clinical trial which may include a sponsor, contract research organization (CRO) or in the case of investigator-initiated academic research studies, research institution or principal investigator.

Authority

Means Tanzania Food and Drugs Authority or its acronym TFDA.

Clinical Trial/Study

A systematic study on Investigational product(s) in human participants (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety.

Contract

A written, dated and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

Contract Research Organization (CRO)

A person or an organization (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

Documentation

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Indemnity:

legal exemption from liability for damages

Insurance:

The act, system, or business of insuring life, one's person, etc., against loss or harm arising in specified contingencies, as accident, death, disablement, or the like, in consideration of a payment proportionate to the risk involved.

Investigational Product

A pharmaceutical form of an active ingredient or placebo, nutritional supplements, Diagnostics, medical device, herbal drugs being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator

A physician, dentist or other qualified person who conducts a clinical trial at a trial site.

Investigator's Brochure (IB)

A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human study participants.

Principal Investigator (PI)

A person responsible for the conduct of the clinical trial at a trial site who is a physician, dentist or other qualified person, resident in Tanzania and a member of good standing of a professional association. If a trial is conducted by a team of individuals at a trial site, the principle investigator is the responsible leader of the team.

Protocol

A document which states the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations, and the conditions under which it is to be performed and managed. The protocol should be dated and signed by the investigator, the institution involved and the sponsor. It can also function as a contract.

Serious Adverse Event (SAE) or Serious Adverse Drug Reactions (Serious ADR)

Any untoward medical occurrence that at any dose:

- Results in death,
- Is life threatening,
- Requires hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect

Sponsor

An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial.

Participant

An individual who participates in a clinical trial either as a recipient of the investigational medicinal product(s) or as a control

Trial Site

The location(s) where trial-related activities are actually conducted.

Unexpected Adverse Drug Reaction

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).

INTRODUCTION AND BACKGROUND

The role of government is to provide the legal framework for clinical trials. The aim is twofold:

- (i) To protect the safety and rights of the subjects participating in a trial
- (ii) To ensure that trials are adequately designed to meet scientifically sound objectives.

In Tanzania, the Tanzania Food and Drug Authority (TFDA) is the responsible authority which has been mandated under section 5(d) of the Tanzania Food, Drugs and Cosmetics Act 2003, to ensure that clinical trials on drugs, medical devices and herbal drugs are conducted in accordance with prescribed standards. Section 67 (b) provides for insurance of participants taking part in the trial against any injury or risk of injury.

Clinical trials are systematic research studies conducted on human participants aimed at determining the safety and effectiveness of new or unproven therapies. They are vital and important for finding new, better and more effective medicine/therapy or procedure for treating disease and for improvement of health and quality of life.

Though investigational products used in clinical trials are made to the highest standards of quality they may still pose risks which may arise due to inherent properties of its ingredients, manufacturing defects and managerial errors. Companies sponsoring clinical trials must therefore be insured so that if a patient is damaged by some unforeseen event due to the drug or devices, compensation can be paid. One of the sponsor's roles is to make sure that there are arrangements for insurance and Indemnity, for legal liability to pay damages or compensation as a result of any claim or claims made by research participants and researchers for bodily injury caused by any act, error or omission in connection with clinical trials. In this regard, clinical trials with no insurance or provision for compensation will not be permitted to be conducted in Tanzania.

The following parties involved in clinical trials are likely to be exposed to clinical liability suits and hence the need for insurance and Indemnity:-

- i) The sponsor company testing the new products / procedure. Basically the sponsoring company finances the entire trial.
- ii) The Clinical Research Organization (CRO) that helps the sponsor manage the study
- iii) The institution where the study is actually carried out
- iv) The professionals (clinicians) who actually conduct and monitor the study on behalf of the sponsor.
- v) Institution Ethics Committees

Each party involved in conducting the trial has moral and legal responsibilities towards the human subject. They all have real and significant exposure to liability. Generally, the target for litigation is the clinical investigators and the research institute involved. The company that sponsors the trial is also exposed to the risk of liability on account of improper disclosure, conflict of interest, violation of good clinical

practices, etc. This being the case, Insurance must form part of any risk management philosophy of the company interested in clinical trial.

Before a drug or medical device is marketed in Tanzania, it must be registered by the Authority. The Authority may register a drug or medical device if it is satisfied of its safety and efficacy. Clinical trials of new drugs or medical devices are conducted to provide evidence of safety and efficacy. Patients cannot be administered with unregistered drugs or medical devices, unless they are the subject of a clinical trial or the drugs or medical devices are available under other special schemes administered by the TFDA.

Phases of clinical trials

A brief description of the individual phases, based on their purposes as related to clinical development of pharmaceutical products, is given below;

Phase I

These are the first trials of a new active ingredient or new formulations in man, often carried out in healthy volunteers. Their purpose is to establish a preliminary evaluation of safety. These trials involve small numbers of individuals (Average sample size 20-80)

Phase II Trials involve a larger group of patients (Average sample size 200-300) to see what treatment effects the drug has, and to further evaluate safety. Their purpose is to demonstrate therapeutic activity and to assess short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended.

Phase III trials are much larger studies, usually involving hundreds or thousands of patients with the targeted disease divided into different treatment groups. The aim is to compare the treatment effectiveness and side effects of the new drug with that of standard treatments (where they exist). If the results of these phased clinical trials show that the drug is safe and effective, it may be registered by the TFDA.

Phase IV Studies performed after marketing of the pharmaceutical product. Trials in phase IV are carried out on the basis of the product characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards as applied in premarketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc. are normally considered as trials for new pharmaceutical products

GUIDELINES FOR INSURANCE, INDEMNITY AND COMPENSATION FOR INJURY RESULTING FROM PARTICIPATION IN A CLINICAL TRIAL

CHAPTER 1: INSURANCE

Roles and responsibilities of key players involved in clinical trials.

1.1 Sponsors

- 1.1.1 Every sponsor shall before initiating a clinical trial have appropriate, current and sufficient insurance to meet their responsibilities as specified in the indemnity agreement. The minimum requirements for indemnity shall be as specified in **Appendix 1**.
- 1.1.2 The sponsor shall insure by purchasing a policy of insurance which must;
 - 1.1.2.1 Cover the sponsor or Tanzanian corporate entity acting as a sponsor.
 - 1.1.2.2 Cover the conduct of the relevant clinical trial in Tanzania.
 - 1.1.2.3 Be provided by an insurer registered by the Tanzanian Insurance Regulatory Authority (TIRA).
 - 1.1.2.4 Contain insurance cover for sufficient amount to indemnify by the degree of risk specified by the ethical committee.
 - 1.1.2.5 The Insurance policy must cover the particular trial on a claim made basis (that is, pays for claims made during the trial and cover be extended depending on the degree of the risk of the Investigational product).
 - 1.1.2.6 The sponsor is advised to provide basic Health Insurance to cover other Routine care costs not related to the clinical trial.

1.2 Clinical trial Host Institutions

- 1.2.1 Institution shall have in place, appropriate insurance at a level sufficient to meet potential liability of its Investigators(s), those acting on behalf of investigators and its research members;
- 1.2.2 Chief Executives shall be responsible for ensuring that appropriate arrangements are in place in relation to a clinical trial that takes place within their Institution. This includes ensuring that mechanisms are in place to ensure that:

- 1.2.2.1 Clinical trials are reviewed by Institution Ethics Committees properly constituted under the National Institute for Medical Research Act No.23 of 1979 or any other law in force.
- 1.2.2.2 The insurance and indemnities provided in respect of clinical trials by registered insurance companies meet the requirements of these guidelines.
- 1.2.2.3 Each member of its Ethical Committee and its Investigators are covered with an indemnity and this should be a condition of appointment of members of Ethical Committee.
- 1.2.2.4 Each Investigator involved in a clinical trial is covered with professional Indemnity to cover legal liability in case of negligence.

1.3 Institution Ethics Committees

Ethics Committees are responsible for assessing the scientific validity of a clinical trial and its ethical acceptability. This involves assessing the risks of the trial to participants, determining whether those risks are ethically acceptable and determining whether the potential benefits of the trial outweigh the potential risks.

- 1.3.1 Research Ethics Committees must be satisfied that arrangements exist to ensure adequate compensation to participants for any injury suffered as a result of participation in a clinical trial.

CHAPTER 2: INDEMNITY

The purpose of an indemnity arrangement is to provide legal protection in the event of an unforeseen adverse circumstance arising during the course of a research project. Indemnity is a form of contract to compensate an individual for loss or damage. To cover the costs that may be incurred as a result of providing indemnification the party providing the form of indemnity should have adequate arrangements in place.

- 2.1 A sponsor will indemnify the institution for any loss the institution may suffer as a consequence of clinical trial participant being injured by an Investigational Product or from any procedure necessary as part of the protocol.
- 2.2 An indemnity shall be in writing and shall contain minimum requirements as prescribed in the standard indemnity form **Appendix I**.
- 2.3 The indemnity must be provided in favour of the clinical trials host institution
- 2.4 The indemnity must be signed by the Sponsor and the Chief Executive of the clinical trial host Institution.
- 2.5 The indemnity states that the sponsor agrees to adhere to these guidelines

CHAPTER 3: COMPENSATION OF INJURED PARTICIPANTS

3.1 The clinical trial participants who suffer physical and mental injury as result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In case of death, their dependants are entitled to compensation. The right to compensation may not be waived. (CIOMS Guideline 13)

3.1.1 Notwithstanding the absence of legal commitment, the Sponsor shall pay compensation to participants in clinical trials suffering personal injury (including death) in accordance with the law.

3.1.2 Compensation should be paid when, on the balance of probabilities, the injury was attributable to the administration or use of a product under trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the participant in the trial.

3.1.3 Compensation shall be paid to a child injured in utero through the participation of the child's mother in a clinical trial as if the child were a Participant with the full benefit of these Guidelines.

3.1.4 Compensation shall only be paid for the serious injury of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or readily curable complaints.

3.1.6 Where there is an adverse reaction to a product under trial and injury is caused by a procedure adopted to deal with that adverse reaction, compensation shall be paid for such injury as if it were caused directly by the product under trial.

3.1.7 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the Subject has freely consented (whether in writing or otherwise) to participate in the trial should exclude a Subject from consideration for compensation under these Guidelines, although compensation may be reduced or excluded in the light of the factors described in paragraph 4.2 below.

3.1.8 For the avoidance of doubt, compensation shall be paid regardless of whether the Participant is able to prove that the company has been negligent in relation to research or development of the product under trial or that the product is defective and therefore the Sponsor is subject to strict liability in respect of injuries caused by it.

3.2 Type of Clinical trials Covered

3.2.1 These Guidelines apply to injury caused to participants involved in clinical trials, that is to say, Participant under treatment and surveillance and suffering from the ailment which the product under trial is intended to treat but for which a registration does not exist or does not authorise supply for administration under the conditions of the trial.

3.2.2 These Guidelines also apply to injuries arising from Phase I studies in either patient or non-patient volunteers, whether or not they are hospitalised.

3.2.3 These Guidelines do not apply to injury arising from clinical trials on marketed products where a registration exists authorising supply for administration under the normal conditions of the approval, except to the extent that the injury is caused to a Participant as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the Participant would not have been exposed had treatment been other than in the course of the trial.

3.3. Limitations

3.3.1 No compensation should be paid for the failure of a product to have its intended effect or to provide any other benefit to the Participant.

3.3.2 No compensation should be paid for injury caused by other registered products administered to or used by the participant for the purpose of comparison with the product under trial.

3.3.3 No compensation should be paid to participants receiving placebo in consideration of its failure to provide a therapeutic benefit.

3.3.4 No compensation should be paid (or it should be reduced as the case may be) to the extent that the injury has arisen through Contributory negligence by the Participant.

3.4 Assessment of Compensation

3.4.1 The amount of compensation paid shall be appropriate to the nature, severity and persistence of the injury.

3.4.2 Compensation may be reduced, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the Participant can reasonably be expected to accept):

- The seriousness of the disease being treated, the degree of probability that adverse reactions will occur and any warnings given;
- The risks and benefits of established treatments relative to those known or suspected of the product under trial.

This reflects the fact that flexibility is required given the particular Participant's circumstances. As an extreme example, there may be a Participant suffering from a serious or life-threatening disease who is warned of a certain defined risk of adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the participant accepts the high risk and should not expect

compensation for the occurrence of the adverse reaction of which he or she was told.

- 3.4.3 In any case where the Sponsor concedes that a payment should be made to a Participant but there exists a difference of opinion between the Sponsor and Participant as to the appropriate level of compensation, it is recommended that the Sponsor agrees to seek at its own cost (and make available to the Participant) the opinion of a mutually acceptable independent arbiter, and that this arbiter's opinion should be given substantial weight by the Sponsor in reaching its decision on the appropriate payment to be made.

CHAPTER 4: MISCELLANEOUS

- 4.1 Claims pursuant to the Guidance should be made by the Participant to the Sponsor, preferably via the investigator, setting out details of the nature and background of the claim and, subject to the Participant providing on request an authority for the Sponsor to review any medical records relevant to the claim, the Sponsor should consider the claim expeditiously.
- 4.2 The undertaking given by the Sponsor extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of the trial but not to injury arising from administration or use of the product beyond the end of the trial. The use of unregistered products beyond the trial period is wholly the responsibility of the treating doctor.
- 4.3 The fact that the Sponsor has agreed to abide by these Guidance in respect of a trial does not affect the right of a Participant to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Any payment made to a Participant by the Sponsor will be made without admission of liability and Participants may be asked to accept that any payment made to them is in full settlement of their claims.
- 4.4 The Sponsor should encourage the investigator to make clear to participating Participants that the trial is being conducted subject to the *Guidance for Compensation for Injury Resulting from Participation in a Clinical Trial* and to have available copies of the Guidance should be requested.

4.5 Clinical Trial Agreements

Clinical trial agreements set out the rights and obligations of the sponsor, the investigator and the clinical trials host institution where the trial is being conducted. Clinical trial agreements must be signed by the Chief Executive of the clinical trials host institution, Sponsor and the Principal Investigator.

Clauses in clinical trial agreements that relate to insurance, compensation, and indemnities shall:

- 4.5.1 Not contradict the Standard Indemnity.
- 4.5.2 Refer to or attach the Standard Indemnity and the Guidelines for Compensation for Injury Resulting from Participation in a Clinical Trial.
- 4.5.3 Clinical trial agreements shall not contain cross-indemnities by the clinical trials host institution to the sponsor.
- 4.5.4 Not hamper the ability for serious adverse events or incidents to be reported as part of the clinical trials host institution's internal reporting requirements.
- 4.5.5 Be signed by a Tanzanian corporate entity. Where the sponsor is an overseas corporation, the services of an Tanzanian corporate research organisation may be used to conduct the trial in Tanzania and sign the

clinical trial agreement in their own right. Agreements should not be signed by a corporation as an agent for an overseas corporation.

4.6 Model clause for patient information sheets: risks and compensation

Every Patient information sheets shall contain information that is available to participants of clinical trials in the event that they suffer injury as appended in **Appendix II.**

APPENDIX I
FORM OF INDEMNITY FOR CLINICAL TRIALS

This form is regarded by the Authority as the basis for agreements between the sponsor and the Research institution that hosts the study to be conducted.

To: *[Name and address of the legal entity (hospital, institution or authority) in which the Study is to be conducted ("the Indemnified Party") Only a single legal entity should be named. Where more than one legal entity is to be indemnified, separate Forms of Indemnity should be used for each legal entity to be indemnified.*

From: *[Name, registered address of the Sponsor or Tanzanian corporate entity acting as a sponsor*

Re: *Protocol No, version and date [], [protocol title including name of product]*

1. The Indemnified Party agrees to participate in the above sponsored study ("the Study") involving [{patients of the Indemnified Party} {non-patient volunteers}] ("the Subjects") to be conducted by [name of investigator(s)] ("the Investigator") in accordance with the protocol annexed, as amended in writing from time to time with the agreement of the Sponsor and the Indemnified Party ("the Protocol"). The Sponsor confirms that it is a term of its agreement with the Investigator that the Investigator shall obtain all necessary approvals from the applicable Human Research Ethics Committee ("Research Ethics Committees") and the Indemnified Party, where appropriate.
2. The Indemnified Party agrees to participate by allowing the Study to be undertaken on its premises or as otherwise agreed, utilising such facilities, personnel and equipment as may reasonably be required for the Study.
3. In consideration of such participation by the Indemnified Party, subject to paragraph 4 below, the Sponsor indemnifies and holds harmless the Indemnified Party and its employees, agents, and members of and advisors to its Research Ethics Committees in respect of and against all claims and proceedings (including any settlements or ex gratia payments made with the consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise) by or on behalf of Subjects (including their dependants and children injured *in utero* through the participation of the child's mother in the Study) against the Indemnified Party or any of its employees, agents or members of and advisors to its Research Ethics Committees for personal injury (including death) to Subjects (and children injured *in utero* through the participation of the child's mother in the Study) arising out of or relating to the administration and/or use of the product(s) under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Subjects would not have been exposed but for the participation of the Subjects in the Study.
4. The above indemnity by the Sponsor will not apply to any such claim or proceeding referred to in paragraph 3 above:

- (i) to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Indemnified Party or any of its employees, agents or members of and advisors to its research ethics committees.
- (ii) to the extent that such personal injury (including death) is caused by the failure of the Indemnified Party, its employees, or agents to conduct the Study strictly in accordance with the Protocol.
- (iii) unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Indemnified Party notifies it to the Sponsor in writing and at the Sponsor's request, and cost, has permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing.
- (iv) if the Indemnified Party, its employees, agents, or members of and advisors to its Research Ethics Committees have made any admission in respect of any such claim or proceeding or taken any action relating to any such claim or proceeding prejudicial to the defence of any such claim or proceeding without the written consent of the Sponsor. Such consent will not be unreasonably withheld. This condition will not be treated as breached by any statement properly made by the Indemnified Party, its employees, agents, or members of and advisors to the Research Ethics Committees in connection with the operation of the Indemnified Party's internal complaint procedures, accident reporting and quality assurance procedures or disciplinary procedures or where such statement is required by law.
- (v) The Sponsor will keep the Indemnified Party and its legal advisers fully informed of the progress of any such claim or proceeding, consult fully with the Indemnified Party on the nature of any defence to be advanced and not settle any such claim or proceeding without the written approval of the Indemnified Party which approval is not to be unreasonably withheld.
- (vi) Without prejudice to the provisions of paragraph 4(3) and 4(4) above, the Indemnified Party will use reasonable endeavors to inform the Sponsor promptly of any circumstances of which it has knowledge and which may reasonably be thought likely to give rise to any such claim or proceeding and will keep the Sponsor informed of developments in relation to any such circumstances even where the Indemnified Party decides not to claim indemnity from the Sponsor. Likewise, the Sponsor will use reasonable endeavors to inform the Indemnified Party of any such circumstances and will keep the Indemnified Party informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
- (vii) The Sponsor and the Indemnified Party will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Subjects (including their dependants and children injured in utero through the participation of the child's mother in the Study).
- (viii) Without prejudice to the foregoing, if injury is suffered by a Study

participant while participating in the Study, the Sponsor agrees to adhere to the “Guidance for Compensation for Injury Resulting from Participation in a Clinical Trial” provided in the guidelines.

(ix) For the purpose of this indemnity, the expression "agents" is deemed to include, but is not limited to:

- a. any person carrying out activities for the Indemnified Party under a contract connected with such of the Indemnified Party's facilities and equipment as are made available for the Study under paragraph 2 above; and
- b. Any health professional providing services to the Indemnified Party under a contract for services or otherwise.

(x) This indemnity will be governed by and construed in accordance with the laws applicable in The United Republic of Tanzania in which the Indemnified Party is established.

DATED the day of in the year.

SIGNED by a duly authorised representative of the Sponsor

.....
(Signature)

.....
(Position)

SIGNED by the Chief Executive or a duly authorised representative of the Indemnified Party

.....
(Signature)

.....
(Position)

APPENDIX II
Model clause for patient information sheet in clinical trials: risks and compensation

Risks

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:
[risks itemised, with information (where possible) about likelihood, severity etc]

Compensation for injuries

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries resulting from the study. Compensation may be available if your injury is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). If you receive compensation which includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medical care, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Tanzanian public hospital. [Where applicable]

The parties to this study agree to follow the *Guidance for Compensation for Injury Resulting from Participation in a Clinical Trial*.