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CLINICAL TRIAL REGULATIONS, 2021

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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

CLINICAL TRIAL REGULATIONS, 2021

[*7th Day of July*, 2021] Commencement.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap N1, LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act (Cap. F33, LFN) 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Minister of Health makes the following Regulations—

Scope of application.

1.—(1) These Regulations shall prescribe good clinical practice requirements for the conduct of Clinical Trials involving medicinal products, with a view to ensuring that the—

(*a*) rights, safety and well-being of trial participants are protected ; and

(*b*) result or outcome of a Clinical Trials are credible.

(2) These Regulations shall apply to Clinical Trials involving medicinal products for gene therapy and somatic cell therapy, including xenogenic cell therapy or medicinal products containing genetically modified organisms.

Prohibition.

2.—(1) A person shall not commence a Clinical Trial or cause a Clinical Trial to be commenced or conduct a Clinical Trial, unless the Agency has given an approval in relation to the Clinical Trial.

(2) An Investigational Medicinal Product (IMP) shall not be manufactured in whole or in part, assembled, divided, packaged, presented, exported or imported except as approved by the Agency.

(3) A gene therapy trial, result in modifications to the participant's germ line genetic identity, shall not be carried out.

(4) Except as provided in these Regulations, failure to comply with any provision set forth in these Regulations in respect of Clinical Trials, including Bioavailability and Bioequivalence studies, shall render such Clinical Trials illegal and the reports from it shall be invalid, and the medicinal products as well as the person, who is responsible for the non-compliance shall be liable to the penalty set out in regulations 18 and 19 of these Regulations.

General requirements for Clinical Trial.

3.—(1) Every Clinical Trial, including bioavailability and bioequivalence studies, shall be—

(*a*) designed, conducted, recorded and reported in accordance with these Regulations ;

(*b*) conducted in accordance with Good Clinical Practice (GCP) principles and ethical principles that have their origin in the Declaration of Helsinki and consistent with GCP practice ;

(*c*) conducted in accordance with the approved protocol, scientifically comprehensive and described in a clear detailed protocol and in compliance with established protocol that has received favorable opinion of the Ethics Committee, after taking into consideration the foreseeable risks, inconveniences and anticipated benefit for the individual trial subject and society, provided that the trial shall only be initiated and continued, where the anticipated benefits justify the risks.

(2) The rights, safety and well-being of the trial subjects shall prevail over interests of science and society.

(3) The available non-clinical and clinical information on an investigational product, shall be adequate to support the proposed Clinical Trial.

(4) The medical care given to, and medical decisions made on behalf of, the subjects shall always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist, who shall be a member of the team.

(5) The handling of the investigational medicinal product shall be the responsibility of a Pharmacist, who shall be a member of the study team.

(6) A person involved in conducting a trial shall be qualified by education, training, and experience to perform the assigned duty and task.

(7) Informed consent shall be obtained from every subject prior to Clinical Trial participation.

(8) A Clinical Trial information, irrespective of the type of media used, shall be recorded, handled and stored in a way that allows its accurate of reporting, interpretation and verification.

(9) The confidentiality of records that could identify subjects shall be protected, respecting the confidentiality rules in accordance with the applicable regulatory requirement.

(10) Manufactured investigational medicinal products shall be handled and stored in accordance with applicable good manufacturing practice and used in accordance with the approved protocol.

(11) Systems with procedures that assure the quality of every aspect of the trial shall be implemented.

(12) Amendments relating to the conduct, design, methodology, investigational medicinal product or the investigator or site of the Clinical Trial, which may have substantial impact on the safety or rights of the participant or on the reliability of the data generated in the Clinical Trial, shall be approved by the Agency.

(13) A person involved in the conduct of a Clinical Trial shall provide complete and accurate information attesting to the absence of conflicting interests in the trial.

(14) A sponsor or investigator shall submit a study report as prescribed by the Agency.

(15) A sponsor or investigator shall register all Clinical Trials with the WHO primary registry before submission of any application to the Agency for approval.

(16) The Agency shall inspect every approved trial sites and facility used or being used for the purpose of a clinical investigation, to ensure compliance with these Regulations.

Investigational medicinal product.

4.—(1) The provisions of Regulation 2 (2) of these Regulations shall not apply to the assembly of an investigational medicinal product, where such assembly is carried out in a hospital or health centre which is Clinical Trial site for a Clinical Trial in which the product is to be used.

(2) An investigational medicinal product shall be—

(*a*) labelled so as to ensure protection of the participant, identification of the product and facilitate proper use of the investigational medicinal product ;

(*b*) traceable, stored, returned or destroyed as appropriate, with the Agency's approval and written records of destruction shall be maintained by the investigator and forwarded to the Agency ; and

(*c*) retrieved where the product is unused or expired, from individual investigator, where participation in the investigation is discontinued or terminated and the sponsor may authorise alternative disposition of unused or expired supplies, provided that this alternative disposition method shall not be a risk to human, environment and the sponsor maintains written records of disposition carried out.

(3) The label on Investigational Medicinal Product shall comply with the requirements of the Agency.

Protection of Clinical Trial participants

5.—(1) Prior to involvement of a participant in a Clinical Trial, the investigator shall inform the participant or person appointed by the participant as his representative (representative), of all pertinent aspects of the trial including the opinion of the ethics committee to the participant or his representative.

(2) The participant or his representative shall freely give a written informed consent, which shall be signed and dated by the participant or his representative and the person who conducted the informed consent discussion.

(3) Informed Consent shall be obtained before the use of investigational Medicinal Product, unless both the investigator and a physician, qualified in that area of specialization, who is not otherwise participating in the clinical investigation certify in writing of the following—

(*a*) the participant is confronted by a life-threatening situation necessitating the use of the investigational medicinal product ;

(*b*) informed consent cannot be obtained from the participant because of the inability to communicate with the participant ;

(*c*) time is not sufficient to obtain consent from the participant's representative ; and

(*d*) there is no available alternative method of approved or generally recognized therapy that can provide equal or greater likelihood of saving the life of the participant.

(4) Where the immediate use of the Investigational Medicinal Product is, in the investigator's opinion, is required to preserve the life of the participant, and time is not sufficient to obtain the independent determination required in sub-regulation (3) of Regulation 5 in advance of using the Investigational Medicinal Product, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the Investigational Medicinal Product, be reviewed and evaluated in writing by a physician, qualified in that area of specialization, who is not participating in the clinical investigation.

(5) The documentation required in sub-regulations (3) and (4) of Regulation 5 shall be submitted to the Ethics Committee within 5 working days after the use of the investigational medicinal product on the participant.

(6) During a Clinical Trial, where a minor reaches the age of legal competence to give Informed Consent, express Informed Consent of such minor shall be obtained before participating in the trial.

(7) A participant may without any resultant detriment, withdraw from the clinical trial at any time by revoking his Informed Consent.

(8) Where a participant withdraws from a Clinical Trial, the withdrawal shall not affect the activities already carried out and the use of data obtained based on Informed Consent before the withdrawal.

(9) Clinical trials on a pregnant or breastfeeding woman shall be conducted only where the trial has the potential to produce a direct benefit to the concerned woman, embryo, foetus or child after birth or where the trial poses a minimal risk to, and imposes a minimal burden on the concerned woman, embryo, foetus or child after birth.

(10) The rights of participant to physical and mental integrity, privacy and to the protection of the data concerning the participant shall be safeguarded.

(11) Provision shall be made for insurance and indemnity to cover the liability of the Investigator and Sponsor, which may arise in relation to the Clinical Trial and negligence and or malpractice.

(12) Incentives or financial inducements shall not be given to a participant except for compensation for expenses and loss of earnings directly related to the participation in the Clinical Trial.

Ethics committee.

6.—(1) The Agency may refuse favourable opinion of Ethics Committee, where there are grounds to believe that the Ethics Committee—

(*a*) was not composed of members with requisite qualifications and experience to review and evaluate the science, medical aspects and ethics of the proposed trial ;

(*b*) has not established, documented and followed its procedures ; and

(*c*) does not have a valid registration certificate issued by National Health Research Ethics Committee (NHREC).

(2) The Ethics Committee shall—

(*a*) carry out its task without any influence or bias from those conducting the trial ; and

(*b*) declare conflict of interest with respect to the trial.

(3) any member of the Ethics Committee having an interest in the trial, shall not participate in the review of the trial, except providing information as may be requested by the Ethics Committee.

The Sponsor of a Clinical Trial.

7.—(1) The sponsor of a Clinical Trial (the "Sponsor") shall be responsible for—

(*a*) selecting qualified investigators ;

(*b*) providing the investigator with requisite information that is necessary for conducting an investigation effectively ;

(*c*) ensuring that the investigation is conducted in accordance with the general investigational plan and protocols for the study ;

(*d*) ensuring proper monitoring of the investigation ;

(*e*) maintaining effective control with respect to the investigations ;

(*f*) ensuring that the Agency and participating clinical investigators are promptly informed of significant new adverse effects or risks with respect the drug ;

(*g*) ensuring the establishment of appropriate compensation mechanism to the participant or investigator arising from the trial ; and

(*h*) the supply of investigational medicinal products that conforms with good manufacturing practice principles.

(2) A sponsor may delegate its function, to a person, provided that the sponsor shall be responsible for the trial.

(3) A sponsor shall ensure that the trial data generated from the trial comply with the requirement of the Agency.

(4) A sponsor or his representative shall be domiciled in Nigeria.

(5) Every essential document relating to the Clinical Trial shall be archived by the sponsor as prescribed by the Agency and be readily available and accessible upon request by the Agency.

(6) Any transfer of ownership of the content of the Clinical Trial master file, shall be documented and the new owner shall assume the responsibility set out in these Regulations.

A Clinical trial investigator.

8.—(1) An Investigator shall have requisite qualification in terms of education, training, and experience to assume the responsibility for proper conduct of the trial in compliance with Good Clinical Practice and other applicable requirements as may be prescribed by the Agency.

(2) Where a Clinical Trial is conducted with more than one investigator, the sponsor shall appoint a principal investigator among the investigators, who shall coordinate and ensure that the trial complies with the requirements of these Regulations.

(3) The principal investigator or an Investigator shall provide Progress Report, close out notification at the end of a trial as prescribed by the Agency to the sponsor and the Agency.

Safety Report.

9.—(1) The sponsor shall review information relevant to the safety of an investigational medicinal product obtained or otherwise received from any source, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the Agency.

(2) The sponsor shall upon the receipt of any safety information, notify the Agency through a written report of—

(*a*) any finding from test in laboratory animal that suggest a significant risk for participant including report of adverse experience associated with the use of the medicinal product that is both serious and unexpected ; or

(*b*) any finding from tests in laboratory animals that suggests a significant risk for participants including reports of mutagenicity, teratogenicity, or carcinogenicity or any other relevant report.

(3) The sponsor shall, within the stipulated period, report to the Agency any unexpected fatal or life-threatening experience associated with the use of the medicinal product after initial receipt of the information.

(4) The sponsor of a Clinical Trial shall, within the stipulated period, report to the Agency, Suspected or Unexpected Serious Adverse Reactions, which occur outside the particular trial the sponsor's has first knowledge.

(5) The Sponsor shall, within the stipulated period, report to the Agency after the sponsor has first knowledge of safety issues, which might materially alter the current benefit-risk assessment of the Investigational Medicinal Product or that would be sufficient to consider changes in the Investigational Medicinal Products administration or in the overall conduct of the trial.

Inactive status of a Clinical Trial.

10.—(1) The Agency may in its opinion or upon request by the sponsor, place a Clinical Trial on inactive status, where there is no progress report sent to the Agency by the investigator for a period of 1 year.

(2) To restart a Clinical Trial after a temporary halt shall be deemed as a substantial amendment.

(3) An investigation that remains on inactive status for 5 years or above, shall be terminated.

(4) Where an investigation is placed on inactive status, investigators shall be notified and stocks of investigational medicinal products shall be returned or disposed of, in accordance with the requirements of the Agency.

Data and Safety Monitoring Board.

11.—(1) The Agency may impose a condition for the establishment of Data Monitoring Committee.

(2) The establishment of Data and Monitoring Board pursuant to sub-regulation (1) of this regulation may depend on any of the following—

(*a*) the design and scientific background of the Clinical Trial ;

(*b*) the benefit and risk assessment of the Clinical Trial ; or

(*c*) any other reason as may be prescribed by the Agency.

(3) Where Data and Safety Board is involved to monitor a Clinical Trial, the Agency shall require the following—

(*a*) a broad statement of the aims and objectives of the Clinical Trial ;

(*b*) terms of reference ;

(*c*) composition of members, at least one member from the Country or Region, conducting the trial ;

(*d*) qualifications of members ;

(*e*) specific roles including responsibility of statistician ;

(*f*) the role of statistical stopping rules ;

(*g*) relationship between the principal investigator and trial management team ;

(*h*) decision-making process ;

(*i*) meeting arrangement ;

(*j*) whether the members will be blinded to treatment ;

(*k*) what options can be recommended ;

(*l*) in what form and to whom the decisions shall be conveyed ;

(*m*) a person to whom the Data and Safety Board shall report to ;

(*n*) the role of the Data and Safety Board in the publication of the outcome of the medical trials ; and

(*o*) disclosure of conflicting interests of any of the Board members.

NAFDAC Expert Advisory Committee.

12.—(1) The Agency shall—

(*a*) constitute expert advisory committee, comprising of experts from different fields of relevant professions ; and

(*b*) define the Terms of Reference for the Expert Advisory Committee.

(2) The Expert Advisory Committee shall be a standing committee and its role shall remain advisory to the Agency.

Insurance and Indemnity.

13.—(1) Without prejudice to the provisions of these Regulations, Clinical Trial shall not be conducted unless the sponsor provides insurance cover for participant in the Clinical Trial from a registered insurance company in Nigeria against any related injuries or harms that may arise in the course of such Clinical Trial.

(2) Subject to sub-regulation (1) of this regulation, the sponsor shall indemnify an investigator against claims arising from the trial, except for claims on malpractice or negligence.

(3) The insurance cover for participants and investigators referred to in sub-regulation (1) of this regulation, shall be in accordance with the applicable insurance law in Nigeria.

Good Clinical Practice Inspection.

14.—(1) The Agency shall at any time it deems fit, conduct clinical inspections to investigators with a view to determining whether the investigator is in compliance with the provisions of these Regulations and other statutory requirements of the Agency.

(2) Investigators shall not disallow the Agency from copying, verifying and evaluating participants' medical records and any other record or report made relating to the handling, storage, usage and disposal of unnecessary medicinal product in compliance with good clinical practice.

(3) The Agency shall carry out on-site inspections on any approved trial site or facilities used or being used for clinical investigation.

(4) The Agency may not give notice of inspection to a Sponsor or Investigator before conducting an inspection.

Foreign Clinical Trials.

15.—(1) The Agency may rely on data obtained from foreign clinical studies to form its decision, provided the studies are designed, conducted, performed by qualified investigator in accordance with global best practices.

(2) Studies meeting these criteria may be utilized to support clinical investigations in Nigeria or marketing approval, provided that, an application based solely on foreign clinical data meeting Nigeria criteria for marketing approval may be approved if the—

(*a*) foreign data are applicable to Nigerian population and Nigeria medical practice ;

(*b*) studies were performed by competent investigators ;

(*c*) data may be considered valid without the need for an on-site inspection by the Agency ; and

(*d*) Agency considers such an inspection to be necessary, shall validate the data through an on-site inspection or other appropriate means.

(3) The Agency may rely on information or regulatory decisions of well-resourced regulatory authorities, regional or international bodies, to form its regulatory decisions.

Registry for Clinical Trial information.

16. Applicant for Clinical Trial shall register with the Nigerian Clinical Trial Registry (NCTR) or the Pan African Clinical Trial Registry (PACTR) and the evidence shall be submitted to the Agency.

Clinical Trials during public health outbreaks.

17. Clinical Trials during public health emergencies shall be conducted as prescribed by the Agency.

Revocation or cancellation of Approval.

18.—(1) The Agency, by a notice in writing may suspend or revoke the licence or permit for such period as may be determined by the Agency due to non-compliance with these Regulations.

(2) The Agency may disqualify or blacklist an investigator, where it has information indicating that the investigator, failed to comply with the requirements of these Regulations or submitted to the Agency or to the sponsor, false information in any required report.

Offences and Penalties.

19.—(1) A person who contravenes any of the provisions of these Regulations, commits an offence and shall be liable on conviction, in the case of—

(*a*) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals, every—

(*a*) director, manager, secretary or other similar officer of the body corporate ;

(*b*) partner or officer of the firm ;

(*c*) trustee of the body concerned ;

(*d*) person concerned in the management of the affairs of the association ; or

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

is liable to be proceeded against and punished for the offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction.

20. A person convicted of an offence under these Regulations shall forfeit to the Federal Government—

(*a*) asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence ; and

(*b*) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

Enforcement of these Regulations.

21. The Agency shall be responsible for the enforcement of these Regulations.

Interpretation.

22. In these Regulations—

"**Adult**" means a person who has attained the age of 18 years ;

"*Adverse event*" means any unpleasant medical occurrence in a patient or Clinical Trial participant, when medicinal product is administered, which may or may not have a causal relationship with the treatment ;

"*Adverse reaction*" means any unpleasant and unintended responses to an investigational medicinal product related to the dose administered ;

"*Agency*" means National Agency for Food and Drug Administration and Control (NAFDAC) ;

"*Amendment*" means changes in the protocol and any other change that may occur in the course of the study ;

"*Approval*" means the affirmative decision of the Agency that the Clinical Trial has been received and may be conducted at the institution site, within the limits set forth by the institution, good clinical practice and applicable regulatory requirements ;

"*Bioavailability*" means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action, for drug bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action ;

"*Bioequivalence*" means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study ;

"*Clinical Trial*" means any investigation in participants intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more investigational medicinal product, or to identify any adverse reactions to one or more investigational medicinal product or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product with the objective of ascertaining its safety or efficacy and this includes Clinical Trials carried out in either one site or multiple sites ;

"*Conflicting interest*" means a set of conditions in which professional judgment concerning a primary interest, such as patient's welfare or the validity of research, tends to be unduly influenced by secondary interest ;

"*Conducting a Clinical Trial*" means—

(*a*) administering, or giving directions for the administration of an investigational medicinal product to a participant for the purposes of trial ;

(*b*) giving a prescription for investigational medicinal product for the purposes of trial ;

(*c*) carrying out any other medical or nursing procedure in relation to the trial ; and

(*d*) carrying out any test or analysis to—

(*i*) discover or verify the clinical, pharmacological or other pharmacodynamic effects of the investigational medicinal products administered in the course of the trial,

(*ii*) identify any adverse reactions to those products, or

(*iii*) study absorption, distribution, metabolism and excretion of those products, but does not include any activity undertaken prior to the commencement of the trial, which consists of making such preparations for the trial as are necessary or expedient ;

"*Data and Safety monitoring Board*" is refer to as monitoring Committee ;

"*Essential documents*" means documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced ;

"*Ethics Committee*" means an independent body, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of participants involved in biomedical research and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities and also on the methods and documents to be used to inform trial participants, obtain their informed consent, initiate and conduct periodic review of such study ;

"*Ethics Committee Approval*" means the determination of the ethics committee that the clinical investigation has been reviewed and may be conducted at an institution within the limits set forth by the ethics committee and by the Agency ;

"*Good Clinical Practice (GCP)*" means a standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of Clinical Trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of the trial participants are protected ;

"*Good Manufacturing Practice (GMP)*" means a part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Clinical Trial authorisation, marketing authorisation, or product specification, good manufacturing practice is concerned with both production and quality control ;

"*Halt*" means stoppage of trial that is not envisaged in the approved protocol and where there is an intention to resume it ;

"*Health professional*" includes doctor, dentist, nurse, ophthalmologist, pharmacist, medical laboratory scientist and pharmacologist ;

"*Informed consent*" means decision, which shall be written, dated and signed, to take part in a Clinical Trial, taken freely after being duly informed of its nature, significance, risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his legal representative; where the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases ;

"*Inspection*" means the act by the Agency of conducting an official review of documents, facilities, records, quality assurance arrangements and any other resources that are deemed by the Agency to be related to the Clinical Trial and that may be located at the site of the trial, at the sponsor's or contract research organisation's facilities or at other establishments which the Agency deems fit to inspect ;

"*Investigational medicinal product*" means a form of an active substance or placebo being tested or used as a reference in a Clinical Trial, including a product with a Certificate of Registration 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 the approved form ;

"*Investigator*" means the authorised health professional responsible for the conduct of Clinical Trial at a trial site and the leader is called the Principal Investigator (PI) ;

"*Investigater's brochure*" means a compilation of the clinical and non-clinical data on the investigational medicinal product, which are relevant to the study of the product in participants ;

"*Legal representative*" means an individual or judicial or other body authorized under applicable law to grant consent on behalf of a prospective participant in the Clinical Trial ;

"*Manufacture*" means any process carried out in the course of making the product, but does not include dissolving or dispersing the product in or diluting it or mixing it with, some other substance used as a vehicle for the purposes of administering it ;

"*Medicinal product*" means any substance or combination of substances which may be administered to human beings or animals with a view to preventing diseases, making a medical diagnosis or restoring, correcting or modifying physiological functions in human beings or in animals ;

"*Minor*" means a person under the age of 18 years ;

"*Multiple Sites* (*Multi-centre*) *Clinical Trial*" means a Clinical Trial conducted according to a single protocol, but at more than one site and more than one investigator, in which the trial sites may be located within and outside the country ;

"*Participant*" means an individual who participates in a Clinical Trial as either a recipient of the investigational medicinal product or a control, a participant may either be a healthy human or a patient ;

"*Person*" means—

(*a*) the sponsor of the trial,

(*b*) a person employed or engaged by, or acting under arrangements made with, the sponsor and who undertakes activities in connection with the management of the trial,

(*c*) an investigator for the trial,

(*d*) a health care professional who is a member of an investigator's team for the purposes of the trial, or

(*e*) a person who provides health care under the direction or control of a person referred to in (*c*) and (*d*) above, whether in the course of the trial or otherwise ;

"*Proceeds*" means any property derived or obtained, directly or indirectly, through the commission of an offence ;

"*Protocol*" means a document that describes the objective(s), design, methodology, statistical considerations and organization of a trial it also refers to the protocol, successive versions of the protocol and protocol amendments ;

"*Qualified person*" means the holder of a certificate or other evidence of formal qualifications awarded on completion of a university or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science, which the Agency has stated to be qualifications sufficient for the purpose of performing the functions of a qualified person ;

"*Serious adverse event or serious adverse reaction*" means any unpleasant medical occurrence or effect that at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect ;

"*Sponsor*" means an individual, company, institution or organization which takes responsibility for the initiation, management or financing of a Clinical Trial ;

"*Trial Site*" means a hospital, health centre, surgery or other establishment or facility at or from which a Clinical Trial, or any part of such a trial, is conducted ; and

"*Unexpected adverse reaction*" means an adverse reaction, the nature or severity of which is not consistent with the applicable product information including investigator's brochure for an unauthorised investigational medicinal product or summary of product characteristics for an authorized product.

Citation.

23. These Regulations shall be cited as Clinical Trial Regulations, 2021.

MADE at Abuja this 7th day of July, 2021.

DR OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health