NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

CLINICAL TRIAL REGULATIONS 2019

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 9th September, 2019).

PLEASE SEND ALL INPUT TO REGULATORYAFFAIRS@NAFDAC.GOV.NG

ARRANGEMENT OF REGULATIONS

Commencement

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drug and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the 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 Honourable Minister of Health hereby makes the following Regulations:-

1. **Scope**
   (1) These Regulations prescribe Good Clinical Practice requirements for the conduct of clinical trials involving medicinal products to ensure that the rights, safety and well-being of trial participants are protected and that the results of the clinical trials are credible.
   (2) These Regulations shall also 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.

2. **Prohibition**
   (1) No person shall 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) No Investigational Medicinal Product (IMP) shall be manufactured in whole or in part, assembled, divided, packaged, presented, exported or imported except with as approved by the Agency.
   (3) No gene therapy trials which result in modifications to the participant's germ line genetic identity shall 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 reports there from invalid. All such medicinal products as well as the person who is responsible for the non-compliance shall be liable to punishment set out Regulations 18 & 19 of these Regulations.

3. **General requirements**
   (1) All clinical trials, including Bioavailability and Bioequivalence studies, shall be designed, conducted, recorded and reported in accordance with these Regulations.
   (2) All clinical trials must be conducted in accordance with Good Clinical Practice (GCP) principles.
   (3) Clinical trials shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP.
   (4) Before a trial is initiated, foreseeable risks and inconveniences shall be weighed against the anticipated benefit for the individual trial subject and society. A trial shall be initiated and continued only if the anticipated benefits justify the risks.
   (5) The rights, safety, and well-being of the trial subjects shall prevail over interests of science and society.

(6) The available nonclinical and clinical information on an investigational product shall be adequate to support the proposed clinical trial.

(7) Clinical trials shall be scientifically sound, and described in a clear, detailed protocol. The trial shall be conducted according to the approved protocol.

(8) A trial shall be conducted in compliance with the protocol that has received prior Ethics Committee (EC) favorable opinion.

(9) 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.

(10) Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s).

(11) Freely given informed consent shall be obtained from every subject prior to clinical trial participation.

(12) All clinical trial information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. This applies to all records, irrespective of the type of media used.

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

(14) Investigational medicinal products shall be manufactured, handled, and stored in accordance with applicable Good Manufacturing Practice (GMP). They shall be used in accordance with the approved protocol.

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

(16) Amendments relating to the conduct, design, methodology, investigational medicinal product, or the investigator or site(s) of the clinical trial and which may have substantial impact on the safety or rights of the participant or on the reliability and robustness of the data generated in the clinical trial, shall be subject to approval by the Agency.

(17) Every 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.

(18) The sponsor or the investigator shall submit study reports as prescribed by the Agency.

(19) The Sponsor/Investigator shall ensure registration of all clinical trials in the WHO primary registry before submission of application to the Agency for approval.

(20) The Agency shall carry out inspection at the approved trial sites and all other facilities used or being used for the purpose of the clinical investigation to ensure compliance with provisions of these Regulations.

4. **The Investigational Medicinal Product**

(1) The provisions under Regulation 2 (2) 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 a clinical trial site for the clinical trial in which the product is to be used.

(2) An Investigational Medicinal Product shall be labelled such as to ensure protection of the participant, traceability to enable identification of the product and trial and to facilitate proper use of the IMP.

(3) The Investigational Medicinal Product shall be traceable, stored, returned and/or destroyed as appropriate. Written records of destruction shall be maintained by the investigator and forwarded to the Agency.

(4) The sponsor shall assure the return of all unused or expired supplies of the investigational medicinal product from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused or expired supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug.

(5) The labeling of an Investigational Medicinal Product shall comply with the requirements of the Agency.

5. **Protection of clinical trial participants**

(1) Prior to involvement of a participant in a trial, the investigator shall fully inform the participant or his legally acceptable representative, of all pertinent aspects of the trial including the favourable opinion by the ethics committee in the language understandable by the participant or his legally acceptable representative.

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

(3) The obtaining of Informed Consent shall be deemed feasible before use of the 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 an inability to communicate with the participant.

(c) time is not sufficient to obtain consent from the participant's legal representative.

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

(4) If immediate use of the Investigational Medicinal Product is, in the investigator's opinion required to preserve the life of the participant, and time is not sufficient to obtain the independent determination required in Regulation 5 (3) in advance of using the Investigational Medicinal Product, the determinations of the clinical investigator shall be made and, within five 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 Regulations 5 (3) or 5 (4) shall be submitted to the Ethics Committee within five working days after the use of the investigational medicinal product.

(6) If during a clinical trial, a minor reaches the age of legal competence to give Informed Consent, his or her express informed consent shall be obtained before the participant can continue to participate in the trial.

(7) The participant may without any resulting 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 using pregnant or breastfeeding women shall be conducted only where the trial has the potential to produce a direct benefit to the concerned women, embryo, foetus or child after birth or where the trial poses a minimal risk to, and imposes a minimal burden on the concerned women, embryo, foetus or child after birth.

(10) The rights of each participant to physical and mental integrity, to privacy and to the protection of the data concerning him 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) No incentives or financial inducements shall be given to a participant except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial.

6. **Ethics Committee**

(1) The Agency shall refuse the favourable opinion given by an Ethics Committee if there are grounds to believe that:

(a) The Ethics Committee is not composed of adequate number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial.

(b) The Ethics Committee has not established, documented and followed its procedures.

(2) The Ethics Committee shall operate in such a manner that its tasks can be executed free from bias and from any influence of those who are conducting the trial.

(3) Ethics Committee members shall make declaration on conflict of interest with respect to each trial.

(4) Any member of the Ethics Committee having a conflicting interest shall not participate in the review, except to provide information requested by the ethics committee.

7. **The Sponsor**

(1) The sponsor shall be responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general

investigational plan and protocols, maintaining an effective control with respect to the investigations, and ensuring that the Agency and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug.

(2) The sponsor shall also be responsible for establishing and ensuring compensation appropriate to the nature and the extent of the risk in the form of insurance, a guarantee, or a similar arrangement for any damage suffered by participants as a result of taking part in the clinical trial.

(3) The sponsor shall be responsible for the supply of Investigational Medicinal Products that conforms with GMP principles.

(4) A sponsor may delegate any or all of his trial-related functions to an individual, a company, an institution or an organisation. However, in such cases, the sponsor shall remain responsible for ensuring that the conduct of the trials and the final data generated from those trials comply with the requirements of the Agency.

(5) The sponsor or a legal representative of the sponsor must be established in Nigeria.

(6) All essential documents relating to the clinical trial shall be archived by the sponsor as prescribed by the Agency and be readily accessible and available upon request by the Agency.

(7) Any transfer of ownership of the content of the clinical trial master file shall be documented. The new owner shall assume the responsibilities set out in these Regulations.

8. **The Investigator**

(1) An Investigator shall be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial in compliance with good clinical practice and the applicable requirements of the Agency.

(2) In clinical trials with more than one investigator, a sponsor shall appoint a principal investigator who shall ensure compliance with the requirements of these regulations at the trial site(s).

(3) The Investigator shall provide progress and final report to the sponsor and the Agency as prescribed by the Agency.

9. **Safety Reporting**

(1) The sponsor shall review all 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, within the stipulated period, notify the Agency through a written safety report after the sponsor's initial receipt of the information of:

(a) any 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.

(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 Unexpected Serious Adverse Reactions which occur outside the concerned trial the sponsor has first knowledge.
(5) The sponsor shall, within the stipulated period, report to the Agency after the sponsor has first knowledge, all other 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

10. **Inactive Status**
(1) The Agency shall on its own initiative or upon request by the sponsor, place a clinical trial on inactive status if no progress report is sent to the Agency from the investigator for a period of 1 year.
(2) The restart of the clinical trial following a temporary halt shall be deemed as a substantial amendment.
(3) An investigation that remains on inactive status for 5 years or more shall be terminated.
(4) If an investigation is placed on inactive status, all investigators shall be so notified and all stocks of investigational medicinal products shall be returned or otherwise disposed of in accordance with the requirements of the Agency

11. **Data and Safety Monitoring Committee**
(1) The Agency reserves discretion to impose a condition for establishment of a Data and Safety Monitoring Board or Data Monitoring Committee.
(2) The establishment of a Data and Safety Monitoring Board or Data Monitoring Committee under Regulation 11 (1) may depend on any of the following-
(a) the design and scientific background of the clinical trial;
(b) the risk and benefit assessment of the clinical trial; and
(c) any other reasons as may be determined by the Agency or Sponsor.
(3) In any case, where clinical trials involve Data and Safety Monitoring Board or Data Monitoring Committee to monitor clinical trials, the Agency shall require the following;
(a) a broad statement of the aims and objectives;
(b) terms of reference;
(c) composition of members;
(d) qualifications of members;
(e) specific roles including responsibilities of statisticians;
(f) the role of statistical stopping rules;
(g) relationship with the principal investigators and trial; management team
(h) clarification on the decision-making powers;
(i) how meetings will be organized;

(j) whether the members will be blinded to treatment
(k) what options can be recommended;
(l) in what form and to whom decisions will be conveyed;
(m) a person to whom the committee will report to
(n) the role of the committee in the publication of results; and
(o) disclosure of competing interests of the committee members.

12. **NAFDAC Expert Advisory Committee:**
(1) The Agency shall create an expert advisory committee comprising of experts from different fields of relevant profession.
(2) The expert advisory committee shall be a standing committee and its role shall remain advisory to the Agency.
(3) The Agency shall define the Terms of Reference for the Expert Advisory Committee.

13. **Insurance and Indemnity:**
(1) Without prejudice to the contents of this Regulation, no clinical trial shall be conducted unless the sponsor provides insurance cover from an insurance company registered in Nigeria to any study participants against any clinical trial related injuries or harms that may arise from investigator's negligence and or malpractice in the course of a clinical trial.
(2) Subject to Regulations 13 (1), the sponsor shall indemnify the investigator against claims arising from the trial, except for claims that arise from malpractice and, or negligence.
(3) The insurance cover for study participants and investigators referred in Regulation 13 (1) shall be in accordance with the applicable law in Nigeria.

14. **Good Clinical Practice Inspection**
(1) The Agency shall at any time it deems fit conduct clinical inspections to determine if the investigators are operating in compliance with the provisions of these Regulations and other statutory requirements.
(2) Investigators who conduct the investigations shall permit the Agency to access, copy, and verify any records or reports made with regard to the handling, storage, use and disposal of the product and participants' medical records.
(3) The Agency's personnel shall perform this oversight function through on-site inspections at the approved trial site(s) and all other facilities used or being used for the purpose of the clinical investigation.
(4) The Agency may conduct both announced and unannounced inspections.

15. **Foreign clinical Trials**
(1) In general, the Agency may rely on data from foreign clinical studies to make its decision provided they are designed, conducted, performed by qualified investigators, and conducted in accordance with global best practices.

(2) Studies meeting these criteria may be utilized to support clinical investigations in Nigeria and/or marketing approval. An application based solely on foreign clinical data meeting Nigeria criteria for marketing approval may be approved if:
   (a) The foreign data are applicable to Nigerian population and Nigeria medical practice.
   (b) The studies have been performed by clinical investigators of recognized competence; and
   (c) The data may be considered valid without the need for an on-site inspection by the Agency or, if the Agency considers such an inspection to be necessary, it is able to validate the data through an on-site inspection or other appropriate means.

(3) The Agency may rely on information and/or regulatory decisions of well-resourced Regulatory Authorities, regional and international bodies to make its regulatory decisions.

16. **National or Regional Registry for Clinical Trial Information**

Applicants for conduct of clinical trials shall be required to register the clinical trial on the Nigerian Clinical Trial Registry (NCTR) and/or the Pan African Clinical Trial Registry (PACTR) and the evidence shall be presented.

17. **Clinical Trials during Public Health Outbreaks**

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

18. **Revocation/cancellation of approval**

(1) The Agency may, by a notice in writing to the holder of a license or permit, forthwith or from a date specified in the notice, suspend or revoke the license or permit for such period as may be determined due to non-compliance with these Regulations.

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

19. **Penalty.**

(1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :
   (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and
   (b) a body corporate, to a fine not exceeding N100, 000.

(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; or
   (b) partner or officer of the firm or
   (c) trustee of the body concerned ;or
   (d) person concerned in the management of the affairs of the association ;or

(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance

20. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-

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

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

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

21. **Interpretation**

In these Regulations unless the context otherwise requires:-

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

"Adverse event" means any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and which may or may not have a causal relationship with this treatment.

"Adverse reaction" all untoward and unintended responses to an investigational medicinal product related to any 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 constraints set forth by the institution, GCP and applicable regulatory requirements.

"Benefit-Risk Profile" means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks i.e. any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health.

"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 Hold" means a directive issued by the Agency to the sponsor to suspend an ongoing trial.

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

"Conflicting interest" means 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 an investigational medicinal product for the purposes of trial,
(c) carrying out any other medical or nursing procedure in relation to that trial, and
(d) carrying out any test or analysis -
    i. to discover or verify the clinical, pharmacological or other pharmacodynamic effects of the investigational medicinal products administered in the course of the trial,
    ii. to identify any adverse reactions to those products, or
    iii. to 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;

"Declaration of Helsinki" means the declaration adopted by the World Medical Assembly in June 1964, or as amended.

"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 research.

"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 constraints 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 authorization, marketing authorization, or product specification. Good manufacturing practice is concerned with both production and quality control.

"Health Professional" means but not limited to doctor, dentist, nurse, ophthalmologist, pharmacist, medical laboratory scientist and pharmacologist.

"Informed Consent" means decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if 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 and/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 if the trial is conducted by a team of authorised health professionals at a trial site, the investigator who is the leader is called the Principal Investigator (PI).

"Investigator's Brochure" means a compilation of the clinical and non-clinical data on the investigational medicinal product(s) which are relevant to the study of the product(s) in participants.

"Labelling" means affixing, marking or otherwise displaying on the investigational medicinal product, a notice describing or otherwise relating to the contents.

"Legal Representative" means an individual or judicial or other body authorized under applicable law to 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.

"Multi-centre Clinical Trial" a clinical trial conducted according to a single protocol but at more than one site, and therefore by more than one investigator, in which the trial sites may be located within and outside the country.

"NCTR" means Nigerian Clinical Trial Registry.

"PACTR" means Pan African Clinical Trial Registry.

"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
(1) The sponsor of the trial,

(2) 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,
(3) An investigator for the trial,
(4) A health care professional who is a member of an investigator's team for the purposes of the trial, or
(5) 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

"Protocol" means a document that describes the objective(s), design, methodology, statistical considerations and organization of a trial. The term protocol 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 untoward 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 and/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.

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

22. **Citation**
These Regulations may be cited as Clinical Trail Regulations 2019

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Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)