(Legislative Supplement No. 45)

LEGAL NOTICE NO. 95

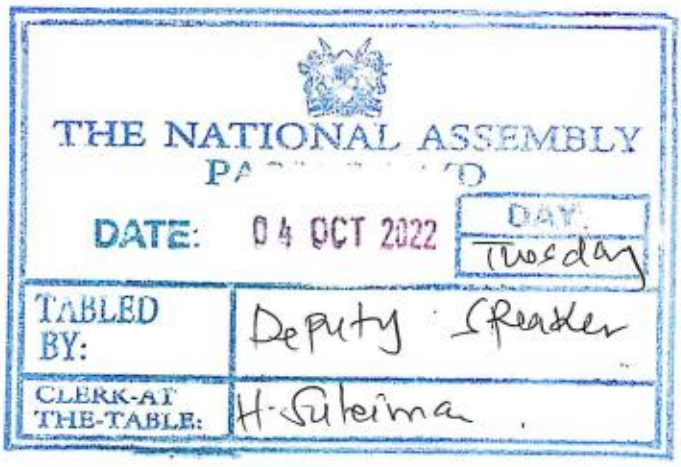
THE PHARMACY AND POISONS ACT

(Cap. 244)

THE PHARMACY AND POISONS (CONDUCT OF CLINICAL TRIALS) RULES, 2022

ARRANGEMENT OF RULES

Rule



PART V—MISCELLANEOUS

SCHEDULES

THE PHARMACY AND POISONS ACT

(Cap. 244)

IN EXERCISE of the powers conferred by section 44 (1) (n) of the Pharmacy and Poisons Act, the Cabinet Secretary, in consultation with the Board, makes the following Rules—

THE PHARMACY AND POISONS (CONDUCT OF CLINICAL TRIALS) RULES, 2022

PART I—PRELIMINARY

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Conduct of Clinical Trials) Rules, 2022.

Interpretation.

2. In these Rules, unless the context otherwise requires—

"adverse drug reaction" means a noxious or unintended response to a clinical trial study or interventional product related to a dose or to a registered health product which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function;

"adverse event" means an untoward medical occurrence in a patient or a participant in a clinical investigation study or intervention product, and which does not necessarily have a causal relationship with the treatment;

"applicant" means a person applying to conduct a clinical trial in accordance with rule 4;

"audit" means a systematic examination that is carried out independently of the persons who are directly involved in a clinical trial to determine whether the conduct of that clinical trial complies with the approved study protocol and whether data reported are consistent with the data on record at the site of the trial;

"blinding" means a procedure in which a participant in a study, investigator or data analyst is unaware of the treatment assignment;

"clinical trial report" means a written description of a clinical trial;

"comparator" means a health product or marketed product, active or placebo, used as a reference in a clinical trial;

"contract research organisation" means an organisation that is contracted by the sponsor to perform one or more of the duties and functions of the sponsor in the conduct of the clinical trial;

"data and safety monitoring board" means an independent board that is appointed in accordance with rule 12;

"double blinding" means blinding which applies to a participant in a study, the investigator and data analyst;

"ethical clearance" means the authorisation issued by an ethics committee to conduct a clinical trial;

"ethics committee" means a scientific and ethical review committee of an institution which is accredited by the National Commission for Science, Technology and Innovation in accordance with the Science, Technology and Innovation (Registration and Accreditation of Research Institutions) Rules, 2014; L.N. 106/2014.

"expert advisory committee" means an expert advisory committee responsible for clinical trials that is appointed by the Board in accordance with rule 6;

"generic product" means a multisource health product which is intended to be interchangeable with the comparator product which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights;

"good clinical practice" means a standard for the design, conduct, performance and 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 participants in a clinical trial study are protected;

"good manufacturing practice" means that part of quality assurance which ensures that investigational health products are consistently produced and controlled to the quality standards appropriate to their intended use and as may be required by the marketing authorization;

"informed written consent" means authority voluntarily given by a participant to confirm the participant's willingness to participate in a particular clinical trial after having been informed of all aspects of the clinical trial that are relevant to the participant's decision to participate;

"interchangeable health product" means a health product which is therapeutically equivalent to a comparator product and can be interchanged in clinical practice;

"investigational health product" means a medical device, health technology or pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a registered health product or technology, when used or assembled (formulated or packaged) in a way that is different from the registered form, or when used for an unregistered indication, or when used to gain further information about a registered use;

"investigator" means an appropriately qualified person responsible for the conduct of a clinical trial;

"investigator's brochure" means a compilation of the clinical and non-clinical data on the investigational health product that is relevant to the clinical trial;

"legal representative" means a person authorised to give informed written consent on behalf of a prospective participant in a clinical trial for that participant's participation in the clinical trial;

"material transfer agreement" means a written agreement between a provider and recipient of research material that is aimed at

protecting the intellectual and other property rights of the provider while permitting research with the material by the recipient to proceed;

"minimum anticipated biological effect level" means an anticipated dose needed to result in a biological effect in a participant of a clinical trial which is recommended as a useful approach to calculate the safe starting dose as the lowest dose that is active;

"monitor" means a person appointed by, and responsible to, the sponsor or contract research organization for the monitoring and reporting of progress of a clinical trial and verification of data therefrom;

"no observed adverse effect level" means the greatest concentration or amount of a substance found by experiment or observation that does not cause any alteration of morphology, functional capacity, growth, development or lifespan of the target organism distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure;

"participant" means an individual who participates in a clinical trial as a recipient of the investigational product or as part of the control group;

"periodic safety update report" means a report containing update safety data pertaining to a registered health product and a scientific evaluation report regarding the benefits and risks of the health product;

"protocol" means a document that states the background, rationale and objectives of a clinical trial and describes the clinical trial's design, methodology and organisation, including statistical considerations, and the conditions under which the trial is to be performed and managed;

"quality assurance" means planned and systematic actions that are established to ensure that the trial is performed and the data are generated, recorded and reported in compliance with good clinical practice requirements;

"quality control" means the operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the activities related to the clinical trial have been fulfilled;

"randomisation" means the process of assigning a participant or control group treatment using an element of chance to determine the assignments in order to reduce bias;

"recognition" means the acceptance of the regulatory decision of another regulator or trusted institution that is based on evidence that the regulatory requirements of that other regulator or trusted institution are sufficient to meet the regulatory requirements of the Board;

"reliance" means taking into account and giving significant weight to the assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, by the

Board in reaching its own decision and involves remaining independent, responsible and accountable for the decisions taken by the Board;

"serious adverse event" means an untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongs hospitalization, results in persistent or significant disability, or is a congenital anomaly or birth defect;

"single blinding" means blinding which applies to a study participant;

"source data" means information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial that is necessary for the reconstruction and evaluation of the trial;

"sponsor" means a person who takes legal responsibility for the initiation, management and financing of a clinical trial;

"suspected unexpected serious adverse reaction" means serious adverse reaction that is not identified in practice, severity or frequency by the reference safety information;

"vulnerable participant" means an individual whose decision to participate in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or by coercion; and

"work sharing" means the sharing of activities to accomplish a particular regulatory task.

Scope of application.

3. (1) These Rules shall apply to the conduct of a clinical trial—

(a) to test an unregistered health product;

(b) to test a registered health product where the proposed clinical trial is on the changes relating to the health product including—

(i) the indications and clinical use;

(ii) the target patient population;

(iii) the administration of the health product; or

(iv) the dosage regimen;

(c) to undertake a comparative bioavailability trial;

(d) to generate data on a health product that is registered in Kenya based on recognition, reliance or a work sharing arrangement;

(e) to establish bioequivalence for registration of a generic health product;

(f) to identify adverse reactions;

(g) to generate data on the absorption, distribution, metabolism and excretion of a health product; and

(h) to conduct a post-marketing study of a registered health product including the efficacy studies monitoring resistance.

(2) These Rules shall not apply to a clinical trial—

(a) that covers randomised controlled clinical trials relating to behavioural intervention;

(b) that involves an adult participant in the use of an educational test, survey, interview or observation of public behaviour unless—

(i) the information obtained is recorded in such a manner that the participant can be identified, directly or through identifiers linked to the participant; and

(ii) a disclosure of the responses of the participant outside the clinical trial could reasonably place the participant at risk of criminal or civil liability or be damaging to the financial standing, employability or reputation of the participant; or

(c) that involves the collection or evaluation of existing data, documents, or pathological or diagnostic specimens which are publicly available or if the information is recorded by the investigator in such a manner that the participants thereof cannot be identified, directly or through identifiers linked to the participant.

PART II—APPROVAL TO CONDUCT CLINICAL TRIAL

Application for approval to conduct clinical trial.

4. (1) A person shall not conduct a clinical trial of any health product without the written authorisation of the Board.

(2) An application to conduct a clinical trial shall be made by a sponsor or the sponsor's legal representative.

(3) An application under sub-rule (2) shall—

(a) be made in a duly filled and signed application form as set out in the First Schedule;

(b) be accompanied by the documents specified in sub-rule (4); and

(c) be accompanied by the fee specified in the Second Schedule.

(4) An application made under sub-rule (2) shall be accompanied by the following documents—

(a) a cover letter addressed to the Board;

(b) the study protocol duly signed and dated by the sponsor and principal investigator;

(c) the proposed participant information leaflet;

(d) the proposed informed written consent form;

(e) the investigator's brochure;

(f) a good manufacturing practice certificate of the investigational health product from the manufacturer issued by a competent health authority in the manufacturer's jurisdiction of origin;

(g) a certificate of analysis of the investigational health product;

(h) a pictorial sample of the investigational health product;

(i) the *curriculum vitae* of the investigator and study pharmacist;

(j) proof of recent training in good clinical practice for core study staff;

(k) the charter, composition and meeting schedule of the data and safety monitoring board;

(l) a statistical analysis plan;

(m) a detailed budget of the study;

(n) a recommendation from the relevant ethics committee;

(o) a valid indemnity cover for the investigator issued by a regulated insurance agency in Kenya;

(p) a valid insurance certificate for the participants issued by a regulated insurance agency in Kenya;

(q) copies of current practice licences or certificates from the relevant professional body that regulates the conduct of the investigators or study pharmacists;

(r) a copy of the approval letter from a collaborating institution or other regulatory authority, if applicable;

(s) a material transfer agreement, if applicable; and

(t) declarations by the principal investigator and sponsor on—

(i) financial disclosure;

(ii) conflict of interest;

(iii) compliance with good clinical practice;

(iv) compliance with legal requirements; and

(v) submission of correct information.

(5) In this rule, "core study staff" means the persons actively involved in the conduct of the clinical trial.

Processing of applications to conduct clinical trials.

5. (1) The Board shall, through the expert advisory committee evaluate an application submitted in accordance with rule 4.

(2) When conducting an evaluation under sub-rule (1), the Board shall consider—

(a) the reliability and robustness of the data generated in the clinical trial;

(b) whether the applicant has complied with the requirements concerning the manufacturing or importation of the investigational health product and any auxiliary health product connected therewith the investigational health medicinal product;

(c) whether the applicant has complied with the labelling requirements set out in the Third Schedule; and

(d) whether the investigator's brochure is adequate.

(3) The Board may approve or reject the application submitted under rule 4 and shall specify the reasons for the rejection in writing.

(4) The reasons for the rejection of an application by the Board under sub-rule (3) may include—

(a) insufficient information provided in the application;

(b) submission of false or falsified information;

(c) lack of a favourable opinion from an ethics committee;

(d) that the investigational health product endangers a participant;

(e) the safety of a participant has not been guaranteed; or

(f) any other reason as may be determined by the Board

(5) The Board shall communicate the decision made under sub-rule (3) in writing to the applicant within thirty working days after the receipt of the application.

(6) The Board shall publish on its website a list of the approved or rejected applications under sub-rule (3) and update the list at least once in every six months.

Expert advisory committees.

6. (1) The Board shall appoint an expert advisory committee for clinical trials which shall assist the Board to efficiently process each application for approval to conduct a clinical trial and study oversight.

(2) The Board shall designate members of the staff of the Board to assist the expert advisory committee in the performance of its functions.

PART III—INVESTIGATORS AND SPONSORS

Principal investigators.

7. (1) A person is qualified to be appointed as a principal investigator if that person—

(a) has a degree in medicine, pharmacy, pharmacology, toxicology, biochemistry, dentistry or a related discipline from a university recognised in Kenya;

(b) has a valid practice licence from the relevant regulatory authority;

(c) has a valid professional indemnity cover;

(d) has had formal training in good clinical practice that was

undertaken at least two years before the date of an application under rule 4;

(e) has previous experience in at least two clinical trials; and

(f) is a citizen of Kenya or is permanently resident in Kenya.

(2) The responsibilities of the principal investigator shall be—

(a) to thoroughly familiarise himself or herself with the characteristics and appropriate use of the investigational health product;

(b) to comply with ethical, good clinical practice and legal requirements in the conduct of the clinical trial;

(c) to facilitate access by the Board to the clinical trial for the purpose of monitoring and auditing the clinical trial or for inspection;

(d) to ensure that the data from the clinical trial is accurately recorded and submitted to the Board;

(e) to maintain records of the delivery processes and health products used in the clinical trial;

(f) to maintain a record of the persons to whom the investigator has delegated duties;

(g) to be responsible for the investigational medical product at the study site; and

(h) to maintain a list of staff who conduct the clinical trial.

(3) The principal investigator shall be liable for all aspects of the conduct of the clinical trial at a study site.

(4) A principal investigator shall not deviate significantly from, or make major changes to, the protocol of the clinical trial or to the information specified in the participant information booklet without the prior review and approval of the Board.

(5) Sub-rule (4) shall not apply where the deviation or change involves a logistical or administrative aspect of the clinical trial, or is based on issues relating to the immediate safety of a participant.

Responsibilities of sponsors.

8. (1) A sponsor shall be responsible for—

(a) implementing and maintaining quality assurance to ensure that a clinical trial is conducted following good clinical practice requirements;

(b) ensuring that the investigational health product provided for the trial has been manufactured following good manufacturing practice; and

(c) ensuring that data is generated, recorded and reported in compliance with good clinical practice requirements and applicable Rules.

(2) A sponsor shall ensure that the clinical trial institution,

contract research organisation, investigator, monitor, study pharmacist and participant have sufficient insurance cover for the clinical trial.

(3) A sponsor shall ensure that adequate treatment of a participant in case of injury or disease occurs during the course of the clinical trial.

(4) A sponsor shall provide an up-to-date investigator's brochure and drug safety update report whenever available, and in any case, at least once in year to the Board, unless there are substantial changes to the previous version to the brochure or report.

(5) A sponsor shall appoint qualified and suitable trained individuals to monitor a clinical trial.

(6) A sponsor shall report to the Board any serious adverse events and suspected unexpected serious adverse reactions that occur during the course of the clinical trial.

(7) An immediate notification of the event referred to in sub-rule (6) shall be made in writing and a detailed written report be submitted within fifteen days after the occurrence of the event.

(8) Despite sub-rule (7), the Board may direct the sponsor to provide additional information in any case where the adverse event causes death or threatens the life of a participant.

(9) A sponsor shall inform the Board in writing of a voluntary suspension or termination of the clinical trial within fifteen days after the suspension or termination and the reasons thereof.

(10) At the conclusion of a clinical trial, the sponsor shall submit—

(a) an executive summary of the report of the clinical trial;

(b) an annual study progress report; and

(c) a copy of the clinical trial report.

PART IV—CONDUCT OF CLINICAL TRIALS

Adherence to protocols.

9. (1) Each clinical trial shall be conducted in compliance with the protocol approved by the Board.

(2) The sponsor of a clinical trial shall submit the protocol of the trial to the Board, which shall contain—

(a) the general information of the clinical trial;

(b) the background information of the clinical trial including non-clinical data;

(c) the objectives of the clinical trial;

(d) the design of the clinical trial;

(e) the selection, treatment and withdrawal of a participant;

(f) the ethical considerations of the clinical trial;

(g) a post-trial access program;

(h) the mode of the assessment of the efficacy of the investigational health product;

(i) the mode of assessment of the safety of the investigational health product;

(j) the mode for collecting, analysing and reporting the statistics of the clinical trial;

(k) the source data documents of the clinical trial; and

(l) the quality control measures of the clinical trial.

Child participants.

10. (1) A sponsor who intends to conduct a clinical trial where the intended participant is a child shall ensure that the information in an approved participant information booklet referred to in rule 4(4)(c) specifies—

(a) the pathophysiology of the disease or subject of the clinical trial;

(b) the methods of diagnosis;

(c) the currently available treatment or prevention strategy in the paediatric population;

(d) the incidence and prevalence of the disease or subject of the clinical trial in the overall population and in the paediatric population; and

(e) the evidence and assumptions on key differences between the disease or subject of the clinical trial in the overall population and the paediatric population.

(2) Where the intended participant is a child, before making an application under rule 4, a sponsor shall ensure that—

(a) the clinical trial has been conducted with a participant who was an adult;

(b) the objective of the clinical trial is to obtain knowledge relevant to the health needs of children;

(c) the legal representative of each participant has been issued with the approved participant information booklet; and

(d) no financial inducement has been offered to the participant or the legal representative of the participant.

(3) When conducting a clinical trial where the participant is a child, an investigator shall ensure that the informed written consent of each legal representative of the participant has been obtained.

(4) The conduct of a clinical trial where a participant is a child shall ensure that the well-being of the participant is not compromised by participating in the clinical trial.

(5) The Board shall consider the following when evaluating an application under rule 4 where a participant is a child —

(a) the prevalence of the condition to be treated among children in the population;

(b) the seriousness of the condition to be treated by the outcome of the clinical trial;

(c) the availability and suitability of an alternative treatment for the condition, including the efficacy and the adverse event profile of that treatment;

(d) whether the investigational health product is novel or one of a class of compounds with known properties;

(e) whether there are unique paediatric indications for the investigational health product;

(f) the need for the development of a paediatric-specific endpoint;

(g) the age ranges of the proposed paediatric patients likely to be treated with the investigative health product;

(h) the unique paediatric or developmental safety concerns of the investigational health product, including any nonclinical safety issues; and

(i) the potential for paediatric formulation development.

(6) An application made under rule 4 where a participant is a child shall specify the following information of the investigational health product—

(a) the genotoxicity;

(b) the reprotoxicity;

(c) the carcinogenicity, if applicable;

(d) the juvenile animal studies, if applicable;

(e) the pharmacokinetics;

(f) the absorption;

(g) the distribution;

(h) the metabolism;

(i) the excretion; and

(j) the pharmacodynamics.

Informed written consent.

11. (1) Before the making an application under rule 4, a sponsor shall obtain a recommendation to conduct the clinical trial from the relevant ethics committee.

(2) An investigator shall submit, in writing, an approved participant information booklet to each participant or the participant's legal representative, in English, Kiswahili or the local spoken language of the participant.

(3) If a participant or the participant's legal representative is unable to read the approved participant information booklet submitted under sub-rule (2), the investigator shall explain to the participant or legal representative, and in the presence of impartial witness, the information in the booklet.

(4) A participant information booklet shall contain the following information—

(a) a declaration that a clinical trial involves research activities;

(b) the objective of the clinical trial;

(c) the treatment that will be employed in the clinical trial;

(d) the procedure to be followed in the clinical trial;

(e) the responsibilities of the participant;

(f) the aspects of the clinical trial that are experimental;

(g) the reasonably foreseeable risks to a participant;

(h) the reasonably expected benefits of the clinical trial, if any;

(i) an alternative procedure or treatment available to participants and the important potential benefit and risk of the alternative;

(j) the compensation or treatment available to the participant in the event of injury or adverse event related to the clinical trial;

(k) that the participation in the clinical trial is voluntary and that the participant may decline to participate or withdraw from the trial at any time without penalty or loss of benefits to which the participant is otherwise entitled;

(l) the anticipated payment, if any, to the participant;

(m) the anticipated expenses, if any, of the participant;

(n) the foreseeable circumstances or reasons under which the participation of the participant may be terminated;

(o) the expected duration of a participant's role in the clinical trial; and

(p) the approximate number of participants involved in the clinical trial.

(5) On receipt the approved participant information booklet under sub-rule (2), the participant or participant's legal representative may submit an informed written consent to an investigator.

(6) If the participant or participant's legal representative agrees with the information submitted under sub-rule (3), the investigator shall prepare an informed written consent and the participant or legal representative, and the impartial witnesses, shall sign and date the informed written consent.

(7) A sponsor, investigator, study pharmacist, monitor and any other person connected with the conduct of the clinical trial shall not coerce or unduly influence a participant or participant's legal representative to participate or to continue to participate in the clinical trial if the participant or legal representative has withdrawn his or her informed written consent.

(8) Where new information is available that would require the informed written consent of a participant, an investigator shall prepare a revised participant information booklet, submit the revised booklet for approval in accordance with rule 4 and thereafter submit the revised booklet in accordance with sub-rule (2) or inform the participant of the revised booklet in accordance with sub-rule (3).

(9) The Board may gain access to a participant's original medical records for verification of data, or the conduct of a procedure or treatment used in the clinical trial without violating the confidentiality of the participant to the extent permitted by the participant or participant's legal representative as specified in the informed written consent authorizing such access.

(10) The information of a participant or participant's legal representative shall be kept confidential and not made publicly available or to any other person without the express written consent of the participant or participant's legal representative.

(11) Where the results of a clinical trial are published, the identity of a participant shall not be disclosed.

(12) The participation of a participant in a clinical trial is voluntary and a participant may decline to participate or withdraw the informed written consent issued by the participant at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Safety reports.

12. (1) A sponsor shall submit to the Board a report of any suspected unexpected serious adverse reaction or serious adverse event that occurs in a clinical trial.

(2) Where a sponsor conducts a clinical trial on the same health product or active pharmaceutical substance in another country, the sponsor shall submit a report of any suspected unexpected serious adverse reaction or serious adverse event that occurs in that other clinical trial to the Board.

(3) A sponsor shall submit a report of an initially fatal or life threatening suspected unexpected serious adverse reaction or serious adverse event as soon as it occurs but, in any case, not later than seven days after the occurrence of the event.

(4) Subject to sub-rule (3), a sponsor shall submit a report on a suspected unexpected serious adverse reaction which is not fatal or life-threatening within fifteen days after the occurrence of the event.

(5) A report of the occurrence of a suspected unexpected serious adverse reaction or serious adverse event shall specify—

(a) the suspected unexpected serious adverse reaction or serious adverse event which is related to the clinical trial; and

(b) the suspected unexpected serious adverse reaction or serious adverse event which is not related to the clinical trial.

(6) A sponsor shall submit to the Board, at least once in each year from the date of authorisation of the clinical trial, and throughout the

conduct of the clinical trial, or on request by the Board, a safety report on the safety information received during the reporting period.

(7) The safety report submitted under sub-rule (6) shall contain a log of serious adverse events and suspected unexpected serious adverse reactions that occur during the clinical trial and indicate —

(a) the age, date of the informed written consent and identity of the participant who was affected by the serious adverse event or suspected unexpected serious adverse reaction;

(b) the type, date of commencement and end date of the serious adverse event or suspected unexpected serious adverse reaction;

(c) the reason for reporting the occurrence as a serious adverse event or suspected unexpected serious adverse reaction;

(d) how the serious adverse event or suspected unexpected serious adverse reaction relates to the investigational health product; and

(e) the outcome of the serious adverse event or suspected unexpected serious adverse reaction.

(8) A sponsor shall notify the investigators involved in the clinical trial of any serious adverse event or suspected unexpected serious adverse reaction related to the clinical trial within fifteen days after the occurrence of the event.

(9) A sponsor shall submit to the Board a report of any new information or change in nature, severity or frequency of risk factors in respect of the investigational health product or conduct of the clinical trial within fifteen days after the sponsor becomes aware of the information or change.

Data and safety monitoring board.

13. (1) The sponsor shall establish a data and safety monitoring board in respect of a clinical trial which shall be responsible for the following—

(a) assessing the progress of the clinical trial;

(b) assessing the safety data of the clinical trial;

(c) assessing the critical efficacy endpoints of the clinical trial; and

(d) recommending to the sponsor whether to continue, modify, or stop the clinical trial.

(2) A sponsor shall appoint a data safety and monitoring board where—

(a) the endpoint of a clinical trial is such that a highly favourable or unfavourable result, or even a finding of futility, at an interim analysis might ethically require termination of the clinical trial before its planned completion;

(b) there are *a priori* justifications for a particular safety concern;

(c) there is prior information suggesting the possibility of toxicity with the treatment offered during the clinical trial;

(d) the clinical trial is being performed in a potentially vulnerable population;

(e) the clinical trial is being performed in a population at an elevated risk of death or other serious outcomes; or

(f) the clinical trial is being conducted for a period exceeding three years and at multiple centres.

(3) The data and safety board shall include the following persons—

(a) a clinician with expertise in the relevant clinical speciality that is the focus of the clinical trial;

(b) a biostatistician who is knowledgeable about statistical methods for a clinical trial and sequential analysis of data generated from a clinical trial;

(c) a toxicologist;

(d) an epidemiologist;

(e) a clinical pharmacologist; and

(f) where a clinical trial involves an unusually high risk or broad public health implication, a medical ethicist who is knowledgeable about the design, conduct and interpretation of clinical trials; and

(g) any other scientist who the sponsor considers to be necessary.

(4) In this paragraph, "medical ethicist" means a medical practitioner or medical professional who specialises in research, moral, legal and ethical issues that arise in health care settings.

Investigational health product.

14. (1) An investigational health product shall be manufactured in accordance with the requirements of good manufacturing practices.

(2) The import, export, storage and destruction of the investigational health product shall comply with the applicable regulatory requirements to ensure integrity and accountability of the products.

(3) An application for import or export of the investigational health product shall be made to the Board and a respective permit obtained.

(4) The Board may revoke or suspend a permit issued under sub-rule (3) for the following reasons—

(a) the investigational health product was manufactured in conditions that were or are not consistent with good manufacturing practices;

(b) the discontinuation of the clinical trial; or

(c) false information provided by the sponsor.

(5) The Board may authorise the disposal of an investigational health product upon written request by the sponsor or the sponsor's legal representative in accordance with the Board's procedures on safe management of pharmaceutical waste.

(6) A sponsor shall submit a certificate of analysis for an investigational health product and for a comparator product when making an application under rule 4.

(7) A sponsor shall specify the following information when making an application under rule 4—

(a) the name and source of the investigational health product;

(b) the method of manufacturing the investigational health product;

(c) the physicochemical properties and structure elucidation of the investigational health product;

(d) the impurities of the investigational health product;

(e) the specifications, test methods and batch analyses of the investigational health product;

(f) the stability and packaging of the investigational health product; and

(g) the proposed dosage form of the investigational health product.

(8) Where the pharmaceutical or chemical properties of an investigational health product have been altered compared to those in use during animal testing or a previous clinical trial, the sponsor shall describe and justify the alteration.

(9) A sponsor shall immediately notify the Board in writing where a pharmaceutical or chemical alteration that may affect the quality, safety or efficacy of the investigational health product occurs in an investigational health product that is used in an ongoing clinical trial.

(10) In this paragraph, "comparator product" means a product of established quality, safety and efficacy that may be used as a reference in a clinical trial or bioequivalence study.

Pharmacy at site for clinical trial.

15. (1) A sponsor shall ensure that a site at which a clinical trial is being undertaken has a designated pharmacy.

(2) The pharmacy designated under sub-rule (1) shall, at a minimum, have—

(a) facilities and equipment that reflect the types of procedures and treatments of the clinical trial that shall be undertaken by the investigator;

(b) a biosafety level cabinet, if necessary;

(c) a controlled environment that prevents microbiological contamination and regulates the temperature; and

(d) a designated storage area, with a quarantine area;

(e) documented procedures that comply with good pharmacy practice; and

(f) a rigorous quality management system.

(3) The designated storage area referred to in sub-rule (2)(d) shall—

(a) have adequate space for the separate storage of different health products;

(b) be temperature-controlled and, if appropriate, humidity monitored, with alarm controls;

(c) be shielded from direct sunlight; and

(d) be mapped to identify and avoid using hot and cold spots, if necessary.

Clinical trial laboratories.

16. A sponsor shall ensure that any laboratory that is used in support of a clinical trial is of a suitable size, construction and location to meet the requirements of the clinical trial and that—

(a) the design of the laboratory provides an adequate degree of separation of different activities of the laboratory;

(b) the equipment used in the laboratory has valid maintenance and calibration certificates;

(c) that the analysis conducted in the laboratory is organised and conducted in such a manner that the findings therefrom are transparent and stand up to retrospective verification;

(d) the roles and responsibilities of the staff of the laboratory are well established and documented before the commencement of the clinical trial;

(e) the laboratory possesses the protocol and any amendments thereto that was approved by the Board for the clinical trial;

(f) the impact of any deviations from the standard operating procedures or documented policies of the laboratory are assessed and documented; and

(g) the laboratory does not perform any analysis on a sample from a clinical trial that is not specified in the protocol that was approved by the Board for the clinical trial.

Quality assurance.

17. (1) A sponsor shall develop a quality assurance process that ensures—

(a) that a research centre, researcher, sponsor, clinical research organisation and any other person involved in a clinical trial

complies with good clinical practice including ensuring—

(i) that the study benefit outweighs risks;

(ii) that the rights and wellbeing of a participant are protected and preserved;

(iii) that the clinical trial is scientifically sound and performed in accordance with the approved protocol;

(iv) that the core study staff are adequately qualified and trained to perform their duties;

(v) that the confidentiality of the information of a participant is maintained; and

(vi) that informed written consent is obtained from a participant before participation in the clinical trial;

(b) that there is regular and continuous monitoring of the clinical trial and the recommendations of the report thereof are implemented;

(c) that the site where the clinical trial is undertaken has valid registration and approval;

(d) that the safety and confidentiality of the information of a participant are not compromised;

(e) that the analysis or evaluation of a sample from the clinical trial is conducted in accordance with the principles of good clinical practice;

(f) that the analysis or evaluation of samples is performed in accordance with the protocol approved by the Board;

(g) that data from the conduct of the clinical trial is recorded and reported accurately, legibly, completely and in a timely manner;

(h) that the equipment used in the conduct of the clinical trial is regularly maintained; and

(i) that the records, including source documents and final reports, are well kept.

(2) A sponsor shall establish an internal audit program for the conduct of the clinical trial once approval is obtained in accordance with rule 5.

Termination of clinical trials.

18. (1) A sponsor shall ensure that the protocol approved by the Board specifies the procedure for the termination of the clinical trial.

(2) If a clinical trial is terminated voluntarily by an investigator or a sponsor, the sponsor shall notify the Board of the termination within fifteen days after the termination.

(3) If a clinical trial is terminated under sub-rule (2), a sponsor shall—

(a) immediately inform, in writing, the investigators of the termination, the reasons for the termination and advise them

on the potential risks to the health of a participant or other person;

(b) if the termination is due to an adverse event, ensure that the affected participant receives medical care where the participant develops or experiences an adverse drug reaction to the investigational health product; and

(c) inform the Board, in writing, of—

(i) the reason for the termination;

(ii) the impact of the termination on the proposed or ongoing conduct of the clinical trial on the investigational health product;

(iii) the accountability and disposal of the investigational health product; and

(iv) the maintenance of records of the clinical trial that has been terminated

(4) The Board may revoke the approval to conduct a clinical trial if the Board determines—

(a) that the safety of a participant has been compromised;

(b) that the scientific reasons for conducting the clinical trial have changed;

(c) that the investigational health product has expired; or

(d) that the investigational health product is not usable.

(5) Where a clinical trial has been terminated, a sponsor shall—

(a) submit an executive summary report of the clinical trial to the Board within thirty days after the termination;

(b) submit a clinical trial report within one hundred and eighty days after the termination; and

(c) dispose of the investigational health products in accordance with the Board's procedures on the safe management of pharmaceutical waste.

PART V—MISCELLANEOUS

Amendments to protocol.

19. (1) A sponsor shall promptly apply to the Board for the amendment to the protocol where new information which affects the conduct of the clinical trial, safety of a participant or manufacture of the investigational health product, that necessitates a change to the protocol, becomes available.

(2) A sponsor shall take appropriate urgent safety measures to protect a participant against any hazard where an occurrence referred to in sub-rule (1) is likely to affect the safety of the participant.

(3) An application under sub-rule (1) shall be accompanied by a copy a recommendation from the relevant ethics committee.

(4) A sponsor shall make an application under sub-rule (1) where the proposed amendment includes—

(a) a change that may affect—

(i) the safety, or physical or mental integrity of a participant;

(ii) the scientific value of the clinical trial;

(iii) the conduct or management of the clinical trial;

(iv) the quality or safety of the investigational health product;

(v) an objective of the clinical trial;

(vi) a primary or secondary endpoint of the clinical trial;

(vii) the addition of a trial arm or placebo group to the clinical trial;

(viii) the inclusion or exclusion of a criterion of the clinical trial;

(ix) the monitoring of the clinical trial;

(x) the data and safety monitoring board;

(xi) an alternative to an investigational health product;

(xii) the dosage of an investigational health product;

(xiii) the mode of administration of an investigational health product;

(xiv) the design of the clinical trial which has an impact on statistical analysis or the risk-benefit assessment of the clinical trial;

(xv) an alternative to the sponsor;

(xvi) the revocation or suspension of the registration of the investigational health product;

(xvii) the manufacturing process or specifications of an active substance or the investigational health product;

(xviii) the reference safety information during the conduct of the clinical trial;

(xix) the site for the conduct of the clinical trial; or

(xx) an alternative to an investigator;

(b) a change that may affect the selection or discontinuation of a participant;

(c) a change that may affect the effectiveness of the investigational health product and safety of a participant; or

(d) a change that may affect the duration of the clinical trial.

(5) An application under sub-rule (1) shall specify—

(a) the proposed amendment;

(b) the justification for the proposed amendment;

(c) the impact of the proposed amendment on the objectives of the clinical trial;

(d) the impact of the proposed amendment on the endpoints and data generated from the conduct of the clinical trial; and

(e) the impact of the proposed amendment on the safety and wellbeing of a participant.

(6) An application under sub-rule (1) shall be accompanied by a favourable opinion by an Ethics Committee and applicable fees as may be prescribed by the Board.

Inspection of clinical trial sites.

20. (1) The Board shall conduct an inspection of the site at which a clinical trial is conducted.

(2) The objectives of an inspection under sub-rule (1) shall be—

(a) to ensure that a participant is not subjected to undue risks;

(b) to ensure that the rights, safety and wellbeing of the participants are protected;

(c) to validate the quality of the data generated;

(d) to investigate a complaint; and

(e) to assess the compliance of a sponsor with the Act and these Rules.

(3) An investigator shall, on the request of the Board, at reasonable times, give the Board access to, and copy and verify any records or reports made by the investigator when conducting the clinical trial.

(4) An inspection may be conducted before the commencement of a clinical trial, or at routine intervals as may be determined by the Board.

(5) The Board may carry out a routine inspection referred to in sub-rule (4) to assess—

(a) the adequacy of the clinical trial;

(b) the protection measures for a participant;

(c) the integrity of the data; or

(d) the historical background of the clinical trial site, a sponsor or an investigator.

(6) Any non-compliance by the sponsor, investigator or any person connected to the clinical trial during an inspection may form the basis of the revocation or suspension of the authorisation to conduct the clinical trial.

Clinical trials involving traditional or alternative medicines.

21. (1) A sponsor shall ensure that good clinical practice is applied when conducting a clinical trial involving traditional or alternative medicines.

(2) A sponsor shall ensure that a traditional medicine practitioner who is familiar with the traditional or alternative medicine proposed for investigation develops the protocol for the conduct of the clinical trial.

(3) The protocol developed under sub-rule (3) shall be submitted to the Board for approval before the commencement of the clinical trial.

(4) The protocol developed under sub-rule (3) shall not be amended without the approval of the Board.

Online registry for clinical trials.

22. Applications for the conduct of clinical trials shall be registered on the Board's online registry.

Clinical trials in special circumstances.

23. (1) The Board may, in special circumstances, through written guidelines, authorise the conduct of a clinical trials under fast-track procedures or non-routine procedures.

(2) The special circumstances referred to in sub-rule (1) may include—

(a) a public health emergency;

(b) the rapid spread of an epidemic disease; or

(c) any other circumstance as may be determined by the Board.

Reliance and recognition.

24. The Board may recognise and use of clinical trial decisions, reports or information from other competent authorities in rule of clinical trials.

Offences and penalties.

25. Any person who contravenes the provisions of these Rules commits an offence and shall be liable to the penalty prescribed under section 51 of the Act.

FIRST SCHEDULE (r. 4 (3) (a))
FORM

Application for Approval to Conduct Clinical Trial
Study Title:
Protocol No:
Version No: Date of Protocol:
Study Drug:
ECCT Ref number (if applicable):
Sponsor:
Contact Person:
Address:
Telephone Number: Fax Number:
Cell Number: E-mail address:
TICK AND PROVIDE NECESSARY DETAILS AS APPROPRIATE
2. NUMBER OF SITES
Single site in Kenya:
If yes, name of site.....
Multiple sites in Kenya:
Number of sites anticipated in Kenya ( )
If yes list the sites.....
Multiple countries:
Number of states anticipated in the trial ( )
If yes above list the countries.....
Does this trial have a data monitoring committee? yes □ no □
3. PARTICIPANTS (SUBJECTS)

3.1 Number of participants in Kenya: 3.2 Total enrolment in each Kenyan site: (if competitive enrolment, state minimum and maximum number per site.) 3.3 Total participants worldwide:
4.0 AGE SPAN
Less than 18 years yes □ no □ If yes specify: In Utero yes □ no □ Preterm Newborn Infants (up to gestational age < 37 weeks) yes □ no □ Newborn (0-28 days) yes □ no □ Infant and toddler (29 days - 23 months) yes □ no □ Children (2-12 years) yes □ no □ Adolescent (13-17 years) yes □ no □ 18 years and overyes □ no □ Adult (18-65 years)yes □ no □ Elderly (> 65 years) yes □ no □
5.0 GROUP OF TRIAL SUBJECTS
Healthy volunteers yes □ no □ Patients yes □ no □ Specific vulnerable populations yes □ no □ Women of child bearing potential yes □ no □ Women of child bearing potential using contraception yes □ no □ Pregnant women yes □ no□

Nursing women yes □ no□ Emergency situation yes □ no□ Subjects incapable of giving consent personally yes □ no□ If yes, specify: Others: yes □ no□ If yes, specify:
6.0 GENDER
Female □ Male □
7.0 CO-ORDINATING INVESTIGATOR (*for multicentre trials in Kenya*)
Given name Middle name, if applicable Family name Qualification Professional address:
8.0 PRINCIPAL INVESTIGATOR *(for multicentre trial; where necessary, use additional forms)*
Given name Middle name, if applicable Family name Qualification Professional address
9.0 ORGANISATIONS TO WHOM THE SPONSOR HAS TRANSFERRED TRIAL RELATED DUTIES AND FUNCTIONS (repeat as needed for multiple organisations)
Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party? yes □ no □ Repeat as necessary for multiple organisations: Organisation:

Name of contact person: Address: Telephone number:
All tasks of the sponsor yes □ no □ Monitoring yes □ no □ Regulatory (e.g. preparation of applications to CA and ethics committee) yes □ no □ Investigator recruitment yes □ no □ IVRS – treatment randomization yes □ no □ Data management yes □ no □ E-data capture yes □ no □ SUSAR reporting yes □ no □ Quality assurance auditing yes □ no □ Statistical analysis yes □ no □ Medical writing yes □ no □ Other duties subcontracted yes □ no □ If yes to other please specify:
10.0 PRINCIPAL INCLUSION CRITERIA
List them here;
11.0 PRINCIPAL EXCLUSION CRITERIA
List them here;
12.0 PRIMARY END POINT(S):

List them here;
13.0 SCOPE OF THE TRIAL – Tick all boxes where applicable
Diagnosis ☐
Prophylaxis ☐
Therapy ☐
Safety ☐
Efficacy ☐
Pharmacokinetic ☐
Pharmacodynamic ☐
Bioequivalence ☐
Dose Response ☐
Pharmacogenetic ☐
Pharmacogenomic ☐
Pharmacoeconomic ☐
Others ☐
If others, specify:
14.0 TRIAL TYPE AND PHASE
Human pharmacology (Phase I) ☐
Is it:
First administration to humans ☐
Bioequivalence study ☐
Other: ☐
If other, please specify
Therapeutic exploratory (Phase II) ☐

Therapeutic confirmatory (Phase III) □ Therapeutic use (Phase IV) □
15.0 DESIGN OF THE TRIAL
Controlled yes □ no □ If yes, specify: Randomised yes □ no □ Open: yes □ no □ Single blind: yes □ no □ Double blind: yes □ no □ Parallel group: yes □ no □ Cross over: yes □ no □ Other: yes □ no □ If yes to other specify: If controlled, specify the comparator: Other medicinal product(s) yes □ no □ Placebo yes □ no □

Other yes □ no □ If yes to other, specify:
16.0 INFORMATION ON PLACEBO (if relevant; repeat as necessary)
Is a there a placebo: yes □ no □ Pharmaceutical form: Route of administration: Composition, apart from the active substance(s): Is it otherwise identical to the INDP? yes □ no □ If not, specify major ingredients:
17.0 Details of Site(s)
Name of site Physical address Contact details Contact person:
18.0 Capacity of Site(s):
Number of staff (including study co-ordinators, site facilities, emergency facilities, other relevant infrastructure): Names: Qualifications: Experience:
19.0 OTHER DETAILS
19.1 If the trial is to be conducted in Kenya and not in the host country of the applicant / sponsor, provide an explanation:

19.2 Estimated duration of trial:

19.3 Name other Regulatory Authorities to which applications to do this trial have been submitted, but approval has not yet been granted. Include date(s) of application:

19.4 Name other Regulatory Authorities which have approved this trial, date(s) of approval and number of sites per country:

19.5 If applicable, name other Regulatory Authorities or Ethics Committees which have rejected this trial and give reasons for rejection:

19.6 If applicable, details of and reasons for this trial having been halted at any stage by other Regulatory Authorities:

SECOND SCHEDULE r. 4 (3) (c)

FEES		
	Purpose of Fees	Amount (Kshs.)
1.	Application for Approval to Conduct Clinical Trial	110,000

THIRD SCHEDULE r. 5 (2) (c)

LABELLING REQUIREMENTS

The final copy of the label of an investigational health product shall contain the following minimum information—

(a) a statement indicating that the product is for "clinical trial purpose only";

(b) the recommended storage conditions;

(c) the protocol code or identification;

(d) the name, address and telephone number of the sponsor, contract research organisation or investigator;

(e) the pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the identifier and the potency;

(f) the batch and code number;

(g) a clinical trial reference code allowing identification of the clinical trial, site, investigator and sponsor, if not given elsewhere;

(h) the identification number or treatment number and, where relevant, the visit number of a participant;

(i) the directions for use;

(j) the period of use in month and year format and in a manner that avoids any ambiguity; and

(k) the complete physical address of the manufacturing site.

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

LEGAL NOTICE NO. 96

THE PHARMACY AND POISONS ACT

(Cap. 244)

THE PHARMACY AND POISONS (PHARMACOVIGILANCE AND POST MARKET SURVEILLANCE) RULES, 2022

ARRANGEMENT OF RULES

Rule

PART I – PRELIMINARY