PHARMACY BOARD OF SIERRA LEONE

GUIDELINES FOR CONDUCTING CLINICAL TRIALS O MEDICINES, FOOD SUPPLEMENTS, VACCINES AND MEDICAL DEVICES IN SIERRA LEONE

Guideline No.	**: PBSL/PVGCT/GDL/CCT/01-2018**
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1.0. INTRODUCTION

In pursuance of Section 55 of the Pharmacy and Drugs Acts, these Guidelines are hereby made by the Pharmacy Board of Sierra Leone (PBSL), hereafter referred to as **The Board**, to define the general norms and scientific principles and to set applicable standards for the conduct, performance and control of clinical trials in human beings in Sierra Leone particularly in relation to granting of marketing authorization. They do not cover veterinary trials.

These Guidelines are addressed to investigators, pharmaceutical manufacturers and other sponsors of clinical trials whether for academic purposes or for generation of data intended for inclusion in the regulatory submissions for medicinal products. They are intended to be applied during all stages of drug development both prior to and subsequent to product registration and marketing.

Clinical trials shall be categorized as follows;
1. Trials initiated by The Board.
2. Trials initiated by pharmaceutical companies or agencies.
3. Trials initiated by pharmaceutical companies on advice of The Board, to be carried out locally for pharmacogenetic or other reasons peculiar to the population in Sierra Leone.
4. Trials initiated by academic and research institutions either locally or as part of an international multi-centre study.

In all the categories above the primary end-point of the trial shall be clearly specified.

2.0. GLOSSARY

The definitions below apply specifically to the terms used in this guideline:

"Adult" A person who is eighteen (18) years of age or over that age.

"Adverse Drug Reaction (ADR)" All noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out.

Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

"Adverse Event (AE)" Any undesirable experience occurring to a subject during a clinical trial, whether or not considered related to the investigational product(s). An unexpected AE is an experience not reported in the current Investigators Brochure or elsewhere.

"Amendment" A written description of a change(s) to or formal clarification of a protocol.

"Applicable Regulatory Requirement(s)" Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

"Approval(s)" The affirmative decision of the appropriate institutions (PBSL, IEC) that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the appropriate institutions, Good Clinical Practice (GCP), and the applicable regulatory requirements.

"Audit Certificate" A declaration of confirmation by the auditor that an audit has taken place.

"Audit Report" A written evaluation by the sponsor's auditor of the results of the audit.

"Audit Trail" Documentation that allows reconstruction of the course of events.

"*Audit"* A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

"Biological Specimen/Sample" means materials derived from various animal and human sources(ranging from fluids like blood, tissues and cells) used to treat and prevent diseases.

"Blinding/Masking" A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually

refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

"Case Report Form" A printed, optical or electronic document designed to record all of the protocol required information. There should be assurance of accurate input and presentation and it should allow verification.

"Certificate of Analysis (COA)" An authenticated document issued by an appropriate authority that certifies the quality and purity of pharmaceuticals, and animal and plant products.

"Child/Minor" A person who is below eighteen (18) years of age.

"Clinical Trial Site" The location(s) where trial-related activities are actually conducted.

"Clinical Trial" means an investigation consisting of a particular description by, or under the direction of a medical practitioner, dentist or veterinary surgeon to the patient or animal where there is evidence that a medicine, medical device or procedure or herbal medicinal product of that description has effects which may be beneficial to and safe to the patient or animal, and the medicine, medical device or procedure or herbal medicine is for the purpose of ascertaining beneficial or harmful effects.

"Contract Research Organization (CRO)" A scientific body (commercial or academic) contracted by a Sponsor to perform some of the Sponsors trial related duties and function

"Data Safety Monitoring Board (DSMB)" An independent data-monitoring committee that may be established by the Sponsor to assess at intervals the progress of a clinical, the safety data, and the critical efficacy endpoints, and to recommend to the Sponsor whether to continue, modify, or stop a trial.

"Date of Commencement" For the purpose of the Clinical Trial Certificate and Quarterly Progress Report Form, this is defined as the date when the clinical trial site shall start to enroll participants in the clinical trial.

"Drug/Medicine" Includes
1. A substance or mixture of substances prepared, sold or represented for use in
i. Restoring, correcting or modifying organic functions in man or animal, and
ii. The diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal, physical state or the symptoms of it, in man or animal, or
2. Nutritional supplements

"Good Clinical Practice (GCP) Inspection" The act by the PBSL of conducting an official review of documents, facilities, records and any other resources that are deemed 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 organization's (CRO's) facilities, or at other establishments deemed appropriate by the PBSL.

"Good Manufacturing Practice (GMP)" The part of pharmaceutical quality assurance which ensures that products are consistently produced and controlled to quality standards appropriate to their intended use and as required by the marketing authorization.

"Herbal Medicinal Product" Includes plant-derived material preparations with therapeutic or any other human health benefits which contain raw or processed ingredients from one or more plants and materials or organic or animal origin.

"Institutional Review Board/Independent Ethics Committee (IRB/IEC)" An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

"Investigational Product" A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial including a product with a marketing authorization when used or assembled in a way different from the approved form, or when used for an unapproved indication or when used to gain further information about an approved use.

"Investigator's Brochure" A collection of data consisting of all the information known prior to the clinical trial concerning the clinical and non-clinical data on the investigational product(s). There should be adequate data to justify the nature, scale and duration of the proposed trial.

"Local Monitor" A person appointed by the Sponsor or CRO to oversee the progress of a clinical trial and of ensuring that it is conducted, recorded and reported in accordance with the SOPs, GCP and the applicable regulatory requirements.

"Lot Release Certificate (LRC)" An official document that authorizes the manufacturer to release a specific lot of a product.

"PBSL" means Pharmacy Board of Sierra Leone

"Placebo" A medication with no active ingredients or a procedure without any medical benefit.

"Principal Investigator / Investigator" The person responsible for the conduct of the clinical trial at the clinical trial site, who is entitled to provide health care under the laws of the Country where that clinical trial site is located.

"Protocol Amendment" A written description of a change(s) to or formal clarification of a protocol.

"Protocol" A document that describes the objective(s), design, methodology, statistical considerations and the organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.

"Research Institution" Any public or private entity, agency, medical or dental facility where clinical trials are conducted.

"Serious Adverse Event (SAE)" means any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect (ICH definition 1997).

"Sponsor" An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a trial. This excludes an individual company, institution or organization which has been requested to provide money for a trial and does not benefit in any way from the results of the trial.

"Sponsor's Medical Expert (Medical Monitor) An Employee of the sponsor (or CRO) who is readily available to advise on trial-related medical questions or problems. If necessary, outside consultant(s) may be appointed for this person.

Sub investigator
Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.

"Vulnerable population" An individual whose willingness to volunteer in a clinical trial may be unduly influenced by the expectations, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.
Examples are pregnant women, cognitively impaired subjects, children and prisoners.
Research concerning vulnerable population should be conducted in line with provisions made in Pharmacy Board of Sierra Leone GCP Guidelines.

3.0. REQUIREMENTS

3.1 Clinical Trial Application

A Clinical Trial Application made to The Board to conduct a clinical trial shall be accompanied by the following:

3.1.1. Covering Letter
3.1.2. A non-refundable Application Fee as per the prescribed Fee Schedule.
3.1.3. A Clinical Trial Protocol
3.1.4. Two (2) copies of completed Pharmacy Board of Sierra Leone Application Forms for Conducting Clinical Trials signed by authorized persons
3.1.5. A proof of registration with a Clinical Trials Registry (approved by The Board)
3.1.6. Investigator's Brochure
3.1.7. Ethics Committee Approval
3.1.8. Insurance Cover
3.1.9. Financial Declaration
3.1.10. Declaration by principal investigator(s)
3.1.11. Declaration of sub-investigator(s) and pharmacist(s)
3.1.10. DSMB charter
3.1.11. Chemistry, Manufacturing and Control (CMC) of the investigational product(s)
3.1.12. Informed consent information and form(s)

All clinical trial application documents shall be submitted in hard copies (15 copies) and soft copy (1).

3.1.1. Cover Letter

Addressed to the Registrar as follows:

The Registrar
Pharmacy Board of Sierra Leone
Central Medical Stores
New England Ville
Freetown
Sierra Leone
P.M.B.322
+232 25 282886
Email. registrar@pharmacyboard.gov.sl
Website: www.pharmacyboard.gov.sl

3.1.2. Application Fees

An application shall be accompanied by a non-refundable application fee as specified in the Pharmacy Board of Sierra Leone Fee Schedule.

3.1.3. Application Form to Conduct a Clinical Trial

Two (2) copies of completed application forms signed by all sponsor or sponsor's authorized person shall contain at least the following as stipulated in the application form:

3.1.3.1. Administrative details

3.1.3.2. Trial details

3.1.3.3. Investigational product details

3.1.3.4. Investigator(s) and pharmacist(s) details including CVs

3.1.3.5. Current Good Clinical Practice certificate (cGCP) for investigators and pharmacist(s)

3.1.3.6. Signed declaration by the Sponsor or authorized person.

3.1.4. Clinical Trial Protocol and Trial Amendment

3.1.4.1. General Information

This shall include:

3.1.4.1.1. Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).

3.1.4.1.2. Name and address of the Sponsor

3.1.4.1.3. Name and address of the Monitor (Local and International)

3.1.4.1.4. Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the Sponsor.

3.1.4.1.5. Name, title, address, and telephone number(s) of the Sponsor's medical expert or medical monitor (or dentist when appropriate) for the trial.

3.1.4.1.6. Name and title of the Principal Investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

3.1.4.1.7. Name and title of the Pharmacist(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

3.1.4.1.8. Name, title, address, and telephone number(s) of the sub-investigators designated by the PI to be responsible for some aspects of the study.

3.1.4.1.9. Name(s) and address(es) of study/trial site(s)

3.1.4.1.10. Name(s) and address (es) of the clinical laboratory (ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

3.1.4.1.11. Contractual agreement between the investigator and Sponsor.

3.1.4.1.12 Signed budget contract for the trial

3.1.4.1.13 Copy of advertisement for recruitment of trial staff

3.1.4.2. Background Information

This shall include:
3.1.4.2.1. Name and description of the investigational product(s).
3.1.4.2.2. A summary of findings from nonclinical studies that potentially have clinical significance to the trial
3.1.4.2.3. Summary of findings from clinical trials that are relevant to the trial.
3.1.4.2.4. Summary of the known and potential risks and benefits, if any, to human subjects.
3.1.4.2.5. Information on local background rates of expected adverse events.
3.1.4.2.6. Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).
3.1.4.2.7. A statement that the trial shall be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).
3.1.4.2.8. Description of the population to be studied.
3.1.4.2.9. References to literature and data that are relevant to the trial and that provide background for the trial.
3.1.4.2.10. Signed declaration by the applicant/sponsor and all investigators and pharmacist(s) that they are familiar with and understand the protocol and shall comply with principles of Good Clinical Practice (GCP) as determined by the Pharmacy board of Sierra Leone in the conduct of the trial.

3.1.4.3. Trial Objectives and Purpose

3.1.4.3.1. A detailed description of the objectives and the purpose of the trial
3.1.4.3.2. Aim of the trial and reason for its execution.

3.1.4.4. Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design should include:

3.1.4.4.1. A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.
3.1.4.4.2. A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.
3.1.4.4.3. A description of the measures taken to minimize/avoid bias, including: Randomization and Blinding.
3.1.4.4.4. A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s).
3.1.4.4.5. Description of the dosage form, packaging, and labeling of the investigational product(s) and sample of label to be used for investigational product.
3.1.4.4.6. The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.
3.1.4.4.7. Quantities of investigational medicines and comparators
3.1.4.4.8. A detailed description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial.
3.1.4.4.9. Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.
3.1.4.4.10. Maintenance of trial treatment randomization codes and procedures for breaking codes.
3.1.4.4.11. The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.

3.1.4.4.12. Number of human subjects to be involved in the trial and the statistical justification.
3.1.4.4.13. Specifications and instructions for anticipated deviations from the protocol.

3.1.4.5. Selection and withdrawal of subjects

3.1.4.5.1. Subject inclusion criteria.
3.1.4.5.2. Subject exclusion criteria.
3.1.4.5.3. Subject withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying:

- 3.1.4.5.3.1. When and how to withdraw subjects from the trial/investigational product treatment.
- 3.1.4.5.3.2. The type and timing of the data to be collected for withdrawn subjects.
- 3.1.4.5.3.3. Whether and how subjects are to be replaced.
- 3.1.4.5.3.4. The follow-up for subjects withdrawn from investigational product treatment/trial treatment.

3.1.4.6. Treatment of Subjects

3.1.4.6.1. The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.
3.1.4.6.2. Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.
3.1.4.6.3. Procedures for monitoring subject compliance.
3.1.4.6.4. Description of treatment applied to control group(s) or control period(s), placebo, and other therapy and any other treatment that may be given concomitantly including measures to be implemented to ensure the safe handling of the products.
3.1.4.6.5. Description of diagnostic devices or kits applied to be used in the clinical trial.
3.1.4.6.6. Description of special analyses and/or tests or procedure to be carried out.

3.1.4.7. Assessment of Efficacy

3.1.4.7.1. Specification of the efficacy parameters.
3.1.4.7.2. Methods and timing for assessing, recording, and analyzing of efficacy parameters.
3.1.4.7.3. Clear procedures for interim assessment of trial.

3.1.4.8. Assessment of Safety

3.1.4.8.1. Specification of safety parameters.
3.1.4.8.2. The methods and timing for assessing, recording, and analyzing safety parameters.
3.1.4.8.3. Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.
3.1.4.8.4. The type and duration of the follow-up of subjects after adverse events.
3.1.4.8.5. Provision for dealing with all adverse events. Copy of form to be used to report adverse event.
3.1.4.8.6. Criteria for the termination of the trial

3.1.4.9. Statistics

3.1.4.9.1. A description of the statistical methods to be employed, including timing of any planned interim analysis.
3.1.4.9.2. The number of subjects planned to be enrolled. In multicentre trials, the numbers of enrolled subjects projected for each trial site should be specified.

3.1.4.9.3. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
3.1.4.9.4. The level of significance to be used.
3.1.4.9.5. Criteria for the termination of the trial.
3.1.4.9.6. Methods for data analyses and evaluation of results.
3.1.4.9.7. Procedure for accounting for missing, unused, and spurious data.
3.1.4.9.8. Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).
3.1.4.9.9. The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).

3.1.4.10. Ethics

General ethical consideration relating to the trial and informed consent sheet or form or otherwise to be given to patients or volunteers.

3.1.4.11. Data Handling and Record Keeping

3.1.4.11.1. Procedure for keeping a list of participating volunteer/patients and detailed records indicated on the case report form (CRF) for each individual taking part in the trial.
3.1.4.11.2. A clear statement on composition and benefit package for clinical trial participants
3.1.4.11.3. All clinical and experimental data (electronic or paper) shall be kept in a secured place for a period of 5 years and 20 years for New Drug Application (NDA) after completion of the trial and be made readily available for review upon request by the Board.

3.1.4.12. Publication of clinical trial report

3.1.4.12.1. Publication policy, if not addressed in a separate agreement.
3.1.4.12.2. Publication policy, including a plan for the publication of the results (publishing plan)

3.1.5. Protocol amendments

3.1.5.1. Any amendment to the trial protocol, trial arrangements and investigational product shall be submitted to the Ethics Committee that originally approved the protocol and the Board for approval by these bodies before such amendments are carried out.
3.1.5.2. If such amendments are necessary to protect the life of subjects, an urgent amendment may be carried out but the investigator who shall inform the ethics committee and the Board of such amendments with an immediate phone call, followed by a written report within forty-eight (48) hours.
3.1.5.3. Reports of all amendments shall include but not be limited to the following:
- 3.1.5.3.1. Reasons for the amendments.
- 3.1.5.3.2. Possible consequences for subjects already included in the trial.
- 3.1.5.3.3. Possible consequences for the evaluation of the study outcome.
- 3.1.5.3.4. All amendment shall attract a fee which shall be determined as per PBSL Fee Schedule

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3.1.6. Investigator's Brochure

Investigators Brochure containing information on the following but not limited to:

3.1.6.1. Chemical, physical and pharmaceutical properties and formulations,
3.1.6.2. Preclinical studies
3.1.6.3. Human pharmacological and clinical data with the substance concerned and any other supporting documentation sufficient to establish quality, safety and efficacy where applicable.
3.1.6.4. Marketing experience in countries where the investigational product is being marketed or approved. Where appropriate there should be discussions of published reports.
3.1.6.5. Summary of Data and Guidance for the Investigator
3.1.6.6. An updated investigator's brochure should be submitted at least once a year, or whenever it is updated within this period. Additional information and any changes that have been incorporated in the updated investigator's brochure should be highlighted for ease of review and evaluation.

- Refer to PBSL GCP guideline for more details.

3.1.7. Ethical Committee Approval

3.1.7.1. Ethical Clearance for all phases of clinical trials in humans shall be sought from the National Independent Ethics Committee (IEC) of Sierra Leone.
3.1.7.2. Submissions to the Board and ethics committees can be done in parallel in case of a public health emergency or as deemed fit by the Board.
3.1.7.3. Original copy of approval letter/certificate from national independent ethics committee shall be required.

3.1.8. Insurance Cover

3.1.8.1. All subjects must be satisfactorily insured against possible injuries that might arise during the conduct of the clinical trial.
3.1.8.2. For all Sponsor-initiated trials, a valid insurance certificate for the duration of the study must be provided prior to study initiation.
3.1.8.3. Sponsors and Principal Investigators shall ensure insurance cover for clinical trial participants and shall submit as evidence a Certificate of insurance cover for participants.
3.1.8.4. Sponsors and Principal Investigators shall ensure insurance cover for trial staff and shall submit as evidence a Certificate of insurance cover for staff.

3.1.9. Financial Declaration

3.1.9.1. The financial aspects of the trial should be documented in an agreement between the Sponsor and the Principal Investigator/Contracted Research Organization/Institution.
3.1.9.2. A declaration must be signed by both the Sponsor and the Principal Investigator which states that there are sufficient funds available to complete the study.

3.1.10. Data Safety Monitoring Board/Committee (DSMB/C) or Independent Data-Monitoring Committee (IDMC) or Data Monitoring Committee (DMC)

3.1.10.1. An independent data-monitoring committee (IDMC) that should be established by the Sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the Sponsor whether to continue, modify, or stop a trial.
3.1.10.2. The Sponsor shall include charter of work, membership and curriculum vitae of the IDMC member.
3.1.10.3. It is recommended that for trials conducted in Sierra Leone, at least one member of the IDMC must be Sierra Leonean.

3.1.11. Chemistry manufacturing and control (CMC)

The chemistry manufacturing and control shall contain the following information but not limited to:

3.1.11.1. Detailed information on the drug substance and drug product

3.1.11.2. Current Good Manufacturing Practice (cGMP) certificate/statement from the country of manufacture for the product/ placebo issued by the competent recognized Authority.

3.1.11.3. Sample(s) of label to be used for the investigational products.

3.2. Responsibilities of Sponsors and Investigators

Sponsors and Principal Investigators shall have as their primary concern the protection of the life, health, privacy and dignity of the patients or healthy volunteers who participate in such trials.

3.2.1. **Sponsor**

Submission to The Board for approval: Before initiating a clinical trial(s) in Sierra Leone, the Sponsor and the Principal Investigator must obtain approval from The Board to begin the trial(s). The protocol should be submitted in duplicate. It is the responsibility of both the Sponsor and the PI to ensure that the protocol satisfies the requirements of the protocol checklist.

3.2.2. **Investigator**

A medical practitioner (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.
The Principal Investigator shall ensure that a qualified pharmacist supervises the management of the investigational product.

3.2.3. **Qualification of Principal Investigators**

Principal Investigator(s) directly in charge of a trial and at each site in a multi-centre trial shall be in good standing with the Sierra Leone medical and dental Council and the Pharmacy Board and should be responsible for the proper conduct of the trial and must;

3.2.3.1. Be a Sierra Leonean and resides in Sierra Leone

3.2.3.2. The Principal Investigator must be an appropriately qualified and competent person having practical experience within the relevant professional area

3.2.3.3. Be sufficiently experienced in clinical and pharmaceutical evaluation of medicinal products and must have had previous experience as a co-investigator in at least two trials in the relevant professional area.

3.2.3.4. Be experts in the pharmaceutical sciences, pathology or epidemiology and the clinical presentation of the particular disease or condition under study

3.2.3.5. Have evidence of Good Clinical Practice training not less than 2 years and the GCP curriculum and materials must be submitted to PBSL for approval

3.2.3.6. Provide evidence of such qualifications specified by the applicable regulatory requirement(s).

3.2.3.7. Non-medically qualified scientists may participate as co-investigators or in other roles, but not as Principal Investigators.

3.2.3.8. A Veterinary Surgeon may be the Principal Investigator or clinician for veterinary studies.

3.3. Responsibilities of the Board

3.3.1. The Board shall approve a clinical trial by issuing a Clinical Trial Certificate in a format as may be prescribed by The Board for the initiation and conduct of clinical trials in Sierra Leone. The approval process shall involve establishing adequate procedures and / or requirement for review of the clinical trial application. The Board may require protocol revisions whenever it deems necessary.

3.3.2. The Board may renew or amend a Clinical Trial Certificate issued if adequate justification for the renewal or amendment is given by an applicant.

3.3.3. A Clinical Trial Certificate issued shall be revoked if conditions for which the certificate was issued are violated.

3.3.4. The Board shall order the person conducting the clinical trial to stop or suspend the trial immediately if at any stage during the conduct of a clinical trial The Board is satisfied that it is in the public interest to do so.

3.3.5. The Board shall monitor a clinical trial from the beginning to the end in order to ensure adequate protection of the general public against the risk or adverse events from authorized clinical trials. This is to satisfy itself that the specific and general conditions to which the trial was authorized are being strictly adhered to by the person(s) conducting the trial and that the trial will achieve its objectives.

3.3.6. The Board shall conduct on-site inspections to ensure:

3.3.6.1. the safety of clinical trial participants,

3.3.6.2. the quality and reliability of data obtained in a trial, and

3.3.6.3. the facilities used continue to be acceptable throughout the clinical investigation

3.4. Reporting and Managing Adverse Events

The Sponsor of a clinical trial and Principal Investigators participating in a clinical trial are responsible for proper reporting of Serious Adverse Events (SAEs). The Sponsor should expedite the reporting of all adverse drug events (AEs) that are both serious and unexpected to The Board. Reporting should occur within the timeframe and format specified by The Board. (Refer to Appendix I)

3.4.1. Any serious adverse event to the investigational product shall receive immediate medical attention and reported to The Board within forty-eight (48) hours.
3.4.2. The SAE report form shall be completed and detailed information such as laboratory results submitted to enable causality assessment report by Expert Committee on drug safety and clinical trials of the Board.
3.4.3. All fatal cases shall be accompanied by a formal autopsy report.
3.4.4. In exceptional circumstances where a formal autopsy is not practicable, provision of a verbal autopsy report shall be prior approved by The Board and shall be given with ample reasons. Verbal autopsy shall be conducted in line with the World Health Organisation guideline for verbal autopsy. The cause of death shall be classified according to current ICD guideline.
3.4.5. Any frequent adverse event to the product shall receive immediate medical attention and reported to The Board within seven (7) days.
3.4.6. The Principal Investigator is required to submit follow-up information as soon as it becomes available. Additional information may include copies of diagnostic test results, laboratory reports, or medical record progress notes. All additional information should be clearly marked as update information and should include the Protocol Number and Participant Number.

3.5. Clinical Trial Reports

3.5.1. Progress Report

3.5.1.1. The Board should be informed in writing on the exact date of commencement of the study.

3.5.1.2. Quarterly reports of the progress of a clinical trial starting from the date of issuance of the clinical trial certificate shall be submitted to The Board in the recommended format. (Refer to Appendix II)

3.5.1.3. Quarterly progress reports must be submitted to The Board within 21 days after the end of the previous quarter. A quarter shall be considered as three months beginning from the date of initiation of a specific clinical trial.

3.5.1.4. If the trial does not begin or is delayed as per the date of commencement on the Clinical Trial Certificate issued, The Board shall be informed of the new date of commencement within ninety (90) days of issuance of the Clinical Trial Certificate.

3.5.1.5. If the trial is interrupted before its purpose is achieved, the reason shall be conveyed in writing to The Board within ten (10) working days. This shall include:

3.5.1.5.1. Justification for the premature ending or of the temporary halt of the trial;

3.5.1.5.2. Number of patients receiving treatment at the time of the study termination;

3.5.1.5.3. Proposed management of patients receiving treatment at the time of halt or study termination;

3.5.1.5.4. Consequences of the evaluation of the results.

3.5.2. DSMB Report

Duly signed and authenticated DSMB reports and / or minutes shall be forwarded to The Board upon request.

3.5.3. End of study Report

3.5.3.1. End of study report starting from the date of issuance of the clinical trial certificate shall be submitted to The Board in the recommended format. (Refer to Appendix II)

3.5.3.2. The Principal Investigator/Sponsor shall notify in writing, the Board not later than 30 days after the completion of a clinical trial and submit preliminary report on the conduct of the trial.

3.5.3. Final Report

In addition to the report referred to above, the person who conducted the trial shall, not later than 90 days after the completion of the trial, compile and submit to The Board a comprehensive formal report conforming at least to the ICH E3 or consolidated system of reporting trials (CONSORT) unless otherwise specified in the conditions specified in the Clinical Trial Certificate issued.

The report shall include a short but comprehensive summary of the essential findings of the trial and of its methodology and course.

The final report shall be submitted in hard and soft copies (15 hard and 1 soft each).

It is recommended that the clinical trial study report be submitted to the PBSL for review before any publication of the study is made.

3.6. Procedure for Importing Investigational products

3.6.1. Approval to import products for clinical trials shall only be granted to recognized clinical research entity whose protocol has been approved by the Board to conduct clinical trial in accordance with these guidelines.

3.6.2. An application for importation of investigational products, placebo and trial products, shall receive prior approval from The Board.

3.6.3. Application to import investigational product and placebo shall be made to The Board by submitting:

3.6.3.1. Letter stating the quantities of each investigational product, placebo and trial related products to be imported

3.6.3.2. Certificate of analysis of investigational product and placebo for all batches to be imported

3.6.3.3. Lot Release certificate (where applicable) for all batches to be imported

3.6.4. An application for import permits must be processed by the Board.

3.6.5. All import permit applications shall bear the full name and address of the investigator, the Sponsor and the recognized clinical research entity, the name/description of the investigational product, placebo and quantity to be imported.

3.6.6. Both the investigational medicinal product and the placebo shall be appropriately labelled with the approved labels to indicate they are samples for the conduct of clinical trials only. Please see appendix III for more details.
3.6.7. Products imported may be inspected by officials of The Board at the port of entry before they are released to the recognized clinical research entity.
3.6.8. The Board may order for destruction or re-exportation of the products intended for clinical trials if The Board has any reason to believe that there is a protocol violation resulting in the termination of the study.
3.6.9. The above notwithstanding, all other statutes governing importation procedures and tax liabilities in Sierra Leone shall apply to imported products regulated by The Board

3.7. Good Clinical Practice Inspections

3.7.1. The Board reserves the right to inspect and interrupt any trial for which authorization has been given, as and when necessary.
3.7.2. Periodic Good Clinical Practice (GCP) Inspections of the trial sites shall be conducted to ensure that the facilities used continue to be acceptable throughout the clinical investigation
3.7.3. GCP inspections shall be conducted in accordance with PBSL-GCP guidelines (Refer to the PBSL GCP Guidelines)**.**

3.8. Clinical trials or study in vulnerable persons

Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied. Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. See guidelines 14, 15, 16 and 17 of CIOMS International Ethical Guidelines for biomedical Research Involving Human Subjects.

3.8.1. **Research involving children (including infants).**

Before undertaking research involving children, the investigator must ensure that:
3.8.1.1. The research might not equally well be carried out with adults;
3.8.1.2. The purpose of the research is to obtain knowledge relevant to the health needs of children;
3.8.1.3. A parent or legal representative of each child has given permission;
3.8.1.4. The agreement (assent) of each child has been obtained to the extent of the child`s capabilities; and,
3.8.1.5. A child`s refusal to participate or continue in the research will be respected.

3.8.2. **Research involving individuals who are cognitively impaired subjects by reason of mental or behavioral disorders are not capable of giving adequately informed consent.**

Before undertaking research involving individuals who by reason of mental or behavioral disorders are not capable of giving adequately informed consent, the investigator must ensure that:

3.8.2.1. Such persons will not be subjects of research that might equally well be carried out on persons whose capacity to give adequately informed consent is not impaired;
3.8.2.2. The purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioral disorders;
3.8.2.3. The consent of each subject has been obtained to the extent of that person's capabilities, and a prospective subject's refusal to participate in research is always respected, unless, in exceptional circumstances, there is no reasonable medical alternative and local law permits overriding the objection; and,
3.8.2.4. In cases where prospective subjects lack capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with applicable law.

3.8.3. Women as research subjects

Investigators, sponsors or ethical review committees should not exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study should not, in itself, be used as a reason for precluding or limiting participation. However, a thorough discussion of risks to the pregnant woman and to her fetus is a prerequisite for the woman's ability to make a rational decision to enrol in a clinical study. In this discussion, if participation in the research might be hazardous to a fetus or a woman if she becomes pregnant, the sponsors/investigators should guarantee the prospective subject a pregnancy test and access to effective contraceptive methods before the research commences. Where such access is not possible, for legal or religious reasons, investigators should not recruit for such possibly hazardous research women who might become pregnant.

3.8.4. Pregnant women as research participants:

3.8.4.1. Investigators, sponsors or ethical review committees should not exclude women of reproductive age from biomedical research.
3.8.4.2. Pregnant women should be presumed to be eligible for participation in biomedical research.
3.8.4.3. The potential for becoming pregnant during a study should not, in itself, be used as a reason for precluding or limiting participation. However, a thorough discussion of risks to the pregnant woman and to her foetus is a prerequisite for the woman's ability to make a rational decision to enrol in a clinical study.
3.8.4.4. In this discussion, if participation in the research might be hazardous to a foetus or a woman if she becomes pregnant, the sponsors/ investigators should guarantee the prospective subject a pregnancy test and access to effective contraceptive methods before the research commences. Where such access is not possible, for legal or religious reasons, investigators should not recruit for such possibly hazardous research women who might become pregnant.
3.8.4.5. Investigators and ethical review committees should ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the foetus and their subsequent offspring, and to their fertility.
3.8.4.6. Research in this population should be performed only if it is relevant to the particular health needs of a pregnant woman or her foetus, or to the health needs of pregnant women in general, and, when appropriate, if it

is supported by reliable evidence from animal experiments, particularly as to risks of teratogenicity and mutagenicity.

3.9. Biological specimen/samples

3.9.1. Consent forms for the research protocol should include a separate section for clinical-trial subjects who are requested to provide their consent for the use of their biological specimens for research. Separate consent may be appropriate in some cases (e.g., if investigators are requesting permission to conduct basic research which is not a necessary part of the clinical trial), but not in others (e.g., the clinical trial requires the use of subjects' biological materials).

3.9.2. Use of medical records and biological specimens. Medical records and biological specimens taken in the course of clinical care may be used for research without the consent of the patients/subjects only if an ethical review committee has determined that the research poses minimal risk, that the rights or interests of the patients will not be violated, that their privacy and confidentiality or anonymity are assured, and that the research is designed to answer an important question and would be impracticable if the requirement for informed consent were to be imposed. Patients have a right to know that their records or specimens may be used for research. Refusal or reluctance of individuals to agree to participate would not be evidence of impracticability sufficient to warrant waiving informed consent. Records and specimens of individuals who have specifically rejected such uses in the past may be used only in the case of public health emergencies.

3.9.3. Secondary use of research records or biological specimens. Investigators may want to use records or biological specimens that another investigator has used or collected for use, in another institution in the same or another country. This raises the issue of whether the records or specimens contain personal identifiers, or can be linked to such identifiers, and by whom. If informed consent or permission was required to authorize the original collection or use of such records or specimens for research purposes, secondary uses are generally constrained by the conditions specified in the original consent. Consequently, it is essential that the original consent process anticipate, to the extent that this is feasible, any foreseeable plans for future use of the records or specimens for research. Thus, in the original process of seeking informed consent a member of the research team should discuss with, and, when indicated, request the permission of, prospective subjects as to:

i) whether there will or could be any secondary use and, if so, whether such secondary use will be limited with regard to the type of study that may be performed on such materials;

ii) the conditions under which investigators will be required to contact the research subjects for additional authorization for secondary use;

iii) the investigators' plans, if any, to destroy or to strip of personal identifiers the records or specimens; and

iv) the rights of subjects to request destruction or anonymization of biological specimens or of records or parts of records that they might consider particularly sensitive, such as photographs, videotapes or audiotapes.

3.9.4 Requirements for material transfer authorization: All institution or individuals that wants to transport and use any clinical information, medical records and biological samples from Sierra Leone to an institution outside of sierra leone fulfill PBSL's requirement for material transfer authorization. See Appendix IV for more details and PBSL material transfer agreement template on PBSL's website at www.pharmacyboard.gov.sl

3.10. Phases of Clinical Trials

The application shall indicate the phase of clinical trial that is intended; see Appendix VI of this Guideline.

4.0. TIMELINES

For timelines relating to the submission of serious adverse events (SAE), refer to Appendix Ia of this Guideline.

5.0. SANCTIONS

A person who contravenes these Guidelines or sections is liable to regulatory sanctions which shall be imposed by the Board. These sanctions may include but not limited to any of the under-listed:

5.1. Suspension of an on-going clinical trial.
5.2. Revocation of a clinical trial certificate issued (stopping of a trial/recall of all investigational products).
5.3. Fines.
5.4. Caution statement to the appropriate person or institution.
5.5. Rejection of trial data.
5.6. Imposition of a timeline to address deviations / violations.

6.0. PENALTIES

In line with the provisions of the Pharmacy and Drugs Act a person who contravenes these Guidelines commits an offence and is liable on summary conviction to a fine of not less than twenty million leones penalty units or to a term of imprisonment of not less than twenty-five (25) years or to both.

7.0. APPENDICES

APPENDIX Ia: Serious Adverse Events (SAE) Reporting Timelines

Type of ADR Report	Time Frame for Reporting	Format
REPORTS FROM SITES IN SIERRA LEONE		
Serious Adverse Events	Immediately where possible and in any event, within 48 hours after becoming aware of the information	A Serious Adverse Events form conforming to the CIOMS format or previously approved by PBSL must be completed and submitted after the site becomes aware of an event. Electronic submissions must be E2B compliant.
□ Follow-up reports	Immediately when any of the under-listed occurs: i. Change in the severity of SAE initially reported. ii. Whenever there is any new development on an initially reported SAE. iii. When the SAE resolves.	Follow-up reports should include an assessment of the importance and implication of any findings. All fatal cases must be followed up with formal autopsy report.
□ Frequent adverse events (greater than or equal to 1% but less than or equal to 10%)	Immediately where possible and in any event, within 7 days after becoming aware of the information	Line listing
Non Serious Adverse Events	On request and where applicable, submitted as part of an application for registration	Individual reporting in accordance with the data elements specified in the ICH guidance Document E2A

REPORTS FROM FOREIGN SITES

(For multicentre studies with Sierra Leone as a participating country)

Serious Events	Immediately where possible and in any event, within 7 days after becoming aware of the information.	Line listing Reports should include an assessment of the importance and implication of any findings.
Foreign regulatory decisions that affect the safety or use of the product	7 days	Detailed report Records with respect to all adverse events in respect of the drug that have occurred inside or outside the country, including information that specifies the indication for use and the dosage form of the drug at the time of the adverse event may be added.

OTHER REQUIREMENTS

Literature reports that affect the safety of the product	7 days	Detailed report and / or copy of the publication Records with respect to the enrollment of clinical trial subjects including information sufficient to enable all clinical trial subjects to be identified and contacted in the event that the sale of the drug may endanger the health of the clinical trial subjects or other persons may be added.
Notification of change in nature, severity or frequency of risk factors	28 days	Complete and accurate records with respect to each change made to the Investigator's Brochure, including the rationale for each change and documentation that supports each change

New information impacting on risk benefit profile of product or conduct of trial	7 days	Communicate with appropriate scientific and medical judgments being applied to each situation. Additional information may include copies of diagnostic test results, laboratory reports or medical record progress notes
Periodic Safety Update Reports (PSUR)	On request by The Board	As a Follow Up Report including copies of diagnostic test results, laboratory reports or medical record progress notes
	Within 30 days when it is a condition of registration for a new medicinal product	

APPENDIX Ib: OTHER TIMELINES

ACTION	**REFERENCE**	**TIMELINE**
Notification for the implementation of an urgent amendment necessary to protect the life of subjects	3.1.5.2	Immediate phone call, followed by a written report within forty-eight (48) hours
Quarterly progress reports	3.5.1.3	Within 21 days after the end of the previous quarter. A quarter in this instance is considered as three months beginning from the date of initiation of a specific clinical trial.
Notification of Trial initiation	3.5.1.4	Immediately trial commences or within ninety (90) days of issuance of the Clinical Trial Certificate if the trial does not begin or is delayed as per the date of commencement on the Clinical Trial Certificate issued
Notification of interruption of an approved trial before achievement of its purpose.	3.5.1.5	Within ten (10) working days
Submission of preliminary report on the ethical evaluation of the trial after completion.	3.5.1.6	Not later than 30 days after the completion of a clinical trial
Final Report of Clinical Trial as per ICH E3 guidelines or CONSORT format (unless otherwise specified on clinical trial certificate)	3.5.3	Not later than 90 days after the completion of the trial

Appendix Ic: PROCESSING OF SUBMITTED DOCUMENTS BY THE BOARD

ACTIVITY	**TIMELINE******
Processing of Clinical Trial Applications	60 days
Processing of import permits for Investigational Products	15 days
Processing of quarterly progress and safety reports	20 days
Notification of receipt of electronic submissions including SAE reports	7 days
Communicating GCP Inspection findings	28 days
Processing of applications for protocol amendment	35 days
Processing of final Clinical Trial reports	40 days

The days refer to working days * * *

APPENDIX II: Pharmacy Board of Sierra Leone Clinical Trials Quarterly Progress Report Form

SECTION A: ADMINISTRATIVE INFORMATION

PBSL Clinical Trial Certificate Number: …… …….	Expected Date of Commencement (as indicated on the certificate):……./…… …./… …….	Actual Date(s) of Commencement (at the Study Centre(s): ……./……./…….	Protocol Number: …… …… …… …….

Study Title:

Reporting Period From…… ……to…… …….

Principal Investigator: Name:
Address: Phone:
Mobile:
E-mail:
Co-Investigators:

Name(s): Phone:
Mobile:
E-mail:

Other Study Contact (if applicable): Name: Phone:
Address: Mobile:
E-mail:

SECTION B: STUDY STATUS (Check one category only)

□Enrollment has not begun

□Actively enrolling subjects

□Enrollment closed on: ..... (insert date): subjects are receiving treatment/intervention

□Enrollment closed on: ..... (insert date): subjects are in follow-up only.

□Analyzing data

SECTION C: INFORMATION ON SUBJECTS & STUDY ACTIVITIES

a. Number of subjects consented and screened.....
b. Total number of subjects consented and screened who are eligible for the study.....
c. Number of subjects to which the investigational product(s) has been administered.....
d. Number of subjects left to be enrolled in the coming months (years).....

e. Number of participants who have discontinued the study:

- by Investigator:
- voluntarily:
- due to SAE:

f. Have there been any Serious Adverse Events (SAEs)? □Yes □ No

g. Total number of SAEs: .....
(attach line list of SAEs documented for the quarter)

□Yes □ No

h. Have these SAEs been reported to the Board

i.If No,
explain……
……
……..... □Yes □ No
.

j. Have there been any changes to the protocol since the Board approved? □Yes □ No

k. Was this amendment submitted to the PBSL?

I. If No,
explain……
……
…….....
.....

m. Date for the end of the study
.....

n. Date for the final study
report.....

SECTION D: COMMENTS (if any)

.....
.....
.....
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.....

SECTION E: SIGNATURE

Signature of Principal Investigator .... Date.....

Return this form and all supporting documentation to:
The Registrar
Pharmacy Board of Sierra Leone
Central Medical Stores
New England Ville
Freetown
Sierra Leone
P.M.B.322
+232 25 282886
Email. registrar@pharmacyboard.gov.sl
Website: www.pharmacyboard.gov.sl

APPENDIX III: CLINICAL TRIAL SITE CLOSE-OUT REPORT
SECTION A: ADMINISTRATIVE INFORMATION

CLINICAL SITE CLOSE- OUT REPORT

I. SITE INFORMATION

Protocol Title:

Protocol Identification number:

Clinical Trial Certificate number:

Name and address of Clinical Site:

Name, address, telephone number and e- mail address of Principal Investigator:

Name, address, telephone number and e- mail address of Sponsor:

Date of last recruitment:

Reason for closure:

NAME	TITLE	CONTACT
	Local monitor	
	Site Coordinator	
	Pharmacist	
	Other	

Date(s) of Report:

Clinical Site Personnel Involved with the Study:

II CLINICAL SITE CLOSE- OUT CHECKLIST

Instructions: Please provide comment (s) for each of the items listed below. Additional sheets may be attached if necessary.

OBJECTIVE	COMMENTS
1. All regulatory and other essential documents as stipulated in PBSL GCP guideline are up- to- date and on file	*Provide list of documents on file at the site*
2. Notification of all relevant oversight bodies of closure of study	
3. Signed, informed consent is on file for each study participant	*Provide list of participants (use codes/ study IDs)*

OBJECTIVE	COMMENTS
4. Documentation of all protocol violations/ deviations and/ or appropriate note- to- files in the relevant essential document	*Provide list*
5. Appropriate follow- up and reporting of all SAEs to PBSL	*Provide number of SAEs reported. Summary of outcome for SAEs listed is relevant*
6. Completion of all Case Report forms for each participant	
7. Entry/ submission of all relevant data into database/ to sponsor/ coordination center. If not complete, indicate the timeline for accomplishing this and document in the comments section	
8. Status of all outstanding data edits, queries or delinquent forms and timeline for their resolution	
9. Tentative date for submission of full Clinical Study Report	
10. Requirements for retention of study records. Indicate if each requirement has been fulfilled	
11. Drug accountability • Quantity of IPs received • Quantity of IPs utilized in the study • Quantity of IPs destroyed (attach copy of destruction certificate (s)) • Quantity of IPs onsite/ returned to sponsor	
12. Status/ shipment/ analyses of all participant specimen according to protocol requirements (including plans for future shipments or period of time they will be stored on-site)	
13. If blinded study drug was used, confirm that the tear- off labels were not opened. For any that were opened, documentation should be obtained noting the reason for unblinding	

CLINICAL SITE CLOSE- OUT REPORT

Additional comments:

III. STATUS OF PAST OBSERVATIONS/ RECOMMENDATIONS MADE DURING MONITORING/ GCP INSPECTIONS: (Have corrective measures been implemented for all observations and recommendations?), Provide summary of measures implemented for each point)

IV. OUTSTANDING ISSUES OR ACTIVITIES TO BE IMPLEMENTED: (Include problems identified, if any, and recommendations/ action items for corrections)

Prepared by: Date:

(Signature)

APPENDIX IV: PBSL Packaging and Labeling requirements for investigational medicinal products (IMP)

(A). Packaging requirements

1. The container in which the product is contained should be of good quality
2. The container and closure should be properly sealed so as to protect the product from the influence of outside environmental factors
3. Each sample should have an insert

(B). Labelling requirements

All information should be in English and the print should be clear, legible and indelible. The following information should be included on labels.

(a) details of sponsor.
(b) pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the name/identifier and strength/potency;
(c) the batch number
(d) a trial reference number
(e) the trial subject identification number
(f) the name of the investigator
(g) directions for use and any warnings or precautions that may be necessary
(h) "For clinical trial/research use only"
(i) storage conditions;
(j) period of use (use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity.
(k) "keep out of reach of children" except when the product is for use in trials where the product is not taken home by subjects.

APPENDIX V: Requirements for material transfer authorization

All institution or individuals that wants to transport and use any clinical information, medical records and biological samples from Sierra Leone to an institution outside of Sierra Leone, must submit the following:

1. An application for export permit should be made through the Ministry of Health and Sanitation (MOHS) to Pharmacy Board of Sierra Leone (PBSL).

2. All applications must be accompanied by the following documents:
    a. Evidence of informed consent for use of medical records, clinical information and biological samples from patients who are alive.
    b. Authorisation from the Ministry of Health and Sanitation for deceased patients
    c. Memorandum of understanding (MOU) between MOHS and applicant
    d. Signed and dated Material Transfer Agreement (MTA).

3. Payment of PBSL prescribed export permit fee.

For further information please see PBSL Material Transfer Agreement template and PBSL Guidelines for conducting clinical trials of Medicines, Vaccines, Food Supplements and Medical Devices on our website at www.pharmacyboard.gov.sl.

APPENDIX VI: Phases of Clinical Trials in vaccines and medicines

VACCINE DEVELOPMENT

Phase I refers to the first introduction of a candidate vaccine into a human population for initial determination of its safety and biological effects, including immunogenicity. This phase may include studies of dose and route of administration, and usually involves fewer than 100 volunteers.
Phase II refers to the initial trials examining effectiveness in a limited number of volunteers (usually between 200 and 500); the focus of this phase is immunogenicity.

Phase III trials are intended for a more complete assessment of safety and effectiveness in the prevention of disease, involving a larger number of volunteers in a multicentre adequately controlled study.

MEDICINE DEVELOPMENT
Phase I refers to the first introduction of a drug into humans. Normal volunteer subjects are usually studied to determine levels of drugs at which toxicity is observed. Such studies are followed by dose-ranging studies in patients for safety and, in some cases, early evidence of effectiveness.

Phase II investigation consists of controlled clinical trials designed to demonstrate effectiveness and relative safety. Normally, these are performed on a limited number of closely monitored patients.

Phase III trials are performed after a reasonable probability of effectiveness of a drug has been established and are intended to gather additional evidence of effectiveness for specific indications and more precise definition of drug-related adverse effects. This phase includes both controlled and uncontrolled studies.

Phase IV trials are conducted after the national drug registration authority has approved a drug for distribution or marketing. These trials may include research designed to explore a specific pharmacological effect, to establish the incidence of adverse reactions, or to determine the effects of long-term administration of a drug. Phase IV trials may also be designed to evaluate a drug in a population not studied adequately in the pre-marketing phases (such as children or the elderly) or to establish a new clinical indication for a drug. Such research is to be distinguished from marketing research, sales promotion studies, and routine post-marketing surveillance for adverse drug reactions in that these categories ordinarily need not be reviewed by ethical review committees (see Guideline 2 of CIOMS guideline).

APPENDIX VIIa: DECLARATION BY PRINCIPAL INVESTIGATORS(S)

Name:

Title of Trial:

Sponsor:

Site:

1. I have read and understood section 3.2 2 of PBSL guideline for the conducting clinical trials of medicines, vaccines, medical devices and food supplements and section 4 of PBSL Good Clinical Practice guideline under 'Responsibility of the Investigator'.
2. I have informed the Pharmacy Board of Sierra Leone of any aspects of the above guidelines with which I do not / am unable to, comply. (If applicable, this may be attached to this declaration)
3. I have thoroughly read, understood, and critically analyzed (in terms of the Sierra Leone context) the protocol and all applicable accompanying documentation, including the investigators brochure, patient information leaflet(s) and informed consent form(s).
4. I will conduct the trial as specified in the protocol
5. To the best of my knowledge, I have the potential at the site(s) I am responsible for, to recruit the required number of suitable participants within the stipulated time period.
6. I will not commence the trial before written authorisations from the Pharmacy Board of Sierra Leone as well as the Sierra Leone Ethics and Scientific Review Committee have been obtained
7. I will obtain informed consent from all participants or if they are not legally competent, from their legal representatives.
8. I will ensure that every participant (or other involved persons, such as relatives), shall at all times be treated in a dignified manner and with respect.
9. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial. (Conflict of interest exists when an investigator (or the investigators institution), has financial or personal relationships with other persons or organisations that inappropriately influence (bias) his or her actions) *Modified from: Davidoff F, et al. Sponsorship, Authorship, and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001).
10. I have*/have not (delete as applicable) previously been the principal investigator at a site which has been closed due to failure to comply with Good Clinical practice (*Attached details.)
11. I have*/have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices. (*Attached details).
12. I will submit all required reports within the stipulated time-frames.

Signature of PI: Date:

Signature of Witness: Date:

APPENDIX VIIb: DECLARATION BY SUB-INVESTIGATORS AND STUDY PHARMACIST(S)

Name:

Title of Trial:

Sponsor:

Site:

Principal Investigator:

1. I will carry out my role in the trial as specified in the protocol.
2. I will not commence the trial before written authorisations from the Pharmacy Board of Sierra Leone as well as the Sierra Leone Ethics and Scientific Review Committee have been obtained
3. If applicable to my role in the trial, I will ensure that informed consent has been obtained from all participant or if they are not legally competent, from their legal representatives.
4. I will ensure that every participant (or other involved persons, such as relatives), shall at all times be treated in a dignified manner and with respect.
5. Using the broad definition of conflict of interest below, I declare that I have a financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial. (Conflict of interest exists when an investigator (or the investigators institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions) **Modified from: Davidoff F, et al. Sponsorship, Authorship, and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001)
6. I have*/have a not (delete as applicable) previously been involved in a trial which has been closed due to failure to comply with Good Clinical Practice. (*Attached details.)
7. I will submit all required reports within the stipulated time-frames.

Signature of investigator/pharmacist Date:

Signature of Witness: Date:

APPENDIX VIIc: JOINT FINANCIAL DECLARATION BY SPONSOR (OR REPRESENTATIVE) AND PRINCIPAL INVESTIGATOR CONCERNING SUFFICIENT FUNDS TO COMPLETE STUDY

Title:

Protocol:

I, <full name> of sponsor or representative

And

I, <full name>, of Principal Investigator

Hereby declare that sufficient funds have been made available to complete the above study.

SPONSOR (or representative)
Name:

Address:

Contact details:

Signed: Date:

PRINCIPAL INVESTIGATOR
Name:

Address:

Contact details:

Signed Date:

APPENDIX VIII: PBSL Clinical Trial Application and Authorisation Fee Schedule

Types of Clinical Trial	Fee(USD)
Industry funded (Phase I)	15,000
Industry funded (Phase II)	12,000
Industry funded (Phase III)	10,000
Investigator/local phases	5,000
Research Institution funded	5,000
Protocol amendment	1000
Renewal of clinical trial certificate(yearly)	150
Export permit for shipment of biological samples	100
Expedited protocol review	1,000

The equivalent in Leones is also accepted.