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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES FOR THE CONDUCT OF CLINICAL TRIALS DURING PUBLIC HEALTH EMERGENCIES AND PANDEMICS IN KENYA

JUNE, 2026

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HPT/PDS/CTR/GUD/023	**Guidelines for the conduct of Clinical Trials during public health emergencies and pandemics in Kenya**	**Revision No.: 01**	**Effective Date:** 12/06/2026 **Review Date:** 11/06/2031

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ABBREVIATIONS AND ACRONYMS

COVID-19	Coronavirus Disease 2019
CRF	Case Report Form
ECCT	Expert Committee on Clinical Trials
EMA	European Medicines Agency
ICH-GCP	International Council for Harmonisation – Good Clinical Practice
MHRA	Medicines and Healthcare products Regulatory Agency
MOH	Ministry of Health
NACOSTI	National Commission for Science, Technology and Innovation
PPB	Pharmacy and Poisons Board
TGA	Therapeutic Goods Administration, Australia
WHO	World Health Organization

FOREWORD

Public health emergencies and pandemics bring about disruptions in the day-to-day activities across the world. These have a great impact on the conduct of clinical trials and therefore calls for establishment of measures to protect the safety and wellbeing of clinical trial participants and staff. In addition, contingency measures need to be put in place to ensure the integrity of the results of ongoing Clinical trials.

Kenya is an important Centre for the conduct of clinical trials and as the National Medicines Regulatory Authority of Kenya, PPB will continue to facilitate clinical trials by ensuring that they are scientifically sound, ethical and are conducted as per International Conference on Harmonization on Good Clinical Practice (ICH GCP).

As health emergencies and pandemics emerge, scientific data and information continue to grow and become clear, the Pharmacy and Poisons Board continuously monitors the situations and update this guidance.

The PPB will collaborate with other national, regional and international partners to facilitate the conduct of clinical trials during such critical times, and also after the public health emergencies and pandemics.

This guidance has therefore been made to assist sponsors and investigators as they carry out their clinical trials during public health emergencies and pandemics. It should be used together with the other existing guidelines.

Finally, as key stakeholders in the conduct of clinical trials, please feel free to submit your feedback on this guidance that we shall be reviewing as we get more information during public health emergencies and pandemics.

Dr. Ahmed I. Mohamed

CHIEF EXECUTIVE OFFICER

LEGAL FRAMEWORK

The regulation for the conduct of clinical trials is governed under the provisions of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya (hereinafter referred to as the "Act") and the Subsidiary Legislation thereunder.

Under the provisions of Section 2 of the Health Laws (Amendment) Act, 2019 (hereinafter referred to as "the Health Laws (Amendment") which amended the Act, Clinical Trial is defined as, any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, identify any adverse reacting to investigational products, to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety.

The Board is statutorily empowered to undertake various duties in execution of her mandate regarding regulation of medicines. With respect to Clinical Trials, the Board is empowered amongst others under Section 3 of the Health Laws (Amendment) to;

a) Grant or withdraw authorization for conducting clinical trials of medical products
b) Constitute technical and expert advisory committees
c) Approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use
d) Approve and regulate clinical trials on medicinal substances
e) Collaborate with other national, regional, and international institutions on medicinal substances regulation.

1.0 INTRODUCTION

Public health emergencies and pandemics cause major disruptions and greatly affect the way the world operates.

There is noticeable disruption of clinical trials conduct due to the public health emergencies and pandemics, majorly owing to the preventive measures put in place which may include Presidential and Ministry of Health directives on. Additionally, there is usually increased demand on health services provision leading to the reallocation of some of the clinical trials staff, coupled with the need of self-isolation by some of the trial participants. These factors are likely to impact on the oversight resulting into a negative impact on the initiation of new trials, difficulties in maintaining a medical oversight of the studies by the investigators, completion of trial assessments, completion of trial follow-up visits and the provision of Investigational Medicinal Products (IMPs).

The impact of public health emergencies and pandemics on ongoing trials, on opening a new trial site in an existing trial, ongoing recruitment, and continued involvement of participants in the trial, or on starting of new trials should be considered. This evaluation should take into consideration the Kenyan Government recommendations and restrictive measures including travel restrictions and confinements of trial participants and trial staff and the availability of trial staff to perform visits, enter data in the Case Report Form (CRF), notify serious adverse events and, more generally, follow the protocol.

Our response to the public health emergencies and pandemics challenge should be in line with several key principles and considerations. These include but are not limited to:

1. Compliance with the WHO and Ministry of Health's Directives on Public health emergencies and pandemics
2. The safety and well-being of patients, research participants and their families, and health care professionals, researchers and other staff involved in patient care and research are paramount.
3. It is critical that public health systems remain able to respond to the needs of the community, both those impacted by public health

emergencies and pandemics and in terms of regular workloads.

4. The conduct of research related to public health emergencies and pandemics is a significant priority; however, the initiation and continuation of other ongoing and proposed research should also be critical for the well-being of patients, participants, communities, and the research sector.
5. Compliance with or adherence to regulations, guidelines, codes, policies, and other standards remains necessary. However, interpretation of research responsibilities in the context of a crisis such as public health emergencies and pandemics should be informed by flexibility, consultation, and good sense to retain the focus on the safety and well-being of those most at risk in our institutions and communities.
6. Possibilities of invalidating outcomes of on-going studies as a result of confounders due to public health emergencies and pandemics and associated factors.
7. Reference to international guidance from e.g., FDA, EMA, MHRA, TGA (but local/national government guidance is supreme)

A risk-based prioritization of the applications to be reviewed under this guideline shall include among others;

i. The nature/epidemiology of the public health emergency
ii. Disease progression/ mortality patterns of the emergency
iii. Available scientific information of the investigational product and the disease condition
iv. Risk- Benefit analysis (RBA) of the investigational product/ proposed intervention(s), and the study design
v. Availability of alternative therapies

1.1. **Purpose and scope**

This guideline provides general information and advice to researchers and sponsors in the context of Public health emergencies and pandemics. It is directed towards those involved in clinical trial and other relevant clinical research. This guidance provides general information and advice to institutions conducting or overseeing research, researchers, and sponsors in

the context of Public health emergencies and pandemics.

The purpose of this guideline is to assist those overseeing, conducting, and reviewing clinical trial research to maximize the safety of research participants and to minimize risks to participants and the community, to researchers and ensure the integrity of the clinical trials.

Compliance with or adherence to regulations, guidelines, codes, policies and other standards remains necessary. That said, interpretation of research responsibilities in the context of the current crisis should be informed by flexibility, consultation, and good sense so as to retain the focus on the safety and well-being of those most at risk in the institutions and communities.

2.0 SUBMISSION OF APPLICATIONS

2.1 All applications for new Clinical Trials to PPB shall be through the online clinical trials portal; www.ctr.pharmacyboardkenya.org

2.2 Review timelines for applications during emergencies shall be shortened (Annex 1).

2.3 Parallel submission of applications (To Ethics and PPB) shall be acceptable as part of the shortened timelines during emergencies.

2.4 The submission fees, content and format shall be similar to routine Clinical Trial (CT) applications as detailed in the Guideline for conduct of Clinical Trials in Kenya (HPT/PDS/CTR/GUD/003; checklist for submission of request for approval of new applications)

2.5 Pre-submission meeting (through video or teleconferencing) with sponsors and investigators can be organized with PPB to clarify issues before formal submission of a clinical trial application (request for a meeting at www.ctr.pharmacyboardkenya.org)

2.6 Inquiries may be done through the Clinical trials email; cta@ppb.go.ke or through Telephone +254 709 770 100.

3.0 ETHICAL REQUIREMENTS AND CONSIDERATIONS

3.1 Notwithstanding the provision for parallel submission (Sec 1.3), PPB approval for the clinical trial shall only be granted following the receipt of a favorable opinion from a National Commission for Science Technology and Innovation (NACOSTI) accredited ethics committee.

4.0 REVIEW OF APPLICATIONS

4.1 Clinical trial applications received and relating to public health emergencies shall be processed under shortened timelines as follows;

a) Screening: 2 days
b) Allocation for review: 1 day
c) Detailed evaluation of protocols: 15 days
d) Regulatory decision (Approval/ rejection): 3 days

4.2 The regulatory timelines described above shall be exclusive of time taken by the applicant to respond to the screening/ assessment queries (Clock stop time).

4.3 The PPB has an Expert Committee on Clinical Trials (ECCT) drawn from a pool of external experts convened quarterly and on ad-hoc basis to provide independent scientific advice and support the review process.

4.4 All individuals involved in the review of clinical trial applications, shall declare any actual, potential, or perceived conflict of interest prior to participating in the evaluation process. Reviewers shall not have financial, professional, or personal interests that could compromise, or be perceived to compromise, their impartiality and objectivity.

4.5 The review shall consider among other things;

4.5.1 Reliability and robustness of the data generated in the clinical trial, taking account of statistical approaches, design of the clinical trial and methodology, including sample size and randomization, comparator and endpoints;

4.5.2 Compliance with the requirements concerning the manufacturing and import of investigational products and auxiliary medical product,

4.5.3 Compliance with the labelling requirements;

4.5.4 The completeness and adequateness of the investigator's brochure.

4.5.5 All decisions will be communicated to the applicant in writing stating whether the trial has been approved as it is, or if it requires certain corrections or if it has been rejected.

4.6 Importation of the Investigational Product will be made to the trade department of PPB by the applicant upon receipt of necessary approval

of the research protocol.

4.7 Reliance decisions for clinical trial applications shall be as per the Board's guidelines on reliance mechanisms.

5.0 STUDY MONITORING AND FOLLOW-UP

5.1 Reporting of the study progress and safety shall be in accordance with the Guideline for Conduct of Clinical Trials in Kenya and the provisions of the Pharmacy and Poisons (Conduct of Clinical Trials) Rules 2022.

5.2 Sponsors are required to monitor the trial and should consider what monitoring needs to be done in real time, and what checks can be undertaken later, taking a risk-based approach.

5.2.1 Remote monitoring visits are encouraged as the first option. These arrangements must adhere to patient confidentiality protocols already in place. Remote source data verification may be done electronically if appropriate security arrangements either are or can be put in place.

5.2.2 Any change to remote monitoring must not result in confidential patient information being sent to the sponsor if this has not already been addressed in the participant information sheet. Trial participants will need to consent to any identifiers leaving the site and be assured that their confidentiality will be protected.

5.2.3 The use of alternative means of oversight such as teleconferences/videoconferences is encouraged.

6.0 MANAGEMENT OF ONGOING CLINICAL TRIALS

6.1 Contingency planning

6.1.1 Institutions, individual principal investigators (PIs) and sponsors should undertake continuous contingency planning to address the potential impact of Public health emergencies and pandemics and responses to the crisis on current, ongoing clinical trials. The planning should include:

1. Priority: assessment of the importance of and the risks associated with continuing the trial as designed or with necessary modifications. Responses could include continuing the trial in its present form, conducting the trial in a modified form, suspending the trial or closing the trial.
2. Participation: assessment of the ability of participants to participate in the trial in accordance with protocol requirements and consideration of alternative models for participation that would not compromise the integrity of the trial.
3. Capacity: assessment of the resources available for continuing the trial, including research staff, clinical support staff, pharmacy support, other support staff, space, equipment, supplies, etc.
4. Contingency planning should be an ongoing process as the pandemic progresses.

6.2 Communications

6.2.1 Decisions and actions in response to the crisis will be most effective if they are taken after appropriate consultation with the key stakeholders in a clinical trial: institutions, researchers, sponsors, regulators and, in some cases, participants. However, the need for rapid responses may require decisions and actions by one or more parties without prior consultation with the others. In such cases, all key stakeholders should be informed of the decisions and actions taken at the earliest opportunity.

6.2.2 Any communication plan developed shall receive prior opinion from the Pharmacy and Poisons Board before implementation.

6.3 Participants

6.3.1 The safety and well-being of trial participants, other patients, family members, researchers and other clinical and support staff is paramount.

6.3.2 Study clinics should institute measures to minimize transmissible Public health emergencies and pandemics e.g., ensuring that all staff and participants wear appropriate personal protective equipment (PPEs), maintain social distance in waiting areas, provide facilities for hand washing or sanitizers in case of pandemics such as COVID-19.

6.3.3 In trials that proceed without modification, participants should explicitly be given the following options:

a) Continuing to participate in the trial
b) Suspending their participation, if this is viable, or
c) Withdrawing from the trial.

6.3.4 Participants who do not attend clinic visits or complete other trial activities may be reminded that these are required; however, if a patient declines or actively refuses to participate in trial activities, then their decision should be respected, and they should be considered to have withdrawn from the trial. These participants should be informed that their decision will not affect their ongoing treatment or participation in future clinical trials.

6.3.5 Participants should be informed of any modifications to the trial, including medical and other trial procedures, ongoing treatment or care and any tests or assessments that will have, or have the potential to have, an impact on them.

6.3.6 In trials that have been modified, participants should explicitly be given the following options:

a) participating in the trial, as modified, inclusive of alternative mechanisms for engagement such as remote visits, data collection, monitoring, etc., as appropriate
b) suspending their participation, if this is viable, or
c) withdrawing from the trial.

6.3.7 Participants should be informed of the importance of notifying the research team in advance of attending any trial visits if;

a) They are experiencing one or more symptoms suggestive of infection, such as a public health emergencies and pandemics
b) Has symptoms suggestive of active infection by the public health emergency and pandemics, or
c) They are experiencing one or more symptoms not suggestive of infection, but suggestive of influenza or other infectious disease or condition that includes respiratory symptoms.
d) Adverse events reporting by the participants should be emphasized if they have been provided with study agents. This should include both the expected and unexpected adverse effects.
e) In addition, research sites may screen all participants by using targeted observation and temperature taking using contactless thermometers before each study visit

6.3.8 In a situation where a trial participant is unable to attend a visit or otherwise fulfil a condition of participation due to public health directives or government policy (such as restricted travel), sponsors and researchers are encouraged to facilitate the participant being able to continue to participate in the trial at a site that is within the limits of any such restrictions. Data collected could then be transmitted to the site that the participant would normally have attended.

6.3.9 Participant rights must not be violated and all protections should be accorded to them during the emergency. If participants need to travel to and from study site, study team need to;

a) Liaise with relevant authorities to facilitate movement,
b) Reconsider mode of transport so that participants are not exposed to unnecessary risks,
c) Reconsider layout in the facility to minimize contacts.

6.3.10 Research sites must adequately dispose of waste related to the

study. Care should be taken to avoid any contamination or risk of sprad of pathogens.

6.3.11 Where a trial participant is unable to attend the site, other measures, such as home nursing, if possible given social distancing needs, or contact via phone or any other means, may be required to identify adverse events and ensure continuous medical care and oversight. However, the limitations and risks of such methods and the requirements for data protection should be considered and such alternative arrangements need to be adequately documented.

6.3.12 The conduct of ongoing clinical trials is critical for the well-being of patients, participants, communities, and the research sector.

6.3.13 The priority should be the safety of trial participants, and this will remain our focus.

7.0 PROTOCOL AMENDMENTS

Amendments to clinical trial protocols that include the addition to an existing trial of new public health emergencies and pandemics related elements, e.g., to enable epidemiological analysis of the pandemic, to add patients with condition of interest to an existing trial of a treatment or to add in testing of the pandemic for safety purposes, (for example where studies include taking samples), is acceptable, so long as appropriate protection is put in place for handling of samples. Such arrangements would be treated as an urgent safety measure with subsequent notification in accordance with usual processes

7.1 The submission to amendments that require PPB's approval shall be done through the application's portal on ctr.pharmacyboardkenya.org.

7.2 Notifications of the amendments shall be through email; cta@ppb.go.ke

7.3 To support the review, compliance to the Guideline for conducting clinical trials in Kenya shall be applicable.

7.4 Shortened review timelines (10 days) shall be applicable.

8.0 OTHER CONSIDERATIONS

8.1 Direct-to-patient deliveries

8.1.1 Sponsors must assess the risks relating to the product and consider any shipping and storage arrangements.

8.1.2 Participants must consent to providing contact details for shipping purposes.

8.1.3 Where participants are self-isolating or in quarantine, arrangements for a nominated person to collect product may be implemented with the participant's consent. Any such temporary arrangements should be handled as a non-substantial amendment that does not require PPB's approval. A notification of the same shall be submitted to PPB.

8.1.4 The IMP storage and handling conditions should be verified before direct-to-patient deliveries are considered during emergencies to ensure product integrity.

8.2 Temporary halting or extending the study duration

8.2.1 If a trial has been halted due to safety concerns for existing participants among other considerations the PPB shall be informed of the reason(s) for the halt and the actions that sites need to take

8.3 Studies that need to be closed

8.3.1 For any studies involving provision of treatment to participants, careful consideration should be given to post-study care.

8.3.2 If this cannot be in line with the information provided in the participant- information sheet, a substantial amendment should be submitted for review and approval.

8.3.3 End of study report should subsequently be provided.

8.4 Restarting a trial after it has been halted

The restart of a previously halted Trial must be communicated to the PPB, and a formal response provided before resumption of trial-related activities

8.5 Participant follow-up

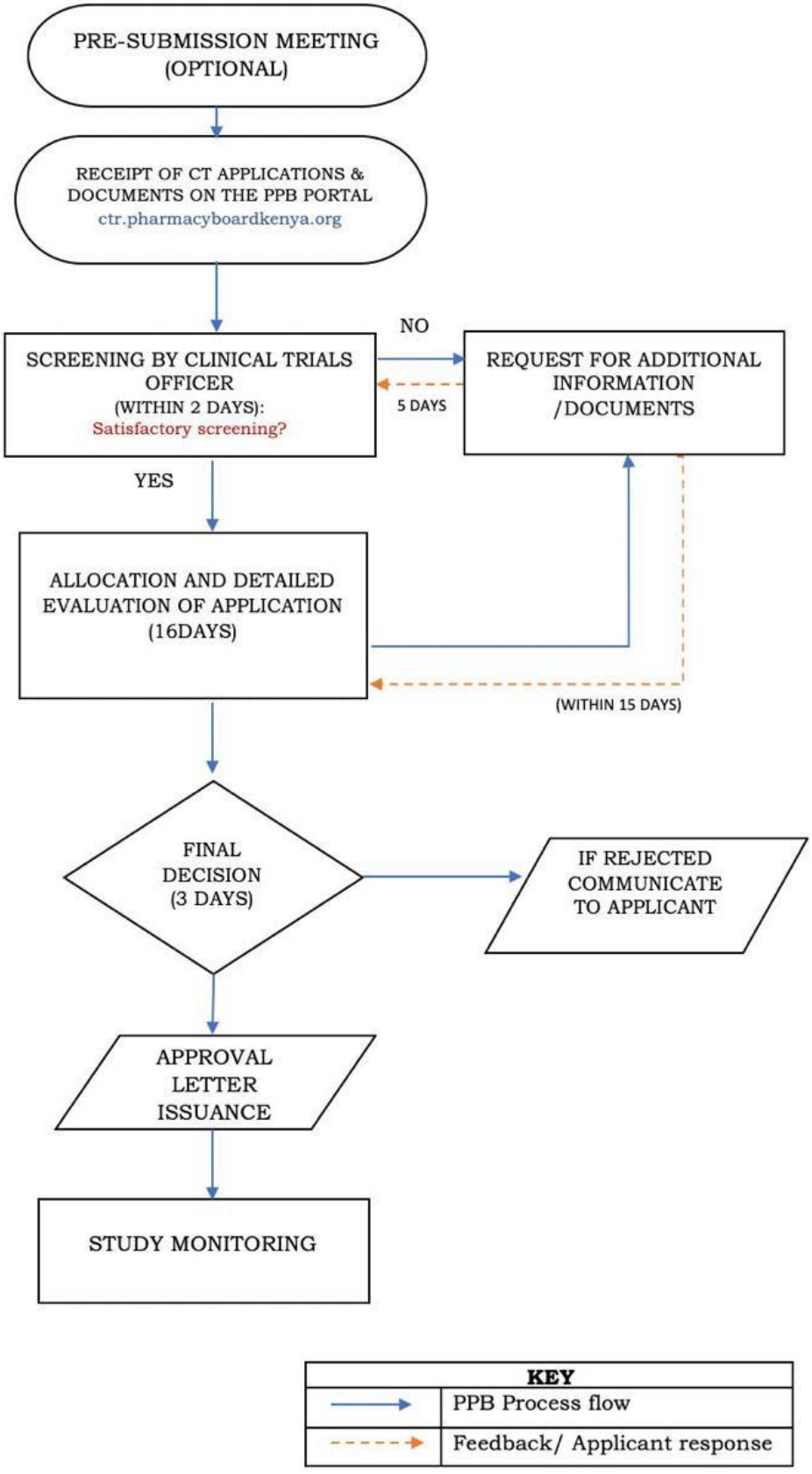
Using phone calls instead of protocol-directed in-person study visits is acceptable where possible. This will not constitute a serious breach of the protocol. A substantial amendment to update the protocol will not be

required.

8.6 Protocol deviations and serious breaches

Protocol deviations should be reported to PPB in the usual manner on the portal: http://ctr.pharmacyboardkenya.org/

Addendum 1: Clinical Trials in Emergencies review flow chart



9.0 REFERENCES

1. Pharmacy and Poisons (Conduct of Clinical Trials) Rules 2022
2. Guidelines for the conduct of clinical trials in Kenya
3. Ethical considerations in developing a public health response to pandemic influenza, World Health Organization 2007
4. Research Ethics in International Emergency Response, WHO Technical Consultation, Geneva, Switzerland, 10–11 June 2009, Meeting Report.
5. Ethical issues related to study design for trials on therapeutics for Ebola Virus
6. Disease, WHO Ethics Working Group Meeting, 20-21 October, Summary of Discussion.
7. CIOMS Guideline 20: Research in disaster situations

10.0 REVISION HISTORY

Revision No.	Date	Prepared by	Section(s) Revised	Description of Change
1	05/05/2026	QAO	Introduction	Include the prioritization framework for review of applications
			Section 3.0	Include the submission requirements and the review process
			Section 4.0	Include aspects of study monitoring for studies
			Section 5.0	Include management of ongoing trials during pandemics
			Addendum 1	Include the clinical trial review flowchart

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