



**KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE
COVID-19 PANDEMIC IN KENYA**

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	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 3 of 45

TABLE OF CONTENTS

DOCUMENT CONTROL SCHEDULE AND APPROVAL	2
ABBREVIATIONS AND ACRONYMS	5
GENERAL GUIDELINES	6
INTRODUCTION	6
1.1 Purpose	7
1.2 General principles and considerations:	7
1.3 Communication on COVID-19 research.....	9
1.4 The legal mandate	9
SECTION 2: GUIDELINES FOR NEW RESEARCH PROPOSALS AMIDST THE COVID 19 PANDEMIC.....	10
2.1 Background/Context	10
2.2 Categories of new studies	10
2.3 Study scope:	12
2.4 Study site layout and facilities	12
2.5 Research Personnel:	13
2.6 Study procedures.....	14
2.7 Community Engagement	15
2.8 Participant Screening:	15
2.9 Sample Declaration for Discussing Safety Information with Study participants	16
2.10 Training	17
SECTION 3: GUIDELINES ON SERU-APPROVED ONGOING RESEARCH DURING THE COVID-19 PANDEMIC.....	18
3.1 Overview.....	18


	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 4 of 45

3.2	General guidelines on ongoing research	18
3.3	Guidelines on specific research categories	24
3.4	Principal Investigator responsibilities to SERU	28
SECTION 4: CONSENT		31
4.1	NON COVID-19 RESEARCH.....	31
4.1.1	Previously Approved Ongoing Studies	31
4.1.2	New Studies	32
4.2	COVID-19 RESEARCH.....	32
4.3	Emergency COVID-19 Research.....	33
4.4	Non-emergency COVID 19 clinical trials.....	34
4.5	Informed Consent in COVID 19 human challenge studies	34
4.6	Non-emergency COVID-19 research collecting sensitive information	35
4.8	Waiver of Consent:	36
4.9	Documenting Remote Consent.....	36
4.10	Guidance on applications for approval of remote consenting by SERU	37
SECTION 5: MONITORING AND EVALUATION		39
5.1	Purpose.....	39
5.2	Introduction	39
5.3	Study Oversight Guidelines.....	39
SECTION 6: TRAINING.....		42
6.1	TRAINING GUIDANCE FOR SERU.....	42
6.2	TRAINING GUIDANCE FOR STUDY TEAMS	42
ACKNOWLEDGEMENT		43
References		44

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 5 of 45

ABBREVIATIONS AND ACRONYMS


COVID-19	Coronavirus Disease- 2019
DG	Director General KEMRI
GCP	Good Clinical Practice
KEMRI	Kenya Medical Research Institute
ICH GCP	International Conference on Harmonization Good Clinical Practice
IMP	Investigational Medicinal Product
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SERU	Scientific and Ethics Review Unit
SOP	Standard Operating Procedures
NACOSTI	National Commission for Science Technology and Innovation
MOH	Ministry of Health
PPE	Personal Protective Equipment

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 6 of 45

GENERAL GUIDELINES

INTRODUCTION

The Coronavirus disease has caused various challenges in daily life and even to the conduct of medical research. To contain the spread of the infection, the Government of Kenya issued directives aiming to control or minimize the movement of people and thus the spread of the infection. The conduct of research has been negatively impacted following the issued directives. However, due to the significance of health research in improving the quality of life including availing possible solutions to the current coronavirus disease, it is important that some guidelines be instituted that will enable research to go on while taking into consideration all the directives that have been given by the government. This document provides information that will guide researchers in carrying out their health-related research activities under KEMRI Scientific and Ethics Review Unit (KEMRI SERU) approval during this pandemic. These guidelines should be used together with all other existing KEMRI guidelines and not in isolation.

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 7 of 45

SECTION 1: GENERAL GUIDELINES

1.1 Purpose

The purpose of this guidance is to provide general information and advice to researchers carrying out studies under the oversight of KEMRI's Scientific and Ethics Review Unit during the COVID-19 pandemic. The guidance applies to the currently ongoing and new proposed research under the oversight of SERU.

These guidelines make further reference to the Memo from the Director General (DG), KEMRI dated 27th March 2020 on the Government's business continuity as part of the corona virus response measures. It was directed that research on clinical trials and similar studies will continue with strict adherence to the approved protocol and that a minimum number of staff will be involved while the patient and staff safety is guaranteed.

In consideration of the guidance provided in this document, researchers are encouraged to discuss as a team together with the relevant funder on how best to proceed with their research and agree on the necessary changes required in order to support safe research progress. Only where absolutely necessary to safeguard the safety and well-being of staff and participants, should the team consider delay or even postponement of research.

Contact the following for further clarifications, comments or suggestions relating to the guidelines:

The Director General,
Kenya Medical Research Institute,
P. O. Box 54840-00200,
Nairobi, Kenya
Attention: Head of SERU
Tel: +254 717 719 477
Email: seru@kemri.org AND kemriseru18@gmail.com

1.2 General principles and considerations:

- 1.2.1 All researchers must take into consideration national guidance including relevant government directives aimed at mitigating the spread of COVID-19 disease including physical distancing, hand washing & sanitization,



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA


REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 8 of 45

staying at home (in as far as it is possible), restricted inter-county and inter – country travels and all other relevant measures and strive to uphold ethical standards and respect for human rights in this regard.

- 1.2.2 The safety and well-being of potential and current research participants and their families, health care professionals, researchers and other staff involved in research should be prioritized at all times.
- 1.2.3 Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and therefore do not require Scientific and Ethics Review (SERU) approval before implementation. For example, if a facility introduces mandatory clinical screening procedures related to COVID-19 for all people who visit the facility, including research participants, these screening procedures do not need to be reviewed by SERU before they may be implemented
- 1.2.4 Potential or current participants reporting possible COVID-19 exposure or symptoms during a study visit – if research staffs determine that a participant has potentially been exposed to COVID-19 or may be infected with COVID-19 - should immediately alert the public health authorities through the hotline number (719) provided to the public or the appropriate local MoH response team. The participant should be provided with a mask and isolated in a private room or an area with limited exposure to other persons while awaiting guidance from the MoH COVID-19 testing team regarding collection of samples and transportation of the participant to one of the determined Covid-19 isolation location
- 1.2.5 In all study procedures that involve physical contact with the participants, additional measures should be taken to factor in participants' opinions and concerns and safeguard against penalties for refusal of participation/continuation.
- 1.2.6 It is the responsibility of the investigator to communicate with the study sponsor on any decision and action relating to the COVID-19 pandemic response and inform the SERU accordingly.

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 9 of 45

1.3 Communication on COVID-19 research

The Director General KEMRI through the KEMRI Corporate Communications department will be responsible for making any official communications regarding COVID 19 research. Additionally, any KEMRI researcher who needs to make any communication to the public through media should use the usual channels of getting approval from the Director General KEMRI through the Corporate Communications department.


1.4 The legal mandate

The development and implementation of these guidelines is advised by the following legal and policy guidelines

- 1.4.1 The Science, Technology and Innovation Act, No. 28 of 2013
- 1.4.2 KEMRI Internal policies including Research Policy

The KEMRI's SERU Committee has been accredited by the NACOSTI to conduct ethics review of research proposals involving Human Participants.

- 1.5 The Scientific and Ethics Review Unit is currently conducting virtual review of new and ongoing research. The Unit continues to hold its three regularly scheduled monthly meetings (Committees A, B and C), as well as *ad hoc* meetings virtually. Researchers seeking SERU review and approval of their ongoing research should do so by submitting their applications through the following contact details; Email: seru@kemri.org AND kemriseru18@gmail.com

	KENYA MEDICAL RESEARCH INSTITUTE		
DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA			
REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 10 of 45	

SECTION 2: GUIDELINES FOR NEW RESEARCH PROPOSALS AMIDST THE COVID 19 PANDEMIC

2.1 Background/Context

Given the rapidly changing circumstances around COVID-19, the priority for all study activities should be to uphold public health obligations as well as safety for both the research team and the participants. All new proposals should, therefore, indicate in detail the measures to be put in place to ensure that the health and safety of researchers, participants, and the general community is guaranteed. The key areas to be covered are discussed below.

2.2 Categories of new studies

The new research proposals will be categorized into the following categories during the COVID-19 pandemic:

New studies Categories	Definition	Guidance
Category 1: High risk (COVID-19 related and any other of high public health priority)	-This refers to Essential new research that must be carried out during this pandemic – this includes COVID-19 related research and other research of high public health priority and importance e.g. polio and research addressing other emerging outbreaks during this period such as cholera outbreaks.	1) All the guidelines outlined below should be adhered to when submitting category 1 proposals. The PI should outline how all the ministry of health guidelines on prevention of COVID-19 will be met during the conduct of the research activities. 2) Refer to Section 4 for guidelines on consenting
Category 2: Moderate Risk	-Any other new research that does not fall under Category 1	1) The PI should outline how all the ministry of health guidelines on prevention of



KENYA MEDICAL RESEARCH INSTITUTE


DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 11 of 45

<p>(Non-COVID-19 related and of high public health priority)</p>	<p>above and is of moderate risk to participants or staff</p> <p>-This includes: Non-Covid-19 clinical trials, studies involving sample collection from participants, studies that involve invasive procedures such as bronchoscopy, sputum collection, sputum induction, and close physical contact with participants and research involving laboratory animals.</p>	<p>COVID-19 will be met during the conduct of the research activities.</p> <ol style="list-style-type: none"> 2) The researchers should as much as possible carry out remote participant interactions. 3) Where remote participant interactions are not feasible or if there is need for the participant to attend a physical study visit, the researchers should adhere to the public health directives in place and comply with Section 3.2.5 of the guidelines below. 4) Refer to Section 4 for guidelines on consenting
<p>Category 3:</p> <p>Low risk</p> <p>(Non-COVID related research, Minimum risk, minimum contact with participants)</p>	<p>-This refers to research that does not fall under category 1 or 2 above.</p> <p>-Research that involves minimum contact with participants or does not involve sample collection can be placed in this category.</p> <p>-Studies that involve analysis of data without contact of participants.</p>	<ol style="list-style-type: none"> 1) The researchers should as much as possible carry out remote participant interactions. 2) Where remote participant interactions are not feasible or if there is need for the participant to attend a physical study visit, the researchers should strictly adhere to the public health directives in place and comply with Section 3.2.5 of the guidelines below.

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 12 of 45

	-Studies involving traditional medicinal plants (in the laboratory), studies that do not involve human samples., economic studies, education studies, etc	3) Other activities that do not require human participant interactions e.g. remote planning of the research, remote training of the staff, and remote engagement of stakeholders if necessary, data abstraction and analysis, etc can continue as planned. 4) Refer to Section 4 for guidelines on consenting
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2.3 Study scope:

To this end,

- 2.3.1 Studies proposing procedures that DO NOT require face to face interaction with human research participants must take measures to reduce the likelihood of exposure to COVID-19 for study participants and research staff.
- 2.3.2 Alternative remote methods of interaction (e.g. through phone/video calls) during research procedures are strongly recommended.
- 2.3.3 For those studies proposing mandatory direct participant interaction for evaluation or to receive treatment or medication or for clinical safety, the PI shall be responsible for providing this service in the safest way possible, based on good clinical practice and optimal social distancing.
- 2.3.4 All studies, including clinical trials, must be based on internationally accepted scientific and ethical principles.

2.4 Study site layout and facilities

- 2.4.1 All study visit areas including the waiting areas must have enough room to allow for physical distancing as per the Ministry of Health guidelines and recommended by the WHO except when contact with the investigator is



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1


PAGE: 13 of 45

necessary to complete study procedures, for example during physical examinations or other study clinical procedures that require contact. Ensure appropriate, clearly marked and adequate zoning of the space and workflow in line with public health guidelines to minimize contamination.

- 2.4.2 Each site must develop documented procedures on physical social distancing and masking when in public in line with the ministry of health's guidance. The site should post alerts such as signs and posters at clinic entrances and in strategic places around the facility with COVID-19 related instructions and information for participants.
- 2.4.3 Ensure the availability of appropriate hand washing and sanitizer facilities are appropriately installed, and all participants as well as staff are using them appropriately as per the site's standard operating procedures for the study.
- 2.4.4 Ensure availability of adequate and appropriate personal protective equipment (e.g. PPE, proper surgical masks) for both study participants and research team;
- 2.4.5 Establish rigorous disinfecting protocols and SOPs for any facilities and study equipment that come in contact with or are used by multiple participants and research personnel.

2.5 Research Personnel:


- 2.5.1 All study personnel who will have direct contact with study participants should undergo requisite training in researching during the COVID-19 pandemic depending on their role in the study.
- 2.5.2 All study personnel who will have direct contact with study participants are required to take a daily health screening survey and temperature checks before reporting to work. This is mandatory to protect other research personnel and participants. Any study personnel with flu-like symptoms should **not** report to work. Any study staff suspected of or diagnosed with COVID-19 **must** report this to the principal investigator and be managed as per the MOH guidelines.

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 14 of 45

2.5.3 All study personnel who will have direct participant contact *must* undergo the COVID-19 Personal Protective Equipment (PPE) and proper masking training, *even if you do not expect to have studies with COVID-19 positive subjects with active infection*. This is important, as it may become necessary to do follow up visits with subjects who have tested positive for COVID-19, or who are less than 28 days out from a COVID-19 infection.

2.6 Study procedures

- 2.6.1 Obtaining any biological *specimens* or performing any activities that may cause an increased risk of COVID-19 exposure to study staff (e.g. sputum specimens, pulmonary function testing, etc.) should be conducted by appropriately trained staff wearing appropriate personal protective equipment as per the MoH guidelines.
- 2.6.2 Participants in clinical (treatment) trials should be managed remotely whenever possible. Study interactions such as interviews or simple study follow-up visits may be conducted virtually via phone or video.
- 2.6.3 Home delivery of investigational medicinal products (IMPs) if feasible after assessment may be considered. Verbal consent from the subject to provide delivery information, as well as all necessary posting/storage requirements must be provided. To ensure IMP quality assurance and accountability, requisite procedures must be developed and validated before implementation.
- 2.6.4 For studies that involve safety monitoring, alternative methods for study safety assessments should be evaluated and any chosen alternate method must be sufficient to assure the safety of study participants, and research integrity.
- 2.6.5 The cleaning of the research rooms and equipment that have been in contact with study participants should be as per current recommendations and clinical guidelines (<https://www.health.go.ke/wp-content/uploads/2020/04/Kenya-IPC-Considerations-For-Health-Care-Settings-1.pdf>). Standard masking/face covering rules still apply.

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 15 of 45

2.7 Community Engagement

- 2.7.1 Prior and during COVID 19 related research appropriate community engagement should be carried out
- 2.7.2 The researcher should adhere to the recommendations provided in section 2.6.5 (<https://www.health.go.ke/wp-content/uploads/2020/04/Kenya-IPC-Considerations-For-Health-Care-Settings-1.pdf>)

2.8 Participant Screening:

- 2.8.1 For studies that involve multiple participant visits, screening for all participants and research personnel must be instituted to minimize COVID-19 exposure risk.
- 2.8.2 Where feasible, the ability to pre-screen study participants for COVID-19 symptoms by phone before the study visit and at the time of the on-site study visit should be considered.
- 2.8.3 Organize to provide study research participants and the research participant's support person(s) with a proper face mask on arrival. If possible, there should be a barrier (plexiglass) between the study staff and the study participant. The screening and research activity times should adhere to the curfew timelines as per the government directives.
- 2.8.4 While the process for screening depends on facility layout and staffing, all study participants and their support persons should be pre-screened on arrival for COVID-19 symptoms based on MOH checklist and protocols: a fever ($T > 37.5^{\circ}\text{C}$) or other symptoms of COVID-19 e.g. cough or shortness of breath, sore throat, fever, muscle aches, headache, new loss of taste or smell, repeated or shaking chills with or without history of exposure to a confirmed COVID-19 case. Individuals who are suspected to be exhibiting COVID-19 symptoms should be referred for management as per the local MOH procedures.
- 2.8.5 For a screening staff, they should wear a face mask but do not need to wear PPE if they are separated from study subjects by a physical barrier such as a glass or plastic window. However, such interactions should be as brief as possible by limiting the interaction to screening questions only.



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1


PAGE: 16 of 45

- 2.8.6 If a staff member must be within six feet (two metres) of a study participant, they should use appropriate PPE, including a face mask, gloves, and eye protection. A gown could be considered if extensive contact with the subject is anticipated.
- 2.8.7 Scheduling of participants should be conducted in such a way to ensure no overcrowding takes place while at the study site as per the government guidelines. Every effort should be made to minimise the time that a participant spends at the study site. To this end workflows should be reviewed to ensure that they are as efficient as is practically possible and where possible waiting should take place in a tented open air area.

2.9 Sample Declaration for Discussing Safety Information with Study participants

The investigators, as part of the consent process, should share a declaration to the participants as an assurance of efforts put in place to ensure the participants' safety, health and well-being, that:-

- 2.9.1 All study investigators, coordinators, nurses, and staff in our research areas are wearing masks, and we will also provide a mask to you and anyone who comes with you when you arrive if you don't have one.
- 2.9.2 All the study team members are screened daily for COVID-19 symptoms before they come into the work station, and we will screen you for symptoms on the day of your visit.
- 2.9.3 We declare that we are careful about who we ask to come for in-person study visits, and when possible are using telephone or video conferencing to reduce the number of research participants coming to our research areas at the same time.
- 2.9.4 We do limit the number of visitors accompanying people for their study visits, and have rearranged and/or removed furniture in our waiting areas to enforce strict social distancing practices.


	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 17 of 45

2.9.5 We confirm meticulous infection control practices, including disinfection, wearing gloves, wearing masks, and hand washing during all our procedures.

2.9.6 We know that COVID-19 will be in our community for many months. We appreciate your continued participation in our study. Please ask if there is anything you are concerned about.

2.10 Training

After the study is approved by SERU the PI is advised to train the research team before embarking on any research activities and give evidence on any training to SERU before starting the project. Training evidence can be in the form of training logs, training videos, training pictures or training certificate copies (Refer to section 6 on training).

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 18 of 45


SECTION 3: GUIDELINES ON SERU-APPROVED ONGOING RESEARCH DURING THE COVID-19 PANDEMIC

3.1 Overview

This section provides guidance on ongoing Scientific and Ethics Review Unit (SERU)-approved research during the novel coronavirus 2019 pandemic (COVID-19). In its guidance, SERU endeavours to focus on the health and safety of research participants, communities and researchers while upholding the principles of bioethics. As the pandemic rapidly evolves in Kenya, this section may be updated to be in line with any government and public health directives issued to contain the pandemic. Given the current circumstances, the research community is encouraged to prioritize public health and safety and to contact SERU directly for more specific guidance relating to their ongoing studies.

3.2 General guidelines on ongoing research

- 3.2.1 Public Health and Clinical Activities: Actions taken for public health or clinical purposes as part of the COVID-19 prevention or treatment measures are not considered research procedures and therefore do not require SERU approval before being implemented. For example, if a health facility implements mandatory clinical screening procedures related to COVID-19 for all people coming to the facility, including research participants, these screening procedures do not need to be reviewed by SERU before they are implemented. In addition, the health facility does not need to seek SERU approval prior to sharing the screening results with the participants, Ministry of Health or other designated public health authorities for purposes of identifying, monitoring, assessing or investigating the COVID-19 outbreak. However, researchers have an obligation to inform research participants of requirements to undergo COVID-19 screening and reporting of such screening results to a public health authority.
- 3.2.2 Legally Required Reporting: Where the law requires information related to an individual's COVID-19 test results to be provided to a public health authority, including individually identifiable information about individuals who are research participants; researchers must comply. Researchers should confirm if

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 19 of 45

- this is consistent with the statements made in the study's consent form and modify where necessary. In such circumstances, investigators should inform the participant of the required reporting of COVID-19 test results. (Refer to Section 5 on consenting)
- 3.2.3 Research Changes to Eliminate Apparent Immediate Hazards: - Researchers may need to implement changes to approved research prior to SERU review and approval, if the changes are necessary to eliminate apparent immediate hazards to the participant. In such cases, the researcher may implement the changes prior to SERU review and approval and inform SERU of the change through a protocol violation report or within 5 working days in accordance with the KEMRI/SERU/SOP/PI/PDVNC - Protocol deviations, violations and non-compliance.
- 3.2.4 Community Engagement
- 3.2.4.1 Prior and during COVID 19 related research appropriate community engagement should be carried out
- 3.2.4.2 The researcher should adhere to the recommendations provided in section 2.6.5 (https://www.health.go.ke/wp-content/uploads/2020/04/Kenya-IPC_Considerations_For-Health-Care-Settings-1.pdf)
- 3.2.5 All ongoing research should, with immediate effect, restrict themselves to remote interactions with human participants unless the research procedures or visits are considered critical (*Refer to item 3.2.5 below on what constitutes critical research visits or procedures*). Remote methods of carrying out study visits/procedures could be carried out using highly secure phone-based or internet-based platforms. The researcher should describe in detail the platforms they propose to use and how they will ensure they are less prone to data security breaches such as hacking. Any in-person interaction with research participants should be postponed until further notice unless it meets the definition of a critical research visit or procedure (*see item 3.2.5 below*).
- 3.2.6 Critical research visits or procedures: - A study procedure or visit is deemed critical if it is required to ensure participants' health, safety or wellbeing. Such procedures include administration of certain types of study interventions, safety



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA


REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 20 of 45

evaluations, management of serious adverse events, laboratory tests to monitor possible adverse effects of drugs, etc. The researcher, the research participant and the participant's care provider, where necessary, shall be involved in the determination of whether a study visit or procedure is critical to the participant's health, safety or wellbeing. This determination must be made in line with the current public health guidance regarding the COVID-19 pandemic in Kenya. Where possible, critical research visits should continue remotely as much as possible. In the absence of feasible remote options for critical visits or procedures, face-to-face interactions may continue as long as they adhere to current public health guidelines to reduce COVID-19 exposure to research participants and staff as follows:

- 3.2.6.1 Immediately before the face-to-face visit, remotely screen the participants for symptoms of respiratory illness such as fever, cough, shortness of breath or difficulty breathing as well as possible recent exposure to individuals with COVID-19 disease. Participants with possible exposure or symptoms suggestive of a respiratory illness similar to COVID-19 should not be invited for face-to-face visits/procedures until COVID-19 has been ruled out. Such participants should be immediately referred to the Ministry of Health for further diagnostic procedures and possible isolation as necessary.
- 3.2.6.2 All research staff who conduct face-to-face visits with participants should, on a daily basis, be screened for COVID-19 exposure and symptoms including daily temperature checks. Only staff who are symptom-free with no history of exposure to COVID-19 should take part in face-to-face interactions while strictly observing the Infection Prevention Control measures (refer to section 2.6.5 (https://www.health.go.ke/wp-content/uploads/2020/04/Kenya-IPC_Considerations_For-Health-Care-Settings-1.pdf)). In addition, all research staff should be encouraged to undergo the free COVID-19 testing availed by the Ministry of Health.

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 21 of 45

3.2.6.3 At the site of the face-to-face visits/procedures, ensure appropriate infection control measures are taken as follows:

- 3.2.6.3.1 Take temperature checks for all participants and other individuals arriving at the research site using a non-contact thermometer
- 3.2.6.3.2 Avail a hand-washing station(s) and hand sanitizers for all to use
- 3.2.6.3.3 Avail 3-ply face masks for participants and research staff to use during the face-to-face interactions
- 3.2.6.3.4 Maintain physical distancing of at least 1.5 metres and proper aeration and air flow in the waiting room and procedure rooms
- 3.2.6.3.5 Healthcare staff use appropriate personal protective equipment, including but not limited to surgical masks, disposable gowns, eye shields, gloves, etc, when conducting close-contact or invasive procedures and handling bio-specimens.
- 3.2.6.3.6 Train all staff on appropriate infection prevention measures to mitigate COVID-19 spread, in line with the government directives. Study sites should keep records of all the people who have been trained and avail such records to SERU when required.
- 3.2.7 SERU-approved studies that do not have any face-to-face participant interactions e.g. data abstraction studies, desk-reviews, etc. purely online-based studies can continue as approved as resources allow.
- 3.2.8 Similarly, study procedures that do not require in-person contact with participants e.g. literature review, research planning, data analysis, publication, etc. can continue as stated in the SERU-approved protocol.
- 3.2.9 Participants reporting possible COVID-19 exposure or symptoms during a study visit – if research staff determine that a participant has potentially been exposed to COVID-19 or is infected with COVID-19, they should immediately alert the public health authorities through the hotline number (719 or appropriate local hotline) provided to the public. Potential or current participants reporting possible COVID-19 exposure or symptoms during a study visit – if research staffs determine that a participant has potentially been exposed to COVID-19 or may be infected with COVID-19 - should immediately alert the public health authorities through the hotline number (719) provided



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 22 of 45

to the public or the appropriate local MoH response team. The participant should be provided with a mask and isolated in a private room or an area with limited exposure to other persons while awaiting guidance from the MoH COVID-19 testing team regarding collection of samples and transportation of the participant to one of the determined Covid-19 isolation location.

3.2.10 Research involving persons particularly vulnerable to COVID-19 disease: -

3.2.10.1 Based on currently available information, persons at high-risk for severe illness from COVID-19 are:

3.2.10.1.1 People aged 65 years and older

3.2.10.1.2 People who live in a nursing home or long-term care facility

3.2.10.1.3 People of all ages with underlying medical conditions, particularly if not well controlled, including:

3.2.10.1.3.1 Chronic lung disease or moderate to severe asthma

3.2.10.1.3.2 Serious heart conditions

3.2.10.1.3.3 The immune-compromised e.g. due to cancer treatment, smoking, bone marrow or organ transplantation, immune deficiencies, poorly controlled HIV or AIDS, and prolonged use of corticosteroids and other immune weakening medications

3.2.10.1.3.4 Severe obesity (body mass index [BMI] of 40 or higher)

3.2.10.1.3.5 Diabetes mellitus

3.2.10.1.3.6 Chronic kidney disease undergoing dialysis

3.2.10.1.3.7 Liver disease

3.2.10.2 Studies involving participants who are at increased risk of severe illness from COVID-19 disease should institute extra protections such as:

3.2.10.2.1 Advising the participants to strictly adhere to recommended prevention measures such as: staying home as much as possible, frequent hand-washing and



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 23 of 45

use of hand sanitizers, avoiding close contact and staying at least 6 feet away from other people, using face masks when in contact with others, etc.

3.2.10.2.2 Where possible, conducting all participant interactions remotely and rescheduling non-critical study procedures until a time when the risk to the participant is reduced

3.2.10.2.3 If absolutely necessary to conduct face-to-face visits, consideration should be taken to conduct such visits at the participants' home in a well aerated area by a COVID-19 screened research staff wearing appropriate personal protective equipment.

3.2.11 Contingency Planning - Study teams should:

3.2.11.1 Continually assess if the disruption of a research protocol might impact the safety of their research participants

3.2.11.2 Determine the best way to dispense investigational products to participants. Assess the feasibility of safe home delivery of such products and appropriate dosing packages. Changes in product quality arising from storage and handling as well as the practicability of administration of the product in the home environment must be considered. If the investigational drugs cannot be dispensed to research participants, the researcher should, in consultation with the clinical trial sponsor and the clinical team caring for the participant, make plans to transition research participants back onto their most appropriate clinically available medications.

3.2.11.3 Assess whether any reduction in staff to allow for MOH directives on physical distancing makes it unsafe to effectively complete the planned research procedures.

3.2.11.4 Make plans for timely review of participant's clinical data e.g. reviewing of lab results or radiological investigations,



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 24 of 45

particularly if this influences the management of the participant.

3.2.11.5 Assess the effect of missing some type of data due to changes in study e.g non-availability of qualitative data obtained from face-to face interactions. This should be viewed in the context of the wider effect on data management and analysis.

3.2.12 For specific guidance on ongoing clinical trials during the COVID-19 pandemic, please refer to the *Guidance to Sponsors and Investigators for Conduct of Clinical Trials During the COVID-19 Pandemic in Kenya, Pharmacy and Poisons Board, April 2020*.

3.2.13 Researchers should remain aware of and abide by all applicable COVID-19 related public health directives, policies and recommendations as issued by Kenya Medical Research Institute, the Ministry of Health or other Kenyan government agencies.

3.2.14 For research approved by a Research Ethics Committee other than SERU, consult the other Committee for guidance on:

3.2.14.1 Whether COVID-19 screening requires prior Research Ethics Committee approval

3.2.14.2 Whether/how to report the restrictions on face-to-face study procedures

3.2.14.3 Whether/how to amend an approved study to allow remote procedures

3.3 Guidelines on specific research categories

Researchers should use the descriptions provided below to determine the category under which their research falls and the specific guidance that applies to those categories.

Category	Definition	Examples	Guidelines
<i>Category 1: Research with high direct benefit to participants or that may be of high public health priority</i>	<ul style="list-style-type: none"> 1) All protocols involving or about COVID-19 2) Protocols in which serious or immediate harm could be caused to the research participants if stopped. 3) Studies that may not have the prospect of high direct benefit but carry the risk of serious or immediate harm if study interactions are stopped 4) Studies addressing other public health emergencies or outbreaks. 	<ul style="list-style-type: none"> 1) Studies on prevention or treatment interventions for COVID-19 2) Studies involving treatments for acute, life threatening health conditions (e.g. some treatment trials for cancers) 3) Protocols where stopping the intervention (e.g., some investigational drugs or vaccines or preventative drug regimens) could be harmful 	<ul style="list-style-type: none"> 1) Can continue if the PI ensures the research can be conducted in a safe manner that protects subjects, researchers, and the community. 2) P.I to submit an amendment to SERU indicating the measures taken to minimize COVID-19 exposure to research participants, staff and the community. These measures should be in line with government-issued public health directives and Section 3.2.5 above 3) Refer to Section 4 for guidelines on consenting
<i>Category 2 – Studies of moderate direct benefit to research participants</i>	Protocols which, if stopped, may pose a risk to the research participant.	<ul style="list-style-type: none"> 1) Protocols in which research participants are receiving interventions or clinical care that is very interrelated to their research participation (e.g., test results coming back that might have clinical implications for their care) 	<ul style="list-style-type: none"> 1) To the extent possible, should continue with remote study visits and interactions. 2) If no feasible remote interaction options possible for some or all the procedures, researcher shall seek an amendment to SERU indicating how face-to-face study

		<ul style="list-style-type: none"> 2) Some protocols evaluating treatments for chronic conditions (e.g., asthma, hypertension, depression, etc.). 3) Protocols involving assessment of the safety or efficacy of an intervention in which, if stopped, the potential societal benefit of the science would be significantly and adversely impacted, for example where a research assessment (blood collection or imaging study) is only valuable if collected at a very specific time. This must be measured against the risk to participants and staff, including the risk of exposure of COVID-19. 	<p>visits will continue while strictly adhering to public health directives and the guidelines provided in Section 3.2.5 above. <i>(The amendment to SERU should indicate the measures taken to minimize COVID-19 exposure to research participants, staff and the community)</i></p> <ul style="list-style-type: none"> 3) Approved in-person contact will be limited to the minimum necessary 4) Recruitment and enrollment of new participants may continue as long as the study team adheres to the government-issued public health directives and the guidance in Section 3.2.5 above. 5) Refer to Section 4 for guidelines on consenting
<i>Category 3 – Research of Low Direct Benefit to Participants</i>	Studies that do not have a direct benefit to the participant or have a very low benefit to participant and whose cessation would not	<ul style="list-style-type: none"> 1) Cohort and natural history studies where delays in data collection have limited impact on scientific objectives 2) Protocols in which delays to starting or pausing of research does not 	<ul style="list-style-type: none"> 1) Study visits and procedures should be conducted remotely through phone-based or internet-based methods. 2) If no feasible remote interaction options possible for some or all

	<p>affect the safety, health and wellbeing of the participants.</p>	<p>substantively impact on research objectives of the research protocol</p> <ol style="list-style-type: none"> 3) Protocols in which risks to research participants are higher (e.g., potentially exposing elderly vulnerable individuals to COVID) and benefits of the study to the participants remain minimal 4) Non-clinical trial research with healthy volunteers 5) Any minimal risk studies that require research subjects to travel, that involve undergraduate students, or that are in a community setting and require direct interaction with researchers 	<p>the procedures, researcher can seek SERU approval to continue with SERU-approved face-to-face study visits while strictly adhering to the guidelines provided in Section 3.2.5 above (<i>P.I to submit an amendment to SERU indicating the measures taken to minimize COVID-19 exposure to research participants, staff and the community</i>).</p> <ol style="list-style-type: none"> 3) Recruitment and enrolment of new participants may continue as long as the study team adheres to the government-issued public health directives and the guidance in Section 3.2.5 above. 4) Refer to Section 4 for guidelines on consenting
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KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 28 of 45

NB: A researcher may request SERU for an exception to the above guidelines for a specific research category if there is a compelling justification to do so. The researcher should submit the request in writing to SERU and indicate the following information:

- 3.3.1 What is the direct benefit to the participant that cannot be obtained outside the study? (Category 1)
- 3.3.2 What is the harm to participants or value of data lost if in-person visits are to cease or be delayed until restrictions are lifted? (Categories 2 & 3)
- 3.3.3 What measures are being taken to minimize in-person visits, e.g. visits may be done remotely or coincide with clinical visits?
- 3.3.4 Any other relevant information

3.4 Principal Investigator responsibilities to SERU

3.4.1 What COVID-19 related changes require to be submitted as amendments?

- 3.4.1.1 SERU-approved studies that had indicated in their protocols they would conduct in-person study visits or procedures should submit an expedited/quick turn-around request for amendment to SERU to request to add remote visits/procedures to their study as necessary.
- 3.4.1.2 Studies that encompass critical research visits/procedures that require ongoing in-person interactions with participants should submit an expedited/quick turn-around request for amendment to SERU indicating the measures that have been taken to highly minimize the risk of COVID-19 exposure to participants and staff.
- 3.4.1.3 Similarly, studies in Category 2 and 3 in part C above that have a compelling reason to continue with face-to-face interactions with participants should submit such requests to SERU through an amendment and indicate the measures that have been taken to highly minimize the risk of COVID-19 exposure to participants and staff.



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 29 of 45

- 3.4.1.4 If a study needs to be temporarily paused to fulfil COVID-19 related measures, and the halting of research activities could result in increased risk of harm or affect the welfare of subjects, the researcher must submit a protocol amendment for SERU review and approval prior to halting research activities¹.

NB: SERU-approved studies that had already stated in their protocols that they would conduct study procedures such as consenting, data collection, etc, remotely, can continue to do so without submitting an amendment to SERU.

3.4.2 What COVID-19 related changes require to be submitted as notifications?

- 3.4.2.1 If a study needs to be temporarily paused to fulfil COVID-19 related measures, and the halting of research activities will have NO effect on the safety or welfare of participants, this should be reported as a notification to SERU and can be reviewed at the SERU secretariat level¹
- 3.4.2.2 If the researcher needs to modify the schedule of study procedures to accommodate COVID-19 related measures, e.g. cancelling or postponing a visit, delivering of investigational product to a participant at home, rescheduling certain study procedures, requiring a participant to undertake inter-county travel for a visit during a lockdown period, etc, they should do so through a notification of planned deviations to SERU. Such modifications should only be undertaken if they do not adversely affect the health, safety or wellbeing of the study participant. If the researcher is uncertain about what measures to take, they should call SERU for further guidance.
- 3.4.2.3 If a study visit needs to be cancelled, participants should be informed of the reason and that they will be contacted again when the visit can be rescheduled. These messages to participants should be submitted to SERU as a notification.
- 3.4.2.4 If the researcher is sending a "Dear Participant Letter" to study participants informing them of a pause or change in



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 30 of 45

study activities in order to fulfil COVID-19 pandemic containment measures, the letter should be submitted to SERU as a notification but the researcher can go ahead and implement the changes.

3.4.3 What COVID-19 related changes require to be submitted as deviations/violations?

- 3.4.3.1 Late or missed visits due to COVID-19-related developments should be reported to SERU as protocol deviations on a quarterly basis.
- 3.4.3.2 If the researcher has to implement an immediate change in study procedures in order to avert an apparent immediate harm to the participant, the change can be implemented without seeking prior IRB approval. However, the researcher should report this change to SERU within 5 working days in a protocol violation report detailing the change implemented and the researcher's rationale for implementing the change prior to IRB approval. If necessary, the researcher should submit an amendment to update the study protocol or tools accordingly
- 3.4.3.3 All other changes to the protocol that are not related to COVID-19 should follow the laid-out instructions in the current KEMRI SERU SOPs.



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 31 of 45

SECTION 4: CONSENT

This section summarizes guidance for consent taking for research participants during COVID-19 pandemic and other health emergencies

For purposes of this guidance remote consenting means the consent process by potential or enrolled research participants that takes place by a means other than face-to-face communication and without the physical presence of the study staff. Acceptable methods include use of electronic signatures, faxing the signed consent forms, online consenting, tele-consent, oral consenting if the consent is obtained through audio/video communication through different applications such as Zoom, Skype, WhatsApp, telephone etc.

4.1 NON COVID-19 RESEARCH

4.1.1 Previously Approved Ongoing Studies

For any ongoing research that will continue, research teams shall consider whether the risks of the study are altered by the COVID-19 pandemic.

Guidance:

In order to maintain consistency during and after the pandemic

4.1.1.1 Where it is determined that the risks of the study are altered by the COVID 19 pandemic, the study shall submit an AMENDMENT of the protocol risk section to SERU and provide as separate risk information sheet related to COVID-19 to reflect that risk and submit for re-review by SERU for use prospectively as an addendum (add-on) to the previously approved consent form. Previously enrolled participants who are still part of the study will need to be taken through the additional participants risk information sheet and be re-consented. The risk information sheet related to COVID-19 will need to be reviewed regularly to reflect any new knowledge.

4.1.1.2 Where it is deemed that the risks of the study are not altered by the COVID 19 pandemic, and there are no new changes to the ICF, but that in-person consenting has to be suspended to comply with social distancing requirements, the study shall



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 32 of 45

submit a NOTIFICATION OF CHANGES of the previously approved consenting process and ICF. The notification shall provide particulars of the remote consenting method to be used as well as a copy of the remote consent document for determination of the adequacy of the procedure and approval of the tools for use.

The study team cannot enrol anyone using a new remote consenting option method until the methodology is reviewed and approved by SERU.

4.1.2 New Studies

A complete informed consent process must be conducted for participant enrolment, unless specific application for waiver is submitted and approved by SERU.

Where the study intends to undertake all study activities remotely, and there is sufficient justification that it will be impractical to obtain in-person signatures on consent forms yet the study has the potential of direct benefits critical to potential participants, the PI is encouraged to request SERU for waiver of requirement for signed consent and provide adequate procedure to document that oral consent. Upon the cessation of social distancing requirements, participants requiring in-person visits with the study staff must be re-consented using normal consent documentation methods.

4.2 COVID-19 RESEARCH

This section provides additional guidance specific to informed consent for COVID 19 positive patients or those undergoing testing.

General guidance:

- 4.2.1** Obtaining consent in COVID-19 research; whether from positive patients or those undergoing testing, shall be conducted in a manner that reduces the potential for viral transmission. Where signed consent forms are used, detailed particulars of measures to avoid contamination shall be provided in the protocol.
- 4.2.2** Compensation to research participants should not result in undue inducement or coercion



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 33 of 45

4.2.3 Specific information should be provided about the circumstances under which participant's data or samples might be shared (whether as a legal or regulatory requirement).

4.2.4 No informed consent, whether oral or written, may include any language through which the participant is made to waive any legal right/s, or releases or appears to release the study team from liability for negligence.

4.3 Emergency COVID-19 Research

Emergency COVID-19 research is when:

4.3.1 Treatment needs to be given urgently, and

4.3.2 It is necessary to take urgent action for the purposes of the study.

Informed consent of the patient or their legally authorized representative (LAR) specifically referencing COVID 19 procedures is necessary before enrolment in a clinical trial, and such informed consent shall be an additional separate procedure to any other consent required in the course of care.

Guidance on Participants Information sheet:

4.3.2.1 Information about the study should therefore be short and easy to read but contain enough detail for the participant to be able to make an informed decision.

4.3.2.2 The participants' information sheet should contain adequate details appropriate to the nature and burden of the study and relevant to potential participants' levels of understanding of medical terminology, different reading abilities and age appropriate. Thus, the Participant Information Sheet for a Clinical Trial will need to be significantly more detailed than questionnaire studies. Challenge studies should involve a rigorous informed consent process.

4.3.2.3 The choice of wording must be careful not to unjustly raise participants' expectations or contribute to stigma.

4.3.3 Guidance on hospitalized patients

4.3.3.1 Obtaining consent from hospitalized COVID-19 positive patients (or those undergoing testing) shall be conducted in a



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 34 of 45

manner that reduces the potential for viral transmission between individuals, preserves personal protective equipment (PPE), and accounts for whether the patient has the capacity to give consent as well as their physical ability to sign informed consent documents.

4.3.3.2 Emergency situations where patients presenting at hospitals and in isolation are too ill and lack capacity to give consent themselves, consent shall be obtained from

4.3.3.2.1 A legally authorized representative; or

4.3.3.2.2 Where it is not reasonably practicable to contact the LAR within the required timeline, consent shall be obtained from two senior health care providers who are not part of the research team or patient care team

4.4 Non-emergency COVID 19 clinical trials

Guidance:

4.4.1 The study informed consent process shall:

4.4.1.1 provide full information about the risks and potential benefits of participation

4.4.1.2 disclose information regarding any accelerated preclinical testing that did not complete sufficient animal testing and the risks involved including the potential for unknown risks

4.4.1.3 include a statement providing information relating to existing or lack of known effective vaccine or treatment

4.4.1.4 include a separate check box offering the participant the choice to be contacted with new relevant data that becomes available during their participation in the study.

4.5 Informed Consent in COVID 19 human challenge studies

Informed consent processes should be particularly rigorous in COVID 19 challenge studies because of the heightened potential risks and uncertainties involved.

Guidance:



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 35 of 45

- 4.5.1** Protocol shall contain relevant evidence regarding how important and complex information shall be conveyed to participants to maximize understanding
- 4.5.2** Protocol shall acknowledge the need to revise ICF when new relevant data becomes available after the study has been approved.
- 4.5.3** Studies shall routinely incorporate tests of participant understanding during the informed consent process.
- 4.5.4** Participants' information shall be based on the best available data regarding risks (and uncertainties).
- 4.5.5** Consent should be revisited periodically throughout the study.

4.6 Non-emergency COVID-19 research collecting sensitive information

Guidance:

- 4.6.1** Studies shall routinely incorporate tests of participant understanding during the informed consent process.
- 4.6.2** In person as well as remote consenting may be acceptable. A complete informed consent process must be conducted for participant enrolment, unless a specific application for waiver is submitted and approved by SERU as provided in this guidance.
- 4.6.3** Where the study intends to undertake all study activities remotely, and there is sufficient justification that it will be impractical to obtain in-person signatures on consent forms yet the study has the potential of direct benefits critical to potential participants, the PI is encouraged to request SERU for waiver of requirement for signed consent and provide adequate procedure to document that oral consent. Upon the cessation of social distancing requirements participants requiring in-person visits with the study staff must be re-consented using normal consent documentation methods.
- 4.6.4** Researchers are encouraged to use platforms or software for remote consenting from reputable providers to prevent data loss or any other unforeseeable legal issues. Information about the platform and process must be provided to SERU for approval.



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 36 of 45

4.6.5 An extra check box on the consent form needs to be provided if filming or recording shall take place for consenting. Participants should have the option to receive transcripts and check through the information documented from them.

4.7 Non-emergency COVID-19 research collecting non-sensitive information

4.7.1. In-person as well as remote consenting may be acceptable.

4.7.2. Researchers are encouraged to use a platform or software from a reputable provider to prevent data loss or any other unforeseeable legal issue.

4.7.3. Information about the platform and process must be provided to SERU for approval.

4.8 Waiver of Consent:

SERU may consider applications for waiver of patients consent for COVID 19 studies involving:

4.8.1 Retrospective studies involving de-identified patient data (though consent from the facility for access to data will still be required)

4.9 Documenting Remote Consent

Electronic and remote informed consent procedures must meet the same regulatory requirements of an in-person paper-based informed consent process.

Guidance:

4.9.1 Documentation of remote consent must include a method to verify the identity of the person being consented or LAR e.g. visual identification, use of identification documents or use of personal questions, etc.

4.9.2 Documentation of remote consent must include a method to verify the age of the person being consented by using information from some form information showing their date of birth e.g. National Identity Card, Passport for an Adult and a birth certificate for a minor.

4.9.3 In the event the research participant is a minor the investigator should consider whether the capability of a minor to assent may be affected by



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 37 of 45

the method used to obtain and/or document assent. The language and presentation of information must be understandable to the minor. In addition, the consent of the parent or LAR should be taken at the same time as the minor.

4.9.4 Consent for a mature or emancipated minor will be as for an adult.

Documentation of remotely obtained verbal consent must comply with (i) and (ii) above, after verbal consent is given the designated member of the study team should sign and date (whether electronic or paper) the consent form in addition to a witness. Upon the cessation of social distancing requirements, participants requiring in-person visits with the study staff, the participant shall be re-consented using written consent documentation methods.

4.9.5 The process must include a witness nominated by the study team who is able to attest to the consent process.

4.9.6 Records in the research study's source documentation shall include:

4.9.6.1 A copy of the full informed consent document signed by the study staff and witness (if there is a witness signature line) and a photograph of the patient signature (if any) OR

4.9.6.2 A copy of the full informed consent signed by the Study Staff and a Witness Attestation Form signed electronically AND

4.9.6.3 A notation by the investigator of how the consent was obtained (e.g., telephone) and how it was confirmed that the patient signed the consent form (i.e. either by attestation of the witness and investigator or the photograph of the signed consent). The note should include a statement of why the informed consent document signed by the patient was not retained (e.g., due to contamination of the document by infectious material).

This same process can be used with the LAR, when applicable.

4.10 Guidance on applications for approval of remote consenting by SERU

Researchers shall have two options:



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 38 of 45

4.10.1 Submit the copy of the remote consent document with the application for approval, if ready, so SERU can determine adequacy of the procedure and tools and approve for use.

4.10.2 If the specific methodology is not ready, issue a notification to SERU of the study team's intention to modify the approved MS word copy of the ICF as the study team should submit as a modification with the approved ICF document.

The study team cannot enrol anyone using a new remote consenting option method until the methodology is reviewed and approved by SERU.



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 39 of 45

SECTION 5: MONITORING AND EVALUATION

5.1 PURPOSE

The purpose of this section is to describe how oversight of studies that have been approved by KEMRI SERU will be conducted during the COVID-19 pandemic period. In response to government regulations, even as physical access becomes increasingly restricted, study oversight activities cannot be put on hold. Suspending study oversight would make it harder to ensure accountability with the research stakeholders for SERU approved research. Study oversight is part of compliance with, among other local and international regulations, ICH GCP requirements to monitor the progress of a clinical trial, and ensure that they are conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practices (GCP) and applicable regulatory requirements.

5.2 INTRODUCTION

Monitoring of a study is a quality control tool for determining whether activities are being carried out as planned, so that deficiencies can be identified and corrected appropriately and promptly. The main aim is to verify that the rights and wellbeing of the participants are protected and the trial conduct is compliant with the approved protocol/amendments, GCP and applicable regulations. All studies approved by SERU may be subjected to either random or triggered monitoring by the SERU

5.3 STUDY OVERSIGHT GUIDELINES

In compliance with the government directives aimed at eliminating or minimizing the spread of COVID-19 infection, inter-county movements have been prohibited unless deemed essential. Therefore, to ensure effective oversight of studies:

5.3.1 Study oversight activities will as much as possible be conducted remotely. However, in instances where there is dire need for on-site oversight, the study team will be notified through formal communication and SERU shall conduct the on-site monitoring visit activity. Additionally, on site monitoring visit will be the preferred oversight method when or if the government restriction on inter-county travel is lifted. The site visit oversight activities will be done as per SERU SOPs (SOP 11_Site Oversight Visits)

5.3.2 For the interactive remote monitoring activities:



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 40 of 45

- 5.3.2.1 All the relevant study documents to be reviewed during the oversight, required as per SERU Study Oversight SOP for a normal study oversight, shall be required in soft copy. In addition, all the documentation and resultant study amendments in response to COVID-19 will also be required.
- 5.3.2.2 The study site should have the documents in soft copy
- 5.3.2.3 The documents shall be in a manner that allows them to be shared electronically during a virtual monitoring meeting to allow for effective scrutiny and deliberations. The oversight team shall request the documents in advance to enable the study team enough time to prepare.
- 5.3.2.4 Study oversight meeting shall be recorded for future reference by SERU
- 5.3.3 Before embarking on an oversight activity, SERU secretariat shall contact the PI to plan and agree on convenient dates for monitoring activities stating the reasons for the proposed monitoring activities
- 5.3.4 An oversight team, constituting three SERU committee members, will engage the study team remotely through a predetermined highly secure virtual platform convenient for both parties.
- 5.3.5 The oversight team will be required to familiarize themselves with the study documents and procedures including the protocol, ICF, questionnaires, safety reporting procedures, and any previous monitoring reports.
- 5.3.6 The study team will be required to submit any relevant study documents, as requested by SERU, before the day of the monitoring activity as per the SOP11_Study Oversight Visits (refer to SERU SOPs)
- 5.3.7 Due to the COVID 19 pandemic and the resultant changes in study procedures aimed at limiting contact between persons, the study team may be required to provide additional information on documents and/or resultant study procedures that have been amended as follows:
 - 5.3.7.1 Participant Recruitment
 - 5.3.7.1.1 The procedure should be in line with government directives



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 41 of 45

- 5.3.7.2 Informed Consent Documents/Informed Consent Process
- 5.3.7.3 The study team shall be required to show proof that informed consenting was done and the documented proof.
- 5.3.7.4 Participant follow-up activities
- 5.3.7.5 The study team shall provide documentation of the process duly followed in adherence to government directives
- 5.3.8 Study Staff training
 - 5.3.8.1 Documentation of training shall be required
- 5.3.9 After completing the monitoring activities, the oversight team shall deliberate further with the PI, study coordinator and site staff. The main findings will be discussed, clarified and corrective and preventive action (CAPA) plans identified.
- 5.3.10 All the monitoring observations and proceedings shall be documented for purposes of preparing the monitoring report. For each of the findings they shall be classified as critical, major or minor. For each, any recommended actions shall be noted.
- 5.3.11 The oversight team shall, within one week of the monitoring, submit a report to the chairman and Head SERU for further deliberation and recommendations at the next SERU committee meeting. The final report shall then be signed and dated by the monitoring team lead and Chair, SERU.
- 5.3.12 The final report and any corrective and preventive actions (CAPA) shall then be circulated, within a specified timeframe, to the site PI, regulator and the sponsor.



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 42 of 45

SECTION 6: TRAINING


6.1 TRAINING GUIDANCE FOR SERU

6.1.1 SERU shall organize online sessions and webinars to promote

- 6.1.1.1 Understanding of the guidance by SERU reviewers in all the committees within 2 weeks of approval by KEMRI management and with facilitation support of members from the technical team that developed the guidance.
- 6.1.1.2 Discussions among researchers on how research can be undertaken ethically and safely during the emergency response to COVID-19 and the guidance provided.
 - 6.1.1.2.1 Trainings shall be undertaken for each centre
 - 6.1.1.2.2 Additional training shall be conducted on needs basis prioritizing request from researchers
- 6.1.1.3 Deliberations among various stakeholders on specific ethical dilemmas in COVID 19 specific research shall be conducted as is reasonably possible and based on availability of human and IT resources.
- 6.1.1.4 Where resources are limited, SERU shall map out and notify researchers on any available opportunities to engage in initiatives by other regional and global partners.

6.2 TRAINING GUIDANCE FOR STUDY TEAMS

- 6.2.1 The study Principal Investigator(s) shall undertake capacity building of research teams on any required changes in study conduct and any measures introduced to mitigate risk and transmission of COVID 19 for those participating in the study within 14 days of approval by SERU.
 - 6.2.1.1 The PI shall notify SERU of completion of such training and provide Documentation and/or Evidence of the training including the date and methodology of such training, a list of participants, a summary of the content covered and the trainers, 2-4 weeks after the training.

	KENYA MEDICAL RESEARCH INSTITUTE		
	DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA		
	REF NO: KEMRI/SERU/REC/GUIDE/001	Version: 1	PAGE: 43 of 45

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KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 44 of 45

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DOCUMENT TITLE: KEMRI SERU GUIDELINES FOR THE CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC IN KENYA

REF NO:
KEMRI/SERU/REC/GUIDE/001

Version: 1

PAGE: 45 of 45

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