KEMRI Wellcome Trust Research Programme: KEMRI and MOH staff _ Information Sheet and Consent Form

Title: Informing scientific and ethical aspects of policy and practice around COVID-19 research agenda: views and experiences of research stakeholders in Kenya

Lay title: Strengthening policies and practice for COVID-19 research by understanding the views and experiences of various research stakeholders in Kenya

Institution	Investigators
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You are being asked to take part in a study. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join.

Key Information for You to Consider
Voluntary Consent. You are being asked to volunteer for a study. You can choose whether you would like to participate or not. If you agree you can change your mind at any time and withdraw from the research. This will not affect your care now or in the future. **Purpose**. We are doing this research to learn more about the studies being done by KWTRP in relation to COVID-19, views and experiences of those involved in these studies, the effect COVID-19 has had in Kenya as well as on planned and ongoing studies and how researchers can ensure their studies are conducted in ways that respect views of those involved. **Duration.** Your participation in this study will last for about one hour. **Procedures and Activities.** We will ask you to participate in an Individual interview, which will happen either via internet and mobile based platforms if still under social distancing, and/or at KWTRP premises or any other place as will be agreed. **Risks or disadvantages.** You will use about one hour in participating in the interview. If participation involves travelling and/or cost related to use of internet and mobile-based platforms, you will be reimbursed data bundle/airtime costs and transport costs incurred. **Benefits**. There are no direct benefits in participating in this study. However, results of this study may lead to development of policies and guidelines on conducting COVID-19 studies or other pandemics in the future.

Introduction

The COVID-19 pandemic has led to a public health emergency in Kenya, and in most other countries in the world. To respond to this, researchers including those in KEMRI Wellcome Trust Research Programme (KWTRP) are conducting or planning to conduct research to help the government of Kenya control the pandemic. In doing this, it is important to understand the

experiences and views of researchers and support staff, study participants and other stakeholders about their roles in these studies, and what might affect them. Understanding these can help advise ongoing and future studies, to make sure such studies are conducted properly.

Who is carrying out this study and what is this study about?
This study is being carried out by KWTRP. KEMRI is a government organization that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit. Sometimes research involves only asking questions about what people know, feel or do. In this study, we would like to learn more about the studies being done by KWTRP to respond to COVID-19, views and experiences of those involved in these studies, the effect COVID-19 has had in Kenya as well as on planned and ongoing studies and how researchers can respond to make their COVID-19 studies stronger, more acceptable, relevant and responsive to this new context, and to the views of key research stakeholders including the communities.

We would like to talk to approximately 150 to 200 people, individually or in groups, from areas where KWTRP conducts its research, including COVID-19 studies. We will also undertake a community survey on perceptions, practices and knowledge about COVID19 and research, and it involve about 400 community members from KHDSS. They will include researchers, support staff, ministry of health staff, study participants, community members, research review and regulation committee members and other stakeholder who will be selected based on their experiences in these studies.

Why do you want to talk to me and what does it involve?
You have been selected to take part in this study because you are involved in conducting or supporting COVID-19 studies in one way or the other. We believe your experiences and views will be very important in informing development of policies and guidelines necessary for the conduct of ongoing and future COVID -19 studies or other studies on similar pandemics. We would like you to take part in an individual interview.

I/my colleague would like to ask you a number of questions about your experiences in conducting or supporting research about COVID-19. If you do not want to answer any of the questions you may say so and the interviewer will move on to the next question. If still under social distancing, the discussions will take place via either mobile or internet-based platform such as Skype for Business, Ms Teams or via email correspondence. Otherwise, where face-to-face interactions are permitted, the discussion will take place either at KWTRP premises or any other place as agreed by the group. Only the people involved in the discussion, the person asking the questions, and a note-taker will be present.

The discussion/interview will be recorded to assist later in fully writing up the information. No-one will be identified by name in the recording.

Are there any risks or disadvantages to me of taking part?
The individual interview will take around 40 minutes to 1½ hours. Where physical distancing measures are removed, you will be provided with refreshments during this time. In case you feel uncomfortable in answering any of the questions, let us know and we will move to the next

question. If participation involves travelling to a different location, we will reimburse your transport costs based on the actual amount spent on public transport.

Are there any advantages to me of taking part?
There are no individual benefits to taking part. In talking to us, you will contribute to knowledge of how to conduct COVID-19 studies and other pandemics that may help researchers in Kenya and elsewhere in the future, for example through developing appropriate guidelines.

Who will have access to the information I give?
We will not share individual information about you or other participants with anyone beyond a few people who are closely concerned with the research.

All our documents/ recordings are stored securely in locked cabinets and on password protected computers. Audio-records will be destroyed as soon as they have been transcribed. The knowledge gained from this research will be shared in summary form, without revealing individuals' identities, within KEMRI, with other research organizations and other stakeholders in Kenya and elsewhere.

In future, information collected or generated during this study may be used to support new research by other researchers in Kenya and other countries on COVID-19 studies and other pandemics. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live, and replace this information with number codes. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.

Who has allowed this research to take place?
All research at KEMRI has to be approved before it begins by several national and international committees who look carefully at the planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What will happen if I refuse to participate?
All participation in research is voluntary. You are free to decide if you want you to take part or not. If you do agree you can change your mind at any time without any consequences. If you do not take part, your care will not be affected**.**

What if I have any questions?
You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Dr. Dorcas Kamuya, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 0722236080 or 0709 983179

If you want to ask someone independent anything about this research please contact:

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386

And

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

KEMRI-Wellcome Trust Research Programme consent form for KEMRI, MOH staff, ERC and Research regulatory staff

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I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to take part to take part in this research

I agree for the interview/discussion to be recorded □ Yes □ No

I understand that I can change my mind at any stage and it will not affect me in any way.

Signature: _____ Date: _____

Participant: _____Time: _____

(Please print name)

I have followed the study procedure to obtain consent from the participant. S/he apparently understood the nature and the purpose of the study and consents to the participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ Date _____

Designee/investigator's name: _____Time _____

(Please print name)

THE PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP