KEMRI Wellcome Trust Research Programme: Participant Information and Consent Form

Study Title Surveillance and epidemiologic evaluation of COVID-19 in Kenya (SEECK)

Lay Title Understanding the distribution, management and outcomes of COVID-19 in Kenya

Institution	Investigators
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You are being asked to take part /allow your child to take part in a research 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/your child is being asked to volunteer for a research study. You can choose whether you/your child would like to participate or not. If you do agree you can change your mind at any time and withdraw [you/ child] from the research. This will not affect you/your child's care now or in the future.
- **Purpose**. We are conducting a study to investigate patterns of the development of immunity against the new coronavirus that causes COVID-19 in Kenya.
- **Duration.** You/ your child's participation in this study will take about two hours
- **Procedures and Activities.** We will ask you to give some information about yourself/ your child such as you/ your child's age and sex. We will collect a blood sample to check if you/ your child has antibodies (germ fighters) against the virus. About half a teaspoon (2 milliliters) of blood will be collected from children younger than 5 years of age and about one teaspoon (5 milliliters) of blood will be collected from individuals 5 years of age or older. A small group will be requested to have an additional blood sample collected using a finger prick.
- **Risks or disadvantages.** Collection of the blood sample can be slightly uncomfortable.
- **Benefits**. There is no direct benefit to you/ your child. There is a benefit to society by helping us understand patterns of exposure to the COVID-19 virus in Kenya.

- **Alternatives** You/ your child's participation in this study is entirely voluntary. You can choose to not participate. You are free to withdraw from the study at any time and it will not affect you/ your child's care.

Who is carrying out this study?

This study is being carried out by KEMRI in collaboration with the Ministry of Health. KEMRI is a government organization that carries out medical research to find better ways of preventing and treating illness for everybody's benefit.

What is this study about?

KEMRI is currently doing research to learn more about COVID-19. COVID-19 is the disease caused by the new coronavirus identified in 2019. We are trying to understand how many Kenyans may have been exposed to the COVID-19 virus. There is an urgent need to understand the pattern of the disease among community members so as to guide decision making on how to best control COVID-19 currently and when the economy is reopened, while protecting the health of the general population.

The study team plans to recruit a total of up to 2,550 children and adults living within Health and Demographic Surveillance Systems in Kilifi County, Nairobi County and Kisumu County for participation in this study.

What will it involve for me/ my child?

We will check if you/ your child is eligible to take part in the study. To be able to take part in the study, you must be a resident of the Health and Demographic Surveillance System in your County and without a medical condition that prevents collection of a blood sample.

Summary of study visit

If you are able to take part in the study and agree to do so, you will:

- Give information about yourself/ your child, such as your contact details and place of residence
- Have a blood sample collected
    - About 1 teaspoon (5 milliliters) of blood will be collected
    - The blood sample will be collected from you/ your child's arm at a health facility
    - About one in 10 participants will be requested to have an additional blood sample collected using a finger prick. The volume of blood collected using a finger prick will be about one-tenths of a teaspoon (half a milliliter).

Are there any risks or disadvantages to me/ my child of taking part?

Risk of blood sample collection

The risks of blood withdrawal from the arm or using a finger prick include discomfort, occasional bleeding or bruising of the skin at the site of needle puncture, and very rarely infection. We will minimize this risk by using highly trained staff and sterile equipment for all the procedures. If an infection of the skin occurs, it will usually go away quickly.

For blood sample collection, this may be done at your home or you/ your child may be required to attend a visit at a health facility or this will be arranged as advised by County COVID-19 response teams. If you have to visit a health Centre, this visit will take a maximum of one hour and you will be reimbursed for public transport costs depending on the distance travelled. Compensation for out of pocket costs will be in line with KEMRI's institutional guidelines currently Ksh. 350 in Kilifi and Kisumu. In Nairobi, we will adopt APHRC guidelines currently Ksh. 1000 for all costs incurred by a participant. You/ your child will be provided with a drink and snack. If at your homestead, you will receive a face mask and sanitizers/soap to help you prevent COVID 19 infection.

Are there any advantages to me/ my child taking part?

There are no direct benefits for your participation. There is a benefit to society by helping us understand the patterns of the spread of COVID-19 in Kenya.

What happens if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want you / your child to take part. If you do agree you can change your mind at any time and withdraw [*you/ child*] from the research. This will not affect you/your child's health care now or in the future.

What happens to the samples?

Individual names are removed from all samples and replaced by codes, to ensure that samples can only be linked to the participants by people closely concerned with the research.

Blood samples will be tested for antibodies (germ fighters) to the COVID-19 virus at the KEMRI-Wellcome Trust Research Programme laboratories in Kilifi. Blood group testing will also be done in KEMRI-Wellcome Trust Research Programme, APHRC, and KEMRI-CGHR laboratories. Leftover blood samples will be stored in Kilifi at the KEMRI-Wellcome Trust Research Programme laboratories and may be used for further studies in the future. This may include exporting samples abroad for research tests. Future research must first be approved by a national independent expert committee to ensure participants' safety and rights are respected.

Genetic testing

You/ your child's blood sample may also undergo genetic testing at the KEMRI-Wellcome Trust Research Programme in Kilifi, the Rockefeller University in the United States, and the Mahidol Oxford Tropical Medicine Research Unit in Thailand. The purpose of the genetic testing is to determine if there are any unique inherited characteristics that make some people more or less likely to acquire COVID-19 infection. You/ your child's genetic makeup is unique to you/ your child, and like a fingerprint, can be used to identify you/ your child and you/ your child's relatives. The results of the genetic testing as with all other study results will be anonymized and kept strictly confidential and only people who are authorized will be able to view them.

Who will have access to information about me/ my child in this research?

All our research records are stored securely in locked cabinets and password protected computers. No one other than the study team, authorised personnel from the study sponsor, monitor and ethics committee are allowed direct access to personally identified study records. When the study is completed, we will combine the test results with those of the other participants, and the overall results will be analysed.

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 health problems. 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.

If genetic testing is performed on you/ your child's sample, we will share anonymized individual and summary information we collect or generate with collaborators at the Rockefeller University in the United States and the Mahidol Oxford Tropical Medicine Research Unit in Thailand in ways that do not reveal individual participants' identities.

University of Oxford is responsible for ensuring that Oxford staff involved in the study in Kenya adhere to the safe and proper use of any personal information you provide, solely for research purposes.

Data protection

The KEMRI-Wellcome Trust Research Programme in Kilifi is responsible for ensuring the safe and proper use of any personal information you provide, solely for research purposes.

Who has allowed this research to take place?

All research at KEMRI must be approved before it begins by several national committees who look carefully at 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 if I have any questions?

You are free to ask questions to any staff at any time.

If you have any questions or concerns after reading this information sheet, you will have a chance to discuss them fully with a member of our team before you decide whether or not to take part. We will also be available throughout the study to answer any questions or address any concerns that you may have later on.

If you have any questions, you can contact the research team using these contacts:

Dr Wangeci Kagucia, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 0757 877560, 0709983676/7

<<Or in Kisumu; Dr. Victor Akello, Telephone: 0722 205 543, Dr. Dickens Onyango, Telephone: 0726 797 844>>

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

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522063, Mobile 0723 342780 or 0705 154386

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 Understanding the Distribution, Management and Outcomes of COVID-19 in Kenya

I, [being a parent/guardian of _____ (name of child)], have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to take part/ allow my child to take part in the research.

I understand that taking part/allowing my child to take part in the research will include shipment of my/my child's samples abroad, including to the United States of America and Thailand.

Please initial the sentences that reflect your choices, and then sign below:

_____ I do wish to be notified by investigators in the event of research findings of possible importance to my family members or myself. **Yes** **No**

_____ I agree that the study team use the identifier that I have provided (telephone number, country ID number, etc.) to locate me in the future. **Yes** **No**

I agree to my/my child's samples being stored and used for future research I **Yes** **No**
agree to my/my child's samples being exported for future research **Yes** **No**

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

Participant/Parent/guardian's signature: _____ **Date** _____

Participant/Parent/guardian's name: _____**Time** _____
(Please print name)

Where participant/parent/guardian cannot read, ensure a witness* observes consent process and signs below:

I attest that the information concerning this research was accurately explained to and apparently understood by the participant/parent/guardian and that informed consent was freely given by the participant/parent/guardian.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____
(Please print name)

**A witness is a person who is independent from the study or a member of staff who was not involved in gaining the consent.*

Thumbprint of the participant/parent/guardian as named above if they cannot write:
_____

I have followed the study procedure to obtain consent from the [participant/parent/guardian]. S/he apparently understood the nature and the purpose of the study and consents to the participation [of the child] 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/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP