ASSENT DOCUMENT

KEMRI Wellcome Trust Research Programme: Patient Information and Assent Form (13-17 years)

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

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

What is this research study trying to find out and why are you being asked to participate?
KEMRI is currently doing research to learn more about COVID-19. COVID-19 is the disease caused by the new coronavirus identified in 2019. In this study we aim to find out how many Kenyans may have been exposed to the COVID-19 virus.
We are asking children and adults living with Health and Demographic Surveillance Systems in Kilifi, Nairobi and Kisumu to participate in the study by providing a sample of blood. This study will involve about 900 children aged 14 years and below, 150 individuals aged 15-19 years and 1,350 adults aged 20-64 years.

You can choose if you want to be in this study:
We have spoken to your parent about this research and they are aware that we are talking to you. All participation in research is voluntary, and you are free to decide whether you want to take part or not. If you agree now, you can change your mind and stop participating in the future and no one will be upset with you. This will not affect you/your health care now or in the future.

If you agree to take part in this research, the following things will happen:

- You and your parent will give information about yourself, such as your contact details and place of residence
- We will collect about 1 teaspoon (5 milliliters) of blood from your arm at a health facility

Are there any disadvantages of taking part?
Taking care of your health and wellbeing is important to us. The risks of blood withdrawal from the arm 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.
You will be required to attend a visit at a health facility for blood sample collection. This visit will take about one hour. Out of pocket and public transport costs will be reimbursed. You will be provided with a drink and snack.

How will you benefit from taking part in this study?
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 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. Some of the research tests that will be done on the sample will be done at the KEMRI Wellcome Trust Research Programme laboratories in Kilifi. Part of the samples will be sent to laboratories overseas, to the Rockefeller University in the United States, and the Mahidol

Oxford Tropical Medicine Research Unit in Thailand. After the research, a small portion of the blood samples will be stored at the KEMRI Wellcome Trust Research Programme laboratories in Kilifi. In the future, new research about any illness may be done on these samples. 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.

Who will have access to the information I give?
The information collected from this study will be stored in securely locked cabinets and password protected computers. This information will only be shared with people who are concerned with the research. The information will be summarised and all the names of the participants will be removed from the documents. This study information may be used for future work; the information will only be provided after a national independent committee checks and agrees that you will not be affected in any way.

What if I have any questions?
You are free to discuss your decision about taking part in this study with your parent/guardian or other people and you can ask to be given time to go and discuss this with them.

You are free to ask questions to any of the staff at any time. You can contact the research team using these contacts:
Dr Ifedayo Adetifa, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 0721 337 598 or 0722 203417, 0733 522063, 041 7522063

If you want to ask someone who is not related to this research about this work 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 Assent form for Understanding the Distribution, Management and Outcomes of COVID-19 in Kenya

I, _____ (name of Participant), 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 in the research.
I understand that taking part in the research will include shipment of my samples abroad, including to the United States of America and Thailand.

I agree to my samples being stored and used for future research **Yes □ No □**
I agree to my 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 in any way.

Subject's signature: _____ **Date** _____

Subject's name: _____**Time** _____
(Please print name)

Where the child 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 child and that informed consent was freely given by the child.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____

**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 subject as named above if they cannot write: _____

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of the study and consents to 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