1. CONSENT FORMS

Statistical and agent-based modeling of complex microbial systems: a means for understanding enteric disease transmission among children in urban neighborhoods of Kenya

Information sheet and consent form

Study Title	**Statistical and agent-based modeling of complex microbial systems: a means for understanding enteric disease transmission among children in urban neighborhoods of Kenya**
Investigator(s)	**Principal Investigator: Prof Kelly Baker, Prof Blessing Mberu**
Study Sponsor(s)	National Institute of Health (NIH)
Collaborators	

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Date of Final Document: January 19th, 2021

Introduction

Hello. My name is _____ and I work with the African Population and Health Research Center (APHRC), an organization that conducts research on issues in health, education, urbanization and on the wellbeing of the people living in urban areas. This time we are conducting a study on child health in Kenya, called **Statistical and agent-based modeling of complex microbial systems: a means for understanding enteric disease transmission among children in urban neighborhoods of Kenya**. The study is being conducted together with the University of Iowa, United States and is funded by the National Institutes of Health. The purpose of this study is to understand how improvements in living conditions in selected neighbourhoods of Kenya influence exposure and infection of infants to pathogens. This is a study in two cities, Kisumu and Nairobi. The results of this study will provide important information needed to support and improve the health and wellbeing of young children in urban areas of Kenya.

Research Procedures

- You are being invited to take part in this study because you are a caregiver of an infant and you live in selected neighbourhoods in Kisumu/Nairobi.
- This form explains what the study is about.
- Your participation is **completely voluntary**. It is your choice whether you participate in the study or not. Even if you agree to participate, you can stop at any time. No one will be upset if you decide not to participate.
- If you agree to take part, you will be asked to sign two copies of this consent form, one which will be offered to you, and we will take the other one for our records.

Selection process

Your household has been selected through a random process, which means your household was selected by chance from a list of households who have children up to 1 year.

Next steps

If you agree to participate, you will be asked to answer questions about your living conditions and your child's health and wellbeing by a trained interviewer. The questions we ask you will take about 1 hour to complete although this may be shorter or longer by a few minutes. You can ask questions about the survey at any time during the interview. The interviewer will be able to give you more information about a question or explain what it means if you do not understand. The interviewer is here to help you and it is important that you feel comfortable and safe. The interview will be conducted at your home or in another private place where you feel comfortable. Upon completion of the survey, we will give you diapers that you will use to collect your child's feces for the next 24 hours. The stool will be used for microbial testing for pathogens.

Tomorrow, we will return to conduct a 5-hour structured observation of the child and document information about the interaction between the child, the environment and all those involved in taking care of the child. This observation should not distract you from your normal activities, and you will not need to worry about us inconveniencing you. Together, we will fit a geo tracker on the infant, and find a suitable place to observe the child. Should the child experience any pain, we will fix the tracker on another part of the infant that is more convenient. This tracker will be on the child for approximately 24 hours. We will then collect the diapers with the stool, collect soil samples, and conduct a rinse of your hands and

the child's for laboratory analysis. On the same day, we will also track the movement of animals that may be within your compound.

We will repeat the same process on day 3, but will remove the geotracker from the infant, collect the toy, and provide the child with another sterile toy to keep. Finally, we will come back to retrieve the calendar on day 15, after you have completed marking all incidences when the child experiences diarrhea. We will return on day 5, 8 and 15 to collect more stool samples from your child. To begin the process, today we will leave you with diapers, a calendar and a sterile toy for your child

Voluntary participation

Your taking part in this interview is voluntary. You do not have to take part. If you do choose to take part, you are free to stop the interview at any time. You will not be penalized in any way for stopping the interview

Benefits

You will not benefit directly from taking part in this study. However, the information you give will help in improving service delivery to community members in informal settlements in Nairobi and the country at large

Risks

You will not be exposed to any serious risks while taking part in this study. However, should you feel any discomfort as a result of the questions asked during this interview, you will be allowed to excuse yourself and not answer the questions and/or stop the entire interview. You will also be referred to a person you can talk to for further support. With regards to the COVID-19 pandemic, we will minimize any risks to you by screening all our staff, using PPE, and maintaining a distance of 2 meters during data collection. All materials that we will bring into and out of your household will be sterilized. We will require that you also use a face mask during our interaction, and will provide you with one if you do not have your own.

Data confidentiality

Only authorized program staff from APHRC and the University of Iowa will have access to the information collected during the interview. All responses will be stored in a locked place under the project control. Your name or other identifying information will not appear anywhere on the notes or reports. Samples, survey data and observations will be stored safely after the project period. These may later be retrieved for use when there will be a need to re-analyze data for further information beneficial to the society and the community. For such purposes, researchers will not seek further consent from the study participants. All data will be de-identified throughout the study, including during use in dissemination of study outputs like manuscripts and policy briefs.

Confidentiality

If you choose to take part, your name will only be recorded on this consent form, which will be kept locked up and separate from the information you give us. No one apart from the project team will be able to identify who discussed what during the interviews. All names and any identifiers such as participant number, phone contacts and address will be removed from the data that will be analyzed. Your record

will be anonymized using a unique code that will not be associated with you before the data is shared for analysis and/ or dissemination. Recordings will be kept in locked drawers where only authorized project team will have access to them. Your audio recording will be destroyed after we have counter-checked the written text with the recorded text.

Compensation

You will not have any costs for being in this research study and you will not be paid for taking part in the interview. However, we will give you a 'thank you' gift package which will include the child's toy, the pictorial calendar, detergent and a food storage container.

Approvals

The ethical aspects of this study have been approved by the AMREF Ethics and Scientific Review Committee and the Human Research Ethics Committee of the University of Iowa. This study will be carried out according to Kenya's laws and policies about research with children.

Contacts

If you have any questions, you can ask anyone from our team now or later. If you have questions later, you may contact

Prof Blessing Mberu
African Population and Health Research Center
P.O. Box 10787-00100, Nairobi, Kenya
Tel: +254 (020) 400 1000

If you have questions about your rights as a research participant, you may contact the AMREF Ethics and Scientific Review Committee at the following address:

The Research Officer, AMREF Kenya
Wilson Airport, Lang'ata Road
P.O. Box 30125-00100 Nairobi, Kenya
Office Tel: +254 (020) 6994000; Fax: +254 (020) 606340

Do you have any questions at this time?

Do you want to participate in the study? ☐ Yes ☐ No

Part II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant	[at least forename and surname]
Signature of Participant	
DD/MM/YYYY	

If physically impaired or non- literate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Participant	[at least forename and surname]
Thumbprint of Participant	
Signature of Witness	
DD/MM/YYYY	

Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participants have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent	[at least forename and surname]
Signature of Researcher/person taking the consent	
DD/MM/YYYY	