



## **Annex 53A – WASH Benefits Environmental Enteropathy Endline Consent – English**

### **Study Title: WASH Benefits - Handwashing, Water Treatment, Sanitation, and Nutrition Interventions and Outcome Measures in Rural Kenya (also known as the Child Health Project)**

#### **Introduction**

My name is \_\_\_\_\_, *[staff name]*, I am from Innovations for Poverty Action (IPA) in [KAKAMEGA/BUNGOMA] Town. I am working with Clair Null Innovations for Poverty Action and with scientists at the University of California, Berkeley in the United States. I am [We are] planning to conduct a follow up to our research study, which I invite you to take part in.

You are being invited to participate in this study because we collected information on your household earlier in our study and would like to learn more about your child's growth and development.

#### **Purpose**

The purpose of this study is to conduct research on children's health to better understand how nutrition and environmental factors might affect child growth and health. We are interested in learning if the exposure of a child to diarrheal disease has long-term effects. We also are interested in learning how certain foods, nutrition, or life experiences in general may interact with diarrhea or other illnesses.

We are also doing research on factors children inherit from their parents that affect the way they fight serious illnesses in this community, such as malaria. Children inherit many things from their parents and grandparents. Most people know about physical characteristics, like height. But children can also inherit factors from their parents that make them stronger or weaker than others at fighting particular illnesses. Finding these inherited factors will help scientists to develop new drugs and vaccines for these illnesses.

We are interested in evaluating your child's blood, stool, saliva, and urine for markers of nutritional status, infections and health.

#### **Procedures**

To achieve the aim of the project, if you agree to be in this study, we will collect a blood, stool, and urine sample from your child. With your permission, we will collect 4 saliva samples from your child. From the blood sample, we will measure nutritional markers, indicators of factors children inherit from their parents, and we will be able to understand whether your child has been exposed to infection. The urine sample will help us understand whether there has been a long-term physical effect as a result of diarrhea. We will also collect a stool sample from your child with your help to measure infections, such as worms. The blood, saliva, and urine samples from your child will help us to understand the long-term physical effects of infections and stress.

If you agree to participate, today a field staff member will administer a short, 15-minute survey and give you a stool collection kit and instruct you how to collect stool from your child. You will be instructed to collect your child's stool tomorrow morning, if the child defecates before the arrival of the field team, by having your child defecate on a sheet of provided aluminum foil or a diaper and by using a plastic scoop to collect a small amount of fresh stool from the top of the pile into a container. The field person will collect this container and the used diaper when they come to collect the other specimens tomorrow. With your permission, using a needle we will also draw a small amount (5ml) of blood from your child's vein. **One drop of blood will be used to check for anemia in your child, a condition of not enough red blood cells. We will provide these results to you after the test.** We will record how your child responds to these procedures. If you agree, we would like to videotape your child during the blood-draw. We will use this information to better understand how these procedures affect child behavior. We will also ask you about how your child reacts to new situations, and what helps your child feel comfortable in new situations, which will take 10-15 minutes. This will help us understand your child's reaction to the different procedures we are administering for this project. We will also collect 4 saliva samples from your child before, during, and after the blood draw. The field representative will also weigh the child using a scale, measure his/her height using a height board and head circumference and mid upper arm circumference using a tape measure and collect general health measures of blood pressure and heart rate. The blood pressure and heart rate results from your child will be provided to you after the testing. The field representative will also weigh you, measure your height and mid upper arm circumference, and collect general health measures of blood pressure and heart rate. Your blood pressure and heart rate results will be provided to you after the testing. Total participation time today will be approximately 3 hours and 15 minutes.

Tomorrow, the main procedure will involve feeding your child sugar syrup and then collecting their urine sample over a period of 5 hours. You/the mother will be requested to not feed your child for at least one hour before we feed him/her the syrup. During this fasting period, we will collect your child's urine for 1 hour by attaching the urine collection bag with a drainage tube (show sample) to the child. We will then give a dose of the sugar syrup to the child and collect the urine for 5 hours. We will ask you to encourage the child to breastfeed or drink water 30 minutes after taking the syrup to help urination. The field representative will remove the urine from the bag, whenever the child urinates. This collection will take place for 5 hours after which the bag will be removed from the child. During the 5-hour period of urine collection, you will be asked about foods and eating practices in your household. You will also be asked about your personal life experiences and health. Total participation time tomorrow will be approximately 7 hours.

Later, at the laboratory, we will measure your child's blood, stool, saliva, and urine samples for markers of nutritional status, infections, and health.

**Study time:** Study participation will take a total of approximately *10 hours and 15 minutes over 2 days*,

**Study location:** Today, all study procedures will take place here at this central location, and tomorrow we will visit you at your home.

### **Benefits**

There is no direct benefit anticipated to you or your child but you will help us to understand the health impact of diarrheal diseases and how certain foods, nutrition, and life experiences in general may interact with diarrhea or other illnesses.

**Risks/Discomforts****Possible risks, discomforts, and/or side effects related to the study procedures include:**

- Some of the questions I would like to ask you may seem private or personal since they touch on your life and health. You may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview. All your answers will be kept as confidential as possible, and we anticipate that the risks from participating in this survey will be very minimal.
- Your child may not like the syrup, even though it is a natural sugar solution that tastes pleasant.
- Drawing blood may cause temporary discomfort from the needle stick, bruising, or very rarely, infection. To minimize these risks the blood will be collected by a trained professional.
- Your child may feel some discomfort due to the presence of urine collection bag for 5 hours.
- Breach of confidentiality: As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk.

**Confidentiality**

- Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.
- To minimize the risks to confidentiality, we will limit access to study records to only the necessary IPA staff and investigators. Any information that identifies you will be separated from your other answers, so that only our researchers will be able to track your answers back to you. All paper data will be sorted in secured locked locations. All electronic data will be encrypted. Your personal information may be given out if required by law.
- All video recordings will be identified by a number only; no recordings will identify you or your child by name. These will be viewed only by trained personnel for coding of your child's response to the procedure. The videos will not be viewed by any other person. The videos will be stored in a locked cabinet accessible by study personnel only. These will never be made available to any persons not participating in the study.

***Retaining research records:*** Your child's blood, stool, saliva, and urine samples will be stored for a long time after the study ends. This is because new laboratory techniques will become available in the future to help us better understand how diarrheal diseases affect children's health. The information collected from this study may be shared with other researchers if needed, but we will strictly maintain your confidentiality and privacy as described previously. The samples may be shipped to other countries for analysis without further consent from you. The videos will be stored indefinitely.

You have the right to refuse to allow your child's blood, stool, saliva, and urine samples to be stored long term for future studies.

**Compensation/Payment**

You will not be paid for taking part in this study.

Child ID |\_|\_|\_|\_|-|\_|\_|\_|-|\_|\_|

FO ID |\_|\_|\_|\_|

## Rights

*Participation in research is completely voluntary.* You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the assistance that IPA may or may not provide to you or your community.

## Questions

If you have any questions or concerns at a later time, you may contact the WASH Benefits hotline at 0728-716-661. If you have additional questions or concerns about your rights and treatment as a research subject, you can contact KEMRI Ethics Review Committee on 0722-205901 or 0733-400003, or the office of UC Berkeley's Committee for the Protection of Human Subjects at +1-510-642-7461 or [subjects@berkeley.edu](mailto:subjects@berkeley.edu).

## CONSENT

**You have been given a copy of this consent form.**

**If you wish to participate in this study, please confirm by indicating if you are willing to participate. Please sign and date below.**

_____	_____	<div>Thumb print</div>
Participant's Name ( <i>please print</i> )	Date	
_____	_____	
Participant's Signature	Date	
_____	_____	
Person Obtaining Consent	Date	

**If you agree to allow your child to participate, please indicate that by checking the boxes of the activities that you will agree or disagree to below:**

**Urine Collection** Yes ☐ No ☐ child

**Venous Blood Collection** Yes ☐ No ☐ child

**Stool Collection** Yes ☐ No ☐ child

**Saliva sample collection** Yes ☐ No ☐ child

**Video recording** Yes ☐ No ☐ child

Child ID |\_|\_|\_|\_|-|\_|\_|\_|-|\_|\_|

FO ID |\_|\_|\_|\_|

### **Consent to long term storage**

Long Term Storage consent

Urine

☐ YES, I do want my child's **urine** samples to be stored long term

☐ NO, I do not want my child's **urine** samples to be stored long term

Venous Blood

☐ YES, I do want my child's **blood** samples to be stored long term

☐ NO, I do not want my child's **blood** samples to be stored long term

Stool

☐ YES, I do want my child's **stool** samples to be stored long term

☐ NO, I do not want my child's **stool** samples to be stored long term

### **Saliva sample**

☐ YES, I do want my child's **saliva** samples to be stored long term

☐ NO, I do not want my child's **saliva** samples to be stored long term

### **Video recording**

☐ YES, I do want my child's **video recordings** to be stored long term

☐ NO, I do not want my child's **video recordings** to be stored long term