# Home

# Annex 55a– WASH Benefits Environmental Enteropathy Repeat Blood Draw 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 from Innovations for Poverty Action and with scientists at the University of California, Berkeley in the United States. We collected information on your child and your household earlier in our study in order to learn more about your child’s growth and development. Today, we would like to ask to take an additional blood sample from your child.

**Purpose**

The purpose of this visit is to talk to you about Sickle Cell Disorder and take blood sample from your child. You may remember that we previously collected blood samples from your child. We tested your child’s blood for Sickle Cell Disorder and the test indicated that your child might have this condition. But, we need to conduct another test to be sure. This is a special visit made just to you and a few other families in the study.

Sickle cell disorder is a condition that affects the blood and is always inherited from both parents. This means that people are born with it, just as they are born with other characteristics such as height or skin color. Although the disorder is inherited, the parents, and even grandparents, of a child with this condition may not have any signs of the disorder.

Sickle Cell Disorder is not an infection, and others cannot catch it from being near person with the condition. However, if your child is confirmed to have the condition, he or she will need special care. If we do find that your child has Sickle Cell Disorder, we will provide you with the results and some additional information about Sickle Cell Disorder. We will also provide you with transportation to the nearest facility which can care for your child.

**Procedures**

If you agree to participate, for this visit, we only need to sit with you and your child for a moment to take a blood sample. We will also answer any questions you may have. This should only take about 15 minutes today.

With your permission, using a needle we will also draw a small amount (0.5 mL) of blood from your child’s vein. We will send this to a laboratory for a repeat test for Sickle Cell Disorder. After the test has been conducted, your child’s blood sample that is taken today will be destroyed and no further tests will be conducted. The results from this blood test will be reported back to you within one month time.

**Study Time:** Participation will take approximately 15 minutes today and time when we deliver the results.

**Study Location:** Today, all study procedures will take place at your home or in a central location near your home.

**Benefits**

The benefit of this visit is that it will allow us to inform you if your child has Sickle Cell Disorder. We will inform you of the test result and, if the test result is positive, we will provide you with a referral and information about where your child can receive treatment.

**Risks/Discomforts**

There are no major risks involved in this visit. 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.

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.

Retaining Research Records

This blood sample will not be retained after the sickle cell test is done.

Compensation/Payment

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

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. If you refuse to have your child’s blood sample taken today, we will not conduct the second test for Sickle Cell Disorder.

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.**

**Venous Blood Collection Yes |\_\_| No |\_\_|**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Thumb print

**Participant's Name *(please print)* Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant's Signature Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Consent Date**