# Annex 5- Consent –EE- Parasite - English

Permission form for environmental enteropathy, parasitic assessment, and breastmilk collection

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

Principal Investigator’s name: Clair Null

Organization: Innovations for Poverty Action, Kenya

**Purpose of the research**

Hello. How are you? I am (name) from Innovations for Poverty Action (IPA), the non-governmental development organization, in Kisumu with offices in Kakamega/Bungoma Town.

We are conducting research on diarrheal diseases and through this particular study we want to learn about the health impact of diarrheal diseases in children. We are interested in learning if the exposure of a child to diarrheal disease has long-term effects. We 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.

**Why are we inviting you to participate in the study?**

We are interested in enrolling your household because we collected information on your household earlier and we are interested in conducting additional testing to evaluate your child’s stool for markers of infections, such as worms. We are interested in evaluating your child’s blood, stool, saliva, hair and urine for markers of nutritional status, infections, and health. We are also interested in evaluating your blood, saliva, hair, and urine for markers of infections, stress and health. We also want to get an idea of how much the contents in breastmilk may contribute to child growth and development.

**What is expected from the participants of the research study?**

Participation in this component of the study will involve three two-day visits over a time period of two years. To achieve the aim of the project we will collect a blood, stool, and urine sample from your child on each of the three visits. With your permission, we might also collect 4 saliva samples and 3-4 strands of hair from your child and a urine sample, a blood sample, 4 saliva samples, and 3-4 strands of hair from you on each of the three visits. 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 parasite infections, such as worms. The blood, saliva, hair, and urine samples from you and your child will help us to understand the long-term physical effects of infections and stress.

We will also collect a small amount of your breastmilk if you are currently breastfeeding. This breastmilk will help us understand what sort of nutrients and immune properties your child is getting when they are fed your unique breastmilk. This information will be determined once we conduct tests in a laboratory.

If you agree to participate, a field research person will visit your household two consecutive days in a row for each of the three data collection events. On the first day of this activity, a field staff member will administer a short, 15-minute survey and deliver a stool collection kit and instruct you how to collect stool from your child. You will be instructed to collect your child’s stool on the following 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. With your permission, we will also draw a small amount (5ml) of blood from your child on the first day. We might also collect a small amount (5ml) of blood from your vein. We might also collect 3 saliva samples each from both you and 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, sweat, and heart rate. The field representative will also weigh you, measure your height and mid upper arm circumference, blood pressure, sweat, and heart rate. The field representative will also cut and collect 3-4 strands of hair from you and your child. Total participation time on this day will be approximately 3 hours.

On the second day, we will ask you to collect your first urine sample of the morning immediately after you wake up. 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 also collect one additional saliva sample from you and your 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. You will be asked about perceptions regarding social norms that may affect a child’s health.

Also during the period of urine collection, a field research person who is visiting your household to take measurements on your child will also assist you in providing breastmilk as a biological sample. You will be instructed to hand express a small volume of milk into a plastic cup, from which the field researcher will properly store for later analyses.

**Risks & Benefits**

There are no major risks involved in this study. The syrup is a natural sugar solution that tastes pleasant. 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, and a little momentary pain during the blood draw. 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. There is a slight risk of breach of confidentiality.

The small volume of breastmilk should not disturb your child’s feeding pattern. You may experience a small amount of discomfort during expressing breastmilk. You will collect the breastmilk in the privacy of your own home.

The benefit of this study is that your child’s participation will help us to gain knowledge on diarrheal disease in children.

**Privacy, anonymity and confidentiality**

All data and specimens collected will be kept confidential as allowed by the law of this country.

Confidentiality of the data and test results will be strictly maintained. We will use the information only for the purpose of the study, and we will not use your name in sharing and publishing the results of this study.

**Future use of information**

The information, along with some of the blood, urine, saliva, hair, stool**,** and breast milk collected 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. The blood, urine, saliva, hair, and stoolsamples may also be shipped to other countries for analysis without further consent from you. The breast milk samples will be shipped to the United States for analysis. If you would rather not have your breast milk sample shipped outside of Kenya, please tell us and we will not collect this sample.

**Right not to participate and withdraw**

Taking part in this part of the study is completely voluntary. You may choose not to allow your child to participate in these activities. You can stop participating in this study at any time, even in the middle of the sample/urine collection. You have the right to refuse participation in this study.

**If you have additional questions about your rights as a research subject, you can contact KEMRI Ethics Review Committee on 0722-205901 or 0733-400003**

**Compensation:**

You need not pay us to take part in this study, and similarly we will not pay you money for your participation in the study.

**Persons to contact:**

If you have any question, you can ask me any time.

If you have any questions or comments about this study you can also speak with people in the IPA office in Kakamega/Bungoma Town (0728716661). If you “flash”[[1]](#footnote-1) them they will call you back.

If you agree to allow your child to participate, please indicate that by checking the boxes of the activities that you will agree to andputting your signature or your left thumb impression at the specific space below.

**Urine Collection |\_\_| mother |\_\_| child**

**Venous Blood Collection |\_\_| mother |\_\_| child**

**Stool Collection |\_\_| child**

**Breastmilk sample collection |\_\_| mother**

**Saliva sample collection |\_\_| mother |\_\_| child**

**Hair sample collection |\_\_| mother |\_\_| child**

Opt-out

**Urine Long-term storage |\_\_| mother |\_\_| child**

**Venous Blood Long-term storage |\_\_| mother |\_\_| child**

**Stool Long-term storage |\_\_| child**

**Breastmilk sample Long-term storage |\_\_| mother**

**Saliva sample Long-term storage |\_\_| mother |\_\_| child**

**Hair sample Long-term storage |\_\_| mother |\_\_| child**

Thank you for your cooperation

Signature or left thumb impression of Guardian Date

Left thumb impression of Guardian

1. “Flashing” is a common practice in Kenya when the caller does not want to bear the cost of the call – by dialing and letting the phone ring only once so that the number registers on the recipient’s line. IPA can then return the call without costing the subject anything. [↑](#footnote-ref-1)