

## **Appendix 1j: English consent form for environmental enteropathy and parasitic assessment**

Protocol Title: Effect of hand washing, water treatment, sanitation and nutritional supplement interventions on child health and development in rural Bangladesh

Principal Investigator's name: Dr. Leanne Unicomb

### **Purpose of the research**

Hello/Assalamualaikum/Namaste. My name is \_\_\_\_\_ and I work with the ICDDR,B (Cholera Hospital) in Dhaka. 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. Malnutrition in children is associated with infections of our intestines that can change our use of nutrients. It is possible that genes in our body, made up of DNA, make some children more susceptible to malnutrition than others. This DNA is inherited from our parents and we also carry genes from many friendly microbes that live on and in our body. 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.

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

We are interested in enrolling this compound because we collected information on your household earlier and we are interested in conducting additional testing to evaluate your child's digestive tract. 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 saliva, hair, blood, and urine for markers of infections, stress and health.

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

Participation in this study will only span a few hours. 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 might also collect 5 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. 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.

If you agree to participate, a field research person will visit your household twice for this purpose. Today a field member will weigh the child using a scale, measure his/her height using a height board, measure arm and head circumference using a tape measure and collect general health measures of blood pressure, sweat, 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 collect general health measures of blood pressure, sweat, and heart rate. Your blood pressure and heart rate results will be provided to you after the testing. The field representative will also cut

and collect 3-4 strands of hair from you and your child. With your permission, we will collect a small amount of blood (equivalent to 1.5 teaspoons) from a vein in your child's arm to determine their blood group and genes (DNA) and test for infections that they may have had in the past, and measure their nutritional status. One drop of blood will be used to test your child for anemia, a condition of lower than normal red blood cells. The field member can provide you with the results of this test during their visit. 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 might also collect a small amount (10ml) 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 using a soft sponge placed under the tongue. The field member will 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 their arrival, by having your child defecate in a clean diaper and use 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 when they come to collect the other specimens on the following day. Total participation time today will be approximately 3 hours and 15 minutes.

Tomorrow, we will ask you to collect your first urine sample of the morning immediately after you wake up. The main procedure will involve a second saliva collection, collecting your child's urine for 1 hour, feeding your child sugar syrup and then collecting their urine sample over a period of 5 hours. We intend to test the urine for the syrup to help us understand the health impacts of diarrhea in children. For a urine sample, due to the age of your child, we will be using a special urine collection bag to collect the urine from your child and we will demonstrate how it is used.

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 two additional saliva samples from your child and one additional saliva sample from you using a soft sponge. We will then give a dose of the sugar syrup to the child and attach the urine collection bag with a drainage tube (show sample) to the child immediately after feeding him/her the syrup. We will encourage the child to 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 6 hours after which the bag will be removed from the child. During the 6-hour period of urine collection, you will be asked the quantities of foods (and the ingredients) you fed the child in the previous day and night. 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. From the stool sample, we will examine whether your child has any worm infections, but this analysis will be done in Dhaka. We will offer your child deworming medication regardless of the stool sample result. Total participation time tomorrow will be approximately 7 hours.

Later, at the laboratory, we will measure your blood, saliva, hair, and urine samples and your child's blood, stool, saliva, hair, and urine samples for markers of nutritional status, infections, and health. You will not receive the results of any laboratory tests.

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

### **Risks & Benefits**

Although we will try to protect your identity there is some possibility that confidentiality could be compromised. The syrup is a natural sugar solution that tastes pleasant. The blood will be collected by a trained professional. You and your child may feel some momentary pain during the blood collection. Your child may also feel some discomfort due to the presence of urine collection bag for 6 hours. 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 no direct benefit for participating in this study, but your child's participation will help us to gain knowledge on the health impact of diarrheal diseases and how certain foods, nutrition, and life experiences in general may interact with diarrhea or other illnesses.

### **Confidentiality**

All data and specimens collected will be kept confidential as allowed by the law of this country. The samples and the test results will be coded without your name or your child's name or personal information, and stored separately for analysis by the researchers. None of these researchers will be able to identify you or your child as the sample donors. Other persons who may have access to your test results include research groups that oversee the safety of the study including institutes such as the University of California Berkeley and the Bill and Melinda Gates Foundation, USA. Because of the potential need to release information to these parties, and the genetic information we are collecting is potentially identifying, we cannot guarantee absolute confidentiality. However, we will ensure every effort that we can to preserve your confidentiality. There is no expiration date to this permission. This information will be coded and it is unlikely that anyone will be able to trace it to you and your child, protecting your confidentiality.

All videotapes 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.

### **Future use of information**

The blood, urine, saliva, hair, and stool samples may be stored until the end of the study, so they can be analyzed in the lab at the same time. If you agree, the information, along with some of the blood, urine, saliva, hair and stool collected will be stored at ICDDR,B for up to 20 years so that we can conduct advanced tests on these samples to understand the infections that you may have had, and to find out what microbes lived in your body. No further consent will be taken from you, and you will not receive the results of these tests. A senior scientist at ICDDR,B will decide who can use the stored samples, and what tests will be done. If you change your mind about having your specimen saved for further testing, you may contact us and the sample will be discarded and not saved. The videotapes will be stored indefinitely.

### **Right not to participate and withdraw**

Taking part in the study is completely voluntary. You may choose not to allow your child to participate in this study. You can drop out of this study at any time, even in the middle of the sample/urine collection. You have the right to refuse participation in this study, which will not affect your family's treatment at the Cholera Hospital in the future.

### **Principle of compensation**

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

### **Persons to contact:**

If you have any questions, you can ask me any time. If you have additional questions about the survey, you may contact:

Masud Parvez: phone: 01817541872., ICDDR,B, Mohakhali, Dhaka 1212. Phone: 8860523-32 # 120

If you have questions about your rights as a participant of a research study, or if you think some harm has been done to you because of the survey, you may contact or meet IRB Secretariat, M.A. Salam Khan:

M. A. Salam Khan, IRB Secretariat, phone: 9886498 or PABX 8860523-32 ext. 3206

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

**Urine Collection** ☐ **mother** ☐ **child**

**Venous Blood Collection** ☐ **mother** ☐ **child**

**Stool Collection** ☐ **child**

**Saliva sample collection** ☐ **mother** ☐ **child**

**Hair sample collection** ☐ mother ☐ child

**Urine Long-term storage** ☐ mother ☐ child

**Venous Blood Long-term storage** ☐ mother ☐ child

**Stool Long-term storage** ☐ child

**Saliva sample Long-term storage** ☐ mother ☐ child

**Hair sample Long-term storage** ☐ mother ☐ child

If you agree to our proposal of enrolling your household in our study, please indicate that by putting your signature or your left thumb impression at the specified space below

Thank you for your cooperation

\_\_\_\_\_  
Signature or left thumb impression of Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature or left thumb impression of the witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of the PI or his/her representative

\_\_\_\_\_  
Date