

APPENDIX 3: Consent Forms

Participant ID# _____

Adult Consent Form (*Flesch-Kincaid Reading level 6.4*)

(NOTE: Consent form will be translated into Haitian Creole for use in the field)

Cholera Serology Survey in Haiti

Haiti's Ministère de la Santé Publique et de la Population (MSPP) and the Centers for Disease Control and Prevention (CDC) are doing a research study on *cholera*. *Cholera is caused by a germ that can cause severe diarrhea. It can be spread in food and water. Many Haitians have become ill from this disease.*

Some people can be infected with the cholera germ without having diarrhea. These people can still transmit the germ without knowing it. We are trying to learn more about why some people get very sick from cholera and some do not get sick at all. You are being asked to participate in this study because your community was affected by cholera. There is no cost to you to participate in this research study.

This survey involves a set of questions about cholera and diarrhea symptoms. These questions will take fewer than 10 minutes to complete.

The survey also involves a blood test. The test does not tell us whether or not a person has cholera. It tells us if someone has come in contact with the cholera germ. If you allow us, we will take a blood sample from the vein in your arm. Sterile instruments and new non-reusable equipment will be used to draw your blood. The blood sample will be about four teaspoons. There might be some slight discomfort from the needle we use. Drawing blood sometimes produces a small mark or bruise on the arm. This mark might remain for a few days. A doctor or trained person acting under the supervision of a doctor or health professional will perform the blood test. This person will be here to answer your questions. He or she will also help you with any problems that might arise during the blood test.

The blood test results will not be given back to you because they will not tell us if you have cholera. They only tell us if a person has come in contact with the cholera germ. If you think you have cholera, please go to a treatment center. The symptoms of cholera are described in the information sheet we will give you. We can also read this information aloud and answer questions.

The only personal information we will collect is your age, sex, and the general location of your house. We will keep the information you give us private to the extent allowed by law. Only the study team, the MSPP, and the ethics committees can see your information. All the information will be kept in locked computer files. Information will be summarized in reports. No one will be able to identify you or anyone else.

This survey is completely voluntary. You may choose not to be part of this survey or to stop being part of it at anytime. You may choose not to answer any question for any reason. You may choose not to have a blood test. There will be no penalty if you decide not to participate. There are no direct benefits to you from participating in this survey either. However, you will help the Ministère de la Santé Publique et de la Population know more about cholera. You will also help

us learn about how to respond better to cholera.

If you have questions or concerns about this survey or the blood test, you can call (*name of contact*) at the Ministère de la Santé Publique et de la Population (MSPP) at (*phone number*). If you have concerns regarding your personal rights in the study, you can call (*name of contact*) from the MSPP Ethics Committee at (*phone number*).

AGREEMENT:

The risks and benefits of this study have been explained to me. I have had a chance to ask questions. All my questions were answered. My family and I can choose to be in this study. We can drop out of the study at any time. I will receive a copy of this form. I agree to participate.

Yes No

CONSENT FOR STORAGE OF BLOOD SAMPLE

We want to store any blood that is left over after we do your test. We plan to use this blood for studies we will do in the future to learn more about cholera and other diseases. We will not test your blood for HIV at any time. Your name and any other identifying information will not be put on your blood sample when we store it. We will store your blood sample labeled with your age, sex, and blood test results. There will be no way to know the blood or the other information is yours. We will not be able to report back any future test results to you. You can refuse to let us store your blood and still be in this survey. The blood will be stored at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia.

I agree that my blood sample can be stored for future use.

Yes No

Participant ID# _____

Parental Permission Form (Children 2-17 Years) (Flesch-Kincaid Reading level 6.4)
(NOTE: Permission form will be translated into Haitian Creole for use in the field)

Cholera Serology Survey in Haiti

Haiti's Ministère de la Santé Publique et de la Population (MSPP) and the Centers for Disease Control and Prevention (CDC) are doing a research study on *cholera*. *Cholera is caused by a germ that can cause severe diarrhea. It can be spread in food and water. Many Haitians have become ill from this disease.*

Some people can be infected with the cholera germ without having diarrhea. These people can still transmit the germ without knowing it. We are trying to learn more about why some people get very sick from cholera and some do not get sick at all. Your child is (*children are*) being asked to participate in this study because your community was affected by cholera. There is no cost to participate in this research study.

This survey involves a set of questions about cholera and diarrhea symptoms. These questions will take fewer than 10 minutes to complete. Children who are 12 years old and older can answer the questions with your permission. We will ask you to answer the questions for children younger than 12 years old.

The survey also involves a blood test. The test does not tell us whether or not a person has cholera. It tells us if someone has come in contact with the cholera germ. If you allow us and your child (*children*) agree(s), we will take a blood sample from the vein in your child's (*your children's*) arm. Sterile instruments and new non-reusable equipment will be used to draw your child's (*children's*) blood. The blood sample will be less than 4 teaspoons. There might be some slight discomfort from the needle. Drawing blood sometimes produces a small mark or bruise on the arm. This mark might remain for a few days. A doctor or trained person acting under the supervision of a doctor or health professional will perform the blood test. This person will be here to answer your questions. He or she will also help your child (*children*) with any problems that might arise during the blood test.

The blood test results will not be given back to the participants because they are not a test for disease. They only tell us if someone has come in contact with the cholera germ. If you think you or your child has (*children have*) cholera, please go to a treatment center. The symptoms of cholera are described in the information sheet we will give you and your child (*children*). We can also read this information aloud and answer questions.

The only personal information we will collect is your child's (*children's*) age, sex, and the general location of your house. We will keep your child's (*children's*) information private to the extent allowed by law. Only the study team, the MSPP, and the ethics committees can see this information. All the information will be kept in locked computer files. Information will be in summarized in reports. No one will be able to identify your child (*children*) or anyone else.

This survey is completely voluntary. You or your child (*children*) may choose not to be part of this survey or to stop being part of it at anytime. You or your child (*children*) may choose not to

answer any question for any reason. You or your child (*children*) may choose not to have a blood test. There will be no penalty if you or your child (*children*) decides not to participate. There are no direct benefits to you or your child (*children*) from participating in this survey either. However, you will help the Ministère de la Santé Publique et de la Population know more about cholera. You and your child (*children*) will also help us learn about how to respond better to cholera.

If you or your child (*children*) have questions or concerns about this survey or the blood test, you can call (*name of contact*) at the Ministère de la Santé Publique et de la Population (MSPP) at (*phone number*). If you have concerns regarding your, or your child's (*children's*), personal rights in the study, you can call (*name of contact*) from the MSPP Ethics Committee at (*phone number*).

AGREEMENT:

The risks and benefits of this study have been explained to me. I have had a chance to ask questions. All my questions were answered. My child (*children*) and I can choose to be in this study. We can drop out of the study at any time. I will receive a copy of this form.

I agree to let my child (*children*) participate.

Yes

No

CONSENT FOR STORAGE OF BLOOD SAMPLE

We want to store any blood that is left over after we do your child's (*children's*) test(s). We plan to use this blood for studies we will do in the future to learn more about cholera and other diseases. We will not test your child's (*children's*) blood for HIV at any time. Your child's (*children's*) name(s) and any other identifying information will not be put on the blood sample(s) when we store it (*them*). We will store your child's (*children's*) blood labeled with your child's (*children's*) age, sex, and blood test results. There will be no way to know the blood or the other information is your child's (*children's*). We will not be able to report back any future test results to you about your child (*children*). You can refuse to let us store your child's (*children's*) blood and still be in this survey. The blood will be stored at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia.

I agree that my child's (*children's*) blood sample(s) can be stored for future use.

Yes

No

Assent Form (Children Aged 7–17 years) (Flesch-Kincaid Reading level 4.5)
(NOTE: Assent form will be translated into Haitian Creole for use in the field)

(Parent or guardian should have already completed the parental consent form)

WHY IS THIS STUDY BEING DONE?

We are asking you to be in a research study. We want to learn about a disease called cholera so that we can better help people with the disease. Cholera *can cause severe diarrhea*. We asked your parents and they said it was fine for you to be in the study if you want to.

WHAT WILL HAPPEN?

If you agree, we will ask you or someone in your home about

- Whether you have had cholera
- Your visits to clinics and hospitals for cholera
- Treatments you have for cholera

You can refuse to answer any question. You can refuse to let others give us any information about you.

The survey also involves a blood test. This test does not tell us whether or not you have cholera. It tells us if you have come in contact with the cholera germ. If you allow us, we will take a blood sample from the vein in your arm. The blood sample is less than 4 teaspoons. Clean and new equipment will be used to draw your blood. The needle we use might be a little uncomfortable. Sometimes it causes a small mark or bruise on the arm. This mark might remain for a few days. A doctor or trained person acting under the supervision of a doctor or health professional will perform the blood test. This person will be here to answer your questions. He or she will also help you with any problems that might arise during the blood test.

You do not get a reward for being in the study, but you will help the Ministère de la Santé Publique et de la Population know more about cholera. You will also help us learn about how to respond better to cholera.

PRIVACY:

What we talk about and your blood test results will be kept private.

VOLUNTARY:

You do not have to be in this study. It is up to you. You do not have to a blood sample if you do not want to. You do not have to answer questions or let other people answer questions about you. You may change your mind at any time.

IF YOU HAVE QUESTIONS:

We gave your parents phone numbers of people to contact if you have questions. I can answer any questions you might have right now about being in the study.

AGREEMENT:

Do you want to be in this study?

Yes

No

Index Patient Consent and Permission Form (*Flesch-Kincaid Reading level 6.3*)
(NOTE: Consent form will be translated into Haitian Creole for use in the field)

Cholera Serology Survey of Household Contacts in Haiti

Haiti's Ministère de la Santé Publique et de la Population (MSPP) and the Centers for Disease Control and Prevention (CDC) are doing a research study on cholera. Cholera is caused by a germ that can cause severe diarrhea. It can be spread in food and water.

Some people can be infected with the cholera germ without having diarrhea. These people can still transmit the germ without knowing it. We are trying to learn more about why some people get very sick from cholera and some do not get sick at all. We are asking for your help because you have had cholera. We are asking for permission to talk with people that live with you. We would like to ask them if they will be part of this study to learn more about cholera. There is no cost to participate in this research study.

This study involves a set of questions about cholera and diarrhea symptoms. These questions will take fewer than 10 minutes to complete.

The survey also involves two blood tests. One blood test is when they start the study. The second blood test is two weeks later. These tests do not tell us whether or not a person has cholera. They tell us if someone has come in contact with the cholera germ. Each blood sample will be about two teaspoons and will come from a vein in the arm. Sterile instruments and new non-reusable equipment will be used to draw the blood. There might be some slight discomfort from the needle we use. Drawing blood sometimes produces a small mark or bruise on the arm. This mark might remain for a few days. A doctor or trained person acting under the supervision of a doctor or health professional will perform the blood test. This person will be able to answer questions. He or she will also help with any problems that might arise during the blood test.

The blood test results will not be given back to the participants because they will not tell us if a person has cholera. They only tell us if someone has come in contact with the cholera germ. If you think you or your child has cholera, please go to a treatment center. The symptoms of cholera are described in the information sheet we will give you. We can also read this information aloud and answer questions.

Each person in the study will be given a number. Their names, address, and these numbers will be put on a list so that we can return for the second blood sample if they agree. After we collect the second sample, this list will be destroyed and there will be no link between their names, blood samples and questionnaires. The general location of their house, their ages and their sexes are the only personal information that will be kept at the end of this study. We will keep the information they give us private to the extent allowed by law. Only the study team, the MSPP, and the ethics committees can see this information. All the information will be kept in locked

computer files. Information will be summarized in reports.

This survey is completely voluntary. A person may choose not to be part of this survey or to stop being part of it at anytime. A person may choose not to answer any question for any reason. A person may choose not to have a blood test. There will be no penalty if a person decides not to participate. There are no direct benefits to people who participate in this survey either. However, they will help the Ministère de la Santé Publique et de la Population know more about cholera. They will also help us learn about how to respond better to cholera.

If you have questions or concerns about this survey or the blood test, you can call (*name of contact*) at the Ministère de la Santé Publique et de la Population (MSPP) at (*phone number*). If you have concerns regarding your personal rights in the study, you can call (*name of contact*) from the MSPP Ethics Committee at (*phone number*).

AGREEMENT:

The risks and benefits of this study have been explained to me. I have had a chance to ask questions. All my questions were answered. I can choose to be in this study. I can drop out of the study at any time. I will receive a copy of this form.

I agree to participate. Yes No

CONSENT FOR STORAGE OF BLOOD SAMPLE

We want to store any blood that is left over after we do your test. We plan to use this blood for studies we will do in the future to learn more about cholera and other diseases. We will not test your blood for HIV at any time. Your name and any other identifying information will not be put on your blood sample when we store it. We will store your blood sample labeled with your age, sex, and blood test results. There will be no way to know the blood or the other information is yours. We will not be able to report back any future test results to you. You can refuse to let us store your blood and still be in this survey. The blood will be stored at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia.

I agree that my blood sample can be stored for future use. Yes No

PERMISSION TO CONTACT HOUSEHOLD MEMBERS:

We are also asking permission to talk to the people that you live with about this study. You can give us this permission even if you do not want to participate yourself.

I give permission to talk to the people that live with me. Yes No

I live at: _____ (*address*)