

Attachment H. Consent Forms for Zika Persistence Study

Flesch-Kincaid reading level = 7.8

This form documents the consent/parental permission/assent of the following (check appropriate box):

Consent	Parental Permission	Assent
<input type="checkbox"/> Adult <input type="checkbox"/> Emancipated minor, age 14-20y <input type="checkbox"/> Legally emancipated <input type="checkbox"/> Married <input type="checkbox"/> Pregnant or likely pregnant <small>(likely pregnant means believes to be pregnant but has not tested)</small> <input type="checkbox"/> Has children <input type="checkbox"/> Lives independent from parents	<input type="checkbox"/> Parent of a child < 7 y of age <input type="checkbox"/> Parent of a child 7-13 years of age (verbal assent of child also required) <input type="checkbox"/> Parent of a non-emancipated child 14-20 years of age (written assent of child also required)	<input type="checkbox"/> Non-emancipated child age 14-20 y (parental permission also required) <i>Assent of children age 7-13 y is to be obtained verbally using script.</i> <i>Assent is not required for children younger than 7 y.</i>

For non-emancipated minors age 14-20 y, assent and parental permission may be documented on the same form, or separate forms may be used.

CONSENT/ASSENT/PARENTAL PERMISSION TO PARTICIPATE IN THE ZIKA VIRUS PERSISTENCE STUDY AT SAINT LUKE'S EPISCOPAL HOSPITAL IN PONCE, PUERTO RICO.

If you are a parent giving permission for your child, references to "you" apply to your child.

Purpose of the study

The Centers for Disease Control and Prevention (CDC) and the Puerto Rico Department of Health (PRDH) work together to detect and prevent Zika in Puerto Rico. The CDC is conducting a research study related to Zika virus and we are inviting you to take part. We are looking for patients who have the virus. The goal of this research study is to learn how long the virus can be found in blood and other body samples. About 350 persons will participate in the study. The main investigator for this research study is Dr. _____ from the _____.

It is your decision to take part or not. Feel free to ask any questions of me, the main investigator, or anyone else at any time.

What will happen if you or your child decides to join the study?

If you join the study, we will ask you to attend between 8 to 20 study visits. If you still have particles of the virus at 9 months, we may ask you to attend additional visits. If you prefer, you can also choose to have a member of the study team come to your house. A member of the study team will call you to remind you about your visits.

At the first visit, we will ask you a set of questions about your health in a private setting. We will ask for samples

of your blood, saliva and urine. We will also ask for a semen or vaginal sample from persons who are 21 years of age or older. Each study visit will last about an hour.

Blood: we will collect about half a tablespoon (7 ml) from a vein in your arm. For children weighing less than 37 pounds, the amount of blood we collect will be less than half a tablespoon.

Saliva: a nurse will place a swab between your cheek and gum, and rub gently for about a minute.

Urine: we will give you a sterile cup to collect a urine sample.

Females 21 years of age or older only: we will give you another soft cotton swab to touch your vagina and collect a sample of vaginal fluids yourself.

Males 21 years of age or older only: for the semen collection, we will ask you to spend time alone in a private room to masturbate and provide semen in a special cup.

We will collect these same samples and ask about your health at follow-up visits. For the first 4 weeks, the visits will be one week apart. After 4 weeks, visits will be 2 weeks apart. These visits will continue until all of your samples test negative for Zika virus twice in a row. We will also ask you to attend additional visits or allow the study team to visit your home at 2, 4, 6 and 9 months after you start in the study, to collect a sample of blood and other body fluids.. The exact number of visits will depend on how long we are able to detect Zika virus in your body. There could be as few as 8 visits, or as many as 20. You may decide to stop your visits at any time during the study.

Samples will be sent to the laboratories at the CDC Dengue Branch in San Juan, Puerto Rico and all samples will be tested to see if parts of the Zika virus are present. Some samples may also be sent to the CDC laboratories in the United States. If the sample tests positive the Zika virus, a portion of that sample will undergo further testing to see if the virus is still alive. Blood samples will also be tested for antibodies (proteins in the blood that fight germs) to Zika virus. You will be given all of your Zika test results and the results will be explained to you.

A pregnancy test will be offered to all women who would like to receive one, and the results will be kept confidential. If you are pregnant we will put you in contact with antenatal care as you wish.

After this study is over, we would like to store your samples so we might use them for other studies to better understand Zika, dengue and other diseases. Your samples will not be used for human genetic testing. If additional diagnostic testing occurs in the future, you will be notified of results that are relevant for your health. You can still take part in this study, even if you do not want us to store your samples. At the end of this form, we will ask you to tell us whether or not you agree to let us store your samples. If you agree, you can contact us at any moment to request removal of your specimens from storage, if you change your mind.

Are there benefits in joining this study?

If you join this study, you will learn if you still have Zika virus present in your body. You will receive the results of Zika tests on your body fluids and counseling on the meaning of the test results as well as information on how to prevent passing the virus to other people. It is your choice whether or not to receive the test results. Either way, the results will help us learn about the Zika virus and how to prevent Zika from spreading in the future. Participants will receive condoms, counseling, and linkages to health services as needed.

Are there risks for participating in this investigation?

The risks of being a part of this study are very small and have to do with getting the blood sample. When we take blood from the arm with a sterile needle, you may feel some pain or get dizzy, and you may get a bruise or

red mark where the needle goes into the skin. Very few people also get an infection. Putting a swab in your mouth to take saliva can feel uncomfortable. There are no known risks for urinating into a cup, but infants may have a local skin reaction caused by the sticky portion of the urine collection bag. Some people may feel embarrassed providing personal information during the health survey, but trained study staff will keep your answers private. For participants age 21 years or older, collection of semen/vaginal fluids may make you feel uncomfortable. Receiving results of Zika testing might be stressful to you. We will not be providing compensation for complications that may arise while enrolled in the study. We will not cover for your prenatal care if you find out you are pregnant.

What about privacy?

We will keep your information private to the extent allowed by the law. We will not share test results with anyone, except you and your doctor. We will keep study records and test results in locked cabinets. Only study staff will be allowed to review this information. When we talk or write about this study, we will not include your name or other facts that might identify you. Your name, phone number and address are requested in this consent form so that we can contact you to tell you the results of your tests, and to remind you about the study visits.

Voluntary participation

You do not need to be in this study. It is your choice. If you agree to be in the study you may change your mind and can leave the study at any time. If you decide not to be in this study, or if you decide to leave the study, you will not lose any healthcare benefits. You can see your doctor or visit your clinic or hospital, as you usually do.

Alternatives

Blood tests for Zika virus can be requested by doctors for people who are sick. But Zika tests of other body fluids is not generally available outside this study.

What will be the costs of the tests?

The tests that will be done for the study are free. You do not have to pay for the results.

You will receive \$50 for each visit for your time, transportation, and effort.

Who can I call if I or my child has problems or question about the study?

We will give you a copy of this paper for you to keep. If you have questions, doubts, believe that you were harmed by being in this study, or want to remove your samples from long term storage, you can contact: Dr. Tyler Sharp at (787) 706-2399, or Project Manager: Mrs. Olga D. Lorenzi at (787) 844-2080 x: 1437. If you have questions regarding your rights as a participant in this study, you should contact Dr. Simon Carlo, Chairman, Ponce School of Medicine and Health Sciences Institutional Review Board at (787) 840-2575, x: 2158.

CONSENT (ASSENT/PARENTAL PERMISSION) STATEMENT

If you agree to be in this study, please sign below. By signing this form, you are saying that:

- You read this entire form or someone read it to you.
- You were given a chance to ask questions and all of your questions were answered.
- You voluntarily accept to be part of this study.
- You agree to answer questions about your health.
- You agree to have your blood drawn and urine, saliva and [age 21 or older semen/vaginal samples] collected for Zika virus testing.
- You were given a copy of this form to keep for your records.

____ *I agree to participate in this study including filling out the forms and giving blood, urine, saliva and semen/vaginal samples.*

Do you agree to let CDC store your samples for future studies?

- YES**, I agree to store my samples and to be used in other studies to understand disease.
- NO**, I do not agree to store my samples.

May we contact you for future studies?

- YES**, I agree to be contacted for future studies.
- NO**, I do not agree to be contacted for future studies.

----- ***I do not agree to participate in this study.***

PATIENT OR REPRESENTATIVE SIGNATURE FOR CONSENT

Patient name (*print*):

Paternal last name Maternal last name First name Second name

For adult patients and minors age 14-20 (both emancipated and non-emancipated):

Patient's signature: _____ **Date:** _____

For parents of non-emancipated minors age 14-20, and parents of children younger than 14:

Parent's name (*printed*): _____

Parent's signature: _____ **Date:** _____

If parental permission is sought verbally by telephone, please confirm the following:

- Participant is a non-emancipated minor age 16-20.
- Participant was not accompanied by a parent.
- The parent gave verbal parental permission via telephone.

Name of staff member obtaining verbal permission: _____

VERBAL ASSENT SCRIPT TO PARTICIPATE IN THE ZIKA PERSISTENCE STUDY AT SAINT LUKE'S EPISCOPAL HOSPITAL, PONCE, PUERTO RICO.

This script must be used to obtain verbal assent for minors 7-13 year old. Child assent should be sought only after written parental permission for the child's participation is obtained.

Hi! My name is *(recruiter's name)*. I am *(student, nurse, resident, physician)*. I would like to ask you be in a study. I want to explain what will happen if you decide to be in the study. Your (mom, dad) will answer some questions about how you feel. A nurse will take a sample of blood from a vein in your arm, swab your mouth, and ask you to pee in a cup. If you agree to be in the study, we will do this every week for the next month, and then every 2 weeks for the next few months after that.

By being in the study, you will help us understand how long the Zika virus can be found in blood and different body fluids, including blood.

Your (mom, dad) have said it's okay for you to be in the study. But if you don't want to be in the study, you don't have to be. No one will be upset if you don't want to be in the study. If you agree but change your mind later, that's okay. You can stop at any time. If there is anything you don't understand you should tell me so I can explain it to you. Do you have any questions for me now?

If you have any questions during the study, you can ask your parents, or any member of the study staff.

Would you like to be in my study? Yes No

NOTES TO RECRUITERS: The child should answer "Yes" or "No." Only a definite "Yes" may be taken as assent to participate.