

Attachment D: Zika Investigation Household & Individual Consent Form, to be administered to the head of household (Flesch-Kincaid grade level – English: 7.7)

The U.S. Centers for Disease Control and Prevention (CDC) and Puerto Rico Department of Health are doing a research study about a disease called Zika. This disease causes rash, fever, and muscle and joint pain. It is carried by the same mosquitoes that transmit dengue virus. Zika virus was only recently introduced into Puerto Rico, so we are trying to find out if more people have been infected with the virus than have been reported to the Department of Health. This will give us a better idea of how much of a problem Zika is in Puerto Rico, which will then make us better prepared to prevent additional people from getting sick.

We are trying to get information about the daily practices of people who got sick to try and figure out where they may have been infected. We also want to get the same information from people who lived in the areas around people who got sick. With this information, we will try to identify risk factors for infection, and also possibly identify people that have been infected but may not have known that they were infected.

We would like your household to take part in this study. If you agree, we will ask you some questions about your household practices. We will also invite all members of your household, including you, to answer a short survey (~10 minutes) about recent illnesses. Each household member would be free to agree to take part or not, or to stop at any time, without penalty. The household may still take part in the study, even if some members choose not to take part.

We would like to collect a small amount of blood (about 2 teaspoons), a urine specimen, and a saliva specimen from each household member that agrees to take part in the study. Blood will be collected through a vein in the arm, using a small needle. This may cause minor pain or bruising. Each household member will be tested to see if he/she has been infected with the virus that causes Zika. We will send individual test results in about 3–6 months.

If any blood, urine, or saliva specimens are left over after we finish this testing, we would like to store what is left for future testing related to infectious diseases. We will not perform human genetic testing or test for HIV. We will send the results of any future tests that may be important for that person's health.

Household members are free to refuse storage for future testing. Those who do not want their blood stored may still take part in the rest of the study. Those who agree to storage may contact the study investigator at the number listed below if they change their minds and want to withdraw their consent for storage.

All of the information collected for this study will be kept private to the extent allowed by law. Only the study staff will be able to see it. There is a small risk that people not involved with the study could see your information. Study reports will be in summary only. No information will be shared with others that can identify you personally.

Your household's part in this study is completely voluntary. You are free to decline your household's part in this study, or to stop at any time, without penalty. You may decline some parts of the study and still take part in others.

If you have any questions about this study, or if you feel you or a member of your household has been harmed by this study, you may contact Dr. Tyler M. Sharp at (787) 706-2399. If you have questions about your rights as a research subject, you may contact Dr. Carmen Pérez at (787) 706-2489.

Please take a moment to decide. Feel free to ask as many questions as you need. When you have decided, please check the boxes below to indicate your choice. If you are the parent or legal guardian of any children in this household, we ask your permission for your child/children to take part in the same activities. If you agree, we will also ask the child directly if he or she wants to take part.

Permission for household participation

I agree for my household to join this study. This includes answering a brief survey (~5 minutes) about household practices, and permission to invite all household members, including myself, to take part in individual surveys and give a small sample of blood as well as urine and saliva specimens.

- Yes
- No
- Please exclude my household from future rounds of this study.

*If you have indicated that you do not want your household to take part in this study, you may skip the rest of this form.*

Individual consent

I give consent to take part in this study. I have been given the opportunity to ask questions, and all of my questions have been answered. I have been told that my participation includes answering a brief survey and giving a small sample of blood as well as urine and saliva specimens.

- Yes
- No

Consent for storage of specimens

I give permission for study investigators to store my leftover samples for future research related to infectious diseases. If I am the parent or guardian of any child in this household, my permission to store or not store my child's/children's leftover specimens is indicated in the next section.

- Yes
- No

Permission to include children

I am the parent or legal guardian of the children listed below. I give permission for the following children to take part in the survey and/or collection of blood, urine, and saliva specimens, and for leftover specimens to be stored for future testing related to infectious diseases, as indicated below.

Child's Name	Survey	Blood draw	Urine specimen	Saliva specimen	Storage of leftover specimens
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

There are no children in this household.

I am not the parent or legal guardian of any children in this household.

Signature

My signature below indicates that I give consent and/or permission for the activities indicated above. I have had the chance to ask questions, and all of my questions have been answered. My consent is given freely.

Name (printed): \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_