

Study of Zika Virus Shedding in Semen and Urine of Adult Men

PHONE SCRIPT & CONSENT

Hello. My name is [NAME]. I work at the U.S. Centers for Disease Control and Prevention (CDC) and received your name from the [HEALTH DEPARTMENT] _____ or [PHYSICIAN] Dr. _____.

I am calling you because we are conducting a study of men who have been infected with Zika virus. You do not have to take part in the study, but I'd like to tell you about it in case you might be interested. It should only take a few minutes to explain. Is now a good time?

[If no] Is there a better time when I might call you back? _____

[If yes - continue]

[If "I'm not interested" - OK. Before we hang up, would it be OK if I quickly review the current recommendations for men, such as yourself, who have been infected with Zika virus? :

[If yes - (read prevention recommendations at end)].

[if no - OK. Please know that they are available on the CDC.gov website. Thank you for your time.

As you may know, Zika is a virus that has been causing illness recently in central and South America. It is usually spread by mosquitoes, but we now know that it can also be spread by men to their sexual partners. Because the virus has been linked to birth defects, this is a big concern for pregnant women or couples trying to get pregnant. The goal of our research is to find out how often - and for how long -- the virus is found in the semen and urine of infected men. This information will help us better advise people on how to prevent sexual transmission of Zika virus and potentially prevent birth defects and other conditions linked to Zika virus.

>Let me stop here briefly: do you have any questions?

<Purpose of the research>

As I said, Zika virus has been found in semen and urine of infected men. In at least one patient, it was found 62 days after the patient's illness. The purpose of our research is to get more information on how long the virus is shed in these fluids so that we can better prevent sexual transmission of this virus.

<Type of Research Intervention>

Our records indicate that you are an adult man who was recently sick with Zika virus, and we are contacting you to ask you to take part in this study. If you agree to be in the study, you will be asked to give samples of your urine and semen every 2 weeks for up to 6 months after your illness started. We will test your samples for Zika virus and give you the results at the end of the study. You will collect the samples at home and will be paid for your time and effort.

<Voluntary Participation>

Being in this research study is up to you. It is your choice whether to take part or not, and your medical care will not change if you decide not to be in the study. You may change your mind and stop being in the study at any time. If you withdraw from the study, we will still give you your test results.

Public reporting burden of this collection of information is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA 0920-XXXX

➤ I'd now like to explain the study in more detail. Would that be OK?

<Overview of Study Procedures>

If you agree to take part, we will ask you a few questions today about the symptoms you had at the time you were sick with Zika virus. Within a few days, we will send you the first sample collection kit with instructions for collection of urine and semen.

We will ask you to collect your samples yourself at home once every 2 weeks, and ship them back to us. For the urine test, we will ask you to pass urine into a cup sent to you in the kit. For semen, you will masturbate and provide the sample in a different cup. You will send the samples back in a special box that will be picked up free of charge at your home by FedEx.

After receiving your first set of samples, we will send you a new sample collection kit within 2 weeks. This will include new cups for your next set of samples, a brief survey about your current health, and a \$50 gift card. This process of sample submission will be repeated every 2 weeks for up to 6 months after the date you became ill with Zika virus. The maximum number of times you can submit specimens will be 12, and the maximum compensation you would receive would be \$600.

Your samples will be tested at the CDC laboratory in Fort Collins, Colorado. We will test to see if pieces of the Zika virus are present. If one of your samples tests positive for Zika virus, part of that sample may be used for more tests to learn about Zika virus.

We will give you your test results after you are done being in the study, and we will explain what your results mean.

All of your information will be kept private. You can decide not to answer any questions for any reason. If you decide not to answer any questions you can still be in the study.

➤ I am almost done explaining the study and will ask you shortly if you would like to take part. Before going further, do you have any questions about what I have said so far?

<Risks and Benefits>

This study has certain risks and benefits. Some people may feel embarrassed answering the health survey, but trained study staff will keep all information private. You may benefit from receiving the results of Zika tests on your urine and semen, and from information on how to stop from giving the virus to other people. It is your choice whether or not to receive the test results.

The results of this study will help us all learn more about Zika virus and how to prevent Zika from spreading.

<Confidentiality>

We will keep your information private to the extent allowed by law. You will receive a unique study ID number to identify you. You can answer questions freely and all answers and results will be kept confidential. Only the study staff will know your study ID number and we will securely store that information. We will not share your identity with anyone outside this study.

<Right to Refuse or Withdraw>

It is your choice to be in this study or not. There is no penalty if you decide not to take part, or to withdraw. If you withdraw from the study you will still get your test results, and we will explain what they mean and what measures you can take to reduce the risk of making other people sick with Zika virus.

<Who to Contact>

You can contact the study manager, Dr. Alison Hinckley, or the Principle Investigator, Dr. Paul Mead, at (970)-221-6400 with any questions you may have. You may also call them if you feel you have been harmed by being in this study. If you have any questions about your rights as a participant in this study, please contact CDC's Human Research Protection Office at (800) 584-8814. Leave a message with your name, phone number, and refer to protocol #XXXX, and someone will call you back.

➤ Do you have any questions? Are you willing to participate in this research study? Yes or No

By answering yes, you _____ [PARTICIPANT'S FULL NAME] agree to participate in the study.

We would also like to ask your permission to store any unused portions of your samples and any samples of Zika virus found in your samples for future testing. Your samples will be stored without a link to your name. We will not test your samples for HIV, or use your samples for human genetic testing. If we share samples with other researchers, they will not be able to find out who you are. However, because we will not have a link to your name, we will not be able to remove your sample from storage if you change your mind later.

You can still be in this study even if you do not agree to let us store your samples.

Agree for laboratory to store samples yes no

If no to above:

Agree for laboratory to store virus only yes no

I, [insert name of staff person seeking verbal consent], attest that I have read this information to the participant, that he appeared to understand the information presented, and that he voluntarily gave his consent to take part in this study.

Researcher Signature: _____ Date: _____

<Introductory Survey>

Thank you for agreeing to take part in this study. Now, I have just a few questions about you and how best to ship to you. I will also ask for other ways to contact you:

What is your current age? _____(Should already be known from surveillance data, this is to confirm).
What is your home address? I need this to send you your collection kits.

Is there any day of the week when you do not want or cannot have packages delivered to you at this address?
Y/N If yes, what day of the week?

Do you have an email address? We will use this to send you reminders about the study. As you know, we will not share your information with anyone outside of the study.

Do you have another phone number at which we could text you? _____

Now I will ask you just a few questions about your recent Zika virus disease:

Date of first symptom: ____/____/____			
Fever	Yes	No	Unknown
Headache	Yes	No	Unknown
Joint Pain	Yes	No	Unknown
Rash	Yes	No	Unknown
Red Eyes	Yes	No	Unknown
Difficulty Urinating	Yes	No	Unknown
Frequent Urination	Yes	No	Unknown
Pain or Burning with Urination	Yes	No	Unknown
Blood in Urine	Yes	No	Unknown
Blood in Semen	Yes	No	Unknown
Other			

<<prevention messages>>

That's all the questions I have. Before we finish, I want to make sure you are aware of the current recommendations for men, such as yourself, who have been infected with Zika virus:

- If your partner is pregnant, you are advised to abstain from sex or use condoms correctly each time you have sex. You should do this until the end of the pregnancy.
- If your partner is trying to become pregnant, you are advised to delay for 6 months. During this time, either abstain from sex or use condoms correctly each time you have sex.
- If you are otherwise worried about giving Zika virus to a sexual partner, you should abstain from sex or use condoms correctly each time you have sex. You should do this for 6 months from the time you became ill with Zika virus.
- Finally, mosquitoes can pick up Zika virus from people who are sick with it. When that happens, mosquitoes can make other people sick. To avoid this, you and any others in your household who are sick with Zika virus should use repellent regularly until symptoms are gone.

Again, thank you for agreeing to take part in this important study. If you have any questions, please feel free to call or email us. Our contact information will be on the forms we send to you in your first kit. At that time, we will also send you more information about this study and about Zika virus disease.

Do you have any other questions before we hang up?