

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

COPY of CONSENT
Please Keep for Your Records

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.

<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.

<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.

<Risks and Benefits>

This study has 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.

If you gave permission, 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.

<Prevention messages>

Here are the current recommendations for men 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.