

3.2 Women's Survey and HIV Testing Consent Form

Form
Approved
OMB NO. _____
Exp. Date _____

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Flesch-Kincaid grade level: 6.6

A. Study Purpose

You are being asked to take part in a research study. The study is being done by [name of Institution] and the Centers for Disease Control and Prevention (CDC).

The purpose of the study is to learn about the things that may put women at risk for getting HIV. HIV is the virus that causes AIDS. This virus hurts your immune system, the part of your body that protects you from infections.

We hope that XXX hundred [Black or Latina] women from [site] will take part in this study. We expect a total of 1350 women to join the study at our three study sites. We are asking you to be in this study because you said that you have had sex with a man in the past 12 months and that you are 18 to 59 years old. As part of the study, we will ask you to do a computer survey and take an HIV test. Before you decide about being in this study, I will read this form to you. Please ask me any questions you may have.

B. Study Procedures

We will use a computer to ask you the survey questions. We will ask you about your sexual behaviors, drug use and other things that may put women at risk for getting HIV. A computer voice will ask you questions and you will enter your answers into the computer to keep your answers private. We will show you how to use the computer. Someone from this study will be nearby if you need help using the computer during the survey. We will also ask you to be tested for HIV. It will take about 1 ½ hours for both the computer survey and the HIV testing.

If you agree to be in the study, you agree to these things:

1. Take a computer survey (about 45 minutes). You can refuse to answer any questions you do not want to answer.

2. Be tested for HIV (45 minutes). The HIV testing will be done in 4 steps.
 - First, we will tell you about HIV and HIV tests. This is called pretest counseling. We will give you a rapid HIV test after the pretest counseling.
 - Second, we will tell you the results of your HIV test in about 30 minutes. We will tell you what your test result means. This is called post-test counseling.
 - Third, a positive HIV test means it is likely that you have HIV. If your rapid HIV test is either positive or uncertain, we will do a different HIV test to check the result.
 - Fourth, if your rapid HIV test result is positive today, we will ask you if you want to have a blood test to check your CD4 cell count. The CD4 cell count tells us about the health of your immune system. These and other study activities are explained next.
 - a. Pre- and Post-test Counseling: You and your counselor will talk about the reason for having an HIV test and what the test result means. Some of the counseling will be done before the rapid HIV test, and some will be done after the rapid HIV test.
 - b. Rapid HIV Test: An HIV testing stick that looks like a square lollipop will be placed in your mouth for a few minutes. Your test result will be ready in about 30 minutes.
 - c. Getting Rapid HIV Test Results: The counselor will tell you your test result before you leave. If your HIV test is negative, the counselor will tell you how you can lower your chances of getting HIV. If your HIV test is either positive or unclear, the counselor will test you again using a different HIV test.
 - d. Confirmatory HIV Test: A second HIV test is done to check all positive rapid HIV test results. This is called a confirmatory test. Like the first test, we take a sample from your mouth. This time, we will send it to a lab to get the result. We will put a code number on the test tube. We will not use your name or other contact information to keep your personal facts private. We will set up a time for you to return in about two weeks to get the result of this HIV test. It is very important that you come back for your test result.

Very rarely, these two test results are different. If that happens, we will do a confirmatory blood test. We will take about 2 teaspoons of your blood by needle from a vein in your arm and send your blood sample to the lab for more HIV testing. We will put your code number on the test tube like before. We will set up a time for you to return two weeks later to get the result of this blood test. Again, it is very important that you come back for your test result.

- e. CD4 count: If you test HIV-positive, we will ask if you would like have your CD4 count checked. This blood test measures the health of your immune system. We will take 3 teaspoons of blood by needle from a vein in your arm for this test.
 - f. Talk to an HIV case manager: It is very important to get proper medical care if you have HIV. If you test positive for HIV, we will help you talk with an HIV case manager if you want this help. An HIV case manager can help you get HIV medical care as well as help you with other things you may need.
 - g. Contact Information: As part of HIV testing and counseling, we will ask for your name, phone number, address and an email address, if you have one. All women in the study will be asked for this information before they take the HIV test. We will use your contact information if we need to reach you to give you your HIV test result. An HIV case manager will use your contact information to get in touch with you if you test HIV positive and you want help getting HIV medical care.
3. We will talk with you about whether you want to invite other [Black or Latina] women you know into the study. If you do not want to do this you can still be in the study and take the computer survey and the HIV test. If you agree to help recruit other women into the study, we will tell you how to do this. This will take about 10 minutes.

C. Risks

There are minimal risks to you if you take part in the study. You may have these risks from being in the study:

1. A positive HIV test means that you have HIV. If your HIV test is positive, you might feel worried or depressed about whether you will get sick from HIV.
2. People with HIV sometimes face discrimination.
3. If your results are negative, the results might be wrong and you could still be HIV positive. Your infection may be too recent to find with the HIV test you take today.
4. Taking blood may cause pain, bruising, swelling and rarely, a local infection or small clot. Some people faint but this is rare. The person who will take your blood sample has been trained to do this.
5. Some questions may ask about things that make you feel uncomfortable or cause you stress. You can refuse to answer any question in the survey.

D. Benefits

This is not a treatment study so there is no direct medical benefit to you. The personal benefits you may get from being in the study include:

1. If you test positive for HIV, you will learn about getting health care and how you can prevent giving HIV to others. We will help you make contact with an HIV case manager who can help you get medical care if you want

this help. You will get a record of your test results so that you can get HIV-related social and medical services.

2. You will learn about how to have safer sex in order to maintain your health.
3. You will learn about other services if you want or need them.

The community benefits from this study may include:

4. The answers to the survey may help us improve HIV prevention programs for Black and Latina women.

E. Keeping Your Records Private

If you test positive for HIV, we must report your name and contact information to the state health department because this is required by state law. The HIV-positive test result and any HIV-related information about you are private based on state laws and regulations. Only study staff and authorized health department staff will see HIV-positive test results.

Only your code number, not your name, will be used in the computer survey. The HIV counselor will not see your survey answers but other people working on the study may see your survey. All of the surveys from the women in this study will be kept on a computer or storage device that is protected by a password. Paper study files, like this consent form, will be locked up and destroyed within five years.

Your contact information in our study files will be destroyed within 3 months after you take part in the study. After your information is destroyed, there will be no way to link you to your survey.

We will keep your records private. This study has applied for a Federal Certificate of Confidentiality. This means we cannot be forced to give out any information that would identify you.

When we write about the results of this study, we will use only numbers and not names or personal facts. No one will be able to link the results back to you. We will do this to keep your personal facts private.

F. Voluntary Participation

You are free to join the study or not. If you do not join, you will not lose any services that you expect to get apart from this study. If you decide to join the study, you are also free to drop out later for any reason. In that case too, you will not lose any services that you may expect apart from this study.

You may refuse to answer any question or simply not talk about a matter that you do not wish to discuss.

G. Alternative Treatment

This is not a medical treatment study. Your alternative is not to be in the study.

H. Costs

There is no cost to you for being in this study.

I. Payment

We will give you \$50 [site to insert gift card or cash] after you complete both the computer survey and HIV testing as a thank you. You may also get up to \$45 [cash or gift certificate] if you bring other women into the study. You may recruit up to three women. You will get \$15 [cash or gift certificate] for each woman you bring into the study who passes the study screening questions and completes the study.

J. Compensation for Injury

There are minimal risks to you if you take part in this study. If you are injured, the study staff will help you get medical care. The cost for that medical care will be billed to you or your insurance company. [Site Name] and the CDC do not pay you for these costs. However, by signing this form you are not giving up any of your rights. Free health care is offered at any public hospital or [Name of local clinic].

K. Questions

If you have questions about this study or if you think you have been harmed as a result of being in this study, you can contact [Local contact person (s), phone number (s) and institution (s)].

If you have questions about your rights as a research subject, you may contact the head of the [Local Institutional Review Board], at [phone number]. You may also contact the office of CDC’s Deputy Associate Director for Science at 1-800/584-8814 where you can leave a brief message with your name, phone number, and CDC protocol number #5011 for this project.

L. Ending Your Participation

If you decide to join the study, you are free to drop out later for any reason.

We will not let you be a part of the study if you are not able to give legal consent to be in the study. If you are not part of this study, you will not receive a payment.

M. Duty to Protect

If you tell us that you plan to harm yourself or another person, we are required to contact the proper authorities.

N. Agreement

I have read (or someone has read to me) the information above. I have had all my questions answered. I have been given a copy of this form. I agree to be in this study including having HIV testing and taking the computer survey.

Date

Participant’s signature, initials, or alias

Date

Signature of person obtaining consent

I want to have a CD4 count blood test done if I test HIV-positive.

I DO NOT want to have a CD4 count blood test done if I test HIV-positive.

Date

Participant's Signature, initials, or alias

Date

Signature of person obtaining consent

