

Attachment 8. Model Consent Form

Grade Reading Level by Flesch-Kincaid Method: 7.2

National HIV Behavioral Surveillance System Model Consent Form

The [Agency Name] and the Centers for Disease Control and Prevention (CDC) invite you to be part of a research study of persons who may be at risk for HIV infection. The information I will give you can help you make a good choice about joining the study.

A. Purpose

The purpose of this study is to learn about risk for HIV. We will use this information to plan better HIV prevention and treatment programs for people in your community. Being in this study is voluntary.

B. Procedures

If you agree to be in this study, this is what will happen.

1. You will do a survey with a trained staff member. The survey has questions about your health, drug use, sex practices, and HIV prevention services. It will take about 40 minutes.
2. If you agree to the survey, we will offer you a free HIV test.
3. *[For sites doing HIV tests via blood draw only]* If you agree to an HIV test, you will also be asked to have your blood sample stored.
4. *[For sites doing additional lab tests]* If you agree to the HIV test, we will also offer you free *[other lab tests]*.

Survey

This is an anonymous survey. We will not ask for your name or other identifying information. The survey has questions that are personal. They may be hard to talk about. You may refuse to answer any questions at any time for any reason. If you refuse to answer a question or want to end the interview you will not be punished in any way.

HIV test

If you agree to the HIV test, you will have a 10- to 15-minute HIV prevention counseling session with a trained staff member. The session will cover the meaning of results from the HIV test. You will also learn about how to reduce your chances of being infected with HIV and other infectious diseases.

The HIV test will be done by a standard or rapid test as discussed below.

Standard Test

For the standard test, we will [draw less than 1 tablespoon of your blood using a needle/swab the inside of your mouth for oral fluid] and test it for HIV. Your test results will be ready within one week. We will set up a day and time for you to get your results. You will get counseling about what the test results mean

and referrals to services, if needed. If you cannot return for your HIV test results, you can arrange to receive your counseling and test results by telephone.

Rapid Test

With the rapid test, you can get the result of your HIV test within 1 hour. We will [stick the tip of one of your fingers to obtain a few drops of blood/take a swab from your mouth]. You will get counseling about what the test result means. You will get referrals to services, if needed. If the rapid test result is reactive, we will [draw less than 1 tablespoon of your blood by needle/stick the tip of one of your fingers to obtain a few drops of blood/swab the inside of your mouth for oral fluid] for a second test to confirm your rapid test result. The result of the confirmatory test will be ready within one week.

Blood Storage

We would like to store any blood that is left over after we do your test. We plan to use this sample for studies we will do in the future. We will store your sample with some data about you, such as your age, race, and sex. We will not put your name on the sample and there will be no way to know it is yours: thus, we will not be able to report back any test results to you. We will not test for any genetic disease or use blood for cloning or commercial purposes. You can decline to let us store your blood and still be in this study.

Linkage

We will link your test results with your survey so we can learn about sexual and drug-use risk behaviors known to be connected with HIV infection. We will link your test results using the same ID assigned to the survey. This is an anonymous test. Your name will not be on the test results or the survey. No one besides you will be told your test results, and neither the survey nor the test will be placed in any medical record.

[Include any additional test to be offered].

C. Discomforts and Risks

There are minimal risks from being in this study:

1. Some of the questions in the survey are about sex and drugs and may make you feel uncomfortable. All answers you give will be kept private.
2. *[If using standard test: Drawing blood may cause temporary discomfort from the needle stick, bruising, bleeding, light-headedness, and local infection.]*
3. You may feel uncomfortable finding out you might have been infected with HIV. You can talk about your concerns with the trained staff member who tells you your HIV test results, if you wish.
4. If your HIV test result is negative, there is a slight chance that the results are wrong and that you could still be infected or test positive at some time in the future.

D. Benefits

Benefits you may get from being in this study include:

1. You will receive some condoms and information on HIV/AIDS and STDs.
2. You may also receive free referrals to other local programs, medical programs, support groups, and health projects, as needed.
3. If your HIV test results *[or additional tests offered]* are positive, you will be counseled about ways to prevent the spread of infection. You will also be referred for medical care.
4. If your test results are negative, you will receive counseling on how to prevent future infections.

Also, information gained from this study will help the **[Agency Name]** to know more about HIV and how it is spread. This information will be used to improve health programs and to develop new ways of helping others prevent disease and promote good health.

E. Alternatives

If you choose not to take part in the study but would like to take an HIV test, we will inform you of agencies or organizations that provide testing. You will get no medical treatment in this study.

F. Compensation

You will be paid for the time you spend taking part in the study. For completion of the survey, you will get \$25. If you take part in the HIV test, you will get an additional \$25.

G. Persons to Contact

This study is run by: *[name of principal investigator and phone number]*. You may call [him/her] with any questions about being in the study.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact *[IRB committee or contact name and phone number]*.

If you want one, you will get a copy of this form to keep.

H. Confidentiality Statement

What you tell us is confidential. Your responses will be labeled with a study number only. No one except the study staff at **[Agency Name]** and CDC will have access to the survey, except as otherwise required by law. Your responses will be grouped with survey answers from other persons.

Survey forms and handheld computers will be locked in a file cabinet at the study office. Computers with study data will be physically secured and protected by coded passwords. Only specific study staff will have access to the locked file cabinet or the computers.

If you know me, you may ask for another staff member so that your answers will be fully private.

I. Costs

You will not be charged for counseling, the HIV test [*any additional tests offered*], safer sex and HIV prevention materials, referrals to appropriate agencies, or any other services provided by this study.

J. Right to Refuse or Withdraw

This study is completely VOLUNTARY. You are not giving up any legal claims or rights for being a part of this study. If you agree to participate, you are free to quit at any time. You can choose to only do the survey and not to have an HIV test.

K. Agreement

Do you have any questions?

Interviewer: Answer the participant's questions about the study before proceeding to the next question.

Consent will be documented by the interviewer in the handheld computer as follows:

Participant consents to the following:

(Check all the apply)

- Taking part in the survey
- HIV counseling and testing
- Having other lab tests (if offered)
- Storing a blood sample for future testing
- Declined participation

If declined:

We're interested in knowing why people do not want to do this study. Would you mind telling me which of the following best describes the reason you do not want to do this study?

- You don't have time..... 1
- You don't want to talk about these topics..... 2
- Some other reason, or 3
- You'd rather not say why..... 9