

Attachment 9

Model Consent Form

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.1

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 CDC sponsored 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. Why we are doing this project

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. What will happen

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. *[For IDU & HET only]* At the end of the survey, I may offer you a chance to recruit up to 5 other people for this study.

2. If you agree to the survey, we will offer you a free HIV test. If you already know that you are HIV-infected, we would still like to offer you an HIV test today so that we can link today's HIV test result with your survey results.

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 hepatitis testing]* If you agree to the HIV test, we will also offer you free hepatitis B and C testing.

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.

*[For sites doing the Standard Test]
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. *[For sites that allow HIV test phone results: If you cannot return for your HIV test results, you can arrange to receive your counseling and test results by telephone.]*

[For sites doing the Rapid Test]

Rapid Test

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 can get the result of your HIV test within 1 hour. You will get referrals to services, if needed. If the rapid test result is reactive, or if you know you are already HIV- infected, 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. We will set up a day and time for you to get your results.

[For sites doing the Rapid Test Algorithm]

Rapid Test Algorithm

We will [stick the tip of one of your fingers to obtain a few drops of blood/take a swab from your mouth]. You can get the result of your HIV test within 1 hour. You will get counseling about what the test result means. If the first rapid test is reactive, or if you know you are already HIV- infected, we will do up to two additional tests to confirm your results. For the additional rapid tests, 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]. Finally, we will use this same [blood/oral fluid] to confirm your rapid test result in a laboratory. The result of the confirmatory test will be ready within one week. We will set up a day and time for you to get your results.

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 survey and HIV 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.

[For sites doing Storage for Additional Tests]

Storage for Additional Tests

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 conduct any genetic testing or use blood for cloning or commercial purposes. You can decline to let us store your blood and still be in this study. Your blood sample will be destroyed after this testing is completed and not be stored for more than 10 years.

[For sites doing Hepatitis B and C Tests]

Hepatitis B and C Tests

If you agree to an HIV test, we can offer you free screening for hepatitis B and C infection. We will collect a blood sample (about 2 teaspoons) with a needle from your arm. You will get counseling about what the test results mean. You will get referrals to services, if needed. The result of the hepatitis B and C tests will be ready within two weeks.

[Include any additional test to be offered].

C. Things to consider

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.
2. *[If doing phlebotomy]* 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.
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.

D. Benefits

Benefits you may get from being in this study include:

1. You will receive condoms and information on HIV/AIDS and STDs.
2. You will receive free referrals to other local programs, as needed.
3. If your HIV *[or additional tests offered]* results 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.

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. Token of Appreciation

You will be given a token of appreciation for taking part in the study. For completion of the survey, you will get *[survey token of appreciation]*. If you take part in the HIV test, you will get an additional *[HIV test token of appreciation]*. *[For IDU & HET only]* You may also get *[recruitment token of appreciation]* each for up to 5 people whom you send to us for the study. *[Tokens of appreciation for additional tests offered if applicable]*

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

This survey is anonymous. Your responses will be labeled with a study number only. The study staff at [Agency name] and CDC will have access to the survey. Collaborators from other project sites will have access to the survey, but will not be allowed to see any information that could identify you. Your responses will be grouped with survey answers from other persons.

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

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 may refuse to answer any question. You can choose to only do the survey and not to have an HIV test. You can also choose not to recruit others.

K. Agreement

Do you have any questions?

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

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your consent to participate in this study.

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

Do you agree to take part in the survey?

- Yes
- No

Do you agree to HIV counseling and testing?

- Yes

No

Do you agree to having other lab tests (if offered)?

Yes

No

Do you agree to storing a blood sample for future testing (if offered)?

Yes

No

If survey 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