

Attachment 10

Model Consent Form

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.9

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 study about HIV in your community. 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. This study is anonymous which means that no one will know your name or be able to identify you. 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 local laboratory-based HIV or other testing on blood and want to store specimens locally]* If you agree to an HIV test, you will also be asked to have your blood sample stored.
4. *[For sites doing hepatitis C testing]* We will also offer you free hepatitis C testing.
5. *[For sites doing STI testing]* We may also offer you free gonorrhea and chlamydia 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. You will get no medical treatment in this study.

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

[For sites doing only one Rapid Test with local Laboratory Testing]

Rapid Test

We will [stick the tip of one of your fingers to obtain a few drops of blood/draw less than 1 tablespoon of blood]. You will get counseling about what the test result means. You can get the result of your HIV test within [1 hour/*maximum time for the specific test used*]. 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/use the blood we drew for the rapid test] 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 that allow HIV test phone results: If you prefer, you can arrange to receive your counseling and confirmatory test results by telephone.]*

[For sites doing the Rapid Test Algorithm]

Rapid Test Algorithm

We will [draw less than 1 tablespoon of blood/stick the tip of one of your fingers to obtain a few drops of blood]. You can get the result of your HIV test within [1 hour/*maximum time for the specific test used*]. You will get counseling about what the test result means. You will get referrals to services as needed. If the first rapid test is reactive, we will do a second rapid test to confirm your results. For the additional rapid test, we will [use the blood we drew for the first test/stick the tip of one of your fingers to obtain a few drops of blood]. If you already know you are HIV-infected, we may only do one rapid test. *[For sites required/choosing to do laboratory confirmation in addition to the algorithm]* Finally, we will use the blood to confirm your rapid test result in a laboratory. The result of the test will be ready within one week. We will set up a day and time for you to get your results. *[For sites that allow HIV test phone results: If you prefer, you can arrange to receive your counseling and confirmatory test results by telephone.]*

[For sites doing Hepatitis C tests]

Hepatitis C Tests

We will offer you free screening for hepatitis C infection. We will perform a rapid hepatitis C antibody test at the same time as performing the finger prick for your rapid HIV test. Additionally, we will collect a blood sample (about 2 teaspoons) with a needle from your veins. You can get the result of your rapid hepatitis C test within [20-30 minutes/*maximum time for the specific test used*]. You will get counseling about what the test results mean. If the rapid test is positive, that only tells us that you have ever been exposed to hepatitis C. Additional tests are needed to tell us whether you have hepatitis C right now. The result of the additional hepatitis C tests will be ready within [two weeks/*maximum time for local lab to return results*]. 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 hepatitis test phone results: If you prefer, you can arrange to receive your counseling and test results by telephone.]*

[For sites doing STI tests for MSM]

Gonorrhea and chlamydia tests

We will offer you free screening for gonorrhea and chlamydia. We will ask you to swab the back of your throat and gently insert a swab in your rectum (butt) to collect samples. The results of the gonorrhea and chlamydia tests will be ready within two weeks. 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 gonorrhea and chlamydia test phone results: If you prefer, you can arrange to receive your results by telephone.]*

[For sites doing STI Tests for HET (women aged 18-30 only)]

Gonorrhea and chlamydia Tests

We will offer you free screening for gonorrhea and chlamydia. We will ask you to swab the back of your throat and gently swab your vagina to collect samples. The results of the gonorrhea and chlamydia tests will be ready within two weeks. 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 gonorrhea and chlamydia test phone results: If you prefer, you can arrange to receive your results by telephone.]*

[Include any additional test to be offered].

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. 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 for local laboratory-based HIV or other testing]

Storage for Additional Tests

We would like to store any blood *[for sites offering STI testing: and other body fluids]* 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 use your sample for cloning. You can decline to let us store your sample and still be in this study. If you do not wish to have us store your sample, your sample[s] will be destroyed after this testing is completed. If you agree to have us store your sample, we will destroy your sample within 10 years.

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. [The fingerstick/drawing blood] may cause temporary discomfort from the needle stick, bruising, bleeding, light-headedness, and local infection.
3. *[For sites offering STI testing]* Collecting pharyngeal (throat) samples may cause gagging and temporary discomfort. Collecting vaginal samples may cause temporary irritation, discomfort, and mild bleeding.
4. You may feel uncomfortable finding out you might have been infected with HIV *[or diseases tested for]*.
5. If your HIV test result *[for sites offering STI testing: or STD test results]* *[for sites offering hepatitis testing: or hepatitis test results]* is/are 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 and you will be able to talk about your concerns, if you wish. 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 *[or additional tests offered]*, we will inform you of agencies or organizations that provide testing.

F. Compensation

For completion of the survey, you will get *[survey incentive]*. If you take part in the HIV test, you will get an additional *[HIV test incentive]*. *[For IDU & HET only]* You may also get *[recruitment incentive]* each for up to 5 people whom you send to us for the study. *[If you take part in other tests offered, you will get (incentives 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 and test results will be labeled with a study number only. The study staff at **[Agency name]** and CDC will have access to the survey. Other collaborators 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 *[or any additional tests offered]*. *[For IDU and HET only]* 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 portable computer as follows:)

Do you agree to take part in the survey?

- ☐ Yes
- ☐ No

If yes:

Do you agree to HIV counseling and testing?

- ☐ Yes
- ☐ No

Do you agree to hepatitis testing (if offered)?

- ☐ Yes
- ☐ No

Do you agree to STD testing (if offered)?

- ☐ Yes
- ☐ No

Do you agree to let us store some of your blood/STD sample/blood and STD sample for future testing?

- ☐ 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
- ☐ You don't want to talk about these topics
- ☐ Some other reason
- ☐ You'd rather not say why