

**Attachment 10 National HIV Behavioral Surveillance
Model Consent Form**

Enter local project
logo or name here

Taking part in this project is up to you. You don't have to be in the project if you don't want to be. If you decide to take part, you may leave the project at any time. There are no penalties or loss of benefits if you choose not to take part or to leave the project early. This project is private, which means no one outside of the project will be able to connect what you tell us back to you.



Why we are doing this project

The [*agency name*] and the Centers for Disease Control and Prevention (CDC) are doing this project to learn about risk for HIV. We will use this information to plan better HIV prevention and treatment programs for people in your community.

If you choose to be in this project, we will:

- Interview you
- Offer you free HIV testing [*include additional testing being offered as applicable*]
- [*RDS only*] At the end of the interview, you may be offered a chance to recruit up to 5 other people for this project

The Interview

The interview will take about 40 minutes. We will ask you questions about your:

- health
- use of medical services
- drug use
- sex practices
- use of HIV prevention services

HIV and Other Testing

If you agree to the interview, we will offer you free HIV testing. If you already know you have HIV, we would still like to offer you HIV testing so we can link the test result with your interview responses.

- [*For project areas doing hepatitis testing*] We may also offer you free hepatitis B and C testing.
- [*For project areas doing STD testing*] We may also offer you free gonorrhea and chlamydia testing.
- We will ask to store samples from the testing you receive.
- You will receive HIV [*and/or insert additional testing offered*] prevention counseling.
- You will get referrals for additional testing and services, if needed.
- You will not get medical treatment in this project.

HIV Testing

If you agree to HIV testing, it will be done using rapid [*and laboratory*] tests:

- We will [draw less than 1 tablespoon of blood/stick the tip of one of your fingers to obtain a few drops of blood] to perform the rapid HIV test. We may also collect a few drops of blood on a small filter paper.
- You can get the result of your rapid HIV test within [*1 hour/maximum time for specific test used*].

[*For project areas doing rapid-rapid HIV testing algorithm*]

- If the first test is reactive, we will do a second rapid test to confirm your results.

[*For project areas required to do HIV laboratory confirmation*]

- If the rapid test is reactive or if you already know you have HIV, 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] to confirm your results in a laboratory. The results of the confirmatory testing will be ready within one week. We will set up a day and time for you to get your results. [*For project areas that allow return of HIV test results by phone: If you prefer, you can arrange to receive your counseling and testing results by telephone.*]

[For project areas doing hepatitis testing]

Hepatitis B and C Testing

If you agree to hepatitis testing, it will be done using rapid [*and laboratory*] tests:

- We will perform a rapid hepatitis C antibody test. The rapid test tells us whether you have ever been exposed to hepatitis C. We will stick the tip of one of your fingers to obtain a few drops of blood for your rapid hepatitis C test. When possible, we will use the same fingerstick performed for your rapid HIV test.
- Additional tests are needed to tell us whether you have hepatitis C right now and whether you have hepatitis B. For these additional tests, we will also collect a blood sample (about 2 teaspoons) with a needle from your veins. [*For project areas conducting phlebotomy for both HIV and hepatitis testing: When possible, we will use the same needlestick performed for your HIV test to collect this blood for the hepatitis tests.*]
- You can get the result of your rapid hepatitis C test within [*20-30 minutes/maximum time for the specific test used*].
- The result of the additional hepatitis 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. [*For project areas that allow hepatitis test phone results: If you prefer, you can arrange to receive your counseling and testing results by telephone.*]

[For project areas doing STD testing]

Gonorrhea and Chlamydia Testing

If you agree to STD testing, gonorrhea and chlamydia testing will be done using laboratory tests:

- [*For project areas doing STD testing for MSM*] We will ask you to swab the back of your throat and gently swab your rectum (butt) to collect samples.
- [*For project areas doing STD testing for HET women*] 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. [*For project areas that allow return of gonorrhea and chlamydia test results by phone: If you prefer, you can arrange to receive your results by telephone.*]

[For all project areas]

Storage for Additional Tests

- As part of today's testing, we would like to store your test sample(s), that is blood [*for project areas offering STD testing: and other body fluids*], for testing we will do in the future.
- If you agree to let us store your sample(s), we
 - Will not use your sample(s) for cloning
 - Will not put your name on the sample(s) and there will be no way to know it is yours
 - Will store your sample(s) with some data about you, such as your age, race, and sex
 - Will destroy your sample(s) within 10 years
- Because there will be no way to know the sample(s) is/are yours, we will not be able to report back any of these results to you.
- You can decline to let us store your sample(s). If you do not let us store your sample(s), your sample(s) will be destroyed after the specific testing you agree to is completed.

Data Linkage

- If you agree to any of the tests we offer, we will link your test results with your interview responses using an ID number assigned to you for this project.
- No one besides you will be told your test results, and neither your test results nor interview responses will be placed in any medical record.

What you can expect from us



Privacy

All information you give us will be private and confidential as much as the law allows. The project staff at [Agency name] and CDC will have access to the interview and testing data. Other collaborators will have access to the interview and testing data but will not be allowed to see any information that could identify you. Your responses will be grouped with interview answers from other persons. Federal law protects the confidentiality of information kept at CDC.

All project materials are kept in a locked cabinet or secure computer.

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

[*For project areas collecting contact information to return lab-based test results*] If you prefer, you can give us your phone number to contact you when your lab-based test results are ready. Your contact information will be kept separate from your responses and test results and only accessible by a few staff members. Once results are returned to you, we will destroy your contact information. If you prefer to not provide your contact

information, you can call *[insert project phone number]* or come to this office to check if your results are available.

Compensation

You will receive \$[20-50] for completing the interview and an additional \$[10-50] if you take the HIV test. *[For [insert additional testing offered], you will get an additional \$[10-50]]. [For RDS only]* You may also get \$[10] each for up to 5 people whom you send to us for the project.

Things to consider



- There are no costs to you to participate in this project
- There are minimal risks from being in this project:
 - *[For project areas conducting blood-based HIV or hepatitis testing]* [The fingerstick/drawing blood] may cause temporary discomfort from the needle stick, bruising, bleeding, light-headedness, and local infection
 - *[For project areas offering STD testing]* Collecting throat samples may cause gagging and temporary discomfort. Collecting *[For MSM: rectal]* *[For HET women: vaginal]* samples may cause temporary irritation, discomfort, and mild bleeding
 - You may feel uncomfortable finding out you might have been infected with HIV *[or other infections tested for]*
 - If your HIV test result *[or other infections tested for]* is/*[are]* negative, there is a slight chance that the results are wrong and that you could still be infected
 - Some of the questions may make you feel uncomfortable or be too personal

Questions?

About this project or compensation for participation, please

- Ask the person who asks you the interview questions
- Call *[local principal investigator]* at *[phone number]*

About your rights and how the project works across the country, please contact

- (If applicable) The institutional review board (IRB) at *[phone number]*
- <https://www.cdc.gov/hiv-data/nhbs/index.html>

Agreement

You have read or had read to you the explanation of this project, 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 project.

(Consent will be documented by the interviewer as follows)

Do you agree to take part in the interview?

If yes to interview:

Do you agree to HIV counseling and testing?

[if offered] Do you agree to hepatitis testing?

[if offered] Do you agree to STD testing?

[if yes to HIV, hepatitis, and/or STD testing] Do you agree to let us store some of your test sample(s) for future testing?