

**National HIV Behavioral Surveillance System
Informed Consent Form
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In collaboration with Louisiana State University Health Sciences Center in New Orleans, CrescentCare, and the Centers For Disease Control and Prevention

The Louisiana Office of Public Health, Louisiana State University Health Sciences Center in New Orleans, CrescentCare, and the Centers for Disease Control and Prevention (CDC) invite you to be part of a study of persons who may be at risk for HIV infection. The information I will give you can help you make a 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. Your answers to the survey are private and no one outside of this project will know who provided the answers or be able to link them back to 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 remotely, either by video call or over the phone. If you are taking the survey by video call, we will collect your email address to send the video call invitation. If you are taking the survey by phone and would like us to call you, we will collect your phone number. If you do not want to provide contact information, you can do the survey by phone and call us. Personal information will be kept separate from the survey and testing data and only limited staff will have access to that information. Once the survey and testing are completed and test results are returned to you, we will destroy your personal information from our systems.
2. The survey has questions about your health, drug use, sex practices, and HIV prevention services. It will take about 40 minutes. At the end of the survey, I may offer you a chance to recruit up to 5 other people for this study.
3. 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 so that we can link the HIV test result with your survey results.
4. If you agree to an HIV test, we will offer you an appointment for in-person HIV testing at our CrescentCare location. If you choose not to take an in-person test, you have the option of doing home-based HIV testing.

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5. If you come for in-person testing, we may also offer you free Hepatitis C testing.
6. If you come for in-person testing, you will also be asked to have your blood sample stored for testing we will do in the future. This could include testing for recent HIV infection, HIV viral load, presence of antiretroviral medications for HIV treatment or PrEP, or other additional testing.
7. Whether or not you choose in-person or home-based HIV testing, we may offer you additional free home-based STI testing, for gonorrhea, chlamydia, and HPV.

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 and Hepatitis C tests will be done by a rapid test as discussed below.

HIV Test

1. If you agree to in-person HIV testing, we will set up an appointment for you to come to our CrescentCare building after your survey is complete. At the appointment, we will prick the tip of your finger to obtain drops of blood for a rapid HIV test. You will receive your results within 30 minutes. You will get counseling about what the HIV test result means. You will get referrals to services, if needed. If the rapid test result is reactive, we will obtain several more drops of blood for a second rapid test to confirm your HIV result. If you already know you have HIV, we may only do one rapid test.
2. If you do not want to come in-person for an HIV test, you can pick up a home-based HIV test kit from our CrescentCare office after your survey is complete. We will set up a video call or phone call to talk you through the test as you are doing it from home, during which time you will report your results to us and we can provide counseling and linkage to care. In brief, you will self-administer the test by gently swiping the test swab along your upper gums once and lower gums once. You will receive your results in about 20 minutes. If the oral HIV test is reactive, you will be referred to services to confirm your HIV result. If you are unable to conduct the test and report the results during a scheduled video call or phone call, you may call us to report your results and to receive counseling and linkage to care. If we have not heard from you within a week of providing you with the test kit, we will contact you using the email or phone number you have given.

STI Tests

If you agree to do STI testing, we will provide you with an STI test kit when you do in-person HIV testing or when you pick up your home-based HIV test. The STI kit will include an oral swab, rectal swab, and a urine collection cup to test for gonorrhea, chlamydia, and HPV. We will register your kit with a unique number on the STI kit company's website. The company will not have any of your personal information and will only provide study staff with your results. We will share the results with you by phone. If you gave us your phone number, we will call you directly. If you have agreed to give us your email, we will notify you by email to call us. If you did not give us any contact information, you should call us within one week of sending your specimens to the lab. No personal information will be attached to those results. If any of your tests are positive, you will be referred to services for further testing or treatment.

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Hepatitis C Test

If you agree to an in-person HIV test, we may offer you free screening for Hepatitis C as part of the in-person testing appointment. We will use drops of blood obtained from the finger prick done for the HIV test to conduct a rapid Hepatitis C antibody test. You will receive the results of your rapid HCV test within 30 minutes. You will get counseling about what the test result means. If the rapid Hepatitis C test result is reactive, that only tells us that you have been exposed to Hepatitis C at some point in the past. We will refer you to services for RNA testing that will determine if your infection is active and to treatment.

Linkage

We will link your HIV, Hepatitis C, and STI test results with your survey responses so we can learn about the relationship between risk behaviors and other experiences with these infections. 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 your interview responses nor the test results will be placed in any medical record.

Storage for Additional Tests

If you agree to in-person HIV testing, we would like to store your test sample, that is blood for testing we will do in the future. This could include testing for recent HIV infection, HIV viral load, presence of antiretroviral medications for HIV treatment or PrEP, or other additional testing. 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 results to you. We will not use your sample for cloning or any human genetic testing. 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 will be destroyed after the specific testing you agree to today 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. You may feel uncomfortable finding out you might have been infected with HIV, Hepatitis C or other STIs.
3. If your HIV or Hepatitis C test result is negative, there is a slight chance that the results are wrong and that you could still be infected.
4. Depending on the type of testing you agree to, drawing blood drops may cause temporary discomfort from the finger stick. Collecting oral samples may cause tingling of the gums or mouth.
5. Self-collection of pharyngeal (oral) samples may cause gagging and temporary discomfort. Self-collecting rectal (butt) samples may cause temporary irritation, discomfort, and mild bleeding.

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D. Benefits

Benefits you may get from being in this study include:

1. You will receive condoms and information on HIV/AIDS, Hepatitis C, and STIs.
2. You will receive free referrals to other local programs, as needed.
3. If your HIV, Hepatitis C, or STI 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, Hepatitis C test, or STI tests, 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 *\$50 in gift cards*. If you take part in the HIV test, you will get an additional *\$30 in gift cards*. You may also get *\$20 in gift cards* each for up to 5 people whom you send to us for the study. You could also receive a \$20 bonus for your first recruit if they complete their survey within 3 days.

G. Persons to Contact

This study is run by William Robinson and Samuel Burgess at (504) 568-7474. You may call them with any questions about being in the study.

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

H. Confidentiality Statement

Your responses and test results will be labeled with a study number only. We will not ask for your name. The study staff at the Louisiana Office of Public Health, CrescentCare, and CDC will have access to the survey and testing data. Collaborators from other project sites will have access to the survey and testing data but will not be allowed to see any information that could identify you. Your responses will be grouped with survey answers from other persons. The email and phone number you provide study staff for the video or phone call, appointment reminders, or home-based testing if applicable, will not be grouped with any study data and will be destroyed immediately after your test results have been returned

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to you. If you prefer to not provide this information, we can discuss how you might participate without providing contact information.

If you know me, you may ask to be interviewed by another staff member.

I. Costs

You will not be charged for counseling, the HIV test, the Hepatitis C test (if one is conducted), the STI test kit (if one is provided), 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, Hepatitis C test, or STI tests. 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 in-person HIV testing or home-based HIV testing?

- In-person
- Home-based

Do you agree to STI testing?

- Yes
- No
- Not offered

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(If in-person is chosen above) Do you agree to a Hepatitis C test?

- Yes
- No
- Not offered

(If in-person is chosen above) Do you agree to let us store some of your test sample(s) for future testing?

- Yes
- No
- Not offered

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

Interviewer Initials:

Date:

Survey ID: