

Project Aware Consent Form

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

National HIV Behavioral Surveillance System

Michigan Department of Health and Human Services in collaboration with The Centers for Disease Control and Prevention

The Michigan Department of Health and Human Services (MDHHS) and the Centers for Disease Control and Prevention (CDC) invite you to be part of a project about HIV in your community. The information I will give you can help you make a good choice about joining the project.

A. Why we are doing this project

The purpose of this project 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 project is private, which means that no one outside of the project will be able to identify you or connect your responses to you. Being in this project is voluntary.

B. What will happen

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

1. You will do an interview with a trained staff member. The questions will ask about your health, drug use, sex practices, and HIV prevention services. It will take about 40 minutes. At the end of the interview, you may be offered a chance to recruit up to 5 other people for this project.

Interviews will be conducted remotely by secure, private phone or video call. Video calls will use Zoom. You do not need to have the app; you can join in a web browser. We will need you to provide an email address and phone number so the video call link and project information can be sent to you. We will not audio- or video-record any interviews.
2. If you agree to the interview, we will offer you a free rapid HIV test. If you already know that you have HIV, we would still like to offer you an HIV test so that we can link the HIV test result with your interview responses. There are a couple of options to choose from when consenting to complete the free HIV test. For either option, the HIV testing appointment will occur during a second, scheduled appointment separate from the initial virtual interview.
 - a. **In-person rapid HIV testing method:** You can schedule an in-person HIV testing appointment with one of our participating locations at the end of your interview. Participating NHBS testing locations are local community-based organizations that follow NHBS guidance and provide anonymous rapid HIV testing. HIV testing results will not be placed in a medical record. Please note that you will have to follow COVID-19 guidelines upon entering the facility.

Rapid Test Algorithm

We will 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 30 minutes. 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 stick the tip of one of your fingers to obtain a few drops of blood. If you already know you have HIV, we may only do one rapid test.

- b. **The self-test HIV testing method:** You can schedule a virtual HIV testing appointment at the end of your interview. You will need to provide your name and mailing address and an OraQuick In-Home HIV self-test kit will be sent to the address of your choice. Your contact information will be kept private and separate from your survey or test results data. Once you receive the self-test kit, you will complete the HIV test with a trained staff member guiding you through the testing process during your second, scheduled virtual appointment. This second session will also be done on Zoom and will not be audio- or video- recorded.

Rapid Oral Self- Test

The oral rapid HIV test will be self-collected and performed by you. A staff member will guide you in performing the test. Do not eat, drink, or use oral care products within the 30 minutes before starting the test. You will gently swipe the test swab along your upper gums once and lower gums once. You can get the result of your HIV test within 20-40 minutes. You will be asked to show and confirm your HIV test result with the counselor.

If you agree to the HIV test, either the in-home self-test option or in-person HIV testing option, you will have about a 10-minute 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 referrals for additional testing and services, if needed. You will NOT get medical treatment in this project.

Linkage

We will link your test results with your interview responses 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 interview. Your name will not be on the test results or the interview. No one besides you will be told your test results, and neither your interview responses nor the test will be placed in any medical record.

C. Things to consider

There are minimal risks from being in this project:

1. Some of the questions in the interview are about sex and drugs and may make you feel uncomfortable.
2. The fingerstick for in-person HIV testing may cause temporary discomfort from the needle stick, bruising, bleeding, light-headedness, and local infection.
3. Collecting an oral sample for the in-home HIV test may cause tingling of the gums or mouth or temporary discomfort.
4. You may feel uncomfortable finding out you might have been infected with HIV.
5. 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 project include:

1. You may 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 results are positive, you will receive counseling 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 project but would like to take an HIV test, we will inform you of agencies or organizations that provide testing.

F. Compensation

For completion of the interview, you will get \$50. If you take part in the HIV test, you will get an additional \$50. You may also get \$20 each for up to 5 people whom you send to us for the project. Incentive payments will be distributed through PayPal or an electronic gift card.

G. Persons to Contact

This project is run by: Emily Higgins, Project Coordinator. You may call her at 313-310-3739 with any questions about being in this project.

If you have questions about your rights as a participant, please contact the MDHHS Institutional Review Board (IRB). The MDHHS IRB protects the rights of people who volunteer to be part of a study. To contact the MDHHS IRB, call (517) 241-1928.

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

H. Confidentiality Statement

This project is private. Your responses and test results will be labeled with a project number only. The project staff at MDHHS 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.

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

We may need your phone number, email address, name, and/or mailing address to offer you easy ways to participate in the interview or testing. Contact information will be kept separate from the interview and testing data and only limited staff will have access to that information. Once the interview and testing are completed and results are returned, we will destroy your contact information. If you prefer to not provide this information, we can discuss how you might participate without providing contact information.

I. Costs

You will not be charged for counseling, the HIV test, safer sex and HIV prevention materials, referrals to appropriate agencies, or any other services provided by this project. If you use a cell phone for your interview or testing appointment, your phone plan might charge you for phone minutes or data use, depending on your plan. We will not reimburse you for phone minutes or data use charges you may incur during participation.

J. Right to Refuse or Withdraw

Participation in this project is completely VOLUNTARY. You are not giving up any legal claims or rights for being a part of this project. 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 interview 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 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?

- Yes
- No

If yes:

Do you agree to HIV counseling and testing?

- Yes
- No

Do you agree to receive your incentive payment through Paypal? Please note: electronic gift cards are available.

- Yes
- No