

Form Approved
OMB No. 0920-New
Expiration Date: XX/XX/XXXX

Injection Drug Use Surveillance Project

Attachment # 6

Project Permission Form

Privacy Act Statement:

This information is collected under the authority of the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)). This information is also being collected in conjunction with the provisions of the Government Paperwork Elimination Act and the Paperwork Reduction Act (PRA). This information will only be used by the Centers for Disease Control and Prevention (CDC) and staff at the University of Washington to develop a surveillance system to monitor drug use risk and prevention behaviors and the infectious disease consequences of high-risk drug use in syringe services programs (SSPs) in rural and urban areas the US.

Public reporting burden of this collection of information is estimated to average 5 minutes to complete the project permission process. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

Injection Drug Use Surveillance Project (IDU-SP)

Model Project Permission Form

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

Injection Drug Use Surveillance Project Model Project Permission Form

The [*name of local agency/organization*], University of Washington and the Centers for Disease Control and Prevention (CDC) invite you to be part of a project about HIV, hepatitis C (HCV), and other important health topics 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 and HCV. We will use this information to plan better HIV and HCV prevention and treatment programs for people in your community. This project is anonymous which means that no one will know your name or be able to identify 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 a survey with a trained staff member.

The survey has questions about your health, drug use, sex practices, and HIV and HCV prevention services. It will take about 30 minutes. At the end of the survey, I may offer you a chance to recruit up to 5 other people for this project.

2. We will offer you a free HIV and HCV test.

If you already know that you have HIV or HCV, we would still like to offer you the tests today so that we can link today's HIV and HCV test result with your survey results

3. If you agree to the HIV and HCV testing, you will also be asked to have your blood sample stored.

If you agree to the HIV and HCV testing, you will have a 10- to 15-minute HIV and HCV prevention counseling session with a trained staff member. The session will cover the meaning of results from the

HIV and HCV tests. You will also learn about how to reduce your chances of being infected with HIV, HCV and other infectious diseases. You will get no medical treatment in this project.

The HIV and HCV testing will be done by rapid tests as discussed below.

Rapid HIV 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 [20-30 minutes/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.

Rapid Hepatitis C Test

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. 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. We will offer you referrals for additional tests that can tell you whether you have hepatitis C right now.

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 or HCV 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 results will be placed in any medical record.

Storage for Additional Tests

We would like to store any blood that is left over after we do your HIV and HCV tests. 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 project. If you do not wish to have us store your sample, your sample 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 project:

1. Some of the questions in the survey are about sex and drugs and may make you feel uncomfortable.
2. The fingerstick 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 or HCV.

4. If your HIV or HCV test results 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 project include:

1. You will receive condoms and information on HIV, HCV and other health topics that may be important to you.
2. You will receive free referrals to other local programs, as needed.
3. If your HIV or HCV 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 project but would like to take an HIV or HCV test, 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 and HV testing, you will get *[test incentive]*. You may also get *[recruitment incentive]* each for up to 5 people whom you send to us for the project.

G. Persons to Contact

This project is run by: *[name of principal investigator and phone number]*. You may call *[him/her]* with any questions about being in the project.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact *[contact name and phone number, or IRB committee]*.

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 project number only. The project staff at University of Washington 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 or HCV test, safer sex and HIV and HCV prevention materials, referrals to appropriate agencies, or any other services provided by this project.

J. Right to Refuse or Withdraw

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 survey and not to have an HIV and HCV 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 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 permission to participate in this project.

(Permission 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 and hepatitis C testing?

- Yes
- No

Do you agree to let us store some of your blood for future testing?

- Yes
- No

If survey declined:

We're interested in knowing why people do not want to do this project. Would you mind telling me which of the following best describes the reason you do not want to do this project?

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

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