

**Attachment 5b. Template Informed
Consent for Standard Structured Interview,
Qualitative Interview, and Blood Collection For
Never In Care Project**

Template Statement of Informed Consent

Surveillance of HIV/AIDS related events among persons not in care
(Never In Care Project)
CDC Protocol #4923

Flesch-Kincaid grade level 7.7

The _____ Department of Health and the Centers for Disease Control and Prevention (CDC) support the Never in Care project. We want to learn about people living with HIV/AIDS who have never been in medical care for HIV. We would like you to join this research project. We invite you to take part in this project because you tested positive for HIV and have never been in medical care for your HIV. The information on this form can help you decide if you want to take part in the research project.

Why we are doing this project

We hope to learn why some people living with HIV/AIDS do not use medical care. We want to know what kind of services people living with HIV/AIDS need to stay healthy. We also hope to learn about ways HIV is being spread. This information will help us improve our programs, improve services for those who have HIV, help people who may have trouble getting HIV services, and prevent other people from getting HIV.

What we will need from you

If you agree to take part in the project, we will ask you to do the following:

- 1) Answer some questions:
This will take about 30 minutes. A trained interviewer will ask you questions about HIV testing, medical and social services you have used or needed, and reasons you have never been in medical care for HIV. The interviewer will also ask questions about your social support, drug use and sex practices. Some of the questions are personal and may be difficult to discuss. You don't have to answer any question if you don't want to, and you may end the questionnaire at any time.

We will write down your answers or type them into the computer, but we will not write down your name on the paper (or type it into the computer). All the information that you give us will be kept private in a locked file. Only the staff of this project will be able to open the file. We will send information from your questionnaire to the CDC, but we will not send your name or any information that would identify you.

If you know the person who is reading this form to you, you may ask for another interviewer so that your privacy will be fully protected.

- 2) Tell us your thoughts and experiences:
The interviewer will ask you another set of questions that will take about 60 minutes more to answer. A trained interviewer will ask you to talk in more detail about reasons you have never been in medical care for HIV. The interviewer may also ask you to talk about medical and social services you have used or needed. You may end the discussion at any time.

During the second interview, we will record your voice with a digital recorder. We will not write down or record your name. The interviewer will also write down your responses on paper or type them into a computer. We will keep all the information that you give us in a locked file. Only the staff of this project will be able to open the file. We will send information from your discussion to the CDC, but we will not send your name or any information that would identify

you. All the information that you give us will be kept private. The information you give us will be used only to improve programs and services for those who have HIV, and to prevent other people from getting HIV.

3) Give some blood from your finger for blood tests:

If you agree, we will prick your finger with a lancet. The lancet has a sharp tip similar to a needle. We will then collect 10 drops of blood from your finger. Taking blood from your finger will take less than 5 minutes. These tests will help us to learn how fast the virus is multiplying, and how your body is fighting the virus.

We will not put your name on the blood sample. The results from your blood tests will be kept private. Your blood sample will not be used for any testing except the testing just described. Your blood sample will be destroyed after this testing is completed.

The tests on your blood are to help us learn more about HIV-infected people who are not getting medical care. The test to learn how fast the virus is multiplying is for research only and is not approved to be used by health care providers for your medical care. We will use the information from the tests to plan for medical care for all the people who are not getting care yet, but who might decide to get medical care soon.

If you would like to know the results of these tests on your blood, please call the number below after _____(date) anytime between ___ and ___ (hours) on these days of the week:
_____.

_____ at _____.
(Contact at the Health Department) (local telephone number)

If you would like us to send the results of these tests on your blood to your health care provider, please provide the name and address below. Although your health care provider cannot use the test to learn how fast the virus is multiplying for your medical care, he or she can do other tests to measure the amount of virus in your blood.

(Name)

(Clinic or Hospital)

Street Address

(City, State, Zip Code)

(Telephone number)

The results will be sent to the health care provider with a code number rather than your name. To follow up with the health care provider whose name you have given us, please use the code number below:

(Study Identification Number)

If you wish, we can help you get medical care, and the health care provider can do tests on your blood that can be used to make decisions about your medical care.

Things to consider

There are minimal risks from being in this project:

- 1) Some of the questions we ask may make you feel uncomfortable. You may feel the questions are too personal. These might include questions on income, drug use, or sex. If you do not wish to answer any questions, you do not have to do so.
- 2) If you agree to have your finger pricked, there may be some discomfort or bruising. You will feel a slight sting (like a pin prick). The lancet we use to prick your finger is clean, so it will not harm you. Also, the amount of blood we take will not harm you at all.
- 3) The area where we stick your finger may become infected, but this is uncommon. If the site of the finger prick gets red and sore, you would need to go to a clinic. To prevent any infection, we will clean your finger with alcohol before we prick it.

The benefits to taking part in this project include:

- 1) You can help your community understand why some people living with HIV/AIDS do not use medical care for HIV.
- 2) You can help us improve services for those living with HIV/AIDS and help people who may have trouble getting these services.
- 3) If you wish, your interviewer can give you information about how to avoid spreading HIV. If you decide not to take part in this project, you can still get this information.
- 4) If you wish, your interviewer can give you information about medical and social services in your area or connect you with someone who can help you get them. If you decide not to take part in this project, you can still get this information.

Privacy

All answers you give will be kept private. [To be added if Confidentiality Certificate is approved: This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the law, we must report suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.] To protect your privacy, we will group your answers together with answers from other persons, so that no one will know how you answered the questions. We will send information from this project to the CDC, but will not send CDC your name or any information that could identify you. Federal law protects the confidentiality of information kept at the CDC.

Voluntary Participation

Taking part in this project is your decision. Your choice to join the project will not affect your right to health care or other services. If you choose to take part in the project, you may stop the questionnaire or discussion at any time. You may choose to participate in the questionnaire only, and decide not to participate in the discussion or take the blood test. We will ask for your consent for the questionnaire, discussion, and blood test separately.

Payment

You will receive:

- 1) \$25 as payment for your time and effort if you agree to be interviewed.
- 2) Another \$25 if you agree to a discussion about reasons you have never been in care for HIV.
- 3) Another \$25 if you agree to have your finger pricked to give a small amount of blood.

Questions

If you have any questions about this project, please ask the interviewer, or call:

_____ at _____.
(Local principal investigator) (phone number)

If you have questions about your rights as a participant in this project, please contact:

- 1) The local institutional review board (IRB):

_____ at _____.
(Local IRB contact) (phone number)

- 2) The office of CDC's Deputy Associate Director for Science at 1-800-584-8814. This is a toll free call. Please leave a brief message including your phone number. Say that you are calling in reference to CDC protocol #4923. Someone will return your call as soon as possible.

Questionnaire Statement of Consent

I have read the explanation of this study, I have been given a copy of this form, the chance to discuss any questions that I might have, and the right to refuse to take part or end the interview at any time. I understand that one of the persons listed above will answer any future questions I may have about the interview and my rights as a participant. I understand that my participation in this interview is voluntary. I agree to be interviewed.

Signature of Participant

Date

Signature of Interviewer

Date

Discussion Statement of Consent

I agree to take part in this discussion. I understand that I can refuse to answer any question or end the interview at any time. I have read this consent form and all my questions have been answered. I understand that one of the persons listed above will answer any future questions I may have about the discussion and my rights as a participant. I understand that my participation in this discussion is voluntary. I agree to take part in the discussion.

Signature of Participant

Date

Signature of Interviewer

Date

Finger Stick Statement of Consent

I have read the explanation about the drawing of drops of blood from a finger so that tests on the blood can be done, including a research test to learn how fast the virus is multiplying. I have had a chance to discuss any questions that I might have about having my finger stuck to draw some drops of blood and my right to refuse to give blood for testing. I have also had a chance to discuss any questions I might have about the tests that will be done on my blood if I agree to have my finger stuck, and how to get the results of these tests. I understand that if I would like to know the results of these tests on my blood, I can call the number below after _____(date) anytime between ___ and ___ (hours) on: _____ (days of the week).

_____ at _____.
(Contact at the Health Department) (local telephone number)

I also understand that I can ask to have the results of the tests on my blood sent to my health care provider if I provide the name and address and sign a release form. I understand that one of the persons listed above will answer any future questions I may have about the blood tests and my rights as a participant. I understand that one of the persons listed above will answer any future questions I may have about the blood test and my rights as a participant. I understand that my participation in this blood test is voluntary. I agree to take part by giving some drops of blood from my finger for testing.

Signature of Participant

Date

Signature of person collecting blood specimen

Date