Sample Information Sheet and Consent Form for RDS Research Participants

Date_____

Study title

A survey of HIV prevalence and risk behavior among (insert group here, e.g., injecting drug users, males who have sex with males, sex workers) in (insert city, country).

Introduction

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

All information you provide for this study is confidential and anonymous. Names are not recorded anywhere, and nothing can be attributed to you personally.

Thank you for reading this.

What is the purpose of the study?

We are interested in finding out about the characteristics of people who (insert behavior here, e.g., inject drugs, engage in sex work, males who have sex with males) and measure HIV prevalence in these populations. The study will help us develop HIV prevention services for (insert group here) in (insert city and/or country here). It is part of a collaborative project between NGOs and health services in (insert city and/or country here), (name any specific organizations, health departments, universities, etc., involved).

Why have I been chosen?

You have been chosen because you have (insert behavior here-injected drugs, are a male who has had sex with a male, engaged in sex work) in the (insert time frame here, e.g., last four weeks). (Include any other important eligibility criteria you have for your study).

Do I have to take part?

You can decide not to take part. It is up to you. If you do decide to take part, you will be provided this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

1. You will be asked to take part in an interview which takes between (insert time period, e.g., 45 minutes). This interview will be conducted with an interviewer (or, if using ACASI, using a computer-mention that help is on hand if needed). You will be asked questions on (list the types of questions here, e.g., sexual behavior, drug use, sharing of injecting equipment, use of health services, contact with the police, imprisonment, etc.). You will be able to skip any questions that you do not want to answer.

2. You will be asked to give a finger prick spot of blood (or some other biological specimen, e.g., urine, venous blood, rectal swab, saliva). A staff member will obtain the blood spot using a "finger prick" device, and he or she will explain how this device works. This spot of blood will be tested for antibodies to HIV (list other infections, diseases). It may also be tested for other viruses in the future, and may be exported to the (list where) for further testing.

   (You may want to talk about whether you will be providing test results to the participant with pre and post-test counseling or not providing test results.)

Will the information I give you be kept confidential?

The questionnaires and the (list biological specimen) are confidential and anonymous. Names are not recorded on the questionnaire or the specimens. What you say in the interview will not be linked to you personally, and any test results will be anonymous; this means they will not have your name on them and you will not be able to obtain the results of the tests.

What will happen to the results of the study?

The results of the study will be written up into a report and into a publication in an academic journal. These publications will be used to inform the development of HIV prevention services for (name the group under study) in (city and/or country). No persons will be identified in any report or publication.

Who is organizing and funding the research?

(List all of the organizers of the research and funding institutions here)

What should I do if I want to know whether I have HIV?

(Describe what will be done in your study, e.g., at the end of the interview, you will be able to obtain the results in around half an hour or you will need to return at a later date. It is up to you whether you decide to have your results.)

Contact for further information

You may speak with any of the staff at this project. You may also contact (provide a contact name and phone number).

We appreciate your participation. Thank you for taking part in the study.
You will be given a copy of this information sheet.

Participant Consent Form

Title of project

Biological and Behavioral Surveillance of HIV prevalence and risk behaviors among (insert group here, e.g., injecting drug users and sex workers) in (insert location here)

Please check

- ❑ 1. I confirm that I have read and understand the information sheet dated (insert date here) for the above study and have had the opportunity to ask questions.
- ❑ 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- ❑ 3. I agree to take part in the above study.

_____ _____

Signature of participant Date

_____ _____

Signature of person taking consent Date

Another Example of a Consent Form

Hello. My name is _____ and I work for the (insert here), sponsored by (insert here). We are asking people we meet some questions related to risk for HIV, the virus that causes AIDS. The goal of these questions is to create programs that will help reduce the transmission of HIV. If you are willing to participate, we will ask you some questions that take about (insert time period here) minutes. Some of the questions are about private things. At any point you can refuse to answer any question. You will receive an incentive at the end as a thank you for your time.

This interview will be completely confidential. That means we will not take your name or any information that could identify you. We ask you to answer our questions honestly and to the best of your ability. No information that you give us today will be connected to you.

We are also asking your permission to do an HIV (list any other) test. The test is (describe the test procedure here). Since we are not taking your name or any other identifying information, we will not be able to let you know the results of this test. But we will give you a coupon for a free HIV test at the (name the center and address here). They will not need to take your name to give you the test results.

If you have already been interviewed with a coupon, we need to stop the interview now. Otherwise, we can continue.

Do you consent to participate in the interview?

(Verbal consent provided: ❑ Yes ❑ No)

Do you consent to participate in the HIV (or other) test?

(Verbal consent provided: ❑ Yes ❑ No)

_____ _____

Signature of interviewer/witness to consent date

Another Example of a Consent Form

HIV Biological and Behavioral Assessment Consent Form

Coupon number: |__|__|__|__|__|__|__|__|__|__|__|__|

Date of Ethics Committee Approval: _____

Introduction

My name is _____(name), and I work in a collaborative project with *(research agency)* and *(implementing agency or NGO)*. We are collecting sexual health data for a project called Biological Behavioral Assessment (BBA) which is supported by *(insert here)*. This consent form gives you information about BBA. We ask that you think about your participation in this study through this consent form. It is necessary for you to receive complete information about this study to participate in it; you can read this form yourself or somebody will read it out to you. If you are willing to participate in this study, you will put today's date and sign this consent form. If you cannot or do not wish to sign, a witness will sign it.

Purpose of study

The information you provide will help us to develop effective prevention and intervention programs to reduce the spread of HIV infection among different population groups.

Your participation in this study

If you agree to participate in this study, we will ask you some personal questions about you, your sexual behavior, substance use, sexually transmitted infections (STIs), etc. The interview is likely to last for about (time period here) minutes. We will also request you to permit us to collect blood and urine *(or put other sample here)* samples. There is no right or wrong answer to any of the questions. You can choose not to answer certain questions, if you do not want to.

After the interview, your blood will be taken with a prick to your finger. Your blood sample will be tested for *(insert here, e.g., syphilis, HIV, HSV2 antibodies, etc.).* The results of the HIV test will not be revealed to you. If you wish to know HIV test results, you will be referred to a nearby voluntary counseling and confidential testing center. This study cannot provide you with treatment for HIV, but study staff will refer you to other available sources of care.

Who is eligible?

You should be 18 years of age or above and willing to participate in this survey. *(List any other important eligibility criteria)*

Risks and benefits of participating in the study

You may feel discomfort when your finger is pricked for blood spots *(or describe other risks with specimen collection)*. You may have a bruise where the prick goes into your finger. You may become embarrassed when discussing sexual behaviors. You will talk

with a trained staff member who will help you deal with any feelings or questions you have.

We will make every effort to protect your privacy and confidentiality.

This study may be of no direct benefit to you. However, you and other community members may benefit in the future from information learned from this study. You will be referred for counseling and testing for HIV. This study cannot provide you with other medical care, but study staff will refer you to other available sources of care.

If you decide not to participate in this study

You may decide not to participate or to withdraw from the study at any time. You will continue to receive the services from your local intervention program, if you were receiving them, and from your routine medical care.

Confidentiality

The study staff will keep your personal information confidential. A code number is used on all forms and specimens.

Compensation for your participation

There is no cost to you to participate in the study. You will be compensated for your time and effort to participate in this study *(enter primary incentive amount*). You will also be compensated for recruiting other people into the study *(enter secondary incentive amount*) for each person you recruit. No other compensation will be provided to you.

Problems about the study

If you ever have any questions about this study, or in case of research-related injuries, you should contact (provide name and number of a contact).

Statement to be made by someone willing to participate in the study

I have read this consent form completely/this consent form has been read out to me. All my doubts have been cleared. I can withdraw my participation anytime. I have received and understood the information about my rights and have been promised that my personal information shall be kept confidential.

I want to participate in this study myself by my own free will and am willing to (Check boxes that are accepted);

- ❑ Answer the questionnaire
- ❑ Provide blood *(list or separate out specimens)*
- ❑ I have been offered a copy of my consent form and (circle number[s] that are accepted);
- ❑ I want a copy of my consent form
- ❑ I don't want a copy of my consent form

_____	_____	_____
Date	***Participant's signature***	***Signature of witness***