Form Approved
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Identification of behavioral and clinical predictors of early HIV infection

(Project DETECT)

Attachment 11a

Phase 2 Consent Form (English)

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) staff to: 1) characterize the performance of new HIV tests for detecting established and early HIV infection at the point of care (POC), relative to each other and to currently used gold standard, non-POC tests, and 2) identify behavioral and clinical predictors of early HIV infection.

UNIVERSITY OF WASHINGTON
CONSENT FORM

Phase 2 Participants

Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence: Group 4

Joanne Stekler, MD MPH	Associate Professor, Medicine	206/744-8312
George Ure	Research Study Assistant	206/744-4394

Emergency 24-hour number Dr. Joanne Stekler 206/744-3000

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

You are being asked to volunteer for this research study because you participated in Part 2 of this study and some of your HIV tests were positive while some were negative. The purpose of this research is to understand when rapid HIV tests can detect HIV in the earliest stage of infection, when people are only beginning to develop anti-HIV antibodies. In this part of the study we are trying to figure out when different rapid HIV tests can detect HIV. Approximately 200 other people in the Seattle area will also be participating in this study. This study is being conducted by the University of Washington and the Centers for Disease Control and Prevention (CDC). The information below is to help you decide whether to take part in the study.

STUDY PROCEDURES

This study will include between one (1) and nine (9) visits over the next 70 days. The complete follow-up schedule will involve return visits at 3, 7, 10, 14, 21, 28, 42, 56, and 70 days after the initial visit. We will ask you to come back until either all of your HIV tests agree or until 70 days have passed, whichever happens sooner. If you agree to participate, we will schedule all nine (9) of your visits today. We will ask you for detailed contact information, and will call or text you the day before each appointment to remind you to come. Because it is very important that

you come to the appointments as scheduled, if you need to miss an appointment for any reason, please call one of the study staff as soon as possible to reschedule.

At each study visit:

We will swab your mouth four times to collect oral fluid samples for four rapid tests – two will be read during your visit and two will be stored for later testing. We will also draw about 4 mL of your blood (less than 1 teaspoon) to use for five rapid HIV tests. If your antibody tests done in the laboratory at your last visit were not positive, a 10 mL tube of blood will also be drawn at this time for follow-up laboratory tests. In addition, we will draw about 20 mL of your blood (about 4 teaspoons) for storage for future testing. During your last visit with the study a small sample of this amount of blood will be used to perform an HIV RNA test which tests your blood for the HIV virus (viral load). We will draw these tubes of blood at one time with one needle stick. Altogether, we will draw about 2 tablespoons of blood.

The research assistant will also complete a set of five rapid HIV tests for you using finger stick samples. You will have your finger pricked with a small needle called a lancet for each test (five times). The small drop of blood from each finger will be tested immediately on each rapid test.

You will also be asked to complete an interview using a computer. The interview will ask you questions about your background, sexual practices and drug use. For example, the interview may ask you about the last time you had sex or if you have ever had an STD in the past. We will also ask you whether you have been to a doctor for HIV, and if you are taking medicines for HIV, called anti-retrovirals. The answers that you give in the interview will not be connected to your name. Only study staff will see the answers you give. Your answers will never be seen by the police, your employer, your health insurance or any health departments. You may refuse to answer any question or item in the interview that you do not wish to answer.

These study procedures should take about 1 ½ to 2 hours to complete at each study visit.

RISKS, STRESS, OR DISCOMFORT

The oral swab, finger sticks or blood draw could cause a small amount of discomfort, bleeding, or bruising. You may experience increased stress or anxiety while having discussions about HIV infection. We will take steps to minimize any stress or anxiety by providing you with factual information about HIV and risks for getting HIV in language that you can understand. We will answer any questions that you may have.

The questions we will ask you about your sexual behavior and drug use may make you feel uncomfortable. However, you do not have to answer any questions that you do not want to answer and you can stop answering the questions at any time. We will not share your answers with anyone outside of the study and study staff will not see your name connected to your answers.

As mentioned above, some of your blood and oral fluid samples will be frozen and stored for future testing. These samples will be processed and stored with a study ID instead of your name. No personal information about you (such as your name or birthdate) will be included. UW, the CDC and other researchers may use these samples for research in the future. Nothing that could be linked to you will be kept with the blood. We are not sure what studies might be done in the future. They might include standard tests as done at hospitals, tests for HIV or other viruses or on your immune system (ability to fight infection). We will not test for genetic problems or use the blood for cloning or commercial purposes. Because nothing that identifies you will be stored with your samples, we will not be able to provide you with results of testing that we may do in the future.

You may decide to withdraw your permission for your samples to be stored and tested later on. If so, write to the study team to withdraw your permission by September 2025, when the link between your name and your specimen will be permanently destroyed:

Joanne Stekler
Project DETECT
325 9th Avenue, Box 359931
Seattle, WA 98125

You may feel that participating in a research study is a breach of your privacy since we are collecting information about you related to your HIV status and may have access to your clinic records. We will take steps to minimize this by talking with you about the research, the purpose of the research, and who may have access to your clinic records as part of this research. We will discuss all of this information with you in a private room.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Your alternative to participating in this study would be to not participate. You will not lose any other benefits in the clinic just because you do not want to be in the study.

BENEFITS OF THE STUDY

If you have recently become HIV infected you may benefit from the additional HIV testing performed as part of this study and from the opportunity to discuss local resources for HIV care and services in the area with study staff. Sometimes tests give a false positive result. This means that the test result was positive for HIV when the person being tested does not actually have HIV. If your test results from the Part 2 study were believed to be false positive, then participating in the Part 3 study may help you learn more about these results.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from the Centers for Disease Control and Prevention (CDC) to conduct this study.

PROTECTION OF RESEARCH INFORMATION

All of the information you provide will be kept private. However, if we learn that you intend to harm yourself or others or that you or someone you know is being abused, we must report that to the authorities.

We will record your name and other personal identifying information while you are in this study in order to contact you for follow-up visits. The data we collect for the study will be coded with a unique study ID, but some members of the UW study team will have access to the link between your personal identity and your study ID to contact you or connect your test results from your clinic record to your study record. The study sponsor, CDC, will not have access to any of your personal identifying information. The link for this data will be destroyed within **five years after** the last date of study enrollment, expected on **September 29, 2020**.

All of the data we collect will be kept in a locked cabinet or password-protected computer files. Results that are published from this study will not include any personal information about you.

If any of your rapid HIV tests show different results, we will help you interpret your results. We will give you the results of all of the rapid tests while you are in the clinic, and you will get HIV RNA results (test that shows HIV in your blood) by phone or at a follow-up visit.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

All answers that you give will be kept private. 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 to the proper authorities suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

There are few other limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without any penalty or loss of benefits to which you are otherwise entitled.

There is no cost to you for the study. You will receive $50 for each visit for participating in this study. You may receive up to $450 for participating in this part of the study if you need to complete all nine (9) study visits.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Joanne Stekler by paging her (206-744-3000) right away. She will treat you or refer you for treatment.

Printed name of study staff obtaining consentSignature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject Signature of subject

Date

Copies to: Researcher
Subject