UNIVERSITY OF WASHINGTON

INFORMATION SHEET

GAIN (Greater Access & Impact with NAT) Study: Aim 5: Multi NAT Group

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We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to participate.

PURPOSE OF THE STUDY

You are being asked to volunteer for this research study because you have told us that you are HIV-positive. The overall purpose of this research is to determine the acceptability and feasibility of integrating the point-of-care nucleic acid test (POC NAT) into clinical care. The POC NATs we will use are called the SAMBA II Semi-Q test, and the Cepheid Xpert HIV-1 viral load test, and they are not yet FDA approved. The SAMBA test can detect whether your viral load is greater or less than about 1000 copies. The Cepheid test can detect a viral load as low as about 40 copies. If you have a higher viral load than that, it can also read a viral load number, unlike the SAMBA test. The viral load refers to how many copies of HIV are present in a milliliter sample of blood.

We want to compare several different POC NATs to see how they perform on patients with a range of different viral loads. Up to 7,100 people in the Seattle area will be participating in this study. These tests are not yet FDA approved. 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

If you agree to participate in this study, we will ask you to complete a blood draw for the POC NATs and laboratory testing, and answer a few questions for a survey.

The POC NAT takes about 2 hours to run before it can be read. After the POC NAT has been started, we will connect you with the clinic staff for your regular visit procedures, if you are having a clinic visit on the same day. When you are done, we will complete your study visit.

We will ask you some questions about yourself for our study visit survey, including questions about things like your race and ethnicity, gender identity, and insurance status. The answers that you give in the survey will not be connected to your name. This data will be stored along with your test results to potentially be used for future research. You may refuse to answer any question or item that you do not wish to answer.

Finally, we will draw about 24 mL (which a little less than 5 teaspoons) to of blood to use for running one of the POC NATs, a laboratory HIV RNA test, and for storage for future testing. If you are having a regular clinic visit today, we will try to draw the blood for your clinical tests at the same time, to minimize the number of needlesticks you have today.

These study procedures should take at most 45 minutes to complete. At the end of your visit today, if your results are not ready to be read yet, you can wait to receive them in person in the clinic or you will be given a card with the phone number and your study ID number to call research staff later for your results.

RISKS, STRESS, OR DISCOMFORT

The blood draw could cause a small amount of discomfort, bleeding, or bruising. You may experience increased stress or anxiety while having discussions about your viral load. We will take steps to minimize any stress or anxiety by providing you with factual information about what your result means in language that you can understand. We will answer any questions that you may have.

You may feel that participating in a research study is a breach of 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. You may choose to have your regular visit done at the clinic instead of participating in this study.

BENEFITS OF THE STUDY

The POC NAT may be able to detect your HIV RNA level to a cutoff level of about 1000 copies within 2 hours. It may be useful to you to know if your viral load is greater than 1000 copies at your visit today.

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.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be anonymous. The data we collect for the study will be coded with a unique study ID. The study sponsor, CDC, will not have access to any of your personal identifying information.

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 we learn that you intend to harm yourself or others, we must report that to the authorities.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

USE OF INFORMATION AND SPECIMENS

Returning Results to You

The result of your POC NATs will be ready to read about 1.5-2 hours after the tests are started. If you wish to stay at the clinic to obtain your result, you may.
If you wish to stay at the clinic to obtain your result from one of the tests (the SAMBA), you may. We will not return the result of the other POC NAT (the Cepheid) to you. If you wish to leave the clinic before the result is ready to read, you may call the research team back later. You will be given a card
with the contact information and your Study ID, by which the study staff will be able to look up your result. The study staff will help you interpret your test results. Because the SAMBA II Semi-Q test is not yet FDA approved, we will rely on the laboratory based tests to
make a final assessment of your viral load.

Using Your Data in Future Research

The information and specimens that we obtain from you for this study might be used for future studies. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you.

OTHER INFORMATION

There is no cost to you for participating in the study. You will receive $20 for participating in this study, and a $5 food voucher.

RESEARCH-RELATED INJURY

If you think you have been harmed as a result of participating in this research, contact Joanne Stekler by paging her (206-744-3000) right away. She will treat you or refer you for treatment.

If you have questions later about the research, you can contact one of the researchers listed on the first page of this consent form. If you have questions about your rights as a research subject, you can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940.