UNIVERSITY OF WASHINGTON

CONSENT FORM

GAIN (Greater Access & Impact with NAT) Study: RCT 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 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 NAT we will use is called the SAMBA II Semi-Q test, and it is not yet FDA approved. It can detect whether your viral load is greater or less than about 1000 copies. The viral load refers to how many copies of HIV are present in a milliliter sample of blood.

We want to understand if getting a POC NAT result will help people who are HIV-positive and have a detectable viral load level achieve an undetectable viral load sooner than if they get the HIV RNA test through the lab and get the results later. The POC NAT is not yet FDA approved. Up to 7,100 people in the Seattle area will 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

If you agree to participate in this study, we will first randomly (by chance) assign you to either receive the POC NAT test or receive the clinical standard of care. If you are assigned to receive the POC NAT, we will ask you to have a fingerstick done for the POC NAT test and answer some questions for a short survey. If you are assigned to the standard clinical care, you will not have the fingerstick, but the other study procedures will be the same.

If you are randomized to POC NAT study arm:

We will prick your finger once to collect the small blood sample necessary to run the POC NAT. This test takes about 2 hours to run before it can be read. After the POC NAT test has been started, we will connect you with the clinic staff for your regular visit procedures. We will let your provider know your POC NAT result, and your provider will communicate that result to you if you are still at your visit. Your provider may use the POC NAT result along with other information to develop an adherence plan with you.

Whether or not you are randomized to POC NAT study arm:

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 stored with 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 in the interview that you do not wish to answer.

We might draw the blood for your clinical tests at the same time as your study visit, to prevent you from waiting at the lab for your blood draw. The study procedures should take at most 45 minutes to complete in total.

We will invite some participants to do an additional 20-minute survey via email, a 45-60 minute long in-person, Zoom, or phone interview, or a 45-60 minute long in-person or online focus group to learn more about the participant's experience of getting the POC NAT test and opinions on the test.

RISKS, STRESS, OR DISCOMFORT

The fingerstick or blood draw could cause a small amount of discomfort, bleeding, or bruising. You may experience increased stress or anxiety while having discussions about your HIV 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.

For participants who participate in the surveys, interviews, or focus groups, some of the questions we may 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 the survey at any time. We will email you the survey up to 3 times to remind you to take it. The survey must be taken within 1 week of receiving the link, or it will expire.

For participants invited to participate in an interview or focus group, the conversations will be audio-recorded so that we can have a transcription company listen to the recording and create a written transcript of the conversation. This way we can capture all the details of the conversation. Once we review the transcript for accuracy, the audio recording will be deleted. We anticipate this will happen within approximately 1 month of the interview or focus group.

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 test may be able to detect your HIV RNA virus level to a cutoff level of +/- 1000 copies within 2 hours. It may be useful to you to know that result at your visit today so that you and your doctor can discuss those results and any changes that need to be made in your medications or how you are taking them.

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 confidential. We will record your name and other personal identifying information in order to contact your provider to follow up with your care for the 6 months after this study visit. The data we collect for the study will be coded with a unique study ID. Some members of the UW study staff team will have access to the link between your personal identity and your study ID, in order 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 **six years after** the last date of study enrollment, expected on **August 31, 2030**.

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.

We have a Certificate of Confidentiality from the federal Centers for Disease Control & Prevention. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

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.

There are some 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 institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;

- authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the CDC funding for this study ends. Currently this is 8/31/2024. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

USE OF INFORMATION AND SPECIMENS

Returning Results to You

The result of your POC NAT test will be ready to read about 2 hours after the test is started. If you are still in the clinic when you result is ready, your provider or study staff will communicate it to you. If you wish to leave the clinic before the result is ready to read, you will be contacted with your result if it comes back with a read of greater than 1000 copies. We will help you interpret your test results. Your POC NAT result will also be noted in your clinical record and may be available via your patient portal.

Using Your Data in Future Research

The information that we obtain from you for this study might be used for future studies. We will remove anything that might identify you from the information. 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. Participants that complete the survey will be emailed a $10 Amazon gift card upon completion. Participants that complete an interview or focus group will be provided a $40 gift card.

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.

Printed name of study staff obtaining consent Signature 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 or call collect at (206) 221-5940. 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