Qualitative Consent Form
Cover Page

Study Title:
Clinical utility and feasibility of a one-step HCV testing algorithm for syringe services program clients

NCT Identification Number:
NCT06634342

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My name is [*name*] and I am a [*role*] at the University of Washington. We are asking you to be in a research study about hepatitis C testing. The information I will give you now can help you make a good choice about joining this project. Feel free to ask questions at any time in this process.

A. Why we are doing this project

We want to learn more about people's experience testing for hepatitis C (HCV) using new technology called the Xpert HCV test. We want to use this information to make HCV testing easier, especially for people who use syringe services programs. This study is funded by Cepheid, the company that developed the Xpert HCV test.

B. What will happen

If you agree to participate, you will take part in a brief interview about your experience testing for HCV with this new technology. We will also ask you about any past experiences with HCV testing and your interest in HCV treatment. We will also ask about other topics related to your health or risk for HCV such as recent drug use. We will talk to you for about 30 minutes.

We will ask to audio record the interview so we can accurately use information from the interview later. We will protect your confidentiality. We will store your name and other identifiable information separate from the study data. Access to your identifying information will be limited to certain members of the study team and individuals from UW, the study sponsor (Cepheid), or other agencies that may need to audit study records.

The recordings themselves will not be published. Instead, we will choose themes from the interviews to be used in written reports. Any quotes from the interviews that we use in reports or presentations will not have any information that could identify you.

You may ask for parts of the recording to be erased during the interview. After the interview is over, you may later contact us and ask for the entire interview to be erased. This does not apply to information that has already been used from the recording.

All recordings will be anonymous with no links to identify you. The recordings will be kept on secure, password-protected computers for 5 years and then destroyed. Study findings will be published in a peer-reviewed manuscript. It is possible that these data could be used in future manuscripts.

C. Things to consider

There are minimal risks for taking part in this study. Some of the questions we will ask may feel personal and may make you feel uncomfortable. However, you can always decline to discuss any issue or answer any question.

We ask you not to identify yourself or others by name during the interview. We will not ask for your name or ask for your signature on a written consent form. While we make every effort to keep your information confidential, it is possible someone may find out you participated in the study.

D. Benefits

There is no direct benefit to you for participating in this study. We hope that information from this study will benefit other people who may be at risk of HCV infection and need HCV testing and HCV treatment.

E. Alternatives

You may refuse to be recorded, but we will not be able to continue with the interview if you refuse to be recorded.

F. Compensation

You will be given a $40 gift card for completing the entire interview.

G. Persons to Contact

This project is run by: Sara Glick at 206-263-2044. You may call her with any questions about being in the project.
If you have questions about your rights as a participant or if you feel that you have been harmed, contact the University of Washington's Human Subjects Division at 206-543-0098.
If you want one, you will get a copy of this form to keep.

H. Confidentiality Statement

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself, we must report that to county mental health providers. If we learn of any child abuse or elder abuse, or that you intend to harm others, we must report that to local police.

J. Right to Refuse or Withdraw

Being in this study is voluntary. This means that you can refuse to sign up. It also means that if you do sign up for the study, you can decide to stop being in the study at any time without penalty.

K. Agreement

Do you have any questions? Do you agree to participate, and may I record our conversation?