Form Approved
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"Demonstration Project of HCV Rapid Testing in HIV Testing Settings"

Attachment 2a. Staff Interview and Focus Group Consent

Date: **Valid for Use Through:**

Study Title: Demonstration Project of HCV Rapid Tests in HIV Testing Settings

Principal Investigator: Alia Al-Tayyib, PhD
COMIRB No: 11-0425
Version Date:03/28/11
Version No:1.0

Staff Consent Form

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

The Denver Public Health Department (DPH) and Alert Health have recently started offering rapid testing for the Hepatitis C Virus (HCV). This study is paid for by the Centers for Disease Control and Prevention (CDC).

The reason for the focus groups and individual interviews is to learn about the best way to do rapid HCV testing. We are asking you to be in the study because you provided a rapid HCV test and you may be able to provide information about how to improve the process.

Up to 100 people will take part in the study.

What happens if I join this study?

1. If you agree to join the study, you will either take part in a focus group with up to 8 other people or be interviewed by study staff one-on-one. This will take between 1 ½ and 2 hours.

2. During the session, people will be asked questions about the following issues:
    a. knowledge of HCV and prior testing experience;
    b. testing for HCV with the rapid test process;
    c. integration of testing with workload;
    d. prior HCV counseling experience
    e. messages about HCV testing;

3. Your responses will be audio recorded.

4. No one except the study staff at DPH, Alert Health, and CDC will have access to the information you provide to us.

5. You can refuse to answer a question at any time. If you do not answer a question or want to leave the focus group, there will not be any penalty to you.

What are the possible discomforts or risks?
There are no physical risks to you by participating in this study. No one will ask about your own behaviors, and you should not share this information during your session.

FOCUS GROUP: Other focus group members may say things that may make you feel uncomfortable. If this happens, the staff will help to resolve the problem.

Because of the nature of focus groups, information may be shared among focus group participants. Please do not share any of the information we talk about with anyone outside this group.

INDIVIDUAL INTERVIEW: Interview questions may make you uncomfortable. If this happens, you can choose not to answer.

What are the possible benefits of the study?
There are no direct benefits by being in this study. The information you give us will help us better understand and improve the rapid HCV testing process.

Who is paying for this study?
This research is being paid for by the Centers for Disease Control and Prevention.

Will I be paid for being in the study? Will I have to pay for anything?
Staff participants will not receive additional payments beyond their usual salary/wages.

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?
The researcher carrying out this study is Alia Al-Tayyib. You may ask any questions you have now. If you have questions later, you may call Alia Al-Tayyib at 303-602-3601.

You may have questions about your rights as someone in this study. You can call Alia Al-Tayyib with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

Who will see my research information?
No one except the study staff at DPH, Alert Health, and CDC will have access to your comments. Any comments made by you will not be attributed to you as an individual but to the collective group of individuals we interview as a whole. The focus groups and interviews will be audio taped.

We will do everything we can to keep your records secure. It cannot be guaranteed. Both the records that identify you and the consent form signed by you may be looked at by others.

- Federal agencies that monitor human subject research
- The Colorado Multiple Institutional Review Board (COMIRB)
- The group doing the study
- The group paying for the study
- Regulatory officials from the institution where the research is being conducted who want to make sure the research is safe

Audio recordings will be kept in a locked file cabinet and will be destroyed once the information is collected.

Agreement to be in this study
I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____