Red Carpet Entry (RCE) Program Implementation Project

Attachment # 4f

Implementation Staff Interviews Consent Script

Red Carpet Entry
Implementation Staff Interview Consent Script

Introduction and Purpose:
The purpose of this interview series is to get your feedback regarding the implementation of Red Carpet Entry (RCE) in your clinic, your personal and clinic preparation for working with RCE, and the RCE implementation toolkit. RTI International, a non-profit research institute in North Carolina is conducting this research. This study is funded by the Centers for Disease Control and Prevention (CDC).

Procedures:
We are inviting you to take part in a series of individual interviews. We will collect this interview information once during the RCE pre-implementation period and over the course of the RCE implementation period (once a month for a total of 7 interviews). The interviews will be digitally audio recorded to make sure that your responses are captured accurately and to help us write a report summarizing the results of the interviews. The interviews are expected to last about 30 minutes each.

Risk/Discomforts:
There are minimal risks to you from being in this study. You can decline to talk about any topic for any reason. You can also stop being in the interview at any time. Your participation is voluntary.

Benefits:
There is no direct benefit to you for being in this study. What we learn from the interviews will help CDC disseminate the RCE intervention that may benefit people living with HIV.

Payment:
You will not receive any payment for your participation.

Confidentiality:
We will digitally record the interviews. The files will be destroyed at the end of the project. Notes will be made of the recordings and the recordings will be transcribed. Your name will not be used in project notes or transcriptions. Your comments will be kept private to the extent allowable by law. The notes will be kept on a password-protected computer. Only authorized project staff will be able to see them. Any forms related to the project that have your name or information that could identify you will be kept in a locked file cabinet. These forms will be destroyed once the project ends. However, there is still a small risk that your privacy could be broken. It is possible that de-identified transcripts could be made available or distributed to another investigator for future research studies without additional informed consent.

This research project has a Certificate of Confidentiality from the Centers for Disease CDC. Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things that you need to know. The Certificate does not protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate

cannot be used to stop a federal or state government agency from checking records or evaluating programs. The Certificate does not stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also does not stop your information from being used for other research if allowed by federal regulations. Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Right to Refuse or Withdraw:
It is your choice to participate in this interview. You can choose not to talk about any topic. You can stop participating in the interview at any time.

Persons to Contact:
The investigator in charge of this study at RTI International is Olivia Burrus, MPH. You may call Ms. Burrus toll-free at 1-866-784-1958, extension 3-4272. You can call Ms. Burrus if you have any problems or questions related to this study.

If you have any questions about your rights as a research subject, you may ask RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

Verbal Consent:
I had a chance to ask questions and my questions were answered. I received a copy of this consent form.