

Red Carpet Entry (RCE) Program Implementation Project

Attachment # 4a

RCE Client Consent Form (English)

Red Carpet Entry Implementation Evaluation Participant Consent Form

THIS STUDY AND ITS PURPOSE

You are being asked to take part in a research study that is being conducted by RTI International. This study is funded by the Centers for Disease Control and Prevention (CDC) to test a program called Red Carpet Entry. The program aims to help improve the health and wellbeing of people with HIV. You are one of approximately 120 individuals who have been diagnosed with an HIV infection being asked to participate in this study.

DO I HAVE TO JOIN THIS STUDY?

Being in this study is completely voluntary. You can stop at any time. Your decision to take part in this study will not stop you from getting any health care or stop your ability to receive services through the Red Carpet Entry program.

WHAT WE'RE ASKING OF YOU

To take part in this 8-month study, you must agree to the following:

- The project staff will access your medical records throughout the study to confirm your HIV status (when you enroll) and record your background information such as age and gender, date of HIV diagnosis, and clinic appointment attendance.

- If your clinic's normal operations are stopped because of COVID-19, the study will be extended by up to 4 months.

RISKS OF PARTICIPATION

There is a small risk that someone outside of the study may see your information. *[Insert Clinic Site Name]* is taking precautions to ensure your data remains safe and confidential. All data will be sent over secured servers and stored on servers that can only be accessed by the project team through password-protected accounts. When you enroll in the study, you will be assigned a random number to identify your data (*described below in 'Confidentiality'*).

Identifying information will not be collected or transmitted to RTI or CDC in any way. The study database that links any of your personal information obtained through the study will be password protected, stored on a secure site at your clinic, and only be used by the project team at your clinic, not by RTI or CDC.

BENEFITS OF PARTICIPATION

You might help other people with HIV by the knowledge gained from this study.

COSTS OF PARTICIPATION

Taking part in the study will not cost you anything.

COMPENSATION

You will be given a \$25 gift card when you enroll in the study.

CONFIDENTIALITY

When you enroll, we will assign you a random ID number that the project will use to identify your medical records. All of your information will be maintained at RTI and will be stored with your study ID number and not your name or anything else that can identify you.

It is possible that your clinic appointment, demographic, and date of diagnosis information could be made available or distributed to another investigator for future research studies without additional informed consent. This information will not include your personal information.

This research project has a Certificate of Confidentiality from 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.

The Certificate of Confidentiality will not be used to stop sharing your information for any purpose you have consented to in this informed consent document, such as accessing your medical records throughout the study to confirm your HIV status (when you enroll) and record your background information such as age and gender, date of HIV diagnosis, and clinic appointment attendance.

[Clinical sites will update with site-specific language about how consents will be stored and other privacy protections for research participants]

TERMINATING PARTICIPATION

You can stop taking part in this study by contacting the onsite project coordinator, [NAME], by phone (NUMBER) or email (EMAIL ADDRESS).

WHO TO CONTACT WITH QUESTIONS?

The investigator in charge of this study at RTI International is Ms. Olivia Burrus. 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 participant in this study, you may contact *[Insert local IRB contact information]*.

STATEMENT OF CONSENT FOR THE INTERVENTION STUDY

Signing the line below indicates that we have described the study procedures to you, asked you to take part, and given you the chance to ask questions. You do not give up any rights by signing this consent form. We can give you an unsigned copy of this form if you would like.

Do you have any questions?

By putting my signature on the line below, I am agreeing to take part in the Red Carpet Entry Implementation Evaluation.

Date

Signature of Individual