Form
OMB No: 0920-1091
Exp. Date: 12/31/2018

The Data to Care (D2C) Public Health Strategy: Successes, Challenges, and Lessons Learned in Identifying, Linking, and Reengaging Persons Diagnosed with HIV to Medical Care

Attachment 2: Informed Consent Forms for D2C Program Staff, and for D2C Clients

D2C Program Staff Informed Consent Form

Consent to be a Research Subject

Title: The Data to Care (D2C) Public Health Strategy: Successes, Challenges, and Lessons Learned in Identifying, Linking, and Reengaging Persons Diagnosed with HIV to Medical Care

Principal Investigator: James W. Carey, PhD, MPH

Project Director: Alisú Schoua-Glusberg, PhD

Funding Source: Centers for Disease Control and Prevention (CDC)

Introduction

You are being asked to be in a research study. This form tells you things you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and leave the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to learn what makes Data to Care (D2C) programs run well. D2C programs find persons living with HIV (PLWH) who are not getting health care, and try to help them get health care. This study will be in five counties in Louisiana, Florida, and Virginia. These three states have existing D2C programs. We will do interviews with PLWH who have received D2C help in the past. We also will do interviews with health department staff, health care providers, and other people who work in D2C programs. The study findings will help CDC learn what makes D2C programs run well. The findings will be used to improve existing D2C programs, and to design new D2C programs.

Procedures

We are asking you to join a research study. This form tells you what you need to know before you decide to be in this study. Participation in this study is not required for employment in D2C programs and your supervisor will not know whether or not you have participated. It is completely up to you if you want to be in this study. If you decide to be in this study, you can stop at any time. You will be asked to take part in an interview that will take about 1 hour. You can skip any questions that you do not want to answer. Participating in this study will not affect

the healthcare you currently receive or may receive in the future. If you decide that you do not want to be in the study anymore, please tell the person who is interviewing you.

Audio Recording

With your permission, the interview will be recorded. The person who does the interview will also take notes. When the interview is over, we will write it up. When we write up your interview, we will not include your name or the names of other people you might talk about. After the study is over and all information has been written, we will destroy the audio recording of your interview.

Risks and Discomforts

There is no risk that we know about if you participate in this study. Some questions might make you feel uncomfortable. You do not have to answer any questions that make you feel uneasy. If something comes up for you that you want to know more about or you think is a problem in your life that you need help with – like depression – we can give you the names of places that are close to where you live and can help you.

The greatest risk to you is a breach of data security resulting in the release of your private information. In order to prevent this from happening, we will assign you a study identification number. Your name will not be used on any study forms. All research documents and audio recordings will be kept in a locked file cabinet in a secure place. When we type up your interview, we will not use your name and we will take out any names you say. No reports will contain any words that will tell someone who you are. Your interview will be kept in a password protected file and only authorized staff can access your information. No information will be given to supervisors about your screening or enrollment in our study. Your privacy will be guarded with no disclosure to employers.

Benefits

This study is not designed to benefit you directly. The study is intended to learn what makes D2C programs run well. The study results may be used to help D2C programs run better. There may be no direct benefit to you as a participant in this study.

Study Consideration

If you are in the study, you will receive $40 as a token of appreciation.

Privacy

We will do everything we can to protect your privacy to the extent allowed by law. In order to reach you to schedule the interview, we have your name and contact information. This information is kept in a locked file cabinet separate from our study records. We will not share your name or contact information with other study participants or your supervisors. Immediately after the study is over and all information has been written, we will destroy any lists containing your name and contact information, along with the audio recording of your interview.

If you decide to participate, we will give you a code number. We will use this number instead of your name in the interview write up and other data sets. Your interview notes and audio recordings will be kept in a locked file cabinet in a secure place and are only accessible to study

staff. When we write up your interview, we will remove any names you might use. Your interview write up will be kept in secure computers and in password-protected files. Your name and other facts that might point to you will not appear when we present this study or publish its results. Immediately after the study is over and all information has been written, we will destroy any lists containing your name and contact information, along with the audio recording of your interview.

Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. Your participation in this study is voluntary. That means it is completely up to you to be in this study. You can stop being in the study even after you agree to be in the interview. You may refuse to do anything you do not feel comfortable with, or refuse to answer any questions that you do not want to answer. Your decision has no effect on your current or future participation in working with D2C programs. We may ask you to stop being in the study at any time if we decide that it is not in your best interest. If we think that you are not following study instructions, or having trouble with the interview, we might ask you to stop participating in this study.

What if I have questions?

If you have any questions about this study or if you feel you have been harmed, please call Dr. Alisú Schoua-Glusberg at 1-847-971-9068. If you have any questions about your rights as a participant in this study, please contact CDC/ATSDR's Deputy Associate Director for Science at 1-800-584-8814. Leave a message with your name, phone number, and refer to CDC protocol # ____, and someone will call you back.

Consent

Please print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____

Name of Subject

_____ _____

Signature of Subject Date Time

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time

D2C Client Informed Consent Form

Consent to be a Research Subject

Title: The Data to Care (D2C) Public Health Strategy: Successes, Challenges, and Lessons Learned in Identifying, Linking, and Reengaging Persons Diagnosed with HIV to Medical Care

Principal Investigator: James W. Carey, PhD, MPH

Project Director: Alisú Schoua-Glusberg, PhD

Funding Source: Centers for Disease Control and Prevention (CDC)

Introduction

You are being asked to be in a research study. This form tells you things you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and leave the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to learn what makes Data to Care (D2C) programs run well. D2C programs find persons living with HIV (PLWH) who are not getting health care, and try to help them get health care. This study will be in five counties in Louisiana, Florida, and Virginia. These three states have existing D2C programs. We will do interviews with PLWH who have received D2C help in the past. We also will do interviews with health department staff, health care providers, and other people who work in D2C programs. The study findings will help CDC learn what makes D2C programs run well. The findings will be used to improve existing D2C programs, and to design new D2C programs.

Procedures

We are asking you to join a research study. This form tells you what you need to know before you decide to be in this study. Participation in this study does not affect D2C services you receive. We will not tell anybody in the D2C program whether or not you have participated. It is completely up to you if you want to be in this study. If you decide to be in this study, you can stop at any time. You will be asked to take part in an interview that will take about 1 hour. You can skip any questions that you do not want to answer. Participating in this study will not affect the healthcare you currently receive or may receive in the future. If you decide that you do not want to be in the study anymore, please tell the person who is interviewing you.

Audio Recording

With your permission, the interview will be recorded. The person who does the interview will also take notes. When the interview is over, we will write it up. When we write up your interview, we will not include your name or the names of other people you might talk about. After the study is over and all information has been written, we will destroy the audio recording of your interview.

Risks and Discomforts

There is no risk that we know about if you participate in this study. Some questions might make you feel uncomfortable. You do not have to answer any questions that make you feel uneasy. If something comes up for you that you want to know more about or you think is a problem in your life that you need help with – like depression – we can give you the names of places that are close to where you live and can help you.

The greatest risk to you is a breach of data security resulting in the release of your private information. In order to prevent this from happening, we will assign you a study identification number. Your name will not be used on any study forms. All research documents and audio recordings will be kept in a locked file cabinet in a secure place. When we type up your interview, we will not use your name and we will take out any names you say. No reports will contain any words that will tell someone who you are. We will not tell any of your health care providers that you participated in this study. Your interview will be kept in a password protected file and only authorized staff can access your information.

Benefits

This study is not designed to benefit you directly. The study is intended to learn what makes D2C programs run well. The study results may be used to help D2C programs run better. There may be no direct benefit to you as a participant in this study.

Study Consideration

If you are in the study, you will receive $40 as a token of appreciation.

Privacy

We will do everything we can to protect your privacy to the extent allowed by law. In order to reach you to schedule the interview, we have your name and contact information. This information is kept in a locked file cabinet separate from our study records. We will not share your name or contact information with other study participants or with D2C program staff. Immediately after the study is over and all information has been written, we will destroy any lists containing your name and contact information, along with the audio recording of your interview.

If you decide to participate, we will give you a code number. We will use this number instead of your name in the interview write up and other data sets. Your interview notes and audio recordings will be kept in a locked file cabinet in a secure place and are only accessible to study staff. When we write up your interview, we will remove any names you might use. Your interview write up will be kept in secure computers and in password-protected files. Your name

and other facts that might point to you will not appear when we present this study or publish its results. After the study is over, we will destroy the audio recording of your interview.

Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. Your participation in this study is voluntary. That means it is completely up to you to be in this study. You can stop being in the study even after you agree to be in the interview. You may refuse to do anything you do not feel comfortable with, or refuse to answer any questions that you do not want to answer. Your decision has no effect on the care, treatment, or services that you get right now or any services that you may get later. We may ask you to stop being in the study at any time if we decide that it is not in your best interest. If we think that you are not following study instructions, or having trouble with the interview, we might ask you to stop participating in this study.

What if I have questions?

If you have any questions about this study or if you feel you have been harmed, please call Dr. Alisú Schoua-Glusberg at 1-847-971-9068. If you have any questions about your rights as a participant in this study, please contact CDC/ATSDR's Deputy Associate Director for Science at 1-800-584-8814. Leave a message with your name, phone number, and refer to CDC protocol # ____, and someone will call you back.

Consent

Please print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____

Name of Subject

_____ _____

Signature of Subject Date Time

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time