Local Effectiveness Assessment Project (LEAP), Part II

2. Informed Consent

Emory University

Consent to be a Research Subject

Title: Local Effectiveness Assessment Project, Part II: Case Studies of Local Jurisdictions Providing HIV Services to Men Who Have Sex with Men (MSM)

Principal Investigator: Paula Frew, PhD, MA, MPH

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

Introduction

You are being asked to be in a research study. This form is designed to tell you the 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 gain a deeper understanding of the different things that influence MSM HIV prevention and care needs. We will measure current conditions in selected local areas through case studies, a detailed study of a person, group or situation. Understanding prevention and protective factors is critical to CDC's ability to create programs and activities. The goal of these programs and activities is to reduce HIV incidence and prevalence in the population. The purpose of this study is to provide CDC and local public health organizations with information needed to design more successful HIV prevention, care, and treatment services.

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. 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 extracted, we will destroy the recording that has your interview.

Risks and Discomforts

There is no risk that we know about if you participate in this study. Some of the 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. 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.

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.

Benefits

This study is not designed to benefit you directly. This study is designed to learn more about the different factors that influence MSM HIV prevention and care needs and outcomes. The study results may be used to help others in the future. There may be no direct benefit to you as a participant in this study.

Study Consideration

You will be offered $40 as a token of appreciation associated with being in this study.

1. Privacy

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Research Compliance. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

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.

Contact Information

Contact the PI Dr. Paula Frew at: 404-712-8546; or by writing to pfrew@emory.edu

- if you have any questions about this study or your part in it, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

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