MyLife MyStyle Project

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Informed Consent Form

A. PURPOSE OF THE STUDY

You are invited to be part of a research study of up to 528 young men. The goal of the research is to find out if being part of a MyLife MyStyle group helps men make healthier choices in their lives. The information on this form can help you make a good choice about joining the study. We will use the information from this study to improve HIV services and programs available to young men in Los Angeles County. You are invited to be part of this study because you are an African American or Black man between the ages of 18 and 29 years and you live in Los Angeles County. In The Meantime Men's Group (ITMT) and the Los Angeles County Department of Public Health (LACDPH) are conducting this study. The study is funded by the Centers for Disease Control and Prevention (CDC).

B. PROCEDURES

If you agree to take part in this study, the following will happen:

1. **You will be asked to complete a survey using a computer. The computer will read the questions to you and you will enter your responses into the computer. The survey has questions about your health, drug use, sex behaviors and access to HIV prevention services. You may refuse to answer any question at any time for any reason. If you refuse to answer a question or want to end the survey you will not be punished in any way. The survey will take about one hour to complete.**
2. Once you finish the survey, you will be randomly assigned to be in Group 1 or Group 2. Random assignment is like flipping a coin.

    a. If you are assigned to Group 1, you will be asked to attend three MyLife MyStyle sessions in the next week or so. Being part of Group 1 means you will attend three weekly sessions of MyLife MyStyle with a small group of up to 11 other men. Each group session will last about 1½ hours. A trained group leader will guide each session and will introduce topics related to healthy life choices, dating relationships, HIV risks, and other topics important to young Black men. If you are not comfortable talking about any of the topics, you can refuse to answer any questions or leave the project at any time. At the end of each group session, you will be asked to fill out a brief survey to describe what you did and did not like about the session. If you are more than 15 minutes late to the first group, you will be asked to leave and attend a different group at a future time.

    b. If you are assigned to Group 2, you will be invited to the same MyLife MyStyle sessions but the groups will start in about seven months from now. Between now and the start of the groups, the group leader will want to keep in contact with you

about once a month so we can be sure to tell you when your group sessions are going to start.

3. **Everyone who decides to be in the study will be asked to take a second computer survey four months after completing the first survey. This second survey will take about one hour to complete.**

4. **Everyone who decides to be in the study will be asked to take a third computer survey. This third survey will take place three months after completing the second survey. The third survey will take about one hour to complete.**

5. **Up to 36 young men from Group 1 will be asked to take part in a one-on-one interview to talk about their opinions of being in the MyLife program. The 90-minute discussion will take place with a trained interviewer within a few weeks of the third computer survey.**

C. RISKS

There are minimal risks from being in this study:

1. Questions in the surveys are about topics that may make you feel guilty or uncomfortable, and drug use that may be illegal. All answers you give will be kept private. This information will not be shared with law enforcement except for things covered under the DUTY TO PROTECT section. Your name will not be connected to your answers in any way.

D. BENEFITS

Benefits to others include:

1. This study will help In The Meantime Men's Group and the HIV Epidemiology Program learn more about the best ways to help young Black men reduce their risks of getting HIV or giving HIV to others.

E. ALTERNATIVES

HIV prevention groups and other types of support groups are available to you whether you take part in this study or not. If you join the study, it will not affect your ability to take part in other groups. You have the option to not join the study. If you are not interested in being in the study, you can get referrals to other types of HIV prevention services that you may need.

F. TOKEN OF APPRECIATION

You will get $20 today for completing the first computer survey.

If you are randomly assigned to Group 1, you will get $25 for each session you attend over the next three weeks. This means that you can get up to $75 for taking part in these group sessions.

If you are randomly assigned to Group 2, you will get $25 for each session you attend. These sessions will begin about seven months from today. This means that you can get up to $75 for taking part in these group sessions.

You will get $30 to complete the second computer survey about four months from today.

You will get $30 to complete the third computer survey about seven months from today.

If you are selected to take part in the one-on-one interview, you will get $50.

G. OFFER TO ANSWER QUESTIONS

This study is run by Jeffrey King at (323-733-4868) and Trista Bingham, MPH, PhD at (213-351-8175). You may call them with any questions about the study. 1If you are hurt as a result of being in this study, treatment will not be provided by LACDPH. LACDPH does not normally pay for harm done to you as a result of being in a research study. However, by signing this consent form and agreeing to be in this study, you are not giving up any of your rights. You can get referrals for free health care that are available in the county. If you believe that you have been harmed, please contact Olga Coronado at the Institutional Review Board Office at 213-250-8675 for information on your rights and advice on how to proceed.

You will get a copy of this form to keep.

H. Privacy STATEMENT

The information you give for this study is secure. No personal identifiers will be attached to your responses. Your rights as a research subject in this study are in accord with US regulation 45CFR46 Subpart C.

Several steps will be taken to protect your privacy:

1. Your name will not be linked to the answers you give.
2. Also, it will be stressed that personal information about people in the group or third parties should not be discussed outside of the group.
3. To guard your privacy, we will give you a unique study ID number.
4. Data will be kept in computer files that are protected by passwords. Hard copies of the data or lists of names and ID codes for participants will be kept in a separate locked file cabinet in the project office.
5. When results of this study are published, your name will not be used.

I. DUTY TO PROTECT

If you tell us about the sexual or physical abuse of a minor, we must report it to the authorities. Also, if you tell us that you plan to harm yourself or another person, we will contact the proper authorities.

J. VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

This study is VOLUNTARY. Whether or not you join will not affect your right to take part in other services offered by ITMT or LACDPH. You are not giving up any legal claims or rights because of your participation in this study. If you do join, you are free to take back your consent and quit the study at any time.

California law states that you must know about:

1. The nature and purpose of the study.
2. The procedure in the study and any drug or device to be used.
3. Discomforts and risks to be expected from the study.

4. Benefits to be expected from the study.
5. Alternative procedures, drugs or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment if complications occur.
7. The option to ask questions about the study or the procedure.
8. The option to withdraw without affecting your future care at this institution.
9. A copy of the written consent form for the study.
10. The option to consent freely to the study without the use of coercion.
11. Liability for research-related injury.

K. AGREEMENT

"I have read (or someone has read to me) the information provided above. I have been given the chance to ask questions and all of my questions have been answered to my satisfaction. The signature below shows that I have chosen to be part of the study, having read the information given to me."

_____	_____	_____
Date	Signature	Person obtaining consent

_____

Principal Investigator (or designee)