EFFECTIVE

4-1-2019

MCW/FH IRB

Medical College of Wisconsin and Froedtert Hospital
INTRODUCTION TO THE INFORMED CONSENT

Name of Subject: _____

Increasing PrEP Use in High Risk Social Networks of African American MSM in Underserved Low-Uptake Cities (Project SNAP)

Network Member Consent

Jeffrey A. Kelly, PhD
Department of Psychiatry and Behavioral Medicine
414.955.7700
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

You are invited to take part in this research. You can decide whether to take part in this project or not. You are free to say yes or no. If there is anything that you do not understand, please ask questions.

Definitions

HIV: Human immunodeficiency virus: the virus that causes AIDS

MSM: Men who have sex with men

PrEP: Pre-exposure prophylaxis: medication taken to prevent HIV infection

Friendship Network: You, your friends, and the friends of your friends

Purpose

This project is being done to test ways to encourage men who have sex with men (MSM) to consider taking a medication (commonly referred to as PrEP) to prevent HIV infection.

Length

- You will be in this research project for about 60 minutes today.
- You will be asked to return to our offices and complete 2 more surveys during the next 18 months.

Project Activities

The project will recruit groups (or networks) of MSM friends. Everyone will be asked to complete 3 surveys: 1 at the beginning of the study, 1 approximately 9 months after the first, and the final survey about 9 months after the second.

Friendship networks will be divided evenly between 2 programs that encourage PrEP use. One training program is short (one session), and one training program is longer.

List of visits:

- Today: 60 minutes
- In 9 months: 60 minutes
- In 18 months: 60 minutes

Procedures/Activities that will occur at various visits:

Invasive Activities

- None.

Non-invasive Activities

- Surveys

Risks

This is a brief list of the most commonly seen risks The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Confidentiality risks:

- The most common risk in a project like this one is a breach of confidentiality. We have created many safeguards against a breach and we will do our best to protect your confidentiality.

Benefits

This project may or may not help you, but we hope the information from this project will help us develop better ways to encourage men who have sex with men to use PrEP.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Jeffrey A. Kelly, PhD, at 414-955-7700.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because someone already enrolled in the study has named you as a member of his friendship network.

A total of about 500 people are expected to participate in this research in Milwaukee, WI, and in Cleveland, OH. Approximately 250 people will participate in each city.

The Director of the project is Jeffrey A. Kelly, PhD in the Department of Psychiatry and Behavioral Medicine at the Medical College of Wisconsin. A research team works with Dr. Kelly. You can ask who these people are.

The National Institutes of Health, a government agency, is funding this research.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. Even if you join this project, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to test ways to encourage MSM to consider taking a medication (commonly referred to as PrEP) that will help them prevent HIV infection. We are focusing on African American MSM because HIV infection rates are much higher in this population and because fewer African American MSM take PrEP than White MSM.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

Recruitment and Enrollment:
You are being asked to participate in an interview during which we will ask you to give us some personal information (like your name, age, gender, phone number, and other information needed for us to contact you). We may also ask you to give us the first name, last initial (but not the last name) of close male or transgendered friends who you know or believe to have sex with men. You will be asked a few questions about each friend (for example, how long have you known him). If we ask you to identify your friends, we will also ask you to give each friend you told us about an invitation to participate in the study. The invitation materials will explain the study and will include study team contact information, our office location, and directions on how to make an appointment to enroll in the study. You will get one invitation for each person you tell us about. In a few days, you may also be asked to call a friend who has not yet made an appointment with study staff.

Everyone who comes in belongs to a “friendship network.” Your friendship network consists of the person who invited you to participate in the study as well as other individuals who were invited. While it is likely you will know most of these people, it is possible you may not know everyone. We will ask all members of each network questions about the person who invited you (for example, how often do you spend time with the person). Responses to these questions will help us identify the people in each network who are most influential.

Research Study Groups:
There will be two groups in this study, and each will consist of several different friendship networks. Members of each group will receive counseling about the benefits of taking PrEP and other ways of reducing HIV risk during the first study visit. The only difference between the two groups is that one group of friendship networks will have their most influential members participate in a program that trains people to talk with their friends about PrEP and other ways to prevent HIV infection, and the other group will not be enrolled in this training program.

Randomization:
Because no one knows which of these groups is best, you and others in your friendship network will be "randomized" into one of the two study groups. Randomization means that each friendship network is put into one of the research study groups by chance. It is like flipping a coin. Each friendship network will have an equal chance of being placed in either group. Neither you nor the study team can choose which group your network will be in, but you will be told which group you are in once the groups have been determined.

Surveys:
You will be asked to complete a survey that asks questions about your sexual behavior, your substance use, and your knowledge and attitudes toward different aspects of HIV prevention, including the use of PrEP, at three separate times during the study. You'll also be asked to update or confirm your personal information so that we may contact you to remind you of your next study visit.

The study visits will occur:
1. Today;
2. Approximately 9 months from today;
3. Approximately 18 months from today

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this project for approximately 18 months.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

The research team may stop your participation in the project at any time for any reason without your consent. We will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems. **You need to tell the research director or a member of the research team immediately if you experience any problems or become too upset to continue**

Many questions on the surveys ask about sex, sexual practices, sexual behaviors, and substance use. The problems that some people have experienced in studies like this one are discomfort or awkwardness over some of the items asked during the survey. You may also feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a

question, you may skip it and go to the next question, or you may stop immediately. If you become upset, please let us know immediately and we may be able to help you.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The study team can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The study team will use the Certificate to resist any demands for information that would identify you, unless:

- you report that you intend to harm yourself or others; or
- you report sexual contact with an adolescent younger than 16.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of reported intent to harm yourself or others, or of reported sexual contact with adolescents younger than 16.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project may or may not help you, but we hope the information from this project will help us develop a better way to encourage PrEP use among MSM.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact a member of the study team.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will be paid $50 in cash after you complete each survey (maximum of 3 surveys: now, 9 months from now, 18 months from now.

Each of these payments is to compensate you for your time in completing the survey and to offset the cost of parking or traveling by public transportation.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Jeffrey Kelly, PhD, at 414.955.7700.

- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, as described below. We will only collect and use information needed for the project.

The health information we will collect and use for this project is:
Health information collected during the study's surveys. This information will include your HIV status (positive or negative) and reported adherence to medical care.

E2. Who will see the health information collected for this project?

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital and at The AIDS Taskforce of Greater Cleveland, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Jeffrey A. Kelly, PhD, at *Department of Psychiatry and Behavioral*

Medicine/CAIR; 8701 Watertown Plank Road, Milwaukee WI 53226. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**

EFFECTIVE

4-1-2019

MCW/FH IRB

Medical College of Wisconsin and Froedtert Hospital
INTRODUCTION TO THE INFORMED CONSENT

Name of Subject: _____

Increasing PrEP Use in High Risk Social Networks of African American MSM in Underserved Low-Uptake Cities (Project SNAP)

Network Seed Consent

Jeffrey A. Kelly, PhD
Department of Psychiatry and Behavioral Medicine
414.955.7700
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

You are invited to take part in this research. You can decide whether to take part in this project or not. You are free to say yes or no. If there is anything that you do not understand, please ask questions.

Definitions

HIV: Human immunodeficiency virus: the virus that causes AIDS

MSM: Men who have sex with men

PrEP: Pre-exposure prophylaxis: medication taken to prevent HIV infection

Friendship Network: You, your friends, and the friends of your friends

Purpose

This project is being done to test ways to encourage men who have sex with men (MSM) to consider taking a medication (commonly referred to as PrEP) to prevent HIV infection.

Length

- You will be in this research project for about 90 minutes today.
- You will then be asked to invite your friends to participate in the project. This part of the project could take 2-3 weeks
- Once the group of friends is enrolled in the project, you will be asked to complete 3 surveys during the next 18 months.

Project Activities

The project will recruit groups (or networks) of MSM friends. Because you are an influential person, we are asking you to be a network seed; that is, you are the first person in your group of friends we have asked to participate. In the next 30-40 minutes we will ask you to give us a list of your MSM friends, ask a few questions about each person, and then give you materials that you will use to invite your friends to participate in the project. We will ask your friends similar questions.

Everyone will be asked to complete 3 surveys: 1 at the beginning of the study, 1 approximately 9 months after the first, and the final survey about 9 months after the second.

Friendship networks will be divided evenly between 2 programs that encourage PrEP use. One program is short (one session), and one program is longer (seven sessions).

List of visits:

- Today: 90 minutes
- In 9 months: 60 minutes
- In 18 months: 60 minutes

Procedures/Activities that will occur at various visits:

Invasive Activities

- None.

Non-invasive Activities

- Surveys

Risks

This is a brief list of the most commonly seen risks The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Confidentiality risks:

- The most common risk in a project like this one is a breach of confidentiality. We have created many safeguards against a breach and we will do our best to protect your confidentiality.

Benefits

This project may or may not help you, but we hope the information from this project will help us develop better ways to encourage men who have sex with men to use PrEP.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Jeffrey A. Kelly, PhD, at 414-955-7700.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you have been identified as an influential person who has a lot of MSM friends.

A total of about 500 people are expected to participate in this research in Milwaukee, WI, and in Cleveland, OH. Approximately 250 people will participate in each city.

The Director of the project is Jeffrey A. Kelly, PhD in the Department of Psychiatry and Behavioral Medicine at the Medical College of Wisconsin. A research team works with Dr. Kelly. You can ask who these people are.

The National Institutes of Health, a government agency, is funding this research.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. Even if you join this project, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to test ways to encourage MSM to consider taking a medication (commonly referred to as PrEP) that will help them prevent HIV infection. We are focusing on African American MSM because HIV infection rates are much higher in this population and because fewer African American MSM take PrEP than White MSM.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

Recruitment and Enrollment:
You are being asked to participate in an interview during which we will ask you to give us some personal information (like your name, age, gender, phone number, and other information needed for us to contact you). We will also ask you to give us the first name, last initial (but not the last name) of close male or transgendered friends who you know or believe to have sex with men. You will be asked a few questions about each friend (for example, how long have you known him). This interview may take 30-40 minutes.

After the interview, we will ask you to give each friend you told us about an invitation to participate in the study. The invitation materials will explain the study and will include study team contact information, our office location, and directions on how to make an appointment to enroll in the study. You will get one invitation for each person you tell us about. In a few days, you may also be asked to call a friend who has not yet made an appointment with study staff.

Your friends will be asked to list their friends who are MSM and then to invite those friends to participate in the study also. The entire group of people (that is, you, your friends, and their friends) is called a “friendship network.” We will ask all members of each network questions about other network members. We will ask you questions about the people you name (for example, how long have you known the person), and we will ask your friends questions about you (for example, how often do you spend time with the person). Responses to these questions will help us identify the people in each network who are most influential.

Research Study Groups:
There will be two groups in this study, and each will consist of several different friendship networks. Members of each group will receive counseling about the benefits of taking PrEP and other ways of reducing HIV risk during the first study visit. The only difference between the two groups is that one group of friendship networks will have their most influential members participate in a program that trains people to talk with their friends about PrEP and other ways to prevent HIV infection, and the other group will not be enrolled in this training program.

Randomization:
Because no one knows which of these groups is best, you and others in your friendship network will be "randomized" into one of the two study groups. Randomization means that each friendship network is put into one of the research study groups by chance. It is like flipping a coin. Each friendship network will have an equal chance of being placed in either group. Neither you nor the study team can choose which group your network will be in, but you will be told which group you are in once the groups have been determined.

Surveys:
You will be asked to complete a survey that asks questions about your sexual behavior, your substance use, and your knowledge and attitudes toward different aspects of HIV prevention, including the use of PrEP, at three separate times during the study. You'll also be asked to update or confirm your personal information so that we may contact you to remind you of your next study visit.

The study visits will occur:
1. Today;
2. Approximately 9 months from today;
3. Approximately 18 months from today

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this project for approximately 18 months.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

The research team may stop your participation in the project at any time for any reason without your consent. We will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems. **You need to tell the research director or a member of the research team immediately if you experience any problems or become too upset to continue**

Many questions on the surveys ask about sex, sexual practices, sexual behaviors, and substance use. The problems that some people have experienced in studies like this one are discomfort or awkwardness over some of the items asked during the survey. You may also feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a

question, you may skip it and go to the next question, or you may stop immediately. If you become upset, please let us know immediately and we may be able to help you.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The study team can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The study team will use the Certificate to resist any demands for information that would identify you, unless:

- you report that you intend to harm yourself or others; or
- you report sexual contact with an adolescent younger than 16.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of reported intent to harm yourself or others, or of reported sexual contact with adolescents younger than 16.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project may or may not help you, but we hope the information from this project will help us develop a better way to encourage PrEP use among MSM.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact a member of the study team.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will be paid $50 in cash for providing us a list of your MSM friends and inviting those friends to participate in the study.

You will be paid $50 in cash after you complete each survey (maximum of 3 surveys: now, 9 months from now, 18 months from now.

Each of these payments is to compensate you for your time in completing the survey and to offset the cost of parking or traveling by public transportation.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Jeffrey Kelly, PhD, at 414.955.7700.

- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, as described below. We will only collect and use information needed for the project.

The health information we will collect and use for this project is:
Health information collected during the study's surveys. This information will include your HIV status (positive or negative) and reported adherence to medical care.

E2. Who will see the health information collected for this project?

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital and at The AIDS Taskforce of Greater Cleveland, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Jeffrey A. Kelly, PhD, at *Department of Psychiatry and Behavioral*

Medicine/CAIR; 8701 Watertown Plank Road, Milwaukee WI 53226. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**

EFFECTIVE

4-1-2019

MCW/FH IRB

Medical College of Wisconsin and Froedtert Hospital
INTRODUCTION TO THE INFORMED CONSENT

Name of Subject: _____

Increasing PrEP Use in High Risk Social Networks of African American MSM in Underserved, Low-Uptake Cities

Consent for Training

Jeffrey A. Kelly, PhD
Department of Psychiatry and Behavioral Medicine
414.955.7700
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

You are invited to take part in this research. You can decide whether to take part in this project or not. You are free to say yes or no. If there is anything that you do not understand, please ask questions.

Definitions

HIV: Human immunodeficiency virus—the virus that causes AIDS

MSM: Men who have sex with men

PrEP: Pre-exposure prophylaxis—a medication that may be taken to prevent HIV infection

Friendship Network—the people who you and your friends socialize with

Purpose

This project is being done to train influential members of each friendship network about PrEP and how to talk with their friends about PrEP.

Length

- You will be in this research project for the next nine weeks, spending 2 hours each week in the training sessions.

Activities

Seven interactive training sessions about PrEP and HIV prevention. These sessions will be approximately 2 hours each.

List of visits:

- Five weekly sessions, plus 2 booster sessions

Activities that will occur at various visits:

Invasive Activities

- None

Non-invasive Activities

- 7 training sessions of 2 hours each

Risks

This is a brief list of the most commonly seen risks The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Training Session risks:

- The most common risk is a breach of confidentiality. You will be in a small group with other study participants, some of whom you may know, and some who may know you. While we ask everyone to maintain confidentiality and respect other participants' privacy, we cannot guarantee everyone will comply. Thus, there is a possibility that your attendance and your statements and actions during sessions may become known outside of the training group.

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Benefits

This project may or may not help you, but we hope the information from this project will help us develop a better way to encourage MSM to take PrEP.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Jeffrey Kelly, PhD, at 414.955.7700.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you have been identified as an influential member of your friendship network. Because you are influential, we are asking you to be trained to talk with your friends about PrEP.

A total of about 500 people are expected to participate in this research in Milwaukee, WI, and in Cleveland, OH. Approximately 30-35 people in each city will be trained as influence leaders.

The Director of the project is Jeffrey Kelly, PhD, in the Department of Psychiatry and Behavioral Medicine at the Medical College of Wisconsin. A research team works with Dr. Kelly. You can ask who these people are.

The National Institutes of Health, a government agency, is funding the research.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. Even if you join this project, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to:

- Train influential people about PrEP;
- Ask them to talk with their friends;
- Study whether this training helps to encourage MSM to take PrEP

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

You are being asked to attend seven training sessions over a 9-week period. Each session will last about two hours. Five or six other network leaders will also attend these sessions, which will be led by two members of the research team. The first 5 training sessions will provide you with accurate information about PrEP through instruction, role plays, and other activities that teach you how to talk about what you learn to members of your friendship group. The last 2 sessions will be booster sessions in which you will talk about what has worked or not worked when talking with your network members. The first 5 sessions will occur once a week for the next five weeks; the last two sessions will be held 2 weeks and 4 weeks after Session 5.

A key part of this training is that you talk with your network members and other friends about what you learn about PrEP and HIV prevention in the training sessions.

Audio Recording of Training Sessions:
All training sessions in this study will be audio recorded to ensure everyone being trained receives the same information. The recordings will be digital and will be stored on password-protected computers. These computers are only accessible to members of the study team. Please indicate your preferences for audio recording below:

_____ I do **not** wish to be audiorecorded. I understand that my decision means that I cannot attend the training sessions, but I will be able to complete the other parts of the study.

_____ I agree to be audiorecorded. I will inform the study team if I change my mind at any time during the study.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in the training sessions for approximately 9 weeks.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

The research team may stop your participation in the project at any time for any reason without your consent. We will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems. **You need to tell the research director or a member of the research team immediately if you experience any problems or become too upset to continue.**

By far the biggest risk is a breach of confidentiality. You will be attending sessions with five or six other people, plus the two members of the research team. Although we ask everyone involved to maintain confidentiality, it is possible that your attendance at a session and/or your statements/actions during a session may be divulged to people beyond the training group.

Because we cannot guarantee complete confidentiality, we ask that you not identify any individual by name and that you not share deeply personal feelings or stories during the training sessions.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The study team can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The study team will use the Certificate to resist any demands for information that would identify you, unless:

- you report that you intend to harm yourself or others; or
- you report sexual contact with an adolescent younger than 16.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of reported intent to harm yourself or others, or of reported sexual contact with adolescents younger than 16.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project may or may not help you, but we hope the information from this project will help us develop a better way to encourage MSM who are at risk of HIV infection to take PrEP.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact Dr. Kelly.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will be paid $50 in cash after each training session for your time and to offset the cost of parking or traveling by public transportation. The maximum amount you may receive is $350 if you participate in all seven sessions.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Jeffrey Kelly, PhD, at 414.955.7700.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**