Consent Form for Participation in a Research Study

Principal Investigator: Michael Copenhaver
Student Researcher: Mistler CB
Study Title: Optimizing evidence-based HIV prevention targeting people who inject drugs (PWID) on PrEP
Sponsor: National Institute on Drug Abuse (NIDA)

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. There are no penalties for withdrawing from this study at any time and your status at the APT Foundation treatment program will not be affected in any way. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision. This research study is being done to help us learn the best ways of delivering HIV prevention groups for people who have some cognitive challenges, like difficulty concentrating or remembering information. Improving how we deliver these groups may assist in helping you reduce health risks while you’re in drug treatment. Participation will involve approximately 90 minutes of your time per interview, with a total of 5 interviews. We also require 1 hour of your time each week after your initial interview to attend groups, and this will continue weekly for 4 weeks until intervention completion. You will be asked to answer person drug and sex related questions, and provide a skills demonstration all 5 interview time points, we will also ask you to supply a blood spot at post, and the 3 follow-up time points. Risks include group participants breaching confidentiality, being identified as a participant in a research study by other patients or staff, feeling upset by some of the material brought up in the group meetings, or by knowing that the meetings are being audio-taped. Risks are described in more detail later in this form. There may also be benefits from participation. We believe that these groups have the potential to be helpful for reducing health risks related to getting infected or transmitting HIV. Before making a decision about whether to participate in this research you should know that there are other options available to you. You may choose to participate in a different harm reduction study that you feel suits your needs better.

A more detailed description of this research follows.

Introduction

First of all, thank you for taking the time to look over this invitation to participate in our study. You are invited to participate in a research study designed to help us learn the best ways of delivering
HIV prevention groups to help you reduce health risks while you’re in drug treatment. You have been asked to participate because you are HIV-negative, enrolled in drug treatment at the APT Foundation, and have reported mild cognitive impairment.

In order to decide whether or not you want to be a part of this study, you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and potential benefits. We also encourage you to ask questions now and at any time. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this consent form, and you will be given a copy.

Why is this study being done?

The purpose of this research study is to help us understand better methods to use in delivering HIV prevention groups to patients in drug treatment so they will better adhere to pre-exposure prophylaxis (PrEP) and lower their risk of getting HIV. We plan to enroll 256 participants in this study for this purpose. The intervention group meetings will focus on ways people can lower their risks of being infected with HIV and ways they can improve their adherence to PrEP medication. We hope that we can help patients reduce their risks for HIV by improving our methods.

What are the study procedures? What will I be asked to do?

If you agree to participate in this study, you will be randomly assigned to one of sixteen different study conditions that will use different ways of teaching HIV prevention. All conditions will involve attending weekly group meetings for four weeks. The meetings will last 60 minutes each and will be held in a private room at the APT Foundation. Each meeting is aimed at teaching different health-related topics, and what you can do to reduce health risks. The content of the topics will include sensitive and explicit information about sexual behavior and substance use. You should know that each meeting also provides information and skills that you may use to reduce health risks. Each meeting will be audio-taped to ensure that the group topics are properly covered by the group leaders. Urine toxicology screens for opiates and cocaine (benzoylecgonine) will also be performed to detect illicit substance use at pre-, post- and at all follow-up assessment points as well as twice weekly during the four week intervention phase of the study. The urine screens will be collected in the clinic and used as data for the study. There are no penalties for using illicit drugs while participating in the study and your results will not be shared with your counselor unless you request it. Additionally, we will collect dried blood spots (DBS) to help us measure the amount of PrEP in your blood. We will ask to do a ‘finger stick’ in order to collect a drop or two of blood from your finger at post-intervention, and at all follow-up assessments. You will be asked to complete several questionnaires on a computer just before you start your first group meeting and just after you complete your last group meeting and then again about 3 months, and 6 months after your last group meeting. In addition to the assessments listed above, we will also ask that you complete a short computerized questionnaire once per week during the four-week intervention period. We will ask for your contact information for future interviews. The questionnaires on the computer will ask about any health risks over the past week due to drug use or sexual behavior as well as how you have been taking PrEP. You may skip any question that you would rather not answer. Completing the questionnaires will take
about 90 minutes each time. As part of your enrollment in this study, we expect that you will show good participation. The Principal Investigator may discontinue you from the study if your attendance is too low at groups, appointments, and bi-weekly urine measures.

**What are the risks or inconveniences of the study?**

The procedures involved in this study may involve risks that are currently unforeseeable. Possible risks associated with this study include group participants breaching confidentiality, being identified as a participant in a research study by other patients or staff, feeling upset by some of the material brought up in the group meetings, or by knowing that the meetings are being audio-taped. Inconveniences may include taking time to complete the questionnaires and the possibility of experiencing discomfort regarding questions related to drug use and sexual risk behaviors in the questionnaires. You are free not to answer such questions and also to withdraw yourself from participating in the research process at any time you like to do so. If you would like to talk to a counselor about your feelings at any time, we can connect you with a counselor at the APT Foundation. As mentioned, in one of our study measures, we will need to collect one or two drops of blood using a finger stick. To do this, we will make a small prick on your finger using a finger-stick with a lancet. You will feel a slight pain when the needle pricks your finger and your fingertip may be sore for a day or two. The biospecimens that we collect will not include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Our research team will tell you about any important new information that we learn during the course of this study that might affect your condition or your willingness to continue participating. You should also know that study identifiers may be removed from our records in the future, and after such removal, the study information may be used for future research studies or given to another investigator for future research studies without asking you to sign another informed consent form.

**What other options are there?**

If you choose not to participate in this study, we will discuss other options with you such as individual meetings with a counselor to discuss HIV-prevention related care.

**What are the benefits of the study?**

We do not know that these groups will be shown to be effective in general, and we do not know whether they will be of any help to you in particular. However, we believe that this study has the potential to help us understand the best ways that HIV prevention can be delivered so that we can help you reduce health risks related to HIV. It is possible that, in the future, results from this study may help individuals who participate in healthcare like the APT Foundation program.

**Will I receive payment for participation? Are there costs to participate?**
Your participation is purely voluntary. For your participation you may be reimbursed a total of $325 in the form of a prepaid debit card for the time we expect it to take for you to participate in all the assessments. This amount will be pro-rated so participants will be reimbursed $25 per week for time spent completing each of four weekly brief assessments during the intervention period of participation and $45 each for assessments conducted at baseline, post-intervention, and at 3-month, 6-month, and 9-month follow-up assessments.

How will my personal information be protected?

We will make every effort to ensure your privacy and confidentiality. If you do not choose to participate in this study, all information that you have given us will be destroyed immediately. If you do choose to participate, in all of our study records, you will be identified by a number and your name will be known only to the researcher. Your name will not appear in any publication or be released to anyone without your written consent. You should understand, however, that there is a risk that you will be recognized by other patients or staff involved in the study and that you may be recognized as a participant in a research program. But this is no greater than the usual risk of identification that occurs in your clinical care.

The following procedures will be used to protect the confidentiality of your data. The researchers will keep all study records (including any codes to your data) locked in a secure location. Research records will be labeled with a code. The code will be derived from a number (e.g. sequential 3-digit code) that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. Any audio-recordings will be viewed and transcribed only by research staff members for accuracy and consistency purposes. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. The master key, audio-recordings, and data will be destroyed 3 years after the completion of this study. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Data that we collect from you may be shared with other researchers in the future, but only after your name and all identifying information have been removed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. Your confidentiality cannot be guaranteed if your record is subpoenaed in a court of law or in the event the researcher determines that you are a clear and imminent danger to yourself and/or others. In addition, confidentiality cannot be guaranteed if you disclose that you are intending to or currently sexually or physically abusing a child or an elderly person.
We have a Certificate of Confidentiality from the National Institute on Drug Abuse (NIDA). This Certificate will protect the investigators from being forced to release any research data in which you are identified, even under a court order or subpoena. This protection, however, is not absolute. For example, if we the researchers learn about serious harm that could come to you or to someone else, we would take steps to protect the person or persons endangered even if it required telling the authorities without your permission. If that happened, we would only disclose information to the extent necessary to prevent harm to the person(s) believed to be endangered. When the results of this study are published, your name will not be used.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services and the APT Foundation research board may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

**Can I stop being in the study and what are my rights?**

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time for any reason. There are no penalties or consequences of any kind if you decide that you do not want to participate. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue. You do not have to answer any question that you do not want to answer.

**Whom do I contact if I have questions about the study?**

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator, Dr. Michael Copenhaver at (203) 781-4690 If you have any questions concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

**Documentation of Consent:**

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

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