Consent Form for Participation in a Research Study

**Principal Investigator:** Dr. Michael Copenhaver  
**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**

This form is used for you to provide consent to complete a brief cognitive screening. This will help us decide if you qualify to participate in the main 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. The cognitive screening is being done because we want to make sure to include people who have at least some cognitive challenges, like difficulty concentrating or remembering information. This will help us learn to improve how we deliver HIV prevention groups while people are in drug treatment. Your participation will take about 10 minutes. Risks are described in more detail later in this form. There may also be benefits from participation. We believe that we will gain a better understanding of the cognitive challenges faced by patients while in drug treatment. Before making a decision about whether to participate you should know that there are other options available to you. For example, you may choose to seek a different cognitive assessment study.

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 this cognitive screening study. You are invited to participate in this research study that may qualify you for our main study, which will help us learn the best ways of delivering HIV prevention groups while people are in drug treatment. You have been asked to participate because you are HIV-negative, enrolled in drug treatment at the APT Foundation, and have expressed interest in our flyer.

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 determine whether your cognitive performance qualifies you for our main study, which will include only people with some cognitive challenges, like difficulty concentrating or remembering information. We plan to enroll 256 participants in this study for this purpose. In addition to helping us screen for cognitive challenges, we will be able to identify how common cognitive challenges are for patients in drug treatment at this facility. This will help us develop better ways to deliver HIV prevention groups to patients while they are in drug treatment.

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

If you agree to participate in this cognitive screening study, a trained member of our research team will ask you a set of questions from the Montreal Cognitive Assessment (MoCA). This instrument is used for many different types of patients to help decide whether they have common difficulties that can affect their daily life, such as with concentration or memory. Taking the MoCA will take about 10 minutes. After that, you will be given feedback about your performance. Then we will discuss with you whether your score qualifies you for the main study. We will also answer any questions you may have about the screening. If your brief cognitive screening results suggest more than mild cognitive challenges, we will discuss this with you. After discussing your results with you, if you want, we can connect you to a treatment provider of your choice to follow up on your condition. As part of your enrollment, we expect that you will complete the questionnaire. The Principal Investigator may discontinue you from this study if you are unable or unwilling to complete the questionnaire.

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

The procedures involved in this screening study may involve risks that are currently unforeseeable. Possible risks associated with this study include being identified as a participant in a research study by other patients or staff. Inconveniences may include taking time to respond to the questions required in the cognitive screening. 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.

A research team member 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 participate. 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 other possible cognitive assessment studies or another treatment provider of your choice if you are interested in getting more information about your cognitive performance.

What are the benefits of the study?

We do not know that this cognitive screening will be helpful in general, and we do not know whether it will be of any help to you in particular. However, we believe that this screening process has the potential to help us understand how common it is for patients in this facility to have cognitive challenges and to design better HIV prevention groups. It is also 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 will be reimbursed a total of $5 in the form of a prepaid debit card for the time we expect it to take for you to participate in the screening.

How will my personal information be protected?

We will make every effort to insure 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 data.
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.

Participant Signature: ____________________  Print Name: ____________________  Date: ____________________

Signature of Person Obtaining Consent: ____________________  Print Name: ____________________  Date: ____________________