COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: *Testing of the integrated rapid access to HIV prevention program for people who inject drugs (iRaPID) program*

Principal Investigator (the person who is responsible for this research):

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Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to improve HIV prevention services by testing a new HIV prevention program for people who inject drugs.
- Study procedures will include getting access to HIV prevention services [e.g., pre-exposure prophylaxis (PrEP) for HIV prevention and medication for opioid use disorder (MOUD; buprenorphine or methadone) for substance use treatment], collecting finger prick blood samples to help us measure the amount of PrEP in your blood, and answering questions that will ask about any health risks you may be experiencing due to drug use or sexual behavior, as well as your knowledge about HIV.
- Study procedures will include being assigned to one of the two programs. Regardless of which group you are assigned to you will be asked for an 8-hour time commitment over the six months. Your involvement will require 4 visits to the research site. After the initial visit, you will be asked to come in for follow-up visits 1 month, 3 months, and 6 months after the first visit. Each study visit is expected to take about an hour and a half. We will also ask that you visit the pharmacy to pick up your prescriptions and have your blood collected at a laboratory.
- There may be some risks from participating in this study. Risks include group participants breaching confidentiality, 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. Finger prick blood draws may hurt slightly.
- There is no direct benefit to you, but the information obtained through this study will potentially benefit the health of other patients receiving the intervention. Additionally, you may benefit from using pre-exposure prophylaxis (PrEP) and MOUD, which are part of standard care for HIV prevention and substance use, respectively.

- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because you are HIV-negative and have ongoing risk for HIV (including injection drug use). We are looking for 50 participants, like you, to be part of this research study.

Who is paying for the study?

The study is funded by the National Institutes of Health (NIH) and by The University of Connecticut (UCONN) Center for Health, Intervention, and Prevention (CHIP).

What is the study about?

The purpose of this research study is to determine whether, by participating in the HIV prevention program, the use of PrEP and MOUD increases. Also, we are interested to see if by participating in the program the risks of being infected or transmitting HIV may be reduced and the adherence to PrEP improves.

What are you asking me to do and how long will it take?

If you agree to take part in this study, you will be randomly assigned to one of two programs. One program will involve attending separate clinic visits (at a different location) to receive PrEP and MOUD, which will take anywhere between 1 and 3 weeks, which is a part of standard care. Whereas, in the other program, you will be prescribed both PrEP and MOUD (if eligible and interested) in a single visit either here at 270 Congress Ave or in the Community Health Care Van. Additionally, you will receive a couple of phone calls or SMS from the clinical staff to check on how you are doing.

Both programs will involve completing interviews at 1-month, 3-months, and 6-months after your initial visit. We ask all participants for an 8-hour time commitment over the 6 months. The questionnaires on the computer will ask about any health risks you may be experiencing due to drug use or sexual behavior, as well as your knowledge about HIV. You may skip any question that you would rather not answer. Completing the questionnaires will take about 90 minutes each time. 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 baseline, 1-month, 3-months and 6-months follow-up assessments. Then, at 6-month follow-up, you might be chosen as one of the 20 participants for an additional focus group session, which will last 60 minutes and will be held in a private room at the New Haven storefront. The group is aimed at sharing your experiences with the program and thoughts on how the program could be improved in the future. The group will be audio-taped to ensure that the group topics are properly covered.

We will ask for your contact information for future interviews. As part of your enrollment in this study, we expect that you will show good participation.

What are the risks and discomforts of participating?

There are minimal risks expected from participating in this study, such as feeling uncomfortable in certain topics being discussed. The PI and all research staff will make every effort to protect the confidentiality of participant information. If you (or others, if a group session) feel uncomfortable, you/they may choose not to answer any part or all of a question. Participant names will not be used or recorded in the qualitative interview. During the open-ended interview, which will be conducted in a private room, participants may choose not to answer a question or part of a question and are free to give as little or as much information as they feel comfortable doing. Participants experiencing significant distress or requesting services will be assisted immediately by the research staff and referred to the appropriate supportive services, as needed, depending on the severity and the participant preference. 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.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

If you would like to talk to a counselor about your feelings at any time, we can connect you with a counselor at the Community Health Care Van (CHCV), which is co-located in the same building.

How can the study possibly benefit me?

You may not directly benefit from taking part in this study. However, taking PrEP and MOUD consistently has been shown to be highly effective in reducing the risk of getting HIV and treating addiction, respectively.

How can the study possibly benefit other people?

We believe that the program has the potential to be helpful for reducing health risks related to getting infected or transmitting HIV, or overdose. It is possible that, in the future, results from this study may help individuals who participate in such a program.

Are there any costs to participation?

If you take part in this study, you will not have to pay for any services, supplies, study procedures, or care that are provided for this research only (they are NOT part of your routine medical care). However, there may be additional costs to you. These can include costs of transportation and your time to come to the study visits. You or your health insurance must pay for services, supplies, procedures, and care that are part of your routine medical care. You will be responsible for any co-payments required by your insurance.

If you need assistance in answering financial questions related to your insurance, contact your study team who can connect you with a representative in the YCCI Clinical Research Billing and QA office at (203) 785-3482. For more information on clinical trials, you can visit the National

Institute of Health's website at: https://clinicaltrials.gov/. To answer any further questions, you may have about clinical trials, you can visit the NIH web site at:

- https://clinicaltrials.gov/ct2/about-studies/learn
- https://support.nlm.nih.gov/knowledgebase/category/?id=CAT-01242&category=clinicaltrials.gov&hd_url=https%3A%2F%2Fclinicaltrials.gov%2Fct2%2Fhome

Will I be paid for participation?

You will be paid for taking part in this study. You will receive $105 (in gift cards) for taking part in this study according the following schedule:

- $35 upon completing your first visit
- $15 upon completing your 1-month follow-up visit
- $25 upon completing your 3- and 6-month follow-up visits
- Additionally, you will be paid $25 if you are chosen and participate in the focus group at the end of the study.

You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?

Instead of participating in this study, you have some other choices. You could:

- Get treatment without being in a study. Treatment would involve the normal standard of care.
- Take part in another study.

How will you keep my data safe and private?

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. When we publish the results of the research or talk about it at conferences, we will not use your name. We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Confidentiality will be maintained by assigning a code to disguise any identifying information that you provide. The code number will not be based on any information that could be used to identify you, for example, name, initials, or birth date. The master list linking names to code numbers will be kept separately from the research data. The master list will be destroyed upon completion of the project. All research information will be kept in a locked file cabinet in a locked office at all times. Electronic data will also be stored in a password protected computer or shared only via encrypted email. Only authorized research staff will have access to the information gathered in this study.

Only the researchers involved in this study and those responsible for research oversight (Yale Institution Review Board) will have access to any information that could identify you that you provide. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases, but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including information in your medical records.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law under what is called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to the Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Name
- Research study records
- Medical and laboratory records of only those services provided in connection with this study.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - HIV test results
    - Hepatitis infection

- Pregnancy (if applicable)
- Sexually transmitted infections
- Pharmacy refill (for PrEP or MOUD)
- Laboratory test results
- Diagnosis and treatment of mental health conditions
- Use of illegal drugs or the study of illegal behavior
- Medical history and treatment questionnaires
- Treatment duration and dose for opioid use disorder
- Linkage to primary care

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The study sponsor (National Institutes of Health)
- The PI, Roman Shrestha, PhD, MPH
- Co-Investigators and other investigators
- The Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study
- The U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about Buprenorphine and Truvada involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to:

Frederick L. Altice, MD
Yale School of Medicine
Department of Internal Medicine

Section of Infectious Diseases – AIDS Program
135 College Street, Suite 323
New Haven, CT 06510
Phone Number: 203.737.2883
Email: Frederick.altice@yale.edu

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance, they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay. However, we expect no injuries or illnesses to result from this study.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in this study if necessary. You will be discontinued under any of these circumstances: 1) completion of the study; 2) acquisition of HIV infection (we will refer you to appropriate care according to existing guidelines); 3) you express intent to move, or be otherwise unavailable for follow-up; 4) you voluntarily choose to leave the study for disclosed or undisclosed personal reasons; 5) request from the provider if they think the study is no longer in your best interest.

What will happen with my data if I stop participating?

When possible, you will have the ability to withdraw your data from the study once it is collected. A situation where this might not be possible is at the end of the study, when all data have been collected and de-identified. We will also not be able to take back any research information that has already been used or shared with others (such as for a paper or conference presentation).

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at 203.737.2883.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date