Texas Christian University

Enrollment Informed Consent to Participate in Research and Authorization to Collect, Use, and Share your Health Information

Title of Research: Addressing risk through Community Treatment for Infectious disease and Opioid use disorder Now (ACTION) among justice-involved populations— **Phase 3 RCT**

NCT05286879

Multiple Principal Investigators: Sandra Springer, MD (Yale), Kevin Knight, PhD (TCU)
Ank Nijhawan, MD (University of Texas Southwestern & Parkland Health and Hospital System)

Overview: You are being asked to participate in a research study. In order to decide if 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 provides detailed information about the research 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 and any risks of the procedures, possible alternatives, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to complete a brief quiz to verify that you understand what you will be consenting to and then sign this form. This process is known as informed consent. Agreement to meet with us and to participate further will not in any way, positively or negatively, affect the medical care you receive anywhere, nor will it impact probation or parole if you are currently involved in this.

To be eligible for participation you must be 1) living in one of our research areas; 2) be 18 years of age or older; 3) able to provide consent in English or Spanish; 4) have justice system involvement within the last 6 months; 5) be living with HIV or being at risk of acquiring HIV and willing to learn about PrEP, 6) willing to be tested for HIV, and 7) have opioid/stimulant use within 12 months prior to being in a controlled setting and/or in the last 6 months in the community and 8) have a history of condomless sexual intercourse (vaginal or anal), an STI diagnosis, and/or injection drug use (or sharing works) in the 6 months prior to be in a controlled setting and/or the last 6 months in the community.

If any of the following apply to you, you will not be able to participate in the study: 1) Severe medical or psychiatric disability making participation unsafe; 2) unable to provide informed consent; 3) not remaining in the local area after release from custody; 4) being released to inpatient care; and 5) posing a risk to research staff.

Study Details: This study is being conducted at four research sites (New London and Windham/Tolland/Middlesex/New Haven/Hartford counties in Connecticut and Dallas and Tarrant counties in Texas) and is supported/sponsored by the National Institute on Drug Abuse (NIDA). The purpose of thisstudy is to compare the effectiveness of two different treatment service models, both of which are designed to help connect people with HIV-prevention/HIV treatments once they released from the justice system. The service models being studied are the use of Patient Navigators and Mobile Health Units (MHU). The study will primarily be

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

at how long it takes for participants after they are released from the justice system to receive either PrEP (Pre-Exposure Prophylaxis) for HIV prevention if they are at risk for acquiring HIV infection or medication to treat HIV, if they are living with HIV.

Additionally, the study will also be looking at how long participants stay on HIV prevention (PrEP) or HIV treatment, how well the HIV infection is controlled in patients who have the virus, and how peoples' risk for acquiring HIV infection changes over time. Study participation will last 12 months with an intervention period of 6 months with a 12-month research follow-up visit.

If you consent to participate, you will be *randomly* assigned to either the Patient Navigation (PN) or Mobile Health Unit (MHU) group. This assignment is randomly generated by the study database computer system. Researchers have no control over who is assigned to each group. Once assigned, you cannot change groups.

The study will also look at how long it takes for participants who have Hepatitis C Virus (HCV) to start and complete treatment; self-report of opioid and/or injection drug use; referral to medication for the treatment of opioid use disorder and how long participants stay on treatment; sexually transmitted infection diagnoses and treatment; and if people return to custody.

Participation will include follow up visits with a research assistant (RA) where interviews will be completed to collect information that will help evaluate the effectiveness of these two services. Participation will also include 9 brief phone check-ins.

Participants: You are being asked to take part because you have been pre-screened and identified as an individual that may benefit from the services being provided in this study, including HIV treatment or prevention, HCV treatment or prevention, and substance use treatment and/or risk prevention. In order to qualify for this study, you must have been involved in the justice system in the last 6 months. Study staff will confirm your self-reported history of justice system involvement by accessing records in the city or county in which you were arrested/detained/incarcerated/placed on community supervision that are publicly available as part of your participation. If you decide to participate in this study, you will be one of approximately 240 participants in this research study at your local site. Approximately 960 individuals will participate in the study across all sites. Participants will be randomly assigned to either the PN or MHU group.
Participants cannot choose or change groups and researchers do not have the ability to change a participant to the other group.

Voluntary Participation: Your participation is voluntary. You do not have to participate in this study to receive services in the community. If you choose to participate, you may also stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits that have accrued up until that point (i.e., appointments already scheduled for medical and/or support services in the community). However, participants that decide to withdraw will lose access to the use of Patient Navigators and the Mobile Health Units for *future* medical and support services.

Confidentiality: Even if we publish the findings from this study, we will keep your study

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

information private and confidential. Anyone with the authority to look at your records must keep them confidential.

What is the purpose of the research? This study will assess the use and retention of services between the two service models, Patient Navigation (PN) and Mobile Health Units (MHU). If you choose to participate in this study, you will have a 50% chance of being assigned to the Patient Navigation group or 50% chance of being assigned to the Mobile Health Unit group. If you are assigned to the Patient Navigator group, you will be assigned a trained individual with knowledge about local services in the community to work with you to identify needs after you have been released. If you are assigned to the Mobile Health Unit group, you will be able to receive your treatment and prevention services for HIV, HCV, substance use, and general care at a mobile health clinic van that will be located in the county where you live. The services provided on the individual Mobile Health Unit may vary due to local administration but can include HIV testing, physical assessments, prescriptions for HIV prevention and treatment medications, HCV testing and treatment, and prescriptions for medications for opioid use disorder. Your participation in this phase of the study will last 6 months, but we will contact you at 12 months after you begin the study for the final research visit follow-up. If you are assigned to the Mobile Health Unit group, you will be transitioned from receiving healthcare services on the Mobile Health Unit to receiving those same services in the community after the 6- month study period. A Community Health Worker (CHW) will help to make sure that you will continue to receive treatment in the community.

What is my involvement for participating in this study? Involvement will look different depending on which group you are assigned to.

Patient Navigator: If you are assigned to the Patient Navigator group you will be meeting with a Patient Navigator on a regular basis for the first 6 months of your participation in the study. The Patient Navigator is a study team member who will help you gain access to services in the community that you may need. Services include HIV prevention or treatment services, HCV prevention or treatment services, substance use treatment and/or risk reduction services, as well as services for other needs and barriers to health care. Patient Navigators will provide linkage to these support services in the community and can help with transportation if needed. We expect meetings with your Patient Navigator to last about 30 minutes or less, but they may be longer if you need help completing applications for services. As a rough estimate, we aim to have the Patient Navigator meet with you as follows: the first time at baseline after you have consented to be a part of the study, and then approximately once a week for the first month. In months 2 and 3 after enrollment, you will meet with the Patient Navigator approximately every other week, and then once a month for Months 4, 5, and 6. There will be about 12 meetings in total. These meetings with the Patient Navigator can be via phone, text, electronic video chat means such as Zoom or Facetime, or in person depending on what method you prefer.

Mobile Health Unit: If you are assigned to the Mobile Health Unit group, you will be linked with a mobile health unit van that will provide you access to a medical provider and other support services, including HIV/HCV treatment/prevention services, medical care, substance use care,

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

and linkage to other services in the community as needed. A Community Health Worker will be your main point of contact with the Mobile Health Unit. The Community Health Worker will work with you to ensure a smooth transition to community services once the 6-month study timepoint is reached.

Regardless of which group you are assigned to, your participation with either the Patient Navigators or the Mobile Health Unit will last 6 months, followed by a final research visit with the Research Assistant 6 months later. In addition to your visits with the Patient Navigator or the Mobile Health Unit, there will be separate research visits where you will meet with a Research Assistant at a designated location to complete study interviews. During these interviews, you will be asked to complete questionnaires that ask about your history of prior substance use, your medical history, including HIV and HCV, and any past justice involvement. You may choose not to answer any questions that you do not wish to answer during these interviews. There will be a total of 5 research interviews that will occur at Day 0, Month 1, Month 3, Month 6, and Month 12 during your study participation. During these research visits you will also be asked to complete the following:

Baseline, Day 0 visit:

1. You will be asked to sign a Release of Medical Information form (ROI) which will provide your consent to release medical information that may include history of drug use, mental health, or HIV treatment, if applicable. This will allow researchers to review your medical records at your facility, including information about your lab tests, diagnoses and medications prescribed. You decide which organizations we can ask for information. We will not talk with or request your medical record information from any person or agency that you have not given us permission to communicate with.

2. If you do not have a previous diagnosis of HIV or HCV infections, you will be tested for these with a rapid test that takes about 20 minutes for results. We will obtain your blood for these tests with a fingerstick (a prick at the tip of your finger to get a few drops of blood). For the rapid HIV test, you will receive information on the procedure, meaning of test results, and an explanation of the window period. The window period is the time period between your potential exposure to the virus and when the test will pick up a positive result. We will refer you to a qualified medical provider if the result of your rapid HIV test is reactive (positive). This medical provider will perform a confirmatory test to measure the amount of virus in your blood. In addition, rapid Hepatitis C Virus (HCV) testing will also be carried out by using blood from the same fingerstick mentioned above. Those who test positive will be referred to a qualified medical professional for post-test counseling, another confirmatory test to measure the amount of virus in your blood and to receive follow-up care. Positive results of HIV and Hepatitis will be reported to CT Department of Public Health.

   In the event blood is unable to be collected for rapid HIV testing, this testing will be conducted by completing an oral swab.

3. Research staff will perform a second fingerstick to obtain several drops of blood to test for sexually transmitted infections (STI) including Hepatitis B and syphilis, if applicable. Results

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

will be provided in approximately 7 days. If you have one of these infections at any point while participating in the study, you will be connected with a qualified medical provider who can treat your infection.

4. You will also be asked to provide a urine sample to test for other sexually transmitted infections such as gonorrhea and chlamydia. If you have one of these infections at any point while participating in the study, you will be connected with a qualified medical provider who can treat your infection. This same urine sample will be tested for opioids, stimulants, and other drugs.

5. After point of care/rapid testing is performed for HIV, HCV, and STIs, participants with reactive results will receive confirmatory testing which will be ordered by research staff and/or occur via linkage to a provider in the community or on the MHU. Immediately after a reactive point of care/rapid test of any kind, research staff will link participants to a licensed medical professional to start treatment. Research staff will obtain an ROI to share confirmatory testing results with the provider to whom the participant was referred and to obtain information pertinent to the study. Any Point of care testing that cannot be completed during your study visit will be completed by referring you to a clinician or to a local lab such as Quest Diagnostics to complete.

6. You will participate in an interview that will include questions about basic characteristics about yourself, your contact information, your HIV-risk behaviors, past drug use, quality of life, social functioning, past justice involvement, drug cravings, and how COVID-19 has impacted you. The information from the screening questions we asked will be transferred into the study dataset and used for this project. You may also receive a phone that can be used during your study participation or assistance applying for a phone through state entitlement programs. You will also receive a travel voucher to get to your initial intervention appointment on the MHU or with the patient navigator. You will also receive travel vouchers for all research visits with the RA.

7. **Follow Up Research Visits**

In order to keep in touch with you throughout the study period, we will obtain locating information such as address(s), phone number(s), emergency contact information, contact information for immediate relatives and two unrelated friends, typical public places you spend time (such as parks, community centers, etc.), and social media handles. This information will only be shared with the study team and used as a way to get in touch with you. The information will be stored in the same manner as the rest of your research data in the REDCap database, which is maintained on a secure server owned by Yale University. Only approved study members will have access to this information and use it to contact you about your study participation.

Month1: You will participate in an interview that will include questions about demographic information such as name, date of birth, and race, past drug use, quality of life, social functioning, medication adherence, engagement in care, past substance use treatments, any

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

instances of substance overdose or any medication effects, and drug cravings.

Month 3: You will be asked to provide a urine sample which will be used to test for substance use, and HIV medication/treatment adherence, if applicable. You will also be asked interview questions related to basic characteristics about yourself, HIV-risk behaviors, past drug use, quality of life, social functioning, medication adherence, engagement in care, past substance use treatments, any instances of substance overdose or any medication effects, and drug cravings.

Month 6: Research staff will perform several finger sticks to obtain drops of blood to test for sexually transmitted infections, HIV, HCV, and HIV treatment/ HIV-prevention medication (PrEP), if applicable. If you have HIV or HCV, recent viral load laboratory results will be obtained from your medical care provider through the release of information [ROI] agreement *or* you will be given an order to obtain the test through a qualified laboratory such as Quest Diagnostics. In addition, a urine sample will be collected for drug and sexually transmitted infection testing. At this visit you will again be asked interview questions related to basic characteristics about yourself, HIV-risk behaviors, past drug use, quality of life, social functioning, medication adherence, engagement in care, past substance use treatments, past justice system involvement, any instances of substance overdose or any medication effects, and drug cravings.

Month 12: Research staff will perform a fingerstick test to test for sexually transmitted infections, HIV/HCV if prior testing was negative, and HIV treatment/HIV prevention medication (PrEP), if applicable. If you have HIV or HCV, recent viral load laboratory results will be obtained from your medical care provider through the release of information [ROI] agreement *or* you will be given an order to obtain the test through a qualified laboratory such as Quest Diagnostics. If laboratory tests are required, your insurance will be billed.

In addition, a urine sample will be collected for drug and sexually transmitted infection testing.

At this visit you will again be asked interview questions related to basic characteristics about yourself, HIV-risk behaviors, past drug use, quality of life, social functioning, medication adherence, engagement in care, past substance use treatments, past justice system involvement, any instances of substance overdose or any medication effects, and drug cravings.

If biotesting has to be repeated for due to any reason, you will be asked to meet again for re-collection of the blood/urine sample and will be compensated with a $25 gift card or similar method of payment. Reasons re-testing may include samples being lost by staff or in the mail, lab rejecting sample for quality issues, etc.

Incentivized Check-Ins

Participation in the ACTION study will also include 9 brief phone check-ins. If there is successful contact between you and a study staff member between baseline (day 0) and your month 1 visit, you will receive $20. The following check-ins will occur in between the scheduled follow up visits at the following timepoints: months 2, 4, 5, 7 ,8, 9, 10, and 11.

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

During these check-ins, study staff will contact you and locating information will be updated, future appointments will be confirmed, and you will be asked a brief questionnaire about interest in PrEP or adherence to PrEP regimen. For each successful monthly check-in, you will be compensated with a $5 payment in the same form as your study visit compensations. For a check-in to be considered successful, communication must be made with the study team member that contacted you.

Are there any alternatives and can I withdraw?

You are free to choose not to take part in this study at any time and continue services through traditional means in the community. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). Your decision to participate or not participate in this study will not impact your involvement with the justice system, health care in jail/prison, your stay in jail/prison, and release from jail/prison.

In order to enroll in the study, you must allow the use of your health information. Your health information is essential to measuring health outcomes of the study interventions. If you do not agree to share your health information, you will not be able to be part of the study, which includes access to Patient Navigator or Mobile Health Unit healthcare services. If you consent to participate in this study, you are free to stop and withdraw from this study at any time. When you withdraw permission, information that has already been gathered about you may still be used. Withdrawing from the study will cancel any study appointments in the future that you have with a Patient Navigator, on the Mobile Health Unit, or with a Research Assistant.

The researchers may withdraw you from the study if necessary. Reasons include violent or inappropriate behavior or not following study rules. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate or decide to withdraw from participation, it will not harm your relationship with your doctors, treatment center, or Yale University/Texas Christian University/University of Texas Southwestern. Any linkages that have already been provided with the help of a Patient Navigator or Community Health Worker on the Mobile Health Unit will not be impacted by the decision to withdraw.

Your personal information collected for this research will be kept as long as it is needed to conduct this research. Once your participation in the research is over, your information will be stored in accordance with applicable policies and regulations. Your permission to use your personal data will not expire unless you withdraw it in writing. You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the Principal Investigator at the following address: 3034 Sandage Ave., Box 298740, Fort Worth, TX, 76129.

For those in CT: You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the local site Principal

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

Investigator at the following address: Sandra Springer MD, 135 College Street, Suite 323, New Haven, CT 06510.

What are the risks for participating in this study and how will they be minimized?
Risks may include:

Although unlikely, there is the possibility of a breach of confidentiality. Research staff will store all identifiable information on a secure, encrypted REDCap database housed at Yale University. Any identifiable information on paper will be kept in a locked cabinet in a locked office. Only authorized research staff will have access to this information. All study staff will be trained to ensure that your privacy is respected at all times. Meetings with Patient Navigators may occur in public settings. You will decide the public settings in which you are comfortable meeting with a Patient Navigator to minimize discomfort and risk of breaching confidentiality.

There is minimal risk of emotional or psychological discomfort that may exist due to potentially sensitive questions. You can choose not to answer any question, particularly those that might make you feel uncomfortable.

You will undergo medical screenings, assessments, and blood draws for laboratory tests. Some risks include discomfort from a finger stick to take blood for testing. It is possible that you may feel discomfort at the site of the finger stick and may experience bruising, lightheadedness, feel faint, feel uneasy at the sight of blood, develop an infection at the site of the finger stick, or experience excess bleeding. There are no experimental procedures or medications for this study and as such, all clinical care delivered on the Mobile Health Unit or through community partners for those assigned to the Patient Navigator group will follow the standards of care for HIV treatment/prevention, HCV treatment, substance use disorder, and general care.

Please tell the research team if you have any injuries or other problems related to your participation in the study. You should contact your primary care physician for treatment. If your injury or sickness is an emergency, you should call 911.

You or your insurance will be billed for any routine clinical care you receive, however any testing completed as part of the research study visits will be covered by the study. Texas Christian University/Yale University/University of Texas Southwestern will not provide compensation or payment for any injury or physical harm that may occur as a result of being in this study nor will they provide compensation for loss of employment, income, or emotional stress that may result from your injury or harm.

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment.

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

What are the benefits of participating in this study?

There may be no direct benefit from participating in this study. However, we anticipate that participation may assist you in the following ways:

Patient Navigator study group: If you are assigned to the Patient Navigator group, you will have the support of a trained Patient Navigator to help you access health care in the community after your involvement with the justice system. You may also have benefits including assistance with employment, job training, and acquiring health insurance. Treatment plans that you have with a medical provider that are facilitated by a Patient Navigator may continue after this study has ended. Patient Navigators can also assist with linkage to other support services within the community.

Mobile Health Unit: If you are assigned to the Mobile Health Unit group, you will receive medical screenings, assessments, and potentially have specimens for laboratory tests obtained on the Mobile Health Unit for the 6-month study period. This includes general care, HIV treatment/prevention, HCV care, and substance use care. The Community Health Worker will work with you as you approach the 6-month study period in order to ensure a swift transfer to care and services in the community.

Will I be compensated for participating in this study?

Study Visits: You will be compensated for your participation after the completion of each research visit with payments of $50 for Day 0 (visit 0), $50 for Month 1 (visit 1), $50 for Month 3 (visit 2), $75 for Month 6 (visit 3) and $75 for Month 12 (visit 4). Therefore, you can earn up to $300 for attending study visits.

Check-Ins: You can earn $20 if you have successful contact with a study team member between day 0 and before the month 1 visit. In addition, you can earn $5 for monthly check-ins on each of the months where there is no research visit. Check-ins will occur in months 2,4,5,7,8,9,10, and 11. If you complete all check-ins, you can earn up to $60 total.

If you are incarcerated, monetary compensation will be held until you are released. Compensation will be provided in the form of a gift card at your next in-person research visit. If needed, you will also receive a voucher to assist with travel to your initial intervention visit (on MHU or to see patient navigator) and for all of your research visits with the research assistant (RA).

For successful completion of all research visits you can earn up to $300. For successful check-ins, you can earn up to $60. Successful completion of all study visits and check-ins will compensate you in the amount of $360.

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

Repeat Bio testing: If repeated bio testing is required, you will be compensated with $25 each time you are asked to provide a secondary blood or urine sample.

Referral Bonuses: Once in the community or under community supervision, you will also have the opportunity to earn a $20 referral bonus for each person that is referred and successfully enrolled into this study. You can refer a maximum of 3 individuals for a total of $60 paid to you in the same payment method that your study visits are compensated. This referral will only be available to you when you are actively in the community. Referral will not be available to you while you are in a custody setting (e.g., jail/prison, correctional residential facility).

To make a successful referral, you will need to have the person you are referring contact a research staff member and they will need to inform the staff member who referred them. We will need to verify with the person who referred them in order to distribute payment to you, therefore you will need to ensure that the name you give us is the same name the person you refer gives to us.

If you are able to earn the full referral bonus in addition to completing all of the study visits and check ins, you can earn a grand total of $420.

What are my costs to participate in the study?

There is no cost to you as a result of participating in this study. Research staff will provide transportation assistance to get to all research visits (with the research assistant) by means that have been identified in each of the study locations such as travel vouchers or bus passes. Transportation assistance will also be offered for participants to get to their initial intervention visit on the MHU or with patient navigator.

Is there any conflict of interest?

There are no conflicts of interest.

How will my confidentiality be protected?

If you decide to participate in this study, the researcher will collect information that identifies you as well as personal health information. This may include information that might directly identify you, such as your name, date of birth, race, medical history information obtained from research interviews, and laboratory results from your study blood/urine tests. In the event HIV, HCV, or other STI testing concludes in a reactive result, your health information will be shared with a qualified health provider for confirmatory testing. By signing this consent form, you agree to the sharing of information gathered from these tests.

To identify you as a study participant you will be given a study number. All information we collect from research interviews will identify you only by this study number. Information linking your name to the study number will be kept in a file that is separate from files with your research information. Your research information will be kept on a secure server and/or in a locked file in a locked office. All computers and files are password protected. Any identifiable information that we get for this study will remain confidential. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

We will limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information as part of the research process. Although unlikely, a breach of confidentiality is possible. All information will be in a secure and encrypted database maintained by Yale University. Any physical information will be in a locked cabinet in a locked office. Your records may be reviewed by authorized University personnel or other individuals who will be bound by the same provisions of confidentiality. De-identified (information that cannot identify you) information will be shared with research partners including Texas Christian University, Yale University, University of Texas Southwestern, and Parkland Health and Hospital System. De-identified information will be shared with our funding agencies (National Institute on Drug Abuse (NIDA) as a part of the National Institutes of Health (NIH) as part of required progress reports throughout the study duration.

Deidentified information, meaning information that cannot directly identify you, will also be shared with the Data Safety Monitoring Board (DSMB). This information will include sociodemographic characteristics, and data regarding Serious Adverse Events (SAEs) that may occur during your participation.

SAE information will be reported on an annual basis to reported to the Justice Community Opioid Innovation Network (JCOIN), Methodology and Advanced Analytics Resource Center (MAARC) at the University of Chicago on a quarterly basis via a REDCap database hosted with the MAARC. The MAARC will not have access to identifying information, nor will they have access to, or knowledge of how participant IDs were generated.

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

To help us protect your privacy, we have been granted a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about you or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate of Confidentiality to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under certain circumstances. The investigative team will voluntarily comply with Texas/Connecticut Statutes and federal regulations, which may mandate or permit certain disclosures (e.g., such as child/elder abuse and neglect, or harm to self or others) of protected information by the investigative team to appropriate individuals.

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider.)

What will happen to the information collected about me after the study is over?

We will keep your research data to use for future research or other purposes. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

We may share your de-identified research data with other investigators. De-identifying data means we take away any information that could directly identify you such as your name, date of birth, etc. and keep it completely separate from the rest of your study data. This study is funded through NIDA as a part of a consortium of research studies on substance use and HIV in justice-involved populations. NIDA will collect de-identified data that may be retained and used for future research or publications.

Who should I contact if I have questions regarding the study or concerns regarding my rights as a study participant?

You can contact Kevin Knight, PhD (Principal Investigator) at ibr@tcu.edu or 866-210-0782 with any questions that you have about the study.

Dr. Brie Diamond, Chair, TCU Institutional Review Board, (817) 257-6152, b.diamond@tcu.edu; or Dr. Floyd Wormley, Associate Provost of Research, research@tcu.edu

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Sandra Springer MD at (203) 605-6314. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Research Protection Program at (203) 785-4688. HIPAA Authorization

This research uses or discloses Protected Health Information as defined by the Health Insurance Portability and Accountability Act (HIPAA). By signing this form, you are permitting Texas Christian University to use your health information for research purposes. The names of the lead researchers who will gather this information from you are listed at top of this document. We will collect the following health information from you:

- HIV test results
- HIV diagnosis, and if applicable:
    - When you started your current HIV treatment
    - CD4 count and viral load (measure of the effectiveness of treatment)
- Access to HIV prevention services, (PrEP), and if applicable
    - Type of PrEP prescribed and initiation date
- HCV test results
- HCV diagnosis, and if applicable
    - If you received HCV treatment, when you started it and when you completed it
- Medications for Opioid Use Disorder (MOUD) prescription history
- Sexually-transmitted infections (STIs)
- Urine toxicology results
- History of any substance use
- Self-reported substance use
- Sexual practices (e.g. unprotected sex, anal sex, oral sex)
- Assessment of your mental health (previous diagnoses, current assessment of mental health status)

You are also allowing us to share your health information with individuals or organizations other than TCU who are also involved in the research and listed below.

- The sponsor, the group paying for the research (US NIDA as part of the NIH), other study research staff and study monitors. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

- the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason
- John Peter Smith (JPS) Health Network
- Texas Department of State Health Services
- Yale University
- University of Texas Southwestern Medical Center (UTSW)
- Parkland Health & Hospital System
- Weill Cornell Medical College
- Alliance for Living (AFL)
- Those providers who are participants in the Electronic Medical Record (EMR) system.
- Health care providers that provide services in connection with this study
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Representatives from Yale University and the Yale Human Research Protection Program
- Your providers who are participants in the Electronic Medical Record (EMR) system
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The study doctor, *Dr. Sandra Springer*, and the Yale study team.

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. You will be given a copy of this document for your records. A copy also will be kept with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

☐ I agree to participate.
☐ I do not agree to participate.

_____
Printed participant name

_____
Signature Date Time

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025

Printed name of person obtaining consent

Signature of person obtaining consent Date Time

Consent to Use Data for Future Research

I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information.

Yes_____No _____

Signature Date Time

Consent to be Contacted for Participation in Future Research

I give the researchers permission to keep my contact information and to contact me for future projects.

Yes_____No _____

Signature Date Time

TCU
1920-275
Approved on 8-9-2024
Expires on 8-8-2025