INSTITUTIONAL REVIEW BOARD

PROTOCOL REVIEW REQUEST

1. **Date:** May 11, 2026 (Amendment 46)

2. **StudyTitle:** Addressing risk through Community Treatment for Infectious disease and Opioid use disorder Now (ACTION) among justice-involved populations
   NCT05286879

3. **Principal Investigator (must be a TCU faculty or staff):** Kevin Knight

4. **Department:** Institute of Behavioral Research

5. **Other Investigators: List all faculty, staff, and students conducting thestudy including those not affiliated with TCU.**
   TCU: Jennifer Pankow;Randi Proffitt; Wayne E. K. Lehman; Jennifer Becan; Yang Yang; Thomas Sease; Stephanie Villaire; Ahrein Johnson Bennett; Leticia Rivera; Emma DiFiore; Mansour Salami; Chelsea Wood; Savannah Hastings; Lynnette Howington; Sabrina "Bre" Roberson; Heather Hines; Renee Castillo; Christy Wooten; Stacey Castiglione; Valeria "Val" Garcia, Crystal Moran, Angelia Rique, Talia Christian; Quinceola Reid, Maria Welch, Mallory Whiteside, Ewaoluwa Olasibi, Sakina Ghafoor, Brianna Pitz, Brooke Preston, Brittney Bell, Morayma Rodriguez, Sofia Crook, Ollie Ansley
   Yale: Sandra Springer (Multiple PI); Ralph Brooks; Robert Heimer; Brent Vander Wyk; Mark Sanchez; Cynthia Frank; Ester Schlossberg; Alysse Schultheis; Erica "Stazja" Stuccio; Angela DiPaola; Luis Ojeda; Barbara Valdes; Yolanda Herring; Sarah Esteves; Linda Lopez; Marinelly Ventura; Rich Lint; Melissa Borker; Lauren Astorino; Richard Colon; Carol Amico; Denise Anderson; Katherine "Katie" Hill; Sheela Shenoi; Elda Martinez; Ronald Valenzuela; Amira Abdelghany; Haley Hammen; Timothy Peiffer; Adati Tarfa; Rene Ortiz; Anne Stevens; Victor Neirinckx, Mark DiLeone Jr
   UTSW/PHHS: Ank Nijhawan (Multiple PI); Laura Hansen; Zoe Pulitzer; Gerald Strickland; Shirley Cooper; Mitchell "Brynn" Torres; Afeefah Khazi-Syed, Carla "Natalie" Noreen; Eston Dixon, Shruti Patel; Jae Choi; Bilal Rehman, Roman Loper, Mahija Ginjupalli, Ashwin Sunderraj, Puranjay Shori
   Others: Irene Kuo (George Washington University); Czarina Navos-Behrends (Weill Cornell); Ali Jalali (Weill Cornell); Cristina Chin (Weill Cornell); Sandra Violette (Connecticut Department of Corrections); Dustin DeMoss (JPS); Jon "Hunter" Scarborough (IES/JPS); Celeste Caliman (JPS Office of Clinical Research); Amairany Escamilla (JPS); Sally Spann (IES/JPS); Winston Luhur (Weill Cornell)

6. **ProjectPeriod (mm/yyyy - mm/yyyy):** 9/01/2020 – 08/31/2025

7. **If you *have* external and/or internal funding for this project – Funding Agency:** National Institute on Drug Abuse

   Project#:1 U01 DA053039-01 Datefor Funding: September 1, 2020

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Appendix Table of Contents

Appendix 1 1A: Screening Consent(TCU) [as of AM15, screening consent process decommissioned]
1A-S: Spanish Screening Consent(TCU) [asof AM15, screening consentprocess decommissioned]
1B: Screening Consent (UTSW) [as of AM15, screening consent process decommissioned]
1B-S: Spanish Screening Consent(UTSW) [as of AM15, screening consentprocess decommissioned]
1C: Screening Consent (Yale) [as of AM15, screening consent process decommissioned]
1C-S: Spanish Screening Consent (Yale)[as of AM15, screening consent process decommissioned]
Appendix 2 2A: Enrollment InformedConsent (TCU)
2A-S: Spanish Enrollment Informed Consent (TCU) 2B: Enrollment Informed Consent (UTSW) 2B-S: Spanish Enrollment Informed Consent (UTSW) 2C: Enrollment Informed Consent (Yale) 2C-S: Spanish Enrollment Informed Consent (Yale)
Appendix 3 Consent Quiz
Appendix 4 Pre-Screening Eligibility Questionnaire ("Pre-screener") [asof AM15, this form decommissioned]
Appendix 5 5A: Yale Site-Specific Bi-Directional Release of Information (ROI)
5B-1: UTSW Site-Specific Authorization to Disclose PHI
5B-2UTSW Site-Specific Authorizationto Verbally Release PHI
5C: UTSW Site-Specific Medical Records Authorizationto Receive PHI
5D: JPS Release of Information (ROI)
5D-S:JPS Release of Information(ROI)-Spanish
5E: TCU Site-Specific ROI
Appendix 6 Screening EligibilityQuestionnaire("Screener")
Appendix 7 Locator Form
Appendix 8 Clinical Data Form
Appendix 9 Research Assistant- Needs Assessment Form
Appendix 10 Community Health Worker-Needs AssessmentForm
Appendix 11 Patient Navigator Needs- Assessment Form
Appendix 12 12: Appointment Reminder Card Templates
12A: Community Health Worker
template 12A-1: UTSW-site specific
12B:Patient Navigator template
12C: Spanish Appointment Reminder Card
12E: Mini Resource Guide
12F: Spanish Mini Resource Guide
12G:SpanishCHWAppointmentCards
12H: Spanish PN Appointment Cards
Appendix 13 13A: All Sites-Recruitment Flyer Template (approved on AM 8; update site- specific on AM13)
13B: UTSW/ParklandHospitalUpdated Recruitment Flyer w/ Logo (English)
13B-S: UTSW/Parkland Hospital Recruitment Flyer w/ Logo (Spanish)
13C: TCU Site-Specific Community Recruitment *updated AM29*
13C-S:TCUSite-Specific CommunityRecruitment Flyer(Spanish) *updated AM29*
13D-1: Yale Site-Specific Corrections Recruitment
13D-1-S:YaleSite-SpecificCorrectionsRecruitment(Spanish)
13D-2A: Yale Site-Specific Community Recruitment
13D-2A-s:Yale Site-Specific CommunityRecruitment(Spanish)
13D-2B: Yale Site-Specific Community Recruitment w/ tabs
13D-2B-S:YaleSite-SpecificCommunityRecruitmentw/tabs(Spanish)
13E-1: UTSW Site- Specific Corrections Flyer

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

13E1-S:UTSW Site-SpecificCorrectionsFlyer(Spanish)
13E-2: UTSW Site-Specific Community Flyer
13E-2S:UTSW Site-SpecificCommunity Flyer(Spanish)
13F-1: TCU Site-specific Self-Referral Recruitment Tool(Qualtrics link questionnaire for collecting contact information)
13F-1S:TCUSite-specific Self-ReferralRecruitment Tool(Spanish)
13F-2: Yale Connecticut Department of Corrections (CT-DOC) Referral Form
13F-3: UTSW Site-Specific Self-Referral Recruitment Tools (Qualtrics link)
13F-4: Yale Site-Specific Self- Referral Contact Form (RedCAP)
13G-1: TCU Site-Specific Poster with QR Code
13G-2: TCU Site-Specific Posterwithout QR Code
13H: TCU Script for Recruitment Video
13H-S: TCU Scriptfor Recruitment Video(Spanish)
13I: TCU Site-Specific Corrections Flyer
13J: TCU Site-Specific Lockbox Poster for Probation Offices

Appendix 14 14: Measures Package

14A-S:Spanish Study Measures(complete packageincludingitemsfrom Appendix 16 & 17)
14A2-S: Spanish Study Measures (orphan questions previously untranslated- AM30)
14B: AM 9 New Measures
14C: AM10 Amended Service UtilizationMeasure
14D: AM 14 Added Measures (PrEP non-uptake & incarcerationsincelastvisit)
14E: AM19 PrEP Check-in, Sexual Orientation & Marital Status
14F: PrEP Readiness Tool (instructions & measure)

Appendix 15 CITItrainingcertificates (rolling basis as neededperamendment)

Appendix 16 16: Spanish Translation Certification letters

16A:CW FluencyTranslationCertificate-AM11
16B:SpanishTranslationCertificate-Mark Sanchez AM14Consents
16C: Spanish Translation Certificate- Luis Ojeda AM14 Consents

Appendix 17 Weill-CornellCost AnalysisInformed Consent

Appendix 18 Weill-Cornell Cost AnalysisInterview-BasedQuestionnaire forStudy Staff

Appendix 19 Point-of-Care Test Results Slip

Appendix 20 Verificationof Research Participation Letter Template

20A:SpanishVerificationofResearchParticipationTemplate
20B: Spanish Income and Residency Verification Form

Appendix 21 21:PrEP Informational Pamphlet

21A: TCU PrEP Pamphlet
21A-1: TCU PrEP Pamphlet
Spanish
21B:UTSWPrEP pamphlet
21C: Yale PrEP Pamphlet (to be submitted in a future amendment)

Appendix 22 Pre-Enrollment BackgroundCheck authorizationform (TCUsite-specific)

Appendix 23 UTSW Site-Specific Contact Slip

Appendix 24 UTSWSite-Specific Participant TargetSchedule (Retentiontool)

Appendix 25 Patient Navigator Information Sheet (all sites)

25-S: SpanishPatient Navigator Information Sheet

Appendix 26 TCU-Site specific Emergency Hotlines Information Card

26A: SpanishTCU Site specific Emergency HotlinesInfo Card

Appendix 27 TCU- Site specific PO recruitment Info Sheet

Appendix 28 Qualitative Staff Interviews

28A: Staff Survey- Clinician Interview Informed Consent (TCU & Yale)
28B: Staff Survey-Clinician Interview Demographics (all sites)
28C: Staff-Survey-Clinician Interview Questions (all sites)
28D:Staff Survey-ClinicianInterviewInformedConsent-UTSW
28E: Staff Survey- CHW Informed Consent (TCU & Yale sites)
28F: Staff Survey-CHW Informed Consent (UTSW site)
28G: Staff Survey- CHW Demographic Survey (all-sites)
28H: Staff Survey- CHW Interview Guide (all-sites)
28I: Staff Survey- PN Informed Consent(TCU & Yale sites)
28J: Staff Survey- PN Informed Consent (UTSW site)

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

28K: Staff Survey- PN Demographic Survey (all-sites)
28L: Staff Survey- PN Interview Guide (all-sites)
28M: Staff Survey- RA Consent (TCU & Yale sites)
28N: Staff Survey- RA Consent (UTSW site)
28O: Staff Survey- RA Demographic Survey
28P: Staff Survey- RA Interview Guide

Appendix 29: ACTIONResearch Visit Timeline
Appendix 30: Qualitative Participant Interview
30A:ParticipantInterview Guide& Questions
30B: Participant Informed Consent (TCU)
30C: Participant Informed Consent (Yale)
30D: Participant Informed Consent (UTSW)
Appendix 31: Participant Zoom Instructions (English)

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

7. Purpose

This study entitled Addressing risk through Community Treatment for Infectious disease and Opioid use disorder Now (ACTION) among justice-involved populations, is a 5-year Hybrid Type1 Effectiveness- Implementation Randomized Control Trial (RCT)that compares two models of linking and retaining individuals recently released from custody to the continuum of community-based HIV and opioid use disorder (OUD) prevention and treatment, medication for opioid use disorder (MOUD), service cascades of care.
A significant innovation of our study is that our RCT will be delivered within four communities where coalition infrastructures have been (or are in the process of being) established as part of the Justice Community Opioid Innovation Network (JCOIN) studies, another NIDA-funded Cooperative Agreement initiative to mitigate the impact criminal justice-involved individuals with OUD are having on local communities, and we will be able to build on that existing infrastructure.

The overall 5-year project will be conducted in four sites. Sandra Springer, MD (Multiple Principal Investigator - MPI) at Yale will oversee activities at the two Connecticut sites, Ank Nijhawan, MD (MPI) at UT Southwestern Medical School will oversee activities at the Dallas County site, and Kevin Knight, PhD (MPI) at TCU will oversee activities at the Tarrant County site. Specifically, we will recruit and enroll up to **960** Criminal Justice (CJ)- involved individuals high-risk communities in Connecticut including New London, Windham, Tolland, Middlesex counties along with the greater Hartford/New Haven areas & Dallas and Tarrant counties in Texas. **The target enrollment is 864 but we are seeking approval for 960 to account for attrition.** HIV status will be assessed via rapid testing after informed consent is obtained. Participants will be randomized to receive either: a) a Patient Navigator (PN) system for care, wherein navigators will assist linking study participants to appropriate community service providers (e.g., OUD/substance use disorder (SUD) treatment including MOUD, Hepatitis C virus (HCV) testing and treatment) during the 6-month post- release intervention period; those without HIV infection will be provided access to pre- exposure prophylaxis (PrEP) services, and those living with HIV will receive assistance with gaining initial or continued access to ART services (see Appendix 11: Patient Navigator Needs Assessment Form), or b) services delivered via a *Mobile Health Unit* (*MHU),* wherein study participants will be linked to a MHU within their community where they will receive HIV PrEP/ HIV treatment antiretroviral therapy (ART), MOUD, harm reduction services on the MHU and/or assistance from a community health worker

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

in linking to appropriate community-based OUD and other medical and behavioral health providers across the 6 month post-release intervention period (see Appendix 10: Community Health Worker Needs Assessment Form). Comprehensive, research assessments will occur either in-person, hybrid (partially in- person/partially virtual), or virtually at baseline, 1, 3, 6 (end of intervention) and 12-month (post-intervention follow-up) timepoints.

During Phase 1 of the study, *we* will conduct a Needs Assessment Survey (NAS) in each of the four communities documenting treatment referral and linkage processes within the participating communities, and learn about existing interrelationships among criminal justice agencies, medical service providers, and community health providers. NAS participants will include representatives from key stakeholder agencies in each community. These agencies will include prisons and jails, community corrections agencies, county health departments, substance use treatment agencies, and HIV service agencies. Online surveys will be used to collect the data. This data will be critical for helping to inform the details of the two interventions in each of the four communities.

During Phase 2 of the study, we will conduct focus groups with a subset of the NAS study population from all four communities. The purpose of the focus groups is to collect in-depth qualitative data on the current services provided along the cascade of care for HIV, OUD/SUD and HCV. And to discuss and uncover gaps for patients moving through services among local networks. There will be an emphasis on the implementation challenges and potential solutions for patient navigation programs and mobile health unit service provision.

During Phase 3 of the study our purpose is to compare the effectiveness of the use of patient navigators (PN) with mobile health units (MHU) on participant length of time to taking initial post-release PrEP (Pre-Exposure Prophylaxis)/ ART (antiretroviral treatment) medication (within 6 months following involvement with the criminal justice system) and to evaluate PN and MHU feasibility, acceptability, and implementation costs.

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
1) Time to post-release initiation of ART medication	Time to post-release initiation of ART for persons living with HIV. Measured by self-reported initiation within 6-months. ART initiation will be measured as the date of self-reported initiation within the 6-month intervention period.	From the day of release/randomization to initiation of ART up to 6 months
2) Time to post-release initiation	Time to post-release initiation of PrEP for participants not living with HIV. Measured by self-reported initiation within 6-months.	From the day of release/randomization

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Outcome Measure	Measure Description	Time Frame
of PrEP medication	PrEP initiation will be measured as the date of self-reported initiation within the 6-month intervention period.	to initiation of PrEP up to 6 months

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
1) Proportion of participants that initiate PrEP	The proportion of participants who initiate PrEP, of those who are not living with HIV, will be assessed via self-report and/or through confirmation with community provider	From the day of release/randomization to initiation of PrEP up to 6 months
2) Proportion of participants prescribed PrEP at end of intervention.	Proportion of participants prescribed PrEP at end of intervention via self-report and/or through confirmation with community provider	6 months
3) PrEP adherence by self-report	For participants who initiate PrEP, adherence will be assessed by self-reported PrEP adherence via Visual Analog Scale (VAS)	6 months
4) Change in HIV status	Change in HIV status for participants testing negative using rapid point of care (POC) via OraQuick ADVANCE HIV tests at baseline that have a follow-up reactive HIV point of care test	Baseline and 12 months
5) ART adherence by self-report	For people with HIV (PLH), adherence to antiretroviral treatment (ART) will be assessed by self-reported ART adherence via Visual Analog Scale (VAS)	6 months
6) HIV viral suppression	For PLH, HIV viral suppression, for those with HIV at time of randomization: the percent who maintain or achieve HIV viral load < 200 copies/mL at 6 months	6 months
7) HIV Risk behaviors	Changes in injection and sexual risk behaviors, a summary item from Dr. Springer's HIV Risk Behavior tool created for NIDA Seek, Test, Treat, and Retain (STTR) will be used to assess sharing of injection equipment and other drug and sexual risk behaviors	from baseline up to 6 months

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Outcome Measure	Measure Description	Time Frame
8) Type of opioids used	Type of opioids used (not as prescribed) will be assessed by the Texas Christian University Drug Screen 5.	6 months
9) Opioid abstinence	The percent of opioid-free months by self-report via the timeline followback (TLFB).	6 months
10) Substance use treatment participation	Substance use treatment participation will be collected via self-report. Treatments include detoxification, residential treatment, and medication treatments.	6 months
11) Type of substances used	Types of other substances used (e.g. stimulant, benzodiazepine, marijuana, synthetic cannabinoids, and alcohol) not as prescribed will be assessed self-reported via Texas Christian University Drug Screen 5	6 months
12) Substance use related overdoses at 6 months	Occurrence of non-fatal and fatal substance use related overdoses, through self-report, confirmation with medical providers, and/or mortality index data	6 months
13) Substance use related overdoses at 12 months	Occurrence of non-fatal and fatal substance use related overdoses, through self-report, confirmation with medical providers, and/or mortality index data	12 months

Other Outcomes of Interest

Outcome Measure	Measure Description	Time Frame
1) PrEP adherence by dried blood spot (DBS) testing	For participants who initiate PrEP, adherence will be measured by DBS testing (Orasure, Inc.) and defined as a tenofovir-disoproxil diphosphate (TFV-DP) level >700 fmol/punch at 6 months, reflecting cumulative dosing over 6-8 weeks and consistent with 4 or more doses of PrEP per week.	6 months
3) Prep adherence by urine sample analysis	For participants who initiate PrEP, adherence will be assessed by TFV-DP urine testing, which measures recent (past 48 hour) dosing (Orasure, Inc.)	6 months

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Outcome Measure	Measure Description	Time Frame
4) PrEP adherence assessed by prescription refill data	For participants who initiate PrEP, the proportion who are adherent based on continuous PrEP prescription refill will be assessed by date of prescription refill and number of pills per refill, via pharmacy data.	up to 6 months
5) Retention in HIV PrEP care	Retention in PrEP care defined as attending 2 or more visits in 6 months post-release will be assessed via self-report and through confirmation with community provider	up to 6 months
6) ART adherence by DBS testing	For participants living with HIV (PLH), adherence to ART treatment measured via the dry blood spot for TFV-DP, level >700 fmol/punch at 6 months	6 months
7) ART adherence by urine sample analysis	For PLH, adherence to ART treatment measured via urine testing for TFV-DP based regimens.	6 months
8) ART adherence by prescription refill	For participants who are prescribed ART, the proportion who are adherent based on continuous ART prescription refill will be assessed by date of prescription refill and number of pills per refill, via pharmacy data.	up to 6 months
9) Retention in HIV ART care	For PLH, retention in HIV ART care: defined as attending 2 or more visits in 6 months post-release will be assessed via self-report and through confirmation with community provider	up to 6 months
10) Hepatitis C incidence	The proportion who test positive on rapid POC Hepatitis C virus (HCV) test with confirmatory reflex HCV viral load at baseline	at baseline
11) Hepatitis C incidence	The proportion who test positive on rapid POC HCV test with confirmatory HCV viral load at 6 months	6 months
12) Hepatitis C linkage	Time to linked appointment for HCV treatment during the 6 month intervention will be assessed via self-report and through confirmation with community provider	Day of release/randomization to appointment time up to 6 months

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Outcome Measure	Measure Description	Time Frame
13) Hepatitis C medication initiation via self-report	Time to HCV direct acting antiviral treatment (DAAs) during the 6 month will be assessed via self-report VAS	From baseline to reported treatment up to 6 months
14) Hepatitis C medication initiation by prescription refill	HCV direct acting antiviral treatment (DAAs) during the 6 month will be assessed via prescription refill data	up to 6 months
15) Hepatitis C medication initiation by confirmation from provider	Initiation of HCV direct acting antiviral treatment (DAAs) during the 6 month will be assessed via confirmation with community provider	up to 6 months
16) Hepatitis C medication completion by self-report	The proportion of participants prescribed DAAs who complete treatment will be assessed via self-report at 6 months	6 months
17) Hepatitis C medication completion by prescription refill	The proportion of participants prescribed DAAs who complete treatment will be assessed via prescription refill data at 6 months	6 months
18) Hepatitis C medication completion by confirmation from provider	The proportion of participants prescribed DAAs, who complete treatment will be assessed via confirmation with community provider at 6 months	6 months
19) Hepatitis C sustained viral remission (SVR)	The proportion of participants who achieve SVR at week 12 upon completion of DAA prescription medication, assessed as undetectable HCV viral load.	up to 6 months

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Outcome Measure	Measure Description	Time Frame
20) Hepatitis C re-infection	The proportion of participants, of those that achieve HCV SVR, that are re-infected with HCV at 12 months, via reactive rapid HCV POC test result	12 months
21) Opioid use	Opioid use (not as prescribed) will be assessed by the proportion of monthly urine samples negative vs. positive/missing	6 months
22) Number of opioid use days	Number of days of opioid use, not as prescribed, will be assessed using the timeline follow back (TLFB) method	6 months
23) Linkage to medications for opioid use disorder (MOUD) via self-report	Time to linked appointment for MOUD treatment during the 6 month intervention will be assessed via self-report	From day of release/randomization to appointment for MOUD up to 6 months
24) Linkage to medications for opioid use disorder (MOUD) via community provider	Time to linked appointment for MOUD treatment during the 6 month intervention will be assessed via confirmation with community provider	From day of release/randomization to appointment for MOUD up to 6 months
25) MOUD retention by community provider	Retention on MOUD type and dose of MOUD via confirmation from community provider	up to 6 months
26) MOUD retention by self-report	Retention on MOUD, using the Justice Community Opioid Innovation Network (JCOIN) instrument via self-reported type and dose of MOUD	up to 6 months
27) Substance use	Use of other substances (e.g. stimulant, benzodiazepine, methylenedioxymethamphetamine, marijuana, and alcohol) not as prescribed, will be assessed by the proportion of monthly urine samples negative vs. positive/missing	6 months

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

8. Background:

Our scientific premise is based on the need to improve HIV and Opioid Use Disorder (OUD) management and implementation for criminal justice (CJ)-involved individuals. Providing the evidence base to support effective approaches that improve linkage to and engagement in integrated community services is highly significant. Our proposed study, called **Addressing risk through Community Treatment for Infectious disease and Opioid use disorder Now (ACTION) among justice-involved populations**, will implement and test Patient Navigation (PN) and Mobile Health Unit (MHU) intervention models to support linkage to HIV and OUD services post-release. *Criminal justice-involved individuals represent a high risk, underserved population with higher rates of OUD/SUD and associated infections than the general population*.[15-17] One third of all opioid users pass through the criminal justice system (CJS) each year,[18] yet few are screened for OUD nor offered medications for OUD (MOUD) while incarcerated or at time of release.[19] Post-release opioid-related overdose mortality is now the leading cause of death among people released from confinement back to the community.[20-22] Rates of OD mortality following release from incarceration without MOUD exceed rates among non-CJ-involved individuals by more than 10 times, with the greatest risk in the first month post-release.[20-23] These high rates also are mirrored by substantial increases recently in HIV and HCV within CJ populations,[15-17,24] where 1 in 7,[25] pass through the CJ system, and HIV is [26,27] more prevalent. *Community-based interventions need to target improvements in access to and engagement in SUD and HIV prevention and treatment services for persons released from correctional settings* [28] Reentry is characterized by a return to pre-

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

incarceration risky behaviors, resulting in high return-to-custody and HIV incident rates.[29,30] These are exacerbated by the challenges of linking these individuals to appropriate community medical and other basic service needs.[31] The critical period after an individual is released from custody provides a reachable moment and an opportunity to provide access to MOUD[31], behavioral health (BH) services for Substance Use Disorders (SUDs), and to engage a vulnerable population at risk or living with HIV in the full cascade of evidence-based prevention (PrEP) and treatment (ART) services. A substantial proportion of PLH in custody are not engaged in HIV care prior to incarceration[32] and, even when provided care during custody, subsequent engagement and retention in HIV care and Viral Suppression (VS) drop dramatically after release.[32] **Knight (MPI)** and colleagues[33] reported that 38% of PLH in TX reported not taking their ART 24 weeks after release. In Dallas, **Nijhawan (MPI**) showed that only 34% of PLH released from Dallas jail were linked to HIV care after release, 28% had VS at 6 months, and substance use (SU) was associated with not linking to care.[34] **Springer (MPI)** has shown the same in CT in 2004 where, although there was a high rate VS prior to release, only 18% maintained VS within 3 months after release[35], and only 30% had VS in 2012.[36,37] Relapse to SU (opioids and stimulants) interferes with the ability of individuals to engage in community services providing ART post release and thus lead to lack of ability to achieve or maintain VS.[7] Research by **MPI Springer** demonstrated that MOUD medications, when offered to PLH with OUD or alcohol use disorders either prior to or at time of release, increases the likelihood of achieving and maintaining VS 6 months after release.[8,38,39] Unfortunately few are linked to MOUD or other SUD treatment at the time of release. Furthermore, the provision of pre- exposure prophylaxis (PrEP; a once daily tablet of tenofovir/emtricitabine to prevent HIV transmission) for CJ-involved individuals is very low.[40] Therefore, expedited linkage approaches to integrated services have the potential to substantially reduce the risks of CJ- involved individuals acquiring and transmitting HIV/HCV infections upon community reentry and are essential in the goal to end AIDS in the U.S.

9. Location

Phase1-NeedsAssessment

The research will be conducted over four counties in two states – Tarrant and Dallas in Texas, and New London and Windham/Tolland/Middlesex Counties and the greater Hartford/New Haven areas in Connecticut. Staff from the correctional and community agencies listed below will be recruited to complete the online survey.

The Yale University research team led by Sandra Springer, MD (MPI) will be responsible for data collection in the two Connecticut sites (New London and Windham/Tolland/Middlesex Counties and the greater Hartford/New Haven areas). Community partners include Alliance for Living, Ledge Light Health District, Perception Programs, and Generations Family Health Center. DOC sites include Corrigan-Radgowski Correctional Center, York Correctional Center, Osborn Correctional Center, Willard-Cybulski Correctional Institution, Robinson

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Correctional Institution, Northern Correctional Institution, and Brooklyn Institution.

The UT Southwestern Medical School research team led by Ank Nijhawan, MD (MPI) will be responsible for data collection in Dallas County. Community partners include Parkland Hospital and Health System (PHHS), Dallas County Community Supervision and Corrections Department (CSCD), and Dallas County Jail.

The TCU research team led by Kevin Knight, PhD (MPI) will be responsible for data collection in Tarrant County. Community partners include AIDS Outreach Center, John Peter Smith (JPS) Health Network, Cenikor Fort Worth, and Tarrant County Challenge, Inc. DOC sites include Tarrant County Jail and Tarrant County CSCD.

Phase2- FocusGroups

This phase of the study involves Focus Groups with key stakeholders in the criminal justice, infectious diseases, and/or substance use disorder fields. Focus Groups will be conducted virtually on the Zoom platform. This study encompasses the counties of Tarrant & Dallas in Texas and the counties of New London, Tolland, Windham, Middlesex counties and the greater Hartford/New Haven areas in Connecticut.

Phase3-RCT: CJ-involvedindividuals

We will recruit CJ-involved individuals in high-risk communities across multiple CT counties/ geographical areas including New London, Windham, Tolland, Middlesex Counties and the greater Hartford/New Haven areas and 2 TX counties including Dallas and Tarrant.

Phase3- RCT: Qualitative Interviews

From each site, we will conduct interviews with a sample of RCT participants from each intervention arm, staff members in each role (CHWs, PNs, and RAs), and clinicians, who are part of the MHU (Mobile Health Unit) intervention arm across all sites. These interviews are intended to gather valuable insights into healthcare delivery and other services provided within the study.

10. Subject Population:

Phase1 – Needs Assessment

Participants in the NAS will be staff recruited from participating agencies in the four communities (listed above). We expect to recruit 10 staff from the partner agencies in each of the communities (total of about 40 staff). Inclusion criteria for staff participants are 1) being currently employed within the partner agency, and 2) working with the target study population or supervising those who work with the target study population. Women and minorities will be included at approximately the rates found in the target community and agency populations. We expect that 60% of the staff samples will be women and 40% will be men. Staff participants will be at least 18 years of age or older.

Phase 2 – Focus Groups

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Focus groups will include a mix of representatives from each service provider type. It is suggested that service providers select representatives for recruitment and voluntary participation who are knowledgeable about the policies and procedures (e.g., leadership) as well as knowledgeable about day-to-day practices (e.g., line staff). These individuals are adults (18 and over), both men and women with a variety of racial and ethnic backgrounds, and professionals in their fields (i.e., criminal justice, health services). It is estimated that 2 to 3 individuals from each service provider will participate, however, more or less could be interested. We suspect that, in total, about (4 counties x 3 provider types x 3 representatives) 36 individuals will participate, perhaps up to 50 at the most.

Phase3– RCTCJ-involved individuals

Weexpecttorecruit up to960 individualsforthe study.

Inclusion criteria:

a. Livingin one of our research areas
b. Age 18 or older
c. Ableto providewritten informed consent in English or Spanish
d. Involvementwiththe criminal justicesystemwithin thelast 6 months
e. Livingwith HIV or being at risk of acquiring HIV and willing to learn about PrEP
f. Willingto be tested for HIV (unless alreadyconfirmed via medical records)
g. Havingahistoryof opioid and/or stimulant usewithin 12monthsprior tobeingin acontrolled settingand/orin thelast 6monthswithin thecommunity
h. Having a history of condomless sexual intercourse, STI diagnosis, and/or IDU within 6 months prior to being in a controlled setting and/or the last 6 months within the community. **Exclusion criteria**:

1) Severe medicalorpsychiatricdisabilitymakingparticipation unsafe
2) Unabletoprovide consent
3) Notremaining inthe local areaafterreleasefrom custody
4) Beingreleasedtoinpatient care
5) Potentialriskto research staff

Phase3– RCT: QualitativeInterview

Across all sites, we will interview a total of up to eighty RCT participants (20 per site, 10 from each study arm), up to six staff members in each role (CHWs, PNs, and RAs), and up to ten clinicians from the MHU intervention arm. The primary objective of these interviews is to obtain information pertaining to the services offered by the different study intervention arms across the care cascade and identify factors that may hinder or facilitate the successful implementation of interventions.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

RCTCost Analysis:

Weill Cornell co-investigators plan to conduct a cost analysis that estimates costs of the PN and MHU interventions. Using established micro-costing methods to identify, measure, and value all resources for the implementation of both interventions. We will estimate costs for the PN and MHU study sites including: start-up costs (e.g., staff training, equipment purchases); variable costs (e.g., labor time for staff providing services to clients); time-dependent costs (e.g., record keeping, vehicle operating costs); and overhead costs. There will be a maximum of 50 participants in this cost analysis. See Appendix 17 for the Informed consent document and Appendix 18 for the interview guide.

Inclusion of Women,minorities, andchildren Women and Minorities

Women and minorities will be included in the sample at approximately the rates found in the target community populations. For the Connecticut sites, we expect that 78% of the sample will be men and 22% will be women; for the Texas sample, we expect that 77% will be men and 23% will be women (we may need to oversample women to reach adequate numbers for analyses). Recruitment strategies will not favor any race or ethnic group. We expect the final sample will include roughly the same proportions of race and ethnic groups as found in the staff and client populations, which may vary by study site. For the Connecticut sites, we expect the samples will be 55% White and 37% Black or African American, and 8% other or more than one race. We also anticipate that the sample will be 37% Hispanic or Latino. For the Texas sites, we expect the samples will be 54% White and 46% Black or African American. We also anticipate that the sample will be 26% Hispanic or Latino.

Inclusion of Children

Children under the age of 18 will not be included in the sample because only adult CJ systems are included; the proposed study does not propose to include juvenile justice settings because of differing operational structures (e.g., need for obtaining assent as well as consent, inclusion of parents or caregivers), and the need to develop different protocols for the PN and MHU for children.

11. Recruitment Procedure:

Phase1 – Needs Assessment

An ACTION Research Assistant (RA) will e-mail information about the project to a designated stakeholder administrator (may or may not be a supervisor), who in turn will forward the e -mail with the attached material (IRB-approved brochure and a copy of the IBR-approved Informed Consent) to agency staff who have direct contact with the target population. The e-mail will underscore the voluntary nature of participation (they can withdraw consent at any time without retribution) and that they should **contactthe respective RA for that community (e.g.,**

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

TCU, Yale, or UT Southwestern) if they wish to participate (and NOT reply to the agency administrator). It will highlight the fact that their participation or lack of participation will not be disclosed to anyone within the agency, including supervisors, and that it will not be used in the evaluation of their job performance. The information and consent form will reiterate these points, highlighting the fact that completion is completely voluntary and that information from the survey will be kept confidential.

Phase2 – Focus Groups

Participants will be identified based upon key stakeholder meetings that each research site (TCU, UTSW & Yale) have conducted with hospitals systems, community justice and public health partners in their respective counties. Key stakeholders will refer individuals that are best suited to participate in the focus groups. However, participation is voluntary and identified individuals may decline participation, or may withdraw from the session at any time. Once these individuals are identified and referred, they will receive an e-mail with information about the project along with a consent form, media release form, and link to a demographic/background questionnaire. Participants who decide to participate will proceed as instructed with consenting procedures.

Phase3– RCTCJ-involved individuals

The local study teams will work with the appropriate jail/prison, community corrections, community partner health and addiction program staff to advertise, identify likely eligible participants, and strategize on trial recruitment. See Appendix 13 for site-specific recruitment materials.

In CT, this system, through MPI Springer's JCOIN project, has already been developed and is actively working with CT DOC Addiction services (co-I, Sandra Violette, CT DOC, see LOS) who have developed an identification and referral process to the Yale research team and the community programs. This includes the PN support via Alliance for Living (AFL) who provide linkage to Community Health Center Inc (CHCI) clinics in the communities designated in this grant. Participants can be referred to the study from inside CT DOC by several ways: 1) flyers will be posted in common areas with study information. Interested individuals can write to addiction services, where they be put in contact with study staff or 2) CT DOC Addiction Services can identify individuals who qualify for the study and put them in contact with study staff.

Approved study flyers will also be posted in the targeted CT communities. Interested individuals can contact study staff, at which time a screener will be conducted (See Section 16 Study Procedures-Phase 3). Similar to the CT DOC referral process, partnered community agencies (e.g., CHC Inc., LLHD, etc.) can identify individuals who might qualify for the study and refer them to the study team for screening. The Yale site-specific corrections- recruitment

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

flyer can be seen in Appendix 13D-1 and the site-specific community recruitment flyer in Appendix 13D-2. Yale will also utilize the Connecticut Department of Corrections (CT- DOC) Referral form (Appendix 13F-2) to obtain referrals from corrections staff.

At UTSW-Parkland site in Dallas, Texas (Dallas County) recruitment will also start during incarceration for some potential participants, following established processes for JCOIN and MPI Dr. Nijhawan's Dallas County Jail pilot RCT. This is often best done through detailing and interviews of individuals with SUD/OUD who are seeking addiction treatment or counseling at jail admission or prior to release and through referrals from jail medical providers. In addition, in Dallas, the research team will recruit from the Judge John C. Creuzot Judicial Treatment Center, where individuals in custody receive court-ordered substance use treatment prior to community re-entry. As above, persons cannot be 'mandated' or required to enroll by CJS agencies or judiciary. The UTSW site-specific corrections-recruitment flyer can be seen in Appendix 13E-1 and the site-specific community recruitment flyer in Appendix 13E- 2.

At the TCU site in Fort Worth/Tarrant County, recruitment will be conducted at community partner agencies including Tarrant County Probation offices, JPS clinics, and other community organizations located throughout the county. Approved study flyers will be hung where permitted and community partner agency staff will be informed about the study and encouraged to refer participants who may be eligible. In addition, participants will be recruited at the JPS Health Network Bridge Clinic. Informational flyers will be distributed within the Bridge Clinic and interested individuals will have access to a (TCU) laptop at the Clinic to complete a Qualtrics contact survey (see Appendix 13C-2). The laptop will be located in a private office at the Bridge Clinic and participants who complete the survey will be contacted (by e-mail or telephone) by a member of the research team. The researcher will then schedule a time to meet with the individual to conduct a consent conference. A site- specific flyer has been developed that will be distributed to interested individuals (see Appendix 13C-1).

Enrollment must be voluntary in keeping with OHRP federal prisoner research standards. We have conducted recent and current jail/prison and community-CJS trials in CT and TX using similar methods and standards and have successfully achieved similar recruitment and accrual rates as well as in our other CJS studies (Preliminary studies).

Research staff will first complete a screening questionnaire to determine eligibility. At the TCU site, self-referred/snowball recruited individuals will be asked to give verbal permission if via phone, sign electronically or hand-sign an authorization if in person to check publicly available criminal history/background check (Appendix 22). Once eligibility is confirmed, the enrollment informed consent process will begin. However, before signing the enrollment informed consent document, a consent quiz will be administered to

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

confirmparticipant comprehension. Any questions the participant answers wrongly on the quiz will be discussed with study staff and then the quiz will be re-administered. After successfully passing the informed consent quiz and signing the enrollment informed consent form, the individual will be enrolled onto the study as a participant and research assessments and data collection will be conducted (See Section 16 Study Procedures-Phase 3). Research staff will discuss participant needs and provide a mobile telephone, if necessary. Research staff will also provide transportation assistance (taxi vouchers, bus passes, etc.) to get to the research visits by means that have been identified in each of the study locations. Transportation assistance will also be offered for participants to get to their initial intervention visit (with a patient navigator or to the MHU). Transportation for subsequent intervention visits will not be paid for by the study. Instead, study staff will identify existing travel assistance and public transit options in the community and provide that information to the participants, if needed.

Once in the community or under community supervision, participants will also have the opportunity to earn a $20 referral bonus for each eligible participant referred and successfully enrolled into this study. The maximum number of referral bonuses will be 3 for a maximum of $60 paid in the same payment method as their study visit compensation. This referral bonus is not available to participants while they are still in a custody setting (e.g., jail/prison, correctional residential facility).

Phase3 – Qualitative Interviews

Prior to conducting the interviews, each site will identify staff members in each role (CHWS, PNs, and RAs) and clinicians for this activity. Identified study staff (CHWs, PNs, RAs and Clinicians) will receive e-mail information about the qualitative interviews and request for their participation. The e-mail will underscore the voluntary nature of participation (they can withdraw consent at any time without retribution) and that they should contact the respective PD/PC for that community (e.g., TCU, Yale, or UT Southwestern) if they wish to participate. It will also highlight the fact that their participation or lack of participation will not be used in the evaluation of their job performance. The information and consent formwill reiterate these points, highlightingthe fact that completion is completely voluntary and that information from theinterview willbe kept confidential. Informed consentwill includeobtaining authorization to audio record the interview for analysis.

For RCT enrolled participants, study staff will identify a convenience sample of participants at each site (from each study arm) and similarly inform them of the opportunity to participate in qualitative interviews, emphasizing its voluntarynature and assurance that theirparticipation willnot affectthe servicestheyreceivewithinthe studyor their justice involvement. Interested participants can inform their respective Research Assistant (RA) or interventionist (PN/CHW) for their community (e.g., TCU, Yale, or UT

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Southwestern)about their willingness to participate. See Appendix 28 for all Phase 3 qualitative interview materials including informed consents, demographicsurveys, and interview guides.

12. Compensation:

Phase1 &2 – NeedsAssessment &FocusGroups

There will be no compensation for completing Year 1 "Needs Assessment Survey" and Year 2 "Focus Groups."

Phase3– RCTCJ-involved individuals

Participants will be compensated for their time at each research visit with payments of $50 for Day 0 (baseline, 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, participants can up to $300 by the end of the study. While a participant is incarcerated, monetary compensation will be held until the participant is released. If there is successful contact between the participant and the study staff between Baseline and Month 1, and attends the participant attends their Month 1 visit, they will receive an additional $20 at the Month 1 visit. At the UTSW site, this contact must be self-initiated by the participant in order for them to receive the additional $20.

Participants will also be compensated $5 for a monthly check-in on each of the months where there is no research visit. Check-ins will also occur at months 2,4,5,7,8,9,10, and 11. Compensation will be provided in the form of a gift card at each time point.

If biotesting has to be repeated for a participant due to any reason, participant 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.

Once in the community or under community supervision, participants will also have the opportunity to earn a $20 referral bonus for each eligible participant referred and successfully enrolled into this study. The maximum number of referral bonuses will be 3 for a maximum of $60 paid in the same payment method as their study visit compensation. This referral bonus is not available to participants while they are still in a custody setting (e.g., jail/prison, correctional residential facility).

Phase 3 – RCT: Qualitative Interviews

Participants will receive a $ 25 gift card for completing the qualitative interview.

13. Consenting Procedure:

Phase1 – NeedsAssessment

The NAS will utilize a waiver of signed informed consent in lieu of needing participants to print out the emailed consent document, sign, scan and email the document back to research staff. The NAS will be delivered via a secured, online platform (REDCap) and the consent information will be presented before beginning the survey. Participants will need to click "I agree" in order to complete the survey. Participants will be given instructions that they may withdraw

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

their participation at any point and may withdraw their survey results at any point after their participation by contacting the Principal Investigator (a toll-free number will be provided as well as e-mail contact information). RAs will be available to answer any questions about the project and the Informed Consent. The Waiver of Signed Informed Consent document is attached in the supporting documents.

Phase2 – FocusGroups

Among our stakeholders, for those expressing interest in taking part in focus groups, a pdf informed consent form and an authorization to be audio/visually recorded will be e-mailed to participants for their records and review. Also included in that e-mail will be a link to the electronic consent form, media form, and a brief demographics survey as well as training for the selected electronic platform (e.g., Zoom training). Once the focus group is scheduled, a member of the research team will send the participant a link to the virtual meeting where only the participants and research team will have the link and password to join.

At the beginning of each focus group or interview session, research staff will verify that each participant has completed the consenting process and remind participants of the highlights of ongoing consent (e.g., voluntary nature, purpose of the project), and remind them that we will begin recording before hitting the "record" button so participants have the option to leave the meeting if they change their mind. Any additional individual interviews thereafter will follow the same consenting procedures.

Procedures for withdrawal. Participants can withdraw from the Focus Group prior to the start of the activity, during or after the recorded Focus Group meeting. To withdrawal before the day of the activity, participants can contact the Principal Investigator at ibr@tcu.edu and indicate that they choose not to participate in the Focus Group.

Prior to the start of each Focus Group session, participants will be informed that (a) they can withdraw from the Focus Group at any time, (b) that there will be no consequences for choosing to withdraw, and (c) if they decide to withdraw during the Focus Group, they should tell the Focus Group facilitator (a member of the research team) or simply log off of the virtual Focus Group call. The facilitator will follow- up after the Focus Group with participants if needed, to confirm the participant decision to withdraw from the Focus Group activity and to ask if they choose to have their recorded comments removed from the study data, in the event that they withdraw during the recorded Focus Group.

Phase3– RCTCJ-involved individuals

Informed Consent. The research staff will complete a screening questionnaire to determine eligibility. Screening will be occurred electronically in most cases (unless there are internet connectivity or other technology issues) using the REDCap database. This process will be done either in person or virtually. If there are internet connectivity or technological issues, a paper version of the screening informed consent form will be used. Once the screening is completed

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

and eligibilityis confirmed, research staff will begin the enrollment informed consent form. The enrollment informed consent covers all study details and includes the HIPAA and pre-enrollment background check authorization (see Appendices 2A-2C for enrollment consent forms and Appendix 22 for pre-enrollment background check authorization form). Researchers will go over the consent form in detail, highlighting the main points of each section. Potential participants will be afforded sufficient time to read the consent form and consider whether or not to participate in this research study before being asked to sign the informed consent form (ICF). If a participant requests assistance reading the informed consent document, the researcher will read the consent to the participant. Before the participant signs the ICF, a consent quiz (see Appendix 3) will be administered to confirm participant comprehension. The candidate must successfully answer all the comprehension quiz items before the ICF can be signed in order to document basic comprehension about their study participation. The Consent quiz can be administered multiple times in order to receive a 100% score. However, research staff should use their best discretion to ensure participants truly comprehend all questions. If an incorrect response is given, or if the study candidate cannot answer an item, the study team member should review the item and explain the correct answer. If, after assistance and review of incorrect quiz responses, the candidate is unable to demonstrate a basic understanding of the study, they will be deemed ineligible to participate in the study.

Study candidates who have read and reviewed the ICF, demonstrate comprehension of the study, and would like to be considered for study participation will be required to sign, date, and note the time on the ICF.

Enrollment informed consent will be obtained electronically in most cases (unless there are internet connectivity or other technology issues) using the REDCap database. This process will be done either in person or virtually. If there are internet connectivity or technological issues, a paper version of the ICF will be used and a copy will be provided to the participant. The ICF will also be signed and dated by the study team member obtaining informed consent. Additional signatures will be requested from the participant on the ICF document for consent to use data for future research and consent to be contacted for future research. The research staff will provide all participants with a copy of the signed ICF (whether signature was obtained electronically or hand- written on a paper form). At some CJS facilities, these handouts may not be allowed or have the potential to be confiscated by correctional officers. Study staff will instead provide this ICF copy to all participants at their first post-release study visit or make other reasonable accommodations if requested. These documents should always be provided to community-dwelling participants prior to the completion of screening visit.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Participants may be asked to consent to social media (Facebook or other platforms) and public records tracking using personal identifiers and locator data for study retention and follow-up purposes. A Federal Certificate of Confidentiality will protect participant confidentiality. Participating in this study is voluntary. Participants are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which a participant is otherwise entitled (such as their health care outside the study, the payment for their health care, and their health care benefits). Involvement with the Department of Corrections, health care received in jail/prison, their stay in jail/prison, and release from jail/prison will not be affected by the decision to participate or not participate in this study. Participants will not be able to enroll in this research study and will not receive study procedures as a study participant if they do not allow use of their information as part of this study.

Personal information collected for this research will be kept as long as it is needed to conduct this research. Once participation in the research is over, information will be stored in accordance with applicable policies and regulations. Permission to use personal data will not expire unless withdrawal from the study is requested in writing by the participant. Participants may withdraw or take away permission to use and disclose information at any time. This is done by sending written notice to the Principal Investigator at each of the sites. For TCU, Kevin Knight, PhD at: 3034 Sandage Ave. Box 298740, Fort Worth, TX, 76129; for Yale, Sandra Springer, MD at 135 College Street, Suite 323, New Haven, CT 06510; for UTSW, Ank E. Nijhawan, MD at UT Southwestern Medical Center Division of Infectious Diseases, Building E, 5323 Harry Hines Blvd. Dallas, TX 75390.

Based on the recruitment strategy used in previous studies by the MPIs involving soon-to-be released individuals, we will collaborate closely with correctional center/facility staff and will post announcements in the respective facilities. For sites that will be recruiting in the DOC, research staff (individuals not affiliated with the Departments of Corrections in the participating communities) will recruit in the correctional facilities by way of referral from DOC staff members or via service providers in the community that work with CJ involved individuals. We will stress the voluntary nature of the recruitment and consent into the study, and agency officials will stress to their staff that client decisions to participate or not participate in the study will not in any way affect their treatment at the facility. After signing the Informed Consent Form, we will ask consented participants to complete a brief demographic form and a locator form which requests phone numbers, addresses, contact information of immediate relatives and two unrelated friends, places where participant regularly frequents, social media handles, etc.; see Appendix 7 Locator Form). All English study documents (upon approval by the IRB) have been translated into Spanish by a certified translator.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Phase 3 – RCT: Qualitative Interview

Participation is voluntary and identified individuals may decline participation, or may withdraw from the interview at any time. Once these individuals are identified, they will receive an e-mail with a link to the ACTION REDCap database to complete the Informed Consent (IC) and demographic questionnaire. If there are internet connectivity or technological issues, a paper version of the IC and demographics survey will be provided to the participant. The consent includes language seeking the participants' permission to be recorded during the interview for the purpose of qualitative analysis (described below). Phone calls may be scheduled with a member of the research team to answer questions about the activity, going over the IC and answering any questions. Participants who decide to participate will proceed as instructed in the email with consenting procedures.

Study Procedures:

Phase1 – Needs Assessment

Participation in the NAS is a one-time event and will entail completing an online survey documenting treatment referral processes within participating communities and learn about existing interrelationships among criminal justice agencies, medical service providers, and community health providers. We will first contact partner agencies in each community including correctional agencies, community treatment providers, health agencies and relevant government agencies with an e-mail asking them to forward to staff who have supervisory or case management responsibility with the target population. The e- mail to be forwarded to staff will include a brochure briefly describing the study and the participant's role (completing the survey). Staff participants will be invited to contact a project RA to indicate their interest in participating and the RA will send a secure, anonymous survey link to the Needs Assessment Survey to be completed on REDCap. Phone calls may be scheduled for describing the study and the survey, going over the Informed Consent and answering any questions. The online survey will collect personal identifiers including: name, role, length of experience. However, the data will be de-identified and demographics will only be presented in aggregate.

The survey will ask questions about the background and experience of the participant (e.g., gender and race/ethnicity, current position, education and training, certifications, years in the field, with current agency, and in current position, and treatment referral processes within their agency and about existing interrelationships among community service providers. The survey should take no longer than 30 minutes to complete and is a one-time event.

Phase2 – Focus Groups

Participants will be asked to participate in: (1) providing consent to participate, to be recorded, and basic demographic information via online survey prior to the focus group session; (2) one 2hour session (either virtual focus groups or virtual interviews); and (3) an

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

optional follow-up survey to gather any additional feedback participants may have after processing what they learned in the sessions, and/or (4) an optional/additional virtual interview to clarify thoughts or add to the information already shared. Focus group sessions will be limited to 6 or less participants with exceptions occurring for reasonable community-specific needs. *Procedures for consenting are outlined in the consent section above.*

At the beginning of each virtual focus group/interview session, participants will be reminded of the elements of the informed consent form and that they will be recorded. For focus groups, specifically, guidelines for interacting during the session will be discussed. Prior to recording and starting the data collection part of the session, participants will be given the opportunity to log off if they no longer wish to participate. Once the record function has been activated, the facilitator will acknowledge that the session is being recorded. The data collection portion will begin at that point. During the session, participants will be introduced to the ACTION project and the HIV service cascade. Questions will focus on the services provided within their agencies and networks, where the gaps for services for recently released individuals may be, and the implementation challenges and possible solutions related to patient navigation and mobile health units. Focus groups and interviews will be transcribed and coded. Following the sessions, a Qualtrics survey link will be e-mailed to participants so they can provide any additional feedback they develop after having some time to process the information presented.

FOCUSGROUPPREPARATION(Stepsand Proceduresto Sharewith Sites)

- Send outfocusgroup materials priortothe group (FedExand/or electronic copy):
- Copyoftheconsentformwithpermissiontoberecorded and linkto demographics/background survey
- Virtualplatformintroduction
- ACTIONproject summary
- Session

  Focus group agenda

  Instructionsforloggingon

  PowerPointslidesfrom ACTION overview

  List of ACTION *Service* questions

  ListofACTION *Implementation Barriers andSolutions* questions

  Service cascade visual

  Instructionsfor accessingthe online surveypost-session 1
- There should be at least 2 hosts – one covering the administration of the focus group and assisting with technical issues (Admin), and one to host the group (Facilitator). Note that there should be a 3rd trained facilitator to serve as an alternate should an issue arise.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

- Test the virtual platform link, recording procedures, and transcript capabilities beforehand to ensure everything works as planned.
- Send a reminder e-mail to participants with a link to the meeting, agenda, and list of the items to have available for the focus group (e.g., the materials mailed out beforehand, etc.).
- Start the meeting 10 minutes early with everyone on mute and no video with a welcome screen showing (the welcome screen needs to be developed beforehand).
- Make sure to include the following in the script.

Welcome everyone

Remind everyone of the pertinent informed consent pieces and that they'll be recorded

Go over the focus group protocols with everyone.

Make sure everyone is aware that the recording is about to begin

Begin the recording.

SESSION 1 PROCEDURES AND SUGGESTED SCRIPT (Steps and Procedures to Share with Sites)

ACTION FOCUS GROUP QUESTION BANK

(Questions will be drawn from this bank – not all questions will be used in sessions)

Services

- What HIV-related or substance use-related services does your agency provide to justice-involved adults? We're specifically interested in those who have been recently released from incarceration.
- Do you provide patient navigation or mobile health unit services currently?
- What are your agency's goals for HIV and/or substance abuse care (testing, referral, prevention, treatment) for the future?
- Walking through the steps of the care cascade,

1. How is the need for HIV or substance use care/prevention identified for clients at your agency?
2. Once a need is identified, what steps are taken to link clients to further care?
3. How do you link clients being released to outside services?
4. How do you handle clients being linked to your services from outside the agency or department?
5. How do you ensure that clients follow-through with the needed care?
6. How do you help your own clients stick with their care/retain clients?
7. How do you help clients maintain their gains (abstinence, viral load suppression)?

- Walking through the experience of a typical client –

1. Once they're released from incarceration, where are they screened for need?
2. What is the process like getting them linked with services?
3. What are the typical frustrations they encounter with starting and sustaining services?
4. What are the challenges they encounter with getting into and sticking with care?

- What are the biggest gaps in care for your clinic population who are released from the criminal justice system?

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

What arethebiggest gaps in care or linkage in this cascade? Where do the breakdownshappen within or between providers?

- What doyou think themain reasons are forthat?
- Whatareyouragenciesbiggest barriers tofulfillingits mission regardingHIV/ substance use care?
- What doyouthink are solutions to these barriers?
- How doesyour agencyorpeople from youragency participate in local interagency collaborative group efforts?
- Arethese groupshelpful?What would make them more useful?
- Are their agencies you would like to partner with which could help you overcome barriers? (e.g. substance use treatment, housing provider, mental health, re-entry organizations)? Implementation
- Do you think there is a need for or that your patients would benefit from patient navigators and/or mobile health units to provide HIV prevention/treatment and MOUD?
- What do you think implementing patient navigators within your agency or network would look like? What might the initial issues be?
- What would you needfromotheragencies(here orin the localnetwork)for this to be successful?
- Walkingthroughthesteps of thecare cascade,

1. How might your agency use or support PN or MHU in terms of diagnosis HIV or SA need? Would it help improve this part of the cascade within your network? How?
2. What might it look like to implement or connect with PN or MHUs within your local care network for justice-involved individuals? Would you need to build more connections across agencies? Would these replace your current linkage efforts for those with a need?
3. How could PN or MHUcomplicatelinkage orservicesat your agency?
4. What are the communication issuesyouforesee with usingPN or MHUservices in yournetwork?
5. What would successful implementation look like for your clients? How would PN or MHU help them stick with HIV or MOUD care?

- What gaps mightPN or MHUhelp fillwith your population?
- Would your agency be willing to make changes to accommodate the implementation of one of these within your network(either at your agency or to improve linkage with the hosting agency)?
- What additional implementation barrier do youthinkwe mayneed to prepare for with PN or MHC?

COVID-19QuestionOptions

Adaptedfromthe CDC[41]

- How would you describeany impact the COVID-19 pandemic has had on your operations in general?
- How would you describe anyimpact theCOVID-19 pandemichashad on clientservicesand client linkage?

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

- How would you describe any impact the COVID-19 prevention strategies have had on client services and client linkage to care?
- How has the COVID-19 pandemic or subsequent prevention strategies affected different populations or groups that you serve – paying special attention to criminal justice-involved clients?
  In your opinion, what community activities do you think are most effective for the prevention of the new coronavirus?[42]

Phase3 – RCT:

Study Timeline:

Potentialparticipantswill first be screened for eligibility. If deemed eligible, potential participants will then be asked to take part in the informed consent process.

StudyEligibility Screening

The research team member will introduce themselves and their role and ask if the participant would be interested to discuss involvement in this randomized control trial. The protocol for screening consent will be followed as detailed in Section 14 Consenting Procedures-Phase 3).

Participants will be asked to answer a screening questionnaire designed to determine eligibility. The screening questionnaire will review inclusion and exclusion criteria to ensure eligibility for the study (See Appendix 6; Section 11 Phase 3 RCT). The screening questionnaire will be housed in the secure REDCap database.

Screening assessments will take approximately 10-15 minutes. Once the baseline screening assessments have been performed, final eligibility can be confirmed. Part of this final eligibility screening at the TCU site, potential participants will be asked to either hand-sign a pre-enrollment Background Check authorization form (Appendix 22) if in person, give verbal permission over the phone, or sign electronically. While the records are publicly and privately available through the DPS CRS Secure Site, this form will be used for community recruitment samples that are not referred through probation, parole, or other justice agencies. Once final eligibility is confirmed the enrollment informed consent process can begin.

RCT STUDY VISITS OVERVIEW: A complete overview of measures that will be collected at all study visits is available below in Table 2.

Table 2.StudyProcedures

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

	Pre-Screen	Consent	Screen	Intervention Period (Baseline-Month 6)						Post-Intervention
				Baseline (v0)	Randomization	Day of Release	Month1 (v1)	Month 3 (v2)	Month 6 (v3)	Month12 (v4)
Procedures										
Release of Information	x									
HIVrapidtest (repeat only negativeat V0)				x					x	x
HIVVL(only if+ HIV rapid test)				x					x	x
HCVrapid test (repeat only if negative V0)				x					x	x
HCVVL(only if+ HCV rapid test)				x					x	x
Sustained PrEP adherence(DBS)				x					x	x
UrineTDF(TDF testing)				x				x	x	x
Urine toxicology				x				x	x	x
STI (Gonorrhea, Chlamydia,HepB, and syphilis)				x					x	x
INTERVIEWS:										
Demographics (JCOIN harmonized)				x			x	x	x	x
HIV risk behaviors				x				x	x	x

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

TLFB (opioid and stimulant use and modeself report)				x			x	x	x	x
Quality of Life (PROMIS-PROPr)				x				x	x	x
PatientHealth Questionnaire (PHQ9)				x				x	x	x
VisualAnalogScale (VAS) for ART/PrEP/MOUD adherence								x	x	x
RapidOpioidUse disorder Screen (RODS)				x						
TCUDrug Screen				x				x	x	x
Engagement in care(Rx for PrEP, ART, MOUD, HCV tx, STI tx)							x	x	x	x
SubstanceUse Treatment (Lifetime and Current History)				x			x	x	x	x
Utilizationof Services							x	x	x	x
Medical History				x			x	x	x	x
Overdose and adverse events							x	x	x	x
Drug craving (VAS)				x			x	x	x	x

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

PrEPReadiness Questions				x					x	
COVID-19 Questionnaire				x					x	x
Stigma				x				x	x	x
Locator Form				x		x	x	x	x	x
Phone				x		x				
Travel Assistance				x		x	x	x	x	x
Compensation				$50			$50/$70	$50	$75	$75

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Baseline Visit &RCT Randomization:

Once initial screening and inclusion criteria are finalized, the RA will begin the enrollment informed consent process (including the consent quiz). See Appendices 2A-2C for enrollment consent forms & Appendix 3 for the consent quiz. Once the enrollment informed consent process is completed, the baseline study visit will begin. This visit will either occur while the participant is housed at a correctional facility or after they have been released and living in the community. The baseline visit will take approximately 90 minutes. If any of the above study assessments reveal presence of an exclusion criteria that was not initially revealed on screening, the participant will be informed and removed from the study.

Baseline assessments will include a battery of questionnaires (see Appendix 14 & 16) for the measures) and the collection of several biological samples and rapid-tests for HIV & HCV. The baseline (and consecutive) study visit will be conducted using an interview-based format. A REDCap electronic database software will be used by the RA to read the measure questions to the participant and the RA will then input the answers into the database. Refer to Table 2 or list of baseline measures and see Appendix 14 & 16 for full-text versions of all measures.

Biological Measures:

The following biological measures will be collected at baseline or day of release if necessary and some will be repeated at months 1, 3, 6, and 12. See Table 2 for specifics on what will be collected at each time point:

- Rapid HepatitisCVirus (HCV)test
- HepatitisBVirus (HBV) test
- RapidHIV test
- Sexuallytransmittedinfection (STI)testingincludinggonorrhea, chlamydia,and syphilis
- Urine(testing for drugtoxicology,gonorrhea &Tenofovir adherence)

The biological assessments will be completed at all research sites (TCU, UTSW, and YALE) for all participants. All biological samples and tests will be collected by a trained research assistant adhering to universal precautions and following all institutional requirements for handling and disposing of biological samples and sharps. The measures include:

(1) Rapid HIV Test: Those who have an unknown HIV status will be offered a rapid test for HIV which consists of collecting a single drop of blood obtained from puncturing a finger with a small lancet. All lancets will be disposed of in a sharps bin and rapid test kits will be disposed of in a biohazard waste container immediately after testing. After point of care/rapid testing is performed, participants with reactive results will receive confirmatory

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

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 rapid test, research staff will link participants to a licensed medical professional to start ART. 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. Participants with a new diagnosis of HIV will receive post- test counseling and assistance in arranging follow-up with an HIV provider. Participants who decline assessing HIV status will not be eligible to participate. Rapid HIV tests will be performed at baseline or day of release, month 6, and month 12. If a blood sample isn't attainable, rapid HIV tests can be conducted using an oral swab. If a blood sample or oral swab isn't attainable, participants can be sent to a clinical laboratory for testing.

(2) Rapid HCV Test: A rapid HCV test will also be conducted using the same finger stick as the HIV rapid test. This will include collecting a single drop of blood. After point of care/rapid testing is performed, 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 rapid test, 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. Repeat HCV testing and VL will be done based on HCV status. Specimens collected for rapid testing will be disposed of immediately after testing. Rapid HCV tests will be performed at baseline or day of release, month 6, and month 12.

If a blood sample isn't attainable, study staff will request the clinician to whom the participant is referred to order laboratory testing incorporating all missed POC testing using blood samples (HIV, HCV, Hepatitis B, Syphilis, and long-term PrEP adherence). Results of this laboratory testing will be requested by study staff, ensuring the proper ROI(s) are signed by the participant.

(3) Urine Toxicology for Drug Use, PrEP Adherence, & STIs: Urine toxicology assessments for opioids, stimulants and other substances will be done at baseline or day of release, month 3, month 6, and month 12 visits. We will be using 13 panel T Cups that tests for multiple illicit drugs as well as some prescription opiates and fentanyl. Using the same urine sample, a urine tenofovir (TFV-DP) will be collected to assess PrEP adherence at months 3, 6, and 12. Chlamydia and gonorrhea will be tested using the same urine sample.

Urine collection: Participants will be asked to provide a urine sample using a standard urine collection cup, collected by the participant themselves in a private restroom. Research staff

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

will not supervise collection of the urine sample.

(4) PrEP Adherence using Dried Blood Spots: Dried blood spot adherence tests (DBS) specimens will be collected to assess PrEP adherence at Month 6. The DBS process is completed by using a lancet to perform a finger stick to collect several small drops of blood which are placed on a testing card and allowed to dry down. The DBS testing card contains 5 collection areas that each require 3-6 drops of blood. The testing cards will be placed inside testing envelopes, then placed inside a sealed biohazard bag, then shipped adhering to courier's biohazard shipment requirements to an outside laboratory for analysis and disposal. (5) Sexually-Transmitted Infection Testing using DBS: DBS will also test for an STI Panel which will[27] include Hepatitis B and Syphilis. Testing will be assessed at Baseline or day of release and Month 6 follow up. For this DBS STI testing, the same procedure noted above will be followed for collection of the blood samples storage, shipment, and disposal. After point of care/rapid testing is performed, 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 rapid test, 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.

The Clinical Data Form (see Appendix 8) will be used to record the results of the biological measures which will then be entered into the REDCap database and also used to share with the clinicians on the MHU (for those enrolled in that arm of the study) to assure continuity of care.

Note on Follow-Up HIV Testing: MPIs Springer and Nijhawan have operated routine HIV testing in previous studies including a justice-involved population and have extensive experience not only complying with state laws for HIV testing, but also with post-test counseling and ensuring engagement in HIV care. As indicated for persons who are living with HIV, a viral load (VL) will be obtained via chart review or if not available it will be done through commercial labs in the community (e.g., Quest Diagnostics, Lab Corps, etc.) or; repeat HIV rapid testing will be done for those who are found to be negative at baseline and will also be completed at Month 6 and Month 12 follow up visits.

Additional LogisticalProceduresforthe Baseline Visit:

At the end of the baseline visit, the RA will complete the Research Assistant Needs Assessment Form to assess the participants' needs and barriers to care (see Appendix 9). In addition, any participant that does not have access to a phone will be referred to state or federal entitlement programs. If the participant is unable to acquire a phone through other

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

sources, study personnel will provide participants with a simple cellular telephone that has only text message and telephone calling capabilities for study purposes. Participants will be expected to return these phones to the study team, but will not be penalized or charged if they do not. Last, all participants will be offered travel assistance for their initial intervention visit (with patient navigator or to the MHU) and all research visits (with the research assistant). If participants are still in custody at the time of the baseline visit, the phone and travel assistance will be provided on the day of release.

Participants will be contacted via text and will also be given the Appointment reminder card to serve as reminder for follow-up visits (see Appendix 12).

RCT Randomization:

Once the baseline visit measures have been collected, the participant will be randomized to either the Mobile Health Unit (MHU) or Patient Navigator (PN) arm of the study (see background section for more information). The randomization will occur via REDCap which will use a computer- generated random sequence to assign to study arm.

Follow-Up Visits

There will be four follow-up visits during the intervention period at 1 month, 3 months, 6 months, and 12 months. Refer to Table 2 for all interview-based and biological measures that will be collected and see above for procedural guidelines for collection of blood and urine and testing. If participants are unable to attend research visits in-person (this includes participants who relocate out of the study site), interviews will be conducted over the phone or video chat and biological samples will be collected by sending the participant to Quest Laboratory and the cost will be covered by the study. In this case, compensation will either be loaded on to a re-loadable gift card provided at baseline or mailed to the participant at the address of their choosing; this includes compensation for check-in calls. Intervention services will not continue for relocated participants out of the study sites.

For the participantpopulation, re-incarceration and becoming lost to follow up due to communication barriers (e.g., loss/theft of mobile devices), periods of uncontrolled substance use, homelessness, and other court-mandated treatment institutionalization is very common. For the 12-month visit, a post-trial follow up (PTFU) approach could be used. Post-trial follow-up (PTFU) is defined as extended follow-up which starts after the end of the scheduled period of the originaltrial, which is 12 monthsfor this current study (Llewellyn-Bennett et al., 2016). Upon re-encountering participants who are discovered in carceral settings, released from carceral or court-mandated settings or otherwise located due to changes in communication ability, housing status change, etc., study staff will offer to conduct the 12-month follow-up visits. The 12- month visitwill be conducted as outlined below, includingequal compensation, biotesting screen for HIV, HCV, & STIs and link participants with referrals and treatment for psychosocial, medical, and other related needs. Study staff will emphasize the voluntary nature of the PTFU 12-month follow-up. While the 12-month data visit is not necessary to meet the primary study outcomes (e.g., time to PrEP/ART), we would like to extend the offer to participants to re-engage in the study data collection in the PTFU time period due to the unique challenges the study population faces with being lost to follow up, the challenges of having a substance use disorder, and exposure to infectious diseases. Extending this opportunity for biotesting and referral for treatment for any positive/preliminarypositive tests willextend oureffort to ensure best medical practice, and improve publichealth outcomes by lessening prevalence of infectious diseases in the community. B a s e current follow-up trends,the PTFU method will only impact a very small number of participa

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Month 1 follow-up assessments will include:

- Engagement in PrEP/ART/MOUD/HCV/STI care
- Demographics
- Adherence to ART/PrEP/MOUD and drug craving using the Visual Analog scale (VAS)
- Frequency of opioid and stimulant use will be assessed using the Timeline Follow Back (TLFB)
- Current and lifetime substance use treatment
- TCU drug screen and opioid supplement
- Overdose and Adverse Event collection
- Justice Involvement & Utilization of Services

The month one follow-up will take approximately 30 minutes.

Month 3 follow-up assessments will include:

- PrEP/ART/MOUD/HCV/STI care
- Demographics
- Adherence to ART/PrEP/MOUD and drug craving using the Visual Analog scale (VAS6)
- Frequency of opioid and stimulant use will be assessed using the Timeline Follow Back (TLFB)
- Current and lifetime substance use treatment
- HIV risk behaviors
- Quality of life (PROMIS-PROPr)
- PHQ9
- TCU drug screen and opioid supplement
- Overdose and Adverse Event collection
- Urine TDF (short-term adherence for PrEP)
- Urine toxicology
- Justice Involvement of Utilization of Services
- Medical History
- Stigma

The month three follow up will take approximately one hour.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Month6follow-up assessments willinclude:

- PrEP/ART/MOUD/ HCV/STI care
- Demographics
- AdherencetoART/ PrEP/MOUD anddrugcravingusingtheVisualAnalogscale (VAS[6])
- Frequencyofopioid and stimulant usewillbeassessed usingtheTimelineFollow Back(TLFB)
- Currentand lifetime substanceuse treatment
- HIVriskbehaviors
- Qualityoflife (PROMIS-PROPr)
- PHQ9
- COVID-19Questionnaire
- TCUdrugscreen and opioid supplement
- Currentutilization of services
- Overdoseand AdverseEvent collection
- HIVRapidtest (repeat ifnegative at baseline)
- HCVRapidtest (repeat if negativeatbaseline)
- PrEPadherencetestusingdried blood spot testing(long-term adherence)
- UrineTDF(short-termadherence for PrEP)
- Urine Toxicology
- STItesting viaDBS & urine
- Medical History
- Stigma

The month six follow-upwill take approximately one hour. Therewill also be a post-intervention final follow-up at Month 12.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Month12follow-up assessmentswill include:

- PrEP/ART/MOUD/ HCV/ STI care
- Demographics
- Adherenceto ART/ PrEP/MOUD and drugcravingusingthe VisualAnalog scale (VAS)
- Frequency of opioid and stimulant usewill be assessed using the TimelineFollow Back(TLFB)
- Currentand lifetime substanceuse treatment
- HIVrisk behaviors
- Qualityof life (PROMIS-PROPr)
- PHQ9
- COVID-19 Questionnaire
- TCUdrugscreen and opioid supplement
- Overdoseand Adverse Event collection
- HIVRapid test (repeat ifnegative at baseline)
- HCV Rapid test (repeat if negative atbaseline)
- Long-TermPrEP adherencetest usingdriedblood spot testing
- UrineTDF (short-term adherence for PrEP)
- Urine Toxicology

Please note: If biotesting at the baseline or follow-up visits has to be repeated for any reason, study staff will schedule a visit with participant to repeat biotesting and participant will be compensated with a $25 payment in the form of a gift card or similar method.

Please see Table 2for a summary of study procedures.

Incentivized Check-ins

To help retain participants in the study, participants who have successful contact with studystaff between Baseline and Month 1, and attend their Month 1 visit, will receive an additional$20 at the Month 1 visit. At the UTSW site, this contact has to be initiated by study participant. There will also be 8 other incentivized phone check-ins. The incentivized check-ins will occur in between the scheduled study visits at the following timepoints: months 2, 4, 5, 7 ,8, 9, 10, and 11. During these check-ins, locating information will be updated and future appointments will be confirmed.

For each other successful check-in after Month 1, participants will be compensated with a $5 payment. Compensation for check-ins can either be mailed to participants, electronically loaded onto cards, or included with the compensation earned at the next scheduled study visit. For a check-in to be considered successful, participants will be required to communicate with study staff via phone in order to receive the additional compensation. Check-in communication is otherwise voluntary.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

1. Medical record data will be obtained from a variety of sources including both records generated by MHU clinical visits and community providers and/or healthcare systems. Medical records to be obtained with the use of a "Release of Information" or ROI document include: HIV test results; HIV diagnosis (including CD4 count and viral load); HIV anti- retroviral prescriptions, initial date, adherence, and other linkage to care; PrEP prescription, initiation date, linkage, prescription fill information, Hepatitis C diagnosis and treatment, MOUD prescription history and use, STI diagnosis and treatment.
2. Criminal history and recidivism data on enrolled participants will be looked up in publicly available criminal justice databases in the necessary jurisdiction. This includes arrest, incarceration history, recidivism, reasons for arrest/incarceration, return-to-custody, total days and times to return. Criminal history and recidivism data will be combined with primary study data to determine secondary outcomes (see secondary outcomes section under "Background").

Phase 3 - RCT: Qualitative Interview

The qualitative interview is anticipated to last approximately 30 minutes and can be conducted either through a virtual platform such as Zoom or in-person. We may contact the interview participants via email or telephone to clarify or resolve any outstanding questions related to interview responses. Interviewees will be reminded that measures will be taken to safeguard their privacy, confidentiality and secure storage of recorded data. The online survey will collect personal identifiers including: name, role, length of experience. However, the data will be de-identified and demographics will only be presented in aggregate. See Appendix 28 for all Phase 3 qualitative interview materials including informed consents, demographic surveys, and interview guides.

The interview will be recorded solely for the access and use of the research team, and the interviewer will ask for consent to record prior to beginning the interview. Recordings will be stored on an encrypted and password-protected device. The interviews will be kept confidential, and the recordings will be destroyed at the end of the study.

14. Data Analysis: Describe how you will analyze your data to answer the study question.

Phase 1- Needs Assessment The purpose of the needs survey in Year 1 is to help inform the PN and MHU interventions so more specifically focus on identified needs in the community. Thus, data analysis will be descriptive and will include frequencies, percentages, and means. We will describe the data separately for each of the four communities and for different types of agencies (e.g., correctional, community treatment).

***Phase2 - Focus*Groups**

Data from the focus groups include: demographic information obtained via online survey, raw recordings of the focus groups with identifiers, and de-identified transcripts of the focus groups for analysis. The demographic data will be used to describe the sample participating

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

in the focus groups and compare the focus group samples (frequencies, primarily) to those of the Needs Assessment surveys (previously approved protocol) if necessary. The raw data (recordings) will be used to create de-identified transcriptions and will then be stored according to TCU policies and best practices for maintaining confidential datasets (i.e., stored in an access restricted, secure share owned by TCU available only to IRB approved research staff). The deidentified transcripts will then be used as part of the qualitative dataset emerging from the study. Approved research staff will analyze the deidentified transcripts using Atlas.ti following accepted qualitative data analysis procedures (e.g., creation of a code-book, inter- coder agreement procedures and standards). Data results presented will include only aggregated and/or de-identified data that will not identify any of the participants or agencies involved in the focus group. An additional "quick coding" analysis will be conducted immediately following the focus groups identifying major themes and immediately actionable observations to include in appropriate tech reports and to help inform training development efforts.

Participants who choose to withdraw from the study at any point after the initiation of data collection will immediately be removed from the study. Their data (i.e. their responses to some or all of the focus groups prompts if that individual participates in part or all of the focus group) will be retained unless the individual states that they wish for their responses to be discarded when contacting us for withdrawal. During the informed consent process, participants are informed that they may leave the Zoom call at any time. If they choose this option, they can contact study staff to request that their responses up until that point not be included in the study; otherwise, their data will be retained up until the point of their withdrawal.

Phase3 – RCT

Quantitative Data. We will examine changes across time on feasibility, acceptability, adoption, and sustainment for both interventions. The Proc Mixed random intercepts multi- level repeated measures model will be used where variations in changes are estimated and the effects of time, study arm (*PN vs MHU*), and their interaction will be tested as fixed effects. Baseline measures of each dependent measure will be used in the analyses as covariates.

We will 1) assess intra-cluster (community) correlations (all conditions); 2) summarize (descriptive stats) individual and community characteristics for each condition (numbers analyzed, the average cluster size, cluster characteristics, and important staff/client characteristics). If differences exist between conditions, the variables will be included as selected covariates in analytic models. Change over time in all primary and secondary outcome measures will be depicted graphically across conditions corresponding to the measurement time points (or 5 in the case of communities). An ITT approach will be used whereby observations are analyzed in their intended condition. Also, protocol implementation measures will be recorded, summarized, and reviewed monthly in order to

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

inform real-time adjustments (e.g., changes in protocols if adherence to the protocol is not met). At project end, difference in proportions will be calculated as a measure of effect, and large-sample 99% confidence limits calculated as a measure of precision.

Cost analyses across both Aims. Weill Cornell co-investigators plan to conduct a cost analysis that estimates costs of the PN and MHU interventions. Using established micro- costing methods to identify, measure, and value all resources for the implementation of both interventions. We will estimate costs for the PN and MHU study sites including: start - up costs (e.g., staff training, equipment purchases); variable costs (e.g., labor time for staff providing services to clients); time-dependent costs (e.g., record keeping, vehicle operating costs); and overhead costs. Costing data will be collected by using site records on numbers of services provided to clients, estimates of the time required to provide services obtained through staff interviews, and site financial records. We will adapt the Drug Abuse Treatment Cost Analysis Program (DATCAP) instrument to conduct this data collection, specifically for the interviews with staff. Costs will be calculated by applying national labor rates (to improve generalizability) to staff time estimates or obtaining direct costs of equipment from financial records. These costs will be calculated from the budgetary perspective of the study sites. Results will be reported as annual costs for each of the arms in total, by cost component (i.e., start-up, ongoing costs, overhead), and per client served. To determine additional healthcare system and societal costs from PN and MHU use, we will use self- reported data on use of medical and substance use treatment services, criminal activity, and engagement with the criminal justice system outside of the study interventions. This data will be collected from participants in the baseline and follow-up assessments and will require use of individual-level data. We will use Medicare fee-for-service payment estimates to approximate healthcare system costs incurred by providers. Differences in levels of health service utilization will be estimated to determine the impact of different interventions on costs to the healthcare system 6 and 12 months after baseline. Other societal costs will focus on criminal activity and engagement with the criminal justice system and we will apply published unit costs for these activities. All analyses will be conducted using a multivariable Generalized Linear Mixed Model (GLMM). The GLMM is an extension of the GLM that allows for the inclusion of random effects for each study site.

Separate multivariable generalized linear mixed models (GLMM) will be estimated to predict[33] the mean value for each resource and outcome, at each time period, by model (PN and MHU) and participating community. The GLMM allows one to choose the most appropriate mean and variance functions according to the fit of the data, and uses all available data for each participant, regardless of whether or not it is complete, making it an ideal statistical procedure for ITT approaches. The method of recycled predictions will be used to obtain the final predicted mean values, which will be summed and tested according to the relevant perspective. To account for sampling uncertainty in point estimates, the p-values and standard errors will be estimated using nonparametric bootstrapping

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

techniques.
Discountingfor time preference will not be required since measureswillnot be obtained beyond 12 months after the baseline interview.

15. **PotentialRisks and PrecautionstoReduceRisk**:

Phase1 – Needs Assessment

Risks for participants completing the needs assessment survey are minimal and include the risk of a potential breach of confidentiality. Participants may choose not to answer any questions they wish, including those that might make them feel uncomfortable. There are no physical risks involved in participation. It is possible that some of the survey items could cause embarrassment or emotional discomfort. In order to improve the Intervention, we will request that participants answer as honest as possible; however, if participants are uncomfortable answering specific questions, they will be instructed that they may choose to skip those questions. Moreover, should participants elect not to take part in the survey, no negative consequences will result. Furthermore, the information provided as part of the study will not be shared with other agency staff or key stakeholders and/or supervising officers.

Phase2 – Focus Groups

Risks are minimal and include potential risks to breach of confidentiality (for example, other members of the focus group might accidentally talk about what was said in the group with people who were not in the group or someone in the background of another participant's environment may see the screen during the session). No physical risks are involved in participation. If you do not want to discuss some of the topics, you are free to skip that topic and not answer any question that makes you feel uncomfortable. We ask only that you answer questions as honestly as you can. Any reports or papers that the researchers write will only include non-identifiable data. Direct quotes or paraphrasing may be used in papers or research posters as an example of certain themes or sentiments, but individuals contributing those thoughts will not be identified.

Phase3 – RCT

Risksare minimaland include:
Risks Associated with Loss of Confidentiality: As with all research, there is a risk for potential breaches of confidentiality, which could occur during the recruitment process at the custody[34] facilities or through recruitment with community partners, during study interviews, or from data management systems. The risk of a breach of confidentiality is minimal, and procedures for protecting patient confidentiality will be followed (i.e., Human Subject Certification of all research staff, all data coded with a research ID number, identifying information and research data stored in under lock and key, electronic data on a secure server without names). The research design requires that participant

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

responses can be linked across time. All participants will be assigned an arbitrary research ID that will be used to link all of their data. The respective MPIs will keep a link file linking names and research IDs on a secure server that does not contain other data. All information will be stored in password- protected, encrypted computers with double-password protection for opening specified files. Survey forms will be identified only with the research ID. Participant names will be needed to obtain provider data, but data forms will only be identified with the research ID.

Risks of Participating in Interviews: Minimal risk of emotional discomfort may exist. Participants will be informed that they can choose not to answer any question, particularly those that might make them feel uncomfortable. Since participants will be asked to provide information regarding sensitive behaviors (e.g., alcohol and drug use, sexual history, criminal history and on- going illicit activities), we have a Certificate of Confidentiality (CoC) from the NIH/HHS to allow the research team to refuse to disclose names or other identifying characteristics of research subjects in response to legal demands. As of October 1, 2017, NIH awardees no longer have to apply for a CoC because the CoC will be automatically issued to awards funded by the NIH. This provides another level of protection for the privacy of the human subjects enrolled in this study. Any reports or papers produced will include data only in aggregate form; no individual responses will be disclosed.

Risks associated with drawing blood: Physical risks are minimal and include a finger stick to obtain a blood sample. Participants may experience discomfort and/or bruising at the site of the finger stick. Infection, excess bleeding, or fainting/lightheadedness at the sight of blood are possible, although unlikely.

RisksAssociatedwith HIV/HCV Testing:

Concern about HIV test results: Participants with a new diagnosis of HIV will receive post- test counseling and assistance in arranging follow-up with a primary HIV treatment provider. Participants in Connecticut will receive confirmatory testing to be ordered by research staff via Quest diagnostics. Research staff will then link patients to a licensed medical professional to start treatment immediately. 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.

Participants who decline assessing HIV status will not be eligible to participate. MPIs Springer and Nijhawan have operated routine HIV testing in previous CJS studies and have extensive[35] experience not only complying with state laws for HIV testing, but with post- test counseling and ensuring engagement in HIV care, as indicated for those HIV positive, no one outside of authorized research staff will have access to individual responses. Reports will only include data that is aggregated so that no individual person can be

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

identified. In accordance with standard procedures used by our collaborating Universities, the confidentiality and privacy of all information will be protected by well-planned and comprehensive procedures. This means datafiles that are created and retained for the research study will remain anonymous and will be entered into computer research files for analysis with only the code numbers as identification. In addition, all research, technical, and other reports issued as a result of the research will exclude any information that could be linked to any individual or agency; rather, reports will be based on aggregate information only. Links between agency names and code numbers will be kept separate in locked cabinets and will be accessible only to authorized research staff. This is the system that has been used without incident for the past 35+ years in similar projects conducted by the research team.

Concern about HCV test results: Anyone who has a preliminary positive HCV test will receive standardized post-test counseling and undergo confirmatory testing, HCV viral load and genotype testing in the community. Participants will receive confirmatory testing to be ordered by research staff via Quest diagnostics. Research staff will then link patients to a licensed medical professional to start treatment immediately. ROI will be obtained to share the results of the testing with the provider the participant was referred to and so research staff can obtain information from the provider that is pertinent to the study. As there are now effective cures, those found to be HCV positive will be offered treatment in the community or by a licensed clinician on an MHU should they be randomized to that study arm.

Participants who test positive for HIV or Hepatitis C will also receive emotional support and post- test counseling on sexual and injection drug use risk behavior and importance of ongoing HIV primary medical care and HCV treatments. They will be assisted in scheduling an appointment with an HIV/HCV provider. There will be at least one practicing Infectious Disease physician at each site to provide any requisite oversight for testing and referrals.

After point of care/rapid testing is performed, participants with positive results will be referred and linked to a licensed medical professional for confirmatory testing. In accordance with CT and TX state laws, any new HIV and HCV confirmatory test results will be reported. The MPIs have operated routine HIV and HCV testing for study participants for decades and have extensive experience not only complying with state laws for HIV testing, but with post- test counseling and ensuring engagement in HIV care if indicated. All results will be kept confidential.

Psychiatric Risks: If someone has a potential new psychiatric diagnosis via any of the structured questionnaires, a study doctor will be notified of the assessment. The participant will be linked for evaluation and care. Participants with existing psychiatric diagnoses will continue their treatments as usual. If someone is actively suicidal (which can be determined by participant self-report, and/or the PHQ-9 assessment, each site will follow

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

theirown general protocol and provide a warmhandoff to appropriate services.

Dataand SafetyMonitoringPlan:

The Data and Safety Monitoring Plan (DSMP) will be consistent with plans and procedures we have used in our other federally funded research projects. These include installation of an 800 (toll free) number in the US for research sites to use for reporting adverse events (AEs) to the PI, Co-I, and research team. The MPIs will serve as liaisons with our university IRB and will monitor and report serious adverse events (SAEs). In conjunction with the TCU research team, the Contact PI will report SAEs to the TCU IRB per report requirements. The MPIs will assume overall responsibility for assuring the safety of study participants and will assure that the TCU IRB is informed of all safety issues.

Collection and Reporting of Serious Adverse Events (SAEs) and Adverse Events (AEs) For this study, the following standard AE definitions are used:

Adverse Event Definition: Any untoward or unfavorable sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the Human Subject's participation in the Research, whether or not considered related to the subject's participation in the Research, including any undesirable and unintended effect of research occurring in Human Subjects as a result of the collection of identifiable private information under the Research; and any problems associated with the use of an investigational device that adversely affects the rights, safety, or welfare of subjects. Medical condition/diseases present before starting the investigational drug/device/intervention will be considered AEs only if they worsen after starting study treatment/ intervention.

SeriousAdverseEvent: AnyAE that resultsin any of thefollowing outcomes:

- Resultsin death;
- Is life-threatening (places the subject at immediate risk of deathfromthe event as it occurred);
- Requiresinpatienthospitalizationorprolongationof existinghospitalization;
- Resultsin apersistent or significant disability/incapacity;
- Resultsin congenitalanomaly/birth defect; or
- Important medical events: Report when event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes.

Unexpected Adverse Event Definition: Any AE occurring in one or more human subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either: The known or foreseeable risk of AEs associated with the procedures involved in the Research that are described in (a) the protocol–related documents, such as the IRB-approved Research protocol, any applicable investigator brochure, and the current IRB-approved informed

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the AE and the subject's predisposing risk factor profile for the AE.

ExpectedAdverseEvents:

The following events are anticipated in this study population who are persons with opioid and other substance use disorders and who may have infectious diseases associated with their underlying addiction. These anticipated events will not require expedited reporting to the contact PI, Dr. Springer or the IRB. These include:

- Non-fatalaccidentaldrugpoisoning (overdose)
- Druguse and comorbid conditionsrelated to druguse (e.g., cirrhosis)
- Newlydiagnosed HIV/ HCV/ HBV /STI infections orother infectious diseases (communicable and non-communicable) such as bacterial infections (e.g., endocarditis, osteomyelitis, etc.)
- Uncontrolledsubstance use
- Mentalhealth crisisor exacerbation of existingmentalhealth conditions
- Suicidalideation or attempt
- Incarceration
  - Court-mandated or voluntary institutionalization(e.g.,treatmentprograms)The **severity of AEs** is graded according to the following scale:

Grade 1 MILD	Grade 2 MODERATE	Grade 3 SEVERE	Grade 4 POTENTIALLY LIFE-THREATENING
Symptoms causing no or minimal interference with usual social & functional activities. This includes transient laboratory test alterations.	Symptoms causing greater than minimal interference with usual social & functional activities. Experience alleviated with simple therapeutic treatments. Includes laboratory test alterations indicating injury, but without long-term risk.	Symptoms causing inability to perform usual social & functional activities. Experience requires therapeutic intervention. If hospitalization (or prolongation of hospitalization) is required for treatment, it becomes an SAE.	Symptoms causing inability to perform basic self-care functions OR Medical or operative intervention indicated to prevent permanent impairment, persistent disability, or death

The studyusesthefollowing **AE attribution scale**:

- **Not related:** The AE is clearly not related to the study procedures (i.e., another cause of the event is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event).
- **Possibly related:** An event that follows a reasonable temporal sequence from the initiation of

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

studyprocedures, but that could readily have been produced by a number of other factors.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

- **Related:** The AE is clearly related to the study procedures.

Plan for Monitoring Adverse Events

Adverse events, including instances of overdose, will be assessed by study staff at each study follow-up visit (i.e., month 1, 3, 6, and 12 visits). The events will be reviewed by the MPIs, or designees, and graded for their severity and attribution and expectedness related to the intervention. Given that the interventions in this study are delivery of care systems, the study will collect reports of all SAEs and those non-serious AEs of moderate [grade 2] and above, per FDA guidelines (see severity grading table above).

Reporting Timeline

Only those SAEs that are unexpected and related to the study protocol will be reported to the IRB in an expedited manner (within 5 business days). All other required event reporting will be done at Continuing Review. All SAEs will be reported to the site PI within 24 hours of awareness and site PI will evaluate SAE severity, relatedness and expectedness for the report. All MPIs will then review report and come to an agreement on designations. Again, SAEs that are designated as **unexpected** and **related** to the study protocol will be reported to the TCU IRB within 5 business days and the full SAE report will include the action taken with regard to continued study participation. **All other SAEs that are expected and unrelated will be reported at Continuing Review.**

All adverse effects that lead to participant removal from the protocol, will also be reported to the IRB within 10 business days. The contact PI will maintain a record of the SAEs, which can be provided to the IRB electronically. The outcome of SAEs also will be reported to NIDA in annual reports. A summary of the SAEs and AEs that occurred during the previous year will be included in the annual progress report to NIDA. AE/SAE reporting to the Justice Community Opioid Innovation Network
(JCOIN), Methodology and Advanced Analytics Resource Center (MAARC) at the University of Chicago will also occur 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. Participant data from research visits will be collected via REDCap and stored on the Yale secure server. Only selected study team members will have access to this data.

Adverse Event Reporting and Procedures

All AEs and SAEs will be reported to the site PI within 24 hours of site awareness, and the contact PI, or designee, will report the event to the TCU IRB using the TCU IRB Event Reporting Form in Cayuse within the appropriate allowable timeframe (within five business days for unexpected & related SAEs and at continuing review for all other SAEs and AEs).

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

In the event that aparticipant either withdrawsfrom the study or the investigators decide to discontinue a participant due to an SAE, the participant will be monitored by the PI via ongoing status assessment until (1) a resolution is reached (e.g., the problem requiring hospitalization hasresolved or stabilized with no further changes; (2) the SAE is determined to be clearlyunrelated to the study intervention; or (3) the SAE results in death. Outcome of SAEs will be reported as additional information becomes available. A summary of the SAEs that occurred duringtheprevious year will be included in the annualprogress report to NIDA The DSMB report, which will be submitted with the annual progress report, will include information organized into the following sections: study description, sociodemographic characteristics of the accumulated participants at baseline (pre-intervention assessment), data on the status of study participants, quality assurance issues, regulatory issues, data on AEs and SAEs, and efficacy.

16. Proceduresto Maintain Confidentiality:

Phase1 – Needs Assessment

Participation is voluntary and staff participants may choose not to participate in any research activity and/or data collection. Agency executives will not be informed if a staff member refuses to participate. Participants will not be identified by name but be assigned a unique identifier code when completing surveys. Procedures for the protection of needs assessment participation confidentiality will be followed (i.e., Human Subject Certification of all research staff, all data coded with a random study ID number, research data stored in a location under lock and key, electronic data on a secure server). The confidentiality of individual responses will be maintained by removing all identifiers connected with information during data cleaning if there are any connections present.

This means that confidentiality will be maintained in all scientific reports prepared by the research team. To minimize the risk that clients or staff could potentially be individually identified by an outside entity, data will not be released to individuals not affiliated with the project (consistent with the CFR Protection of Human Subjects and related protections and regulations). Researchers with access to data are all required to sign confidentiality statements. All data use and access will be governed by these regulations, policies, and procedures. The data from the surveys will be stored on a secure server at TCU and accessed only for research purposes by the investigator and authorized research staff. TCU computers are secured by a redundant firewall and password access (to both the network domain and email user accounts).

We will have a Certificate of Confidentiality (CoC) from the NIH/HHS to allow the research team to refuse to disclose research subject participation. As of October 1, 2017, NIH awardees no longer have to apply for a CoC because the CoC will be automatically issued to awards funded by the NIH. This provides another level of protection for the privacy of the human subjects enrolled in this study.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

TCU serves as the sIRB and Yale and UT Southwestern Medical School have agreed to follow the guidelines and procedures of the authorization agreements between our institutions. All data sharing, reporting of AEs and SAEs across sites will abide by the procedures outlined in the authorization agreements.

Phase2 – FocusGroups

The confidentiality of your answers will be maintained. All responses will be de-identified (your name and any other information that could identify you will be removed). This means no person will be identifiable in any scientific report prepared by the research team. In addition, the recordings will be transcribed, names of individuals and agencies will be removed, and data coded so that no personally identifying information will be visible.

Digital recordings will be stored at Yale, UTSW, and TCU research sites on their agency secure servers and used only for research purposes by authorized research staff. Yale and UTSW research sites will upload transcribed audio (de-identified) documents for the TCU study team via the encrypted TCU Box server where TCU authorized research staff for immediate download to TCU computers, secured by redundant firewall and password access (to both the network domain and e-mail user accounts).

Phase3 – RCT

Participants will not be identified by name but will be assigned a unique identifier code. Research staff will follow all protocols and procedures for the specific corrections institutions, county level department of corrections and state level mandates regarding the handling of data. Participant records will be obtained using formal information requests to the state and/or county department of corrections or community partner agencies. All data sharing, reporting of AEs and SAEs across sites will abide by the procedures outlined in the authorization agreements. To minimize the risk that clients or staff could potentially be individually identified by an outside entity, data will not be released to individuals not affiliated with the project (consistent with the CFR Protection of Human Subjects and related protections and regulations). Researchers with access to data are all required to sign confidentiality statements. All data use and access will be governed by these regulations, policies, and procedures.

To ensure protection of confidentiality, assessment/questionnaire data will be entered into the study REDCap database with no personal identifiers and source documents will only identify participants by study ID number. Personal identifying information (including locator information) will be kept in a separate REDCap database. In the event that study personnel have to collect personally identifiable information in a paper format due to internet outages or technology malfunction, the paper forms will be kept in a locked cabinet within a locked office. Access to computers used for data entry, data management, and analysis will be password protected and limited to study investigators. All data that includes PHI will only be stored on the secure REDCap servers at Yale University, no PHI will be stored on tablets or

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

computers. All computers/tablets used for studypurposes have been encrypted.

Access to locator data will be restricted to specific study staff. This information will be collected from each participant at baseline and updated at follow-up visits. Contact information will include the participant's name, phone number, address, email address, aliases (if used), and alternative contacts and their contact information. We will only reach out to alternative contacts if we cannot locate or communicate with the participant.

All information will be stored in password-protected tablets or computers with double password protection for opening specified files. All research data not entered into the REDCap system will be stored in double-locked research offices at each study site. Client level data will be stored with a research study number and without any unique identifiers. All identifiers that link study number to study subject will be housed in PGP encrypted, password-protected computers available only to the Project Coordinator, Data Manager, co- Principal Investigators, and Statistician. All computers used for study purposes have been encrypted.

17. Potential Benefits:

Phase1 &2 – NeedsAssessment &FocusGroups

There are no direct benefits to staff for participation in the surveys. However, from a larger perspective, participation will provide information that will help focus the PN and MHU interventions to better meet the needs of justice-involved individuals in accessing services in the community. This information may help to improve the quality-of-care justice-involved individuals receive.

Phase3 – RCT

Participants in the PN group will have the benefit of a qualified, trained Patient Navigator to help them navigate the post-release period. Participants will receive assistance to ensure that any clinical care they had been receiving will not be interrupted. The Patient Navigator will guide a patient through the continuum of care including: screening, diagnosis, treatment initiation (e.g., PrEP, ART, and MOUD), and follow-up. The Patient Navigator will assist with communication between the participant and their healthcare provider, assisting with setting up appointments for doctor visits and medical tests, and helping to secure financial, legal, and social support. Participants may also have benefits including assistance with obtaining employment, job training, and acquiring health insurance. Participants will also have begun a treatment plan with a medical provider and facilitation by a Patient Navigator that may continue after this study has ended.

Participants in the MHU group will receive free medical screenings, assessments and potentially lab work on the mobile clinics for the 6-month study duration. Participants will also have the benefit of trained and qualified community health workers to assist them in

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

navigating the post- release period by providing linkage to community services that are not available on the MHU. The CHW will be a trained, non-specialist healthcare worker to assist individuals with HIV & HCV as well as OUD & stimulant use disorder treatment prevention and linkages to community services and public assistance. The community health worker will support basic research operations on the MHU during participant encounters (e.g., may drive the MHU, collect data, assist with participant flow) and will also work to link participants to external care that is not able to be provided on the MHU (e.g., HCV evaluation, specialty care, etc.) Each site will have community health workers who will work closely with study participants who have been randomized to the MHU in coordination with the clinician and nurse.

Research staff will work with participants before the 6-month study period has culminated to identify where the participant will continue to receive medical care in the community and ensure a smooth transition once the 6-month study time period is reached.

Regardless of study arm, all participants will receive continued medical care. Persons living with HIV will be maintained or initiated on ART, persons at risk for HIV will be offered PrEP, and persons with opiate use disorder and/or stimulant use disorder will be offered appropriate treatment.

18. **Training for Protecting Human Research Participants:** See Appendix 15 for on-going submission of new study personnel Human Subjects training certificates.

19. **Check List for the Items That Need to be Submitted: Please combine all the files into one pdf document before submitting the materials electronically to the IRB. To prevent any delay in the approval of your protocol, use the most recent template for the protocol, consent document, and HIPAA form by downloading them from www.research.tcu.edu each time you prepare your materials.**

a. Protocol
b. Consent document
c. HIPAA form if applicable
d. Protecting Human Research Participants Training certificate for each investigator
e. Recruitment flyers, letters, ads, etc
f. Questionnaires or other documents utilized in screening

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

and data collection

PrincipalInvestigator Assurance

20. Bysigningbelow, I certifyto thefollowing:

- The project described herein will be conducted in accordance with applicable TCU policies and[43] procedures, as determined by the IRB of record. All Human Subject Research projects occurring at TCU must be conducted in compliance with the Office of Human Protection ("OHRP") regulations at 45 CFR 46 and all other applicable federal and state laws and regulations (collectively "Applicable Law")
- Ihaveaworkingknowledgeof ApplicableLaw
- All personnel who work with human participants under this protocol have received, or will receive, appropriate training in protocol procedures and protection of human subjects prior to working with humans.
- All experiments involving human participants will be performed only by the qualified individuals listed in this protocol and individuals not listed in this protocol will not participate in the protocol experiments.
- Procedures on experimental subjects described in this IRB protocol accurately reflect those described in the funding applications and awards, if externally supported.
- I and all personnel have read and will comply with any pertinent safety information, IRB requirements, and security procedures.
- I will maintain records of all human participants and the procedures carried out throughout the entire term of my project.
- As Principal Investigator, I am aware that I have the ultimate responsibility, on a day-to- day basis, for the proper care, treatment, and protection of the human participants.

Kevin Knight

5/11/2026

SignatureofPrincipal Investigator

Date

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

WaiverofSigned InformedConsent Request

We are requesting that participants (Criminal Justice Staff, Community MOUD, HIV/STI/HCV and Behavioral Health Providers) indicate consent or no consent to participating in the virtual focus groups and/or interviews and online surveys via check-box instead of a more traditional signature. To qualify for a waiver, a study must meet one of the criteria below. This studymeets criteria (ii for staff).

(i) That the only record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

The Needs Assessment participants are criminal justice staff, medical providers of MOUD for substance use, health care professionals that prescribe PrEP for HIV prevention, medical providers for STI and HCV services, etc. The Needs Assessment will be delivered online. This Needs Assessment is a survey format that will ask discrete questions regarding whether a particular service is provided bytheir organization and/or their criminal justice office. There will also be opportunities for open ended responses.
Demographics of the individual completing the Needs Assessment, including title, sector, etc. will be collected however those demographics are only for aggregate analysis. The principal risk for this portion of the study is breach of confidentiality. This study presents no more than minimal risk of harm to staff participants, asks participants for the type of feedback they would ordinarily provide in their professional roles during the development of a tool like ours, and collects data from adult participants that will be de- identified.

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

Bibliography

1. Wheeler DP, Fields SD, Beauchamp G, et al. Pre-exposure prophylaxis initiation and adherence among Black men who have sex with men (MSM) in three US cities: results from the HPTN 073 study. J Int AIDS Soc 2019;22:e25223.
2. Anderson PL, Liu AY, Castillo-Mancilla JR, et al. Intracellular Tenofovir- Diphosphate and EmtricitabineTriphosphate in Dried Blood Spots following Directly Observed Therapy. Antimicrob Agents Chemother 2018;62.
3. Brooks KM, Anderson PL.Pharmacologic-Based Methods of Adherence Assessment in HIV Prevention. Clin Pharmacol Ther 2018;104:1056-9.
4. Martin M, Vanichseni S, Suntharasamai P, et al. The impact of adherence to preexposure prophylaxis on the risk of HIV infection among people who inject drugs. AIDS 2015;29:819-24.
5. Daughtridge G, Hebel S, Fischl M, et al. Development and validation of a point- of-care, urine assay to measure adherence to PrEP and ART. 10th International AIDS Society Conference on HIV Science. Mexico City, Mexico: IAS; 2019.
6. Amico KR, Fisher W, Cornman D, et al. Visual analog scale of ART adherence: association with 3-day selfreport and adherence barriers. J Acquir Immune Defic Syndr Hum Retrovirol 2006;42:455-9.
7. SpringerSA,DiPaola A,Barbour R,AzarMM, Altice FL.Extended-release Naltrexone Improves Viral Suppression Among Incarcerated Persons Living with HIV and Alcohol use Disorders Transitioning to the Community: Results From a Double- Blind, Placebo-Controlled Trial. J Acquir Immune Defic Syndr 2018;79:92-100.
8. Springer SA, Di Paola A, Azar MM, et al. Extended-Release Naltrexone Improves Viral Suppression Among Incarcerated Persons Living With HIV With Opioid Use Disorders Transitioning to the Community: Results of a Double-Blind, Placebo- Controlled Randomized Trial. J Acquir Immune Defic Syndr 2018;78:43-53.
9. Springer SA. HIV Risk Behavior Tool. https://wwwdrugabusegov/research/research-data-measuresresources/data- harmonization-projects/seek-test-treat- retain/addressing-hiv-incriminal-justicesystem 2010.
10. McLellan AT, Alterman AI, Cacciola J, Metzger D, O'Brien CP. A new measure of substance abuse treatment. Initial studies of the treatment services review. J Nerv Ment Dis 1992;180:101-10.
11. Reeve BB, Hays RD, Bjorner JB, et al. Psychometric evaluation and calibration of health-related quality of life item banks: plans for the Patient-Reported Outcomes Measurement Information System (PROMIS). Med Care 2007;45:S22- 31.
12. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001;16:606-13.
13. SpitzerRL,Kroenke K,Williams JB. Validationandutility of aself-report

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

versionofPRIME-MD: thePHQ primary care study.Primary Care EvaluationofMentalDisorders.Patient Health Questionnaire. JAMA 1999;282:1737-44.
14. TaxmanF. Seek, Test,Treatand Retain for Criminal Justice Populations: Data Harmonization Measure: Criminal Justice Risk Screener and Legal Status. https://d14rmgtrwzf5acloudfrontnet/sites/default/files/sttrfiles/Criminal_Justice_Statusp df.
15. Hennessey KA, Kim AA, Griffin V, Collins NT, Weinbaum CM, Sabin K. Prevalence of infection with hepatitis B and C viruses and co-infection with HIV in three jails: a case for viral hepatitis prevention in jails in the United States. J Urban Health 2009;86:93-105.
16. Rich JD, Beckwith CG, Macmadu A, et al. Clinical care of incarcerated people with HIV, viral hepatitis, or tuberculosis. Lancet 2016;388:1103-14.
17. Zaller N, Brinkley-Rubinstein L. Incarceration, drug use, and infectious diseases: a syndemic still not addressed. Lancet Infect Dis 2018;18:1301-2.
18. Rich JD, Wakeman SE, Dickman SL. Medicine and the epidemicof incarceration in the United States. N Engl J Med 2011;364:2081-3.
19. Springer SA. Commentary on Larney (2010): a call to action-opioid substitution therapy as a conduit to routine care and primary prevention of HIV transmission among opioid-dependent prisoners. Addiction 2010;105:224-5.
20. Binswanger IA, Stern MF, Deyo RA, et al. Release from prison--a high risk of death for former inmates. N Engl J Med 2007;356:157-65.
21. Binswanger IA, Blatchford PJ, Mueller SR, Stern MF. Mortality after prison release: opioidoverdose and other causes of death, risk factors, and time trends from 1999 to 2009. Ann Intern Med 2013;159:592600.
22. Joudrey PJ, Khan MR, Wang EA, et al. A conceptual model for understanding post-release opioidrelated overdose risk. Addiction science & clinical practice 2019;14:17.
23. Wilson E, Hofmeister MG, McBee S, et al. Notes from the Field: Hepatitis A Outbreak Associated with Drug Use and Homelessness - West Virginia, 2018. MMWR Morb Mortal Wkly Rep 2019;68:330-1.
24. Martin NK, Vickerman P, Dore GJ, Hickman M. The hepatitis Cvirus epidemics in key populations (including people who inject drugs, prisoners and MSM): the use of direct-acting antivirals as treatment for prevention. Curr Opin HIV AIDS 2015;10:374-80.
25. Meyer JP, Chen NE, Springer SA. HIV Treatment in the Criminal Justice System: Critical Knowledge and Intervention Gaps. AIDS Res Treat 2011;2011:680617.
26. Spaulding AC, Seals RM, Page MJ, Brzozowski AK, Rhodes W, Hammett TM. HIV/AIDS among inmates ofand releasees from US correctional facilities, 2006: declining share of epidemicbut persistent public healthopportunity. PLoS ONE 2009;4:e7558.
27. Underhill K, Dumont D, Operario D. HIV prevention for adults with criminal justice involvement: a systematic review of HIV risk-reduction

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

interventions in incarcerationandcommunity settings. Am JPublic Health 2014;104:e27-53.

28. Knight K, Simpson DD, Hiller ML. Three-year reincarcerationoutcomes for in- prison therapeutic community treatment in Texas. The Prison Journal 1999;79:337-51.
29. Seal DW, Eldrige GD, Kacanek D, Binson D, Macgowan RJ, Project SSG. A longitudinal, qualitative analysis of the context of substance use and sexual behavioramong 18- to 29-yearoldmen after their release from prison. Soc Sci Med 2007;65:2394-406.
30. Luther JB, Reichert ES, Holloway ED, Roth AM, Aalsma MC. An exploration of community reentry needs and services for prisoners: a focus on care to limit return to high-risk behavior. AIDS Patient Care STDS 2011;25:475-81.
31. Iroh PA, Mayo H, NijhawanAE. The HIV Care Cascade Before, During, and After Incarceration: A Systematic Review and Data Synthesis. Am J Public Health 2015;105:e5-16.
32. Wohl DA, Golin CE, Knight K, et al. Randomized Controlled Trial of an Interventionto Maintain Suppressionof HIV Viremia After Prison Release: The imPACT Trial. J Acquir Immune Defic Syndr 2017;75:81-90.
33. Ammon B, Iroh P, Tiruneh Y, et al. HIV Care After Jail: Low Rates of Engagement in a Vulnerable Population. J Urban Health 2018;95:488-98.
34. Springer SA, Pesanti E, Hodges J, Macura T, Doros G, Altice FL. Effectiveness of antiretroviral therapy among HIV-infected prisoners: reincarceration and the lack of sustained benefit after release to the community. Clin Infect Dis 2004;38:1754-60.
35. Meyer JP, Cepeda J, Springer SA, Wu J, Trestman RL, Altice FL. HIV in people reincarcerated in Connecticut prisons and jails: an observational cohort study. The lancet HIV 2014;1:e77-e84.
36. Meyer JP, Cepeda J, Wu J, Trestman RL, Altice FL, Springer SA. Optimization of human immunodeficiency virus treatment during incarceration: viral suppression at the prison gate. JAMA internal medicine 2014;174:721-9.
37. Garner BR, Zulkiewicz B, Donohoe TJ, et al. Substance use disorders among individuals living with HIV who are not virally suppressed: Results from a national interactive survey. RTI International 2019.
38. Springer SA, Qiu J, Saber-Tehrani AS, Altice FL. Retention on buprenorphine is associated with high levels of maximal viral suppression among HIV-infected opioid dependent released prisoners. PLoS ONE 2012;7:e38335.
39. Centers for Disease Control (CDC). Preexposure Prophylaxis for the prevention of HIV infection in the United States-2014: a clinical Practice Guideline. In: DHHS) UDoHaHS, ed. Bethesda, MD2014.
40. Springer SA, Merluzzi AP, Del Rio C. Integrating Responses to the Opioid Use Disorder and Infectious Disease Epidemics: A Report From the National Academies of Sciences, Engineering, and Medicine. JAMA 2020.
41. Iroh PA, Mayo H, Nijhawan AE. The HIV Care Cascade Before, During, and After Incarceration: A Systematic Review and Data Synthesis. Am JPublic Health. 2015 Jul;105(7):e5-16. doi: 10.2105/AJPH.2015.302635. Epub 2015

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026

May14.Erratum in: Am JPublic Health.2018 Mar;108(3):e18.PMID: 25973818; PMCID: PMC4463395.

42. UNICEF; International Red Cross Red Crescent Movement. (2020). *Focus group discussion guide for communities.* New York.
43. SobellMB.SobellLC.Anexcellent springboard. Addiction2000;95:1712-5.
44. Sobell L, Sobell M. Timeline followback: a technique for assessing self- reported ethanol consumption. In: JA , RZ L, eds. Measuring Alcohol Consumption: Psychosocial and Biological Methods. Totowa, NJ: Humana Press; 1992:41-72.
45. McMillan DE, Gilmore-Thomas K. Stability of opioid craving over time as measured by visual analogscales. *Drug Alcohol Depend*. 1996;40(3):235–239.
46. Wickersham JA, Azar MM, Cannon CM, Altice FL, Springer SA. Validation of a Brief Measure of Opioid Dependence. *Journal of Correctional Health Care*. 2015;21(1):12-26. doi:10.1177/1078345814557513
47. InstituteofBehavioralResearch.(2020).TexasChristianUniversityDrugScreen 5.FortWorth: TexasChristianUniversity, Institute ofBehavioral Research.
48. Llewellyn-Bennett, Bowman, & Bulbulia, 2016. Post-trial follow-up methodology in large randomized controlled trials: a systematic review protocol. Systematic Reviews, v.5, published online.DOI:10.1186/ s13643-016-0393-3

TCU
1920-275
Approved on 5-12-2026
Expires on 8-7-2026