Prevention Support For People Leaving Jail

Intervention Study Protocol

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Introduction

The purpose of this study is to inform an intervention designed to reach a high-risk population at a critical point for increased risk of HIV infection – men who have sex with men (MSM) and transgender women (TG women) who have substance use disorders and are leaving jail. It will test a new intervention (called Mobile Enhanced Prevention Support or MEPS) that involves a GPS-based mobile app (called GeoPassport), incentives, and peer support for promoting the use of HIV prevention and related services by comparing it to the case management services that these individuals can routinely have access to following jail release. We hypothesize that the intervention will increase rates of service utilization and use of pre-exposure prophylaxis (PrEP) for HIV prevention over the standard-of-care case management.

Background

In the United States, men who have sex with men (MSM) and transgender women are disproportionately impacted by HIV. Those with criminal justice involvement have particularly high HIV burdens. HIV prevalence estimates in jail populations are four times those of the general US population, and MSM and transgender populations experience elevated rates of incarceration. A majority of people in jail have substance use disorders (SUDs). The period following community reentry from incarceration is critical for addressing potential risks of HIV/STI acquisition and negative sequelae of substance use. This study leverages recent Medi-Cal investments in treating populations with SUDs who are leaving incarceration by building on a new jail-based treatment program in the Los Angeles County jail.

Periods of incarceration disrupt stable social and sexual relationships.[21, 22] Given the barriers and complex interactions that formerly incarcerated people must negotiate upon release, the experience of transitioning from the correctional setting to the community is marked by *shocks* to social and sexual networks. The network shocks experienced at the time of detention and release have important health implications for BMSM with CJI and even those connected more distally. For example among young men re-entering the community after detention, an estimated 50% report inconsistent social networks (interactions with different individuals pre- and post-incarceration).[23] These may contribute to diminished social support and increased risk taking behaviors.

Characteristics of the subject population

In the United States, men who have sex with men (MSM) continue to be disproportionately impacted by HIV. Between 2008 and 2010, MSM accounted for more than half of all new annual infections, while only representing approximately 2% of the US population (CDC 2012). HIV prevalences in jail populations are estimated to be four times those of the general US population even after adjustment for

gender, age, and sex 1. Most of the excess risk observed in jail and prison populations appears to be associated with risk behaviors that these individuals engage in while in the general community rather than during periods of incarceration 2,3. Both men who have sex with men and transgender women experience elevated rates of incarceration and of HIV infection. The period immediately following release from jail or prison has been associated with risky sexual, drug using behaviors and is implicated in elevated rates of mortality in populations of people with criminal justice involvement (CJI). Hence, interventions that can successfully intervene during the critical reentry period in order to connect people with CJI to ongoing services systems are critical for reducing risk for HIV and other STIs.

This study will focus on the MSM and transgender K6G unit of the Men's Central Jail. This unit houses individuals who self-identify as homosexual, bisexual, and male-to-female transgender. It is a voluntary unit in which people are housed for their own protection. Initial screening for entry occurs at jail intake. The unit was established based on a documented pattern of abuse of gay- and transgender-identified people by other inmates in the LA County jails. It is a protected custody unit, with limited access to other inmates. Individuals must pass additional screening regarding their sexual orientation to be housed in the unit.[1] Substance abuse affects an estimated 28-35% of the LGBT population (vs. 10-12% of the general population),[2-5] yet only 7% of 854 U.S. treatment programs surveyed provide SUD (Substance Use Disorder) treatment specific to LGBT groups.[3] The L.A. CADA START Project was specifically tailored for this MSM and TG women.

The K6G unit houses approximately 350 people at any given time in three large dormitories. Based on research by Harawa et al,[6] approximately 30% of the unit is HIV positive. Transgender women comprise approximately 10% of the unit at any given time. SUDs are extremely common and estimated by LASD to affect over 80% of the population (Personal communication, Cox 2015, LASD). During its initial weeks of screening men in the K6G unit for Project START, the L.A. CADA team identified SUDs in over 90% using the Texas Christian University screening instrument. Several studies have been conducted in the K6G unit because the limited but very high-risk population exhibits a high-need for intervention and the LASD has been receptive to research in this setting. Voluntary testing in the unit,[7] found high prevalences of HIV (13.4%), chlamydia (3.1%), gonorrhea (1.7%), and syphilis (1.6%). However, the 13.4% HIV positive does not include those who declined HIV testing because of a prior HIV diagnosis. Cost-effectiveness analyses have indicated that routine screening for gonorrhea and chlamydia in the unit would lead to cost savings. [8] This also supports the idea that ongoing screening post release would be cost effective.

Overview and aims of the randomized controlled trial:

We will enroll 266 people in jail and conduct a trial comparing a control group that receives customized prevention referrals and substance abuse-focused case management to the intervention group that receives customized referrals in addition to the GeoPassport App, incentives, and the support of a trained Peer Mentor for six months. The GeoPassport App will provide participants with tools for tracking goals and progress toward meeting them, assistance in locating services, appointment and medication reminders, opportunities to provide feedback on service providers, and built-in tracking and distribution of rewards (incentives) for service utilization. GeoPassport will assist Peer Mentors in monitoring participants' service utilization. The Peer Mentors will provide encouragement, role modelling, accompaniment to appointments, and assistance with goal setting, problem solving, and reducing logistical and psychosocial barriers to service engagement. Participants in both groups will be followed to assess whether those offered the GeoPassport intervention are more likely to meet the specific prevention targets described in the Specific Aims.

The RCT's specific aims are to:

Determine the effectiveness of the intervention compared with the standard-of-care in achieving the following:

1) PrEP-related outcomes following jail release (PrEP continuum of care):

a) establish a primary care provider, who can prescribe PrEP,

b) obtain screening for PrEP,

c) begin PrEP,

d) adhere to PrEP, and

e) remain on PrEP for at least 3 months.

2) Infection and prevention screening tests in the community:

a) HIV every 3 months,

b) bacterial STIs every 6 months; and

c) HCV at least once.

3) Obtaining and remaining engaged in treatment for substance use disorders (SUDs) in the community, according to each participant's recommended American Society of Addiction Medicine level of care.

Participant-related Study Methods

Overview

A total of 266 HIV-negative or HIV status unknown men who have sex with men (MSM) and transgender women (TGW) will be enrolled in this randomized controlled trial prior to being released from Men's Central Jail. Participants will be recruited from a unit of the jail that is designated as protective custody for self-identified gay and bisexual men and for transgender women. Participants will be randomized into either the standard-of-care condition or the intervention condition that involves an innovative new GPS-based mobile app and incentives for utilization of prevention-related services, in addition to the support of a Peer Mentor (app+incentives+PM). Each condition will include up to 150 participants. The standard-of-care condition will consist of the substance-abuse focused transitional case management and referral services provided by the LA Center for Alcohol and Drug Abuse's **S**ubstance **T**reatment **A**nd **R**e-entry **T**ransition program (Project START Program)

1. Recruitment and screening

Study eligibility will be based on the following criteria:

i. *Inclusion* 1) housed in K6G unit, 2) ages 18-44 years, 3) screens positive for SUDs via Project START, 4) reports condomless sexual intercourse with a male or male-to-female transgender woman in the six months prior to jail entry, 5) is likely to be remain custody for at least four more days, but less than 45 days based on scheduled court dates, current sentence, etc., 6) has not received an HIV diagnosis (based on self-report), and 7) plans to reside in Los Angeles County following jail release.

ii. *Exclusion* 1) has a planned release directly to one of Project START's housing program, 2) is not able to speak and understand English, and 3) is able to use mobile applications. The numbers of non-English speaking people in this jail unit is small, and we lack the capacity to develop both English and Spanish versions of the App at this stage of our research.

These eligibility criteria will allow us to have sufficient time to complete the enrollment and Passport (i.e., prevention/treatment plan) processes prior to participants' release, ensure that our population has some risk for both HIV infection and negative SUD sequelae, limit the length of time between the baseline survey and jail release. Project START clients who transition directly into LA CADA's residential program are offered services that also involve peer navigations; hence, they will be excluded from this study.

Certain eligibility information is routinely collected from all inmates at Men's Central Jail during the inmate classification process including self-identification as homosexual and transgender. Most of these individuals are placed in a protective custody unit called K6G. Offered within the K6G unit is a jail-based case management and referral services program provided by the LA Center for Alcohol and Drug Abuse called Project START or **S**ubstance **T**reatment **A**nd **R**e-entry **T**ransition program. Potential participants will be enrolled from the Project START program described below. Study staff will make arrangements to meet with the potential participant in a classroom area, an office, or another similar semi-private location in the jail. Each participant will be called in individually and, where required, jail staff or a transitional case manager will escort the participant from their dormitory to this space. Once inside the interview setting, the jail staff will maintain some visual and very limited audio contact. They must maintain some audio contact in case of emergency; however, these personnel will not be able to hear the survey questions or respondents' answers. LASD custody staff will only be told that it is a study to identify the best ways to keep people healthy following release.

The interviewer will introduce themselves and the study using the script in the **In-Person Consent Screen.** If the individual gives consent to learn more after the brief introduction, they will finish the study description and continue with the screening questions, if the individual remains interested. These questions are listed on page two of the **In-Person Consent Screen.** Eligible individuals will be assigned a sequential, unique, non-identifying subject ID#, then go through the consent and enrollment process. The ID#s are assigned at this point because individuals are randomized prior to the recruitment.

2. Consent and enrollment

Written informed consent (**see ICFs**) will be obtained by a trained research staff person who has completed all required Human Subject Protection training via CITI. After reviewing the informed consent form for the group to which the study participant was previously assigned (**See Section 6. Randomization**) and providing potential participants with the purpose of the study, the study's goals, potential risks, and safeguards for confidentiality, participants will be given the opportunity to ask questions and have them answered. Moreover, the interviewer will ask the participant questions to confirm their understanding by asking them to explain in their own words what the study entails, along with the study's goals, main procedures, and risks and benefits (see **Evaluation to Sign a Consent Form for Research**). Only if those able to respond satisfactorily will be asked to sign the informed consent form. Only those still interested in participation will complete this process, others may indicate this at anytime and return to their dormitories.

Other documents to be completed between interviewer and the participant will be to sign a **Release of Information Form** so that the study team can access their START assessments, as well as a detailed **Contact Information Form.**

3. Contact Information and Release of Information Forms

A locator form (See **Contact Information Form)** will be used to determine where and how we should attempt to reach participants post release in order to contact them for follow-up surveys and Peer Mentor meetings. In addition, participants will be encouraged to contact the study's phone number or e-mail following their release from custody. Release dates will be solicited during the interview and tracked on publicly available inmate locator websites in order to establish target dates for the follow-up interviews. so the study team may reach them for follow-up once they are released from jail. On the **Contact Information Form**, participants will be asked to designate whether or not messages may be left and how they want study team members to refer to the study when leaving messages with their indicated contacts.

Participants will also complete a **Release of Information Form**, authorizing release of information from Project START for any substance use disorder assessments conducted with the participation and information on utilization of their services, including case management services following release.

4. Assessments

The baseline surveys will occur in the Men's Central Jail in Los Angeles and will be conducted by a trained research assistant. Participants will complete a 75-minute survey in a classroom, office, or other similar semi-private location. The survey covers the following topics: 1) demographics, 2) criminal justice history and status, 3) HIV/STI knowledge, risk perception, 4) medical mistrust, 5) substance use, 6) self-efficacy and readiness/motivation, 7) service utilization and needs, 8) sexual risk behaviors, and 9) health conditions. Some questions are asked during both interviews, others during only the baseline or specific follow-up interviews.

In addition, we will collect basic information on participants' current and prior arrests (e.g., reason, date, location, length of jail stay) from the publically available LASD inmate locators (https://app4.lasd.org/iic/ajis_search.cfm) and link this information with the survey data. By matching survey participants with these data, we will augment the surveys with accurate record-based information on participants' criminal justice involvement.

The data will be collected via Audio Computer Assisted Self-Interview (ACASI), where the survey is read to the participant via headphones and responses are recorded directly into the laptop. However if security issues occur that restrict the use of laptops, a pen-and-paper version of the survey will be used and for later entry into the database. The laptop will not contain a webcam and Wi-Fi will be disconnected/ disabled. The A-CASI method of collection and setting allows sufficient security and privacy to protect participants and the confidentiality of their information. The first follow-up interviews are intended for completion in the community. However, they will be conducted in jail if a participant is reincarcerated at that time. These surveys will last about 60 minutes. They will be conducted by a trained research assistant in a study office or a mutually agreeable and private field site.

5. Development of wellness plan (i.e., Passport)

Initial Passport Development will occur at the end of the interview process using pen-and-paper templates developed for this purpose. To aid this process, the Passport Developers will use a Summary Report generated within the survey software, based on participants' responses to the baseline assessment. This report will summarize potential sexual behavior and substance use risk factors, gaps in knowledge regarding HIV and STIs, history of PrEP use, prior testing for HIV, STIs and HCV, lack of access to primary or mental health care, lack of social support, religious conflict, and unmet needs in a range of areas (e.g., cash and nutrition benefits, housing) that the participant experienced prior to incarceration.

Using the Summary Report from the baseline assessment, the Passport Developer (either a trained full-time member of the study team or a trained substance abuse counselor from Project START) work with participants in the jail to determine which of the identified concerns he or she finds most problematic and is most motivated to address post release from jail. Goals related to PrEP uptake will vary based on participant's "stage of change" in this area and may range from accessing PrEP information from pre-identified, online sites to reestablishing an existing PrEP prescription on release. Activities related to SUDs will depend on the recommended American Society of Addiction Medicine (ASAM) level of care based on results of the screener for substance use disorders (SUDS) as defined by the DSM V.

The 15-25 minute Passport development process will involve a discussion of priorities and risks. It will result in a list of at least three specific goals and 8-12 activities that will facilitate reaching those goals, as well as the utilization of at least two of the health services that are part of the study outcomes. The process will also include education to ensure that the participant is aware of the importance of

HIV/HCV/STI testing and treatment, information regarding PrEP, and information to address any reported misconceptions about HIV and STDs.

For example, a participant's goals may be to: 1) reduce his binge drinking, 2) avoid HIV infection, and 3) take care of his dental issues. Through the needs assessment and Passport development, it becomes clear that his binge drinking relates to social isolation and discomfort with his sexuality, and that he has not considered PrEP because he assumes that he cannot afford it. Furthermore, he lacks a primary care provider but is not interested in having one because of medical distrust. The Passport for this client might include: 1) attending an educational event to learn more about PrEP and hear how other MSM overcome their medical distrust concerns to obtain this intervention; 2) accessing screening for HIV every 3 months and bacterial STIs every 6 months through a storefront testing site; 3) meeting with a substance abuse treatment counselor several times to develop and implement a plan to address his binge drinking; 4) attending at least four different events at organizations such as In The Meantime Men's Group, AIDS Project Los Angeles, or the Los Angeles LGBT Center; and 5) applying for MediCal so that he can obtain dental care. The listed community based organizations offer discussion groups, game nights, plays, exercise classes, and other social events in a welcoming low-key environment with other MSM. Engagement in these non-stigmatizing communities may help some MSM to create social connections and to witness other men like themselves who have embraced their own sexuality. Those not willing to attend a gay-identified venue will be encouraged to participate in other social activities including, for example, those offered through 12-step program events, the Community Coalition, Chuco's Youth Justice Center, the Watt's Labor Coalition and Community Center, and the Underground Museum.

Within 3-4 days of the baseline interview, the study team will provide a printed copy of each individual's Passport, augmented with detailed information on the referral agencies and resources discussed during the Passport planning meeting.

6. Randomization

Random assignment to the intervention (MEPS) or control conditions will be assigned by recruitment week or month, with all individuals recruited in that time period given the same random assignment. Participants will be given a consent form describing the study arm to which they were assigned and told that their outcomes will be compared to participants receiving a different intervention. The Data Manager will develop a computer-generated list of assignments and provide a new one to the Project Manager at the start of each randomization period. No study team members, other than the Data Manager, will know of this assignment prior to this. This double consent approach has been used by McCusker et al. (1997) to examine the impact of residential substance abuse treatment length on both substance use and HIV risk

behaviors. This approach is selected to minimize dissension and conflict among potential study participants and within the jail dormitories, between those assigned to the study arm that receives incentives and those assigned to the standard-of-care arm.

7. Case-management (Standard-of-Care) intervention arm

Los Angeles Centers for Alcohol and Drug Abuse (L.A. CADA) Jail Health Services program, called Project **S**ubstance **T**reatment **A**nd **R**e-entry **T**ransition or Project START is one of only four jail-based SUD treatment programs in L.A. County. The program is supervised and funded by the L.A. County Substance Abuse Prevention and Control (SAPC) Division of the Department of Public Health (DPH). The program goal is to address substance use disorders (SUDs) that correlate with high rates of recidivism in order to reduce the public burden due to repeat drug offenses and drug-related-crime. Project START is part of L.A. CADA's extensive criminal justice services division that includes residential treatment and outpatient treatment delivered in close collaboration with the justice system. START provides gay and transgender County jail inmates in the segregated K6G unit of Men's Central Jail a program with comprehensive clinical assessments and services conducted by a certified substance abuse counselor. Both in-patient and transitional services are offered. Transitional services involve assessments and case management.

Intensive Case Management (ICM) is provided in Project START to link gay and transgender clients to post-release and aftercare services and to local providers. These providers are also intended to address social determinates of health and help facilitate participants' substance abuse treatment plans. ICM is a highly individualized strategy designed to overcome personal barriers to recovery and care coordination (including barriers related to sexual identity/gender, language, culture, trauma, and social determinants of heath). The intensity or dosage of case management is tailored to individual needs. START case managers link clients to gender identity-specific, age-appropriate, culturally relevant, and criminogenic-informed community resources at release, as per individual need. To encourage participation in HIV/STI/HCV services, START case managers will be given copies of the Passports developed for their clients who are also study participants. Project START clients are offered access to L.A. CADA's broad continuum-of-care, with locations in two of the County's high-risk service planning areas (East and Metro) for outpatient treatment, family counseling, HIV services, and domestic violence services (perpetrator and victim). They also receive referral coordination support to other community providers to ensure that they have access to a full range of needed services.

8. Mobile Enhanced Prevention Support (MEPS) Intervention Arm

The MEPS intervention is designed to support, motivate, and facilitate engagement in preventive health care activities in the period of community reentry following jail. It involves three components: support from a selected Peer Mentor or PM, incentives, and a newly developed mobile application. It is a client-driven approach, in which, participants are encouraged to address the priorities and immediate needs that they identify through the Passport Development process, especially social determinants of health that may discourage or undermine preventive health measures.

a. Peer Mentor & Client Interaction:

Participants *assigned to the intervention arm* will view pictures and short introductions to each of the available PMs, and then select the PM with whom he or sheet anticipates the greatest level of comfort and support. They may also select a back-up Peer Mentor, if circumstances make a given Peer Mentor unavailable. Next, the selected Peer Mentor will receive a copy of the Participant's passport and his or her contact information from the Project Director or RA and discuss with them the participants' major issues and strengths. Then he will arrange to meet the participant following their release from custody.

Peer Mentors will meet with their participants approximately every one to two weeks, for the first 8 weeks to provide support and guidance and to work with them to address barriers in accessing services listed in their Passport. They will also accompany them to key appointments, assist them in addressing other issues, and encourage productive communication with providers. Furthermore, the PMs will engage participants in ongoing evaluation of progress toward their goals and in considering new goals and Passport modifications. PMs will be trained to utilize Motivational Interviewing techniques to help participants resolve ambivalence that might undermine adherence to their services plan (i.e., Passport). After the first 2 months, participants will be expected to check-in with their PMs and meet in-person with their PMs less frequently. See **Intervention Schedule and Sessions**.

During the final 2 months, the Peer Mentors will begin working with the participants to strategize for a successful transition from peer mentorship and incentives. This will include identifying other external motivators as well as internal motivators for engaging in prevention-related services and behaviors and, if appropriate, encouraging participants to actively identify and engage members of their social network as supports in ongoing maintenance of their health-related goals. Ensuring this smooth transition will be a key focus of the last month of engagement and emphasized at the final in-person meeting. All participants completing the final session and at least 9 of their scheduled sessions will receive printed certificates of completion.

b. Incentives

Over the course of the study, intervention participants may receive up to $500 total in gift card incentives for completing Passport activities. Most of these activities will take place over six months and are each valued at just $5-15. These include medically related visits (HIV/STI/HCV screening, PrEP evaluation), substance abuse treatment appointments, in-person meetings with their study Peer Mentor or START program Case Manager, and non-medically related items on their Passports (e.g., support group meetings for gay and bisexual men or TG women or trainings at an employment service center). A full schedule of activities and the amount of accompanying incentives is provided below:

Passport Activity	**Maximum**	**Amount**
Link to a PCP who will prescribe PrEP	1	$ 15
PrEP screening/evaluation	1	$ 15
Begin PrEP	1	$ 15
HCV test	1	$ 15
STI tests	2	$ 15
HIV tests	4	$ 15
Substance abuse treatment services (including AA/NA meetings) or case managers	8-14	$ 10
Meetings with PMs	14	$ 5-15
Other	6-10	$ 15

The Passport's incentive structure is designed to provide more compensation for those study components that are directly related to HIV/STD biomedical intervention or prevention, however, the largest portion is for SUD services that are likely to be recommended to occur much more frequently. Frequency for HIV (every 3 months)/STI (every 6 months)/HCV (at least once) screening is based on CDC recommendations for MSM at increased risk for HIV. For the SUD-related services, participants will only be compensated for the number of visits recommended per their American Society of Addiction Medicine (ASAM) level of care. In addition, the incentives are intended to encourage initial linkage visits to other needed services and then capped in order to avoid a situation in which participants repeatedly complete incentivized activities after they are no longer beneficial. Once participants take part in a particular service, resolve barriers to service access with a Peer Mentor, and identify providers they like, it is hoped that they will continue to engage with those services as, needed, regardless of the opportunity for an incentive.

c) Mobile Application

Intervention participants will receive a new mobile App developed for this purpose, called 'GeoPassport'. The App will create a mobile Passport that incorporates personalized client goals with other features that facilitate and motivate accessing needed services. These features include reminders, access details for service providers, and positive automated feedback when services are utilized and goals attained. The App will require clients to provide feedback on services accessed in order to obtain the associated incentives, the incentives will be provided in the form of mobile gift cards that may be redeemed via downloadable bar codes or physical gift cards. The feedback will involve close-ended responses to 4 short questions (see **Service Evaluation Survey**) and the opportunity to enter narrative feedback. Geolocation will validate service utilization and ping participants to complete the feedback surveys when they attend providers or agencies.

GeoPassport will allow PMs to view these data so that they can tailor the subsequent guidance and support that they offer participants. PMs will receive push notifications and be able to follow-up with participants in real time. GeoPassport also will upload detailed information to a HIPAA-compliant central data repository that will store all App-based survey and geolocation data, as well as other information on participants' service utilization activities (e.g., dates, times, type, and frequency). Geolocation is based on matches to a comprehensive database of Los Angeles area service providers developed for the study. No other geographic data or other information will be collected by the application or from participants' cellular phones.

This application will be implemented on smartphones (Apple and Android) and non-smartphones alike, thus creating three different platforms on which it can operate. All smartphones-based App versions will be GPS-enabled while the non-smartphones-based version will be able to collect participants' coordinates from the nearest mobile tower locations.

9. Post-Custody Follow-up Interviews

Three, six and 12 months following the date at which a participant was released from jail, participants will be asked to participate in post-custody follow-up interviews to examine changes in behaviors and rates of service utilization. These interviews will take place in a private office space at the Charles R. Drew University or LA CADA. Participants will be located for these interviews through the locator information they provide during custody. No attempts will be made to conduct follow-up with those who are not released from jail but transferred to prison. Except for the setting, the interview procedures will be consistent with those described in-custody. Those who are released and then reincarcerated at the

scheduled times for their follow-up interviews will be interviewed in custody in the same settings and using the same procedures as described for the In-Custody Baseline Interviews. Their reincarceration will be identified through the Internet-based publically available inmate locator for LASD.

10. Compensation for study-related activities

A small stipend will be placed on the participants' inmate commissary accounts ($25), in compensation for their completion of the baseline survey and any follow-up surveys completed in custody due to reincarceration. The compensation amount is based on three considerations: the amount of time involved in the surveys, the minimal costs related to getting to the survey location, and the greater potential for financial inducement in custody than in the community. Participants interviewed outside of custody will receive $50 cash compensation for each follow-up survey, to account for the increased transportation and opportunity costs associated with participation outside of custody. As indicated below, additional compensation will be provided throughout the study period for maintaining contact with the study team. Bus tokens will also be provided to those who need them for the monetary transportation costs associated with these interviews. To cover the costs of transfers to and from the interview site, the cost associated with four fares, currently valued at $7, in total, will be allotted for each interview.

Interview	**Amount**
Baseline interviews	$ 25
3 month	$ 50
6 month	$ 50
12 month	$ 50
Total	$ $160

11. Retention

Participants in both study arms will be given $10 per month toward their cellular phone service for initiating contact with the study on release and providing up-to-date contact information each month. After completing the in-custody survey, we will provide participants an information card with the study phone number and email address for this purpose. This contact can be in the form of text, calls, email, or during their meetings with their Peer Mentors, for the control arm. Regardless of study arm, participants requesting referrals for services will be provided this information during these contacts.

If a Participant does not have access to a cell phone, the RA or Peer will arrange with him or her to obtain one of the free Obamaphones. The Obamaphone program is still in existence and has ongoing funding that is paid for by small fees assessed on all phone bills. Most individuals who receive other government assistance (e.g., SSI, Medi-Cal, GAIN, or CalWORKS) are eligible for an Obamaphone (www.obamaphone.com). Those not receiving government assistance are eligible, provided their income is below specific thresholds. The CA Obamaphone plans provide unlimited talk and text, along with very limited data at no cost (500 MB/month). Additional data can be purchased for anywhere from $10 to $33 per month (https://www.safelinkca.com/TracFoneWeb/en/index2.html?PromoCode=WACA0081#/). The $10/month for those who maintain ongoing contact with the study would generally pay for an additional 1.5 GB of data per month.

We are establishing a process for obtaining real-time information on the release of study participants from the LASD. A list of study participants who are allocated to the intervention and who consent to sharing the fact of their study participation will be provided to jail administrative personnel. These personnel will notify the study manager when a participant is planned for release within the next 48 hours. The Study Manager will then notify the participant's designated Peer Mentor and arrange for this Peer to meet the participant in the area individuals are routinely released. This approach was successfully implemented in a prior research study involving peer navigation with individuals once housed in Men's Central Jail. However, for a range of reasons, study team members did not always received this advance notification. In addition, the web-based Los Angeles Sheriff Departments' (LASD) Inmate Locator: https://app4.lasd.org/iic/ajis_search.cfm will be used to track participants' release dates.

Once a participant is released, we will initiate attempts to contact them using information on the **Locator Form,** if they do not reach out to the study team. We will attempt to maintain contact with participants in the control arm ever 2-4 weeks, to ensure that their contact information has not changed. If we lose contact with an individual via their personal and family/friend's contact information, we will attempt to locate them through any parole or probation officer or social service providers they have listed and given use permission to contact on the **Locator Form.** We will also send a follow-up letter using a **Follow-up Letter (to be added)**. Contacts will only be made with entities or individuals for whom we have been given permission. The manner in which participants are contacted will also follow the preferences indicated by participants on the locator form. Finally, field-based efforts will be made to locate individuals who we struggle to contact, these will focus on hangout venues listed on the Locator Form, but may include the residences of participants whose phone numbers have been disconnected.

12. Human Subjects Research Training

All Investigators, study personnel, Peer Mentors, and START team members who are directly involved with participants will have passed the certification courses required by UCLA and Charles R. Drew University of Medicine and Science (CDU) before they will be allowed to be involved in the study. To facilitate thorough understanding of this material, Peer Mentors and full-time study personnel will review key aspects of the CITI trainings as a group during their training but must complete and pass the assessments on their own.

13. Maintaining Confidentiality of Study Data

a. Databases

Study and participant-related information will be maintained in secure databases accessible only to key members of the PI, Data Manager, and the L.A. CADA study team:

The personally identifying information on study participants will be separately maintained using one of two approaches REDCap (Research Electronic Data Capture) or an MS Access database maintained in the Mednet version of UCLA Box, which is HIPAA compliant. REDCap is a secure, web-based electronic data capture system that uses a MySQL database for data storage and facilitates dissemination and analysis of research study surveys as well as secure management of data from clinical trials and other clinical and basic science studies. REDCap provides: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources. CDU's REDCap servers are hosted by the RCMI Translational Network (RTRN) Data and Technology Coordinating Center (DTCC) in Jackson, Mississippi. Vanderbilt University, with collaboration from a consortium of institutional partners, developed REDCap specifically around HIPAA-Security guidelines. REDCap can be used to easily build and manage online surveys and databases and all web-based information transmission is encrypted. REDCap currently supports over 400 consortium partners worldwide with over 50,000 research end-users (www.project-redcap.org). CDU's implementation of REDCap can be found at https://redcap.cdrewu.edu.

Only authorized field staff and the Project Director will have access to participant's identifying information, because they will need it to carryout retention activities, provide incentives, and to conduct follow ups and Peer Mentorship. Peers will use REDCap to input notes regarding all contacts, attempted, and meetings with their participants. With the exception of the information generated in the summary

report used to develop the Passport at baseline, only the PI, Project Director, and Data Manager will have access to the participants' survey data. These data will be collected/entered using Questionnaire Design Software and maintained in secure password-protected databases. These will be maintained on a server at CDU or in UCLA Mednet's Box service. Survey data will not contain any personally identifying information and will be labeled with a unique study identification number.

- Encrypted data and communication: All of the laptop computers (at all work sites) are provisioned with an automatic full disk encryption system to protect against loss of sensitive data should any of these machines be lost or stolen.
- Access control/authentication: Access to any data files will be password projected. Passwords will meet stringent requirements for length and complexity and changed on a regular basis.
- Virus protection: All computers in the project will employ the centrally managed anti-malware software and distribution of the latest security patches services from one of the participating Universities.
- Storage of master keys: The keys that link the study ID# and name of the subject for the coded data sets are kept in separate, password-protected files. These will be located on a secure server with limited access.
- Storage of deidentified data: Prior to any potential future sharing of survey datasets created from this study; all data will be given a labeled with new ID#s and the link will be stored in a separate file from the study database. The link between the new label and previous label will not be shared outside of the research team.

b. Paperwork:

All forms, such as Informed Consents and locator forms will be securely stored in a locked file cabinet to which only the Investigator and authorized staff will have access. PMs will have short forms, with check-off lists and space for brief notes that provide guidance for each session with their participants. These forms will include only the session date and Study ID#. These Informed Consents and Locator Forms will not include participants' Subject ID #s. Staff will be trained in maintaining the security of study-related paperwork.

c. Dissemination:

The data will be analyzed and presented through scientific manuscripts, and national and international conferences. Only aggregate data will be presented in data dissemination. On completion of the study, including all analyses, the data will be destroyed.

14. Data security related to the GeoPassport App

GeoPassport will be subject to layers of protection to ensure that the App is signed and verified, and sandboxed to protect user data. These elements will provide a stable, secure platform for GeoPassport without affecting system integrity. They will allow users to access GeoPassport on their smartphones devices without undue fear of viruses, malware, or unauthorized attacks. GeoPassport will require participants to input a PIN. Peer Mentors and study team members will be required to input a username and password. They will be instructed in how to create strong passwords for this purpose and encouraged to use a password or other security for the mobile devices that carry the app. Mobile devices assigned to study team members will be encrypted, in compliance with UCLA DGSOM policies. Additional security measures for the app on smartphones are listed below

a. App code signing

GeoPassport app must also be validated and signed, using either an iOS or Android-issued certificate, depending on the platform. Mandatory code signing extends the concept of chain of trust from the OS to apps, and prevents GeoPassport app from loading unsigned code resources or using self-modifying code.

b. Runtime process security

GeoPassport app will be sandboxed, so any other app is restricted from accessing the data files of this app. This will prevent other apps from gathering or modifying information stored by GeoPassport. GeoPassport will have a unique home directory for its files, which will be randomly assigned when the app is installed on the smartphone device. In this way, no other third-party app can access privacy data belonging to GeoPassport.

c. Data protection in GeoPassport

GeoPassport app will implement data protection on smartphones using latest development tools. Local data storage will also be encrypted using keys derived from the user's identity keys, plus a random nonce (an arbitrary number that may only be used once). Additionally, data synchronization between devices and smartphones' respective data-hosting providers will be handled as an opaque blob. The most recent blob will be stored in Smartphone to enable synchronization, but will not be used for any other purposes. Because it will be encrypted using keys that are available only on the users' smartphone devices, its contents will be inaccessible during transmission and remote storage. All communication from the app to the remote central data registry will be encrypted using Station-to-Station protocol and per-session keys.

d. Security of data transmission

All sensitive information from GeoPassport will be encrypted during transmission over any network or communication link. Only data related to Passport goals, associated steps, dollars accrued, and appointments will be stored with the participants' app. After all other data has been entered and submitted, it will not be displayed in plain text anywhere in the application. Since GeoPassport uses passwords and other sensitive data, this information will not be stored in the device and not echoed when entered into the application. Security also includes secure code development and code signing to help protect applications from being compromised by other apps or the code from being unknowingly manipulated.

15. Confidentiality

Information obtained in connection with this study will remain confidential to the extent allowed by law. A code number will be assigned and used to identify participants' study data. A master table linking individuals' study identification (ID) numbers to their personal information will also be maintained in REDCap and accessible only to key members of the investigative team. If outside review occurs, the records will identify only the ID number and not the participant. If the results of this study are presented in a professional meeting or journal, information will be presented so that no individual identifiers will be revealed.

Participants will be encouraged to share as much as they feel comfortable disclosing to their Peer Mentors. Peer Mentors will receive extensive training on maintaining confidentiality and proper professional boundaries while conducting work with participants.

It is possible that the study participants will disclose potentially illegal activities such as the use of illicit substances. This study will apply for an NIH *Certificate of Confidentiality* (COC). The team will use the appropriate wording of the consent for both the COC and the human subjects' requirements. Under law, the privilege of confidentiality, however, does not extend to information about the sexual or physical abuse of a child and/or dependent adult. It is our desire to help report these incidents and/or to work with supportive agencies such as Child or Adult Protective Services. The obligation to report includes alleged or reasonably suspected abuse, as well as known abuse. The PIs and the research team will make every effort to ensure the safety of participants and others throughout implementation. Furthermore, if a participant indicates a desire or plan to harm himself, we will take appropriate steps in order to protect the individual, including contacting the Clinical Supervisor (Dr. Charles Hilliard) or one of the trained counselors with the L.A. CADA Project START team. If none of these individuals is available, the team member will remain with the participant and contact the Suicide Hotline. In the community, Peer

Mentors will also be equipped with emergency referrals to provide where necessary and possible, for resources such as emergency food, housing, domestic violence, and medical/psychiatric care.

If a serious, emergent risk of harm to a participant or other person is revealed during a participant interaction outside of jail, these steps may involve contacting an emergency response team. If a serious, emergent risk of harm to a participant or other person is revealed in the jail, the START team or study staff will inform the jail-based medical services personnel. Participants will be informed of these exceptions to confidentiality.

16. Potential risks to study participants

Interviewed participants will be subject to minimal risk through their participation, with the greatest risk resulting from potential disclosure of sensitive information that is shared with the study. As indicated above, extensive efforts are planned to minimize this risk. In addition, it is possible that the surveys or Peer Mentor interactions will cause some psychological discomfort, given the sensitive or private information. We will try to limit this by assuring privacy and confidentiality, using well-trained interviewers and Peer Mentors, clarifying the type of questions that will be asked prior to conducing the surveys, and using sufficiently private interview locations. Participants can opt not to answer specific questions.

a. Protection against risks

Participants will be made aware prior to the start of baseline survey that the assessments will include questions on sensitive issues such as sexual risk behaviors, substance use/abuse, and a mental health issues. Participants will be informed about these types of survey questions at the screening and again during the initial the informed consent process. Intervention participants who are diagnosed with a sexually transmitted infection or other health condition during the encouraged screenings will receive support from their Peer Mentors in obtaining the follow-up care and treatment that they need. Participants in the control arm can access the study team for referrals to free services or obtain these from LA CADA.

Interviewed participants will be informed about their rights as research subjects. They may withdraw at any time during the study without penalty or loss. Furthermore, interviewed participants will be told that unless required by law, only the study investigators, members of the project staff, representatives of UCLA Institutional Review Board, National Institutes of Health, and U.S. Office of Human Research Protections will have the authority to review study records. In such cases, they too will be required to

maintain confidentiality. The data collected will only be accessible to the research team and the Institutional Review Boards. It will be identified via non-identifying subject codes (e.g., sequential identifiers for each site), with the key to other study IDs and names kept in a separate password protected file. Only the local study team members who conduct the follow up interviews will have the information linking individual subjects to these codes. Any paper version of such information collected from the jail will be kept in locked cabinets within locked rooms at the Charles R. Drew University.

We will obtain a Federal Certificate of Confidentiality and maintain the certificate will throughout the life of the research project. We will inform study participants of the above procedures and the limits of confidentiality during the consent process, prior to data collection. Specifically, we will inform participants that criminal behavior (i.e., illicit substance use) is not reported to authorities and that the security of this information is protected by the Federal Certificate of Confidentiality; but we will clarify that information like child abuse and threats of homicide or suicide or in-custody sexual assault (per PREA) will be reported to authorities. Our study survey does not directly assess for suicidal thoughts. However, if these are expressed to study staff during an in-custody interview, the interviewer will report this to jail mental health services who will follow-up with the participant. If this were to occur during an interview outside of jail, the interviewer would assist the respondent in calling the suicide hotline and provide referrals for mental health services.

b. Avoiding potential coercion

Eliminating the possibility of coercion by not awarding stipends would make it impossible to conduct many studies, and would shortchange subjects who provide time and energy to the study, and who may incur costs such as gasoline or carfares. The resolution to this problem is to ensure that stipends are not inappropriately large and to probe potential subjects to ensure they have not been coerced. We believe we meet these conditions with a modest stipend of $25 in custody and $50 post custody and a deliberate consent process that clarifies the potential risks and benefits associated with participation. For those interviewed in custody, this stipend will be placed in the participants' commissary accounts. The account monies can be used to purchase commissary items while in custody or they can be refunded to the participant upon release. For interviews that take place outside of custody, the stipend will be paid in cash.

c. Disclosure of abuse, homicide, or suicide risk

A number of procedures will be taken to minimize risk to the participants. The consent procedures will explicitly state that participation in the research is voluntary, and that interviews will include questions

regarding sexual behavior, substance use, mental health, and health conditions. Participants will be informed of the confidentiality of their responses as well as the limits of that confidentiality. They will be informed that sharing any information about the study with others can potentially affect relationships and cause emotional distress to others and self – particularly if this disclosure occurs in custody. Participants will be informed that disclosure of homicide or suicide risk will require notification of the health unit within the jail or, if the participant is outside of jail, referral to appropriate authorities or health care facility for an evaluation by trained mental health experts to determine the best course of action. They will also be informed that conditions of immediate danger or harm may require reporting or notifying appropriate authorities (i.e. the police or the Department of Children and Family Services/DCFS). Participants will be informed that disclosure of violence or victimization relating to someone under the age of 18 or to an elderly adult will require reporting to authorities (i.e., the police or the Department of Children and Family Services/DCFS). Though participants will not be asked about experiences of assault or abuse while incarcerated, we will inform participants that we are required to inform the jail authorities if they do report such incidents. This requirement stems from the Prison Rape Elimination Act.

A determination of the decision-making capacity of the participants will be done prior to obtaining consent and will pay particular attention to participants' understanding of the risks associated with disclosure of information and the implications of that disclosure in accordance with state law. To aid this process, we will use the CDU "**Evaluation to Sign a Consent Form for Research**" with each participant. This asks the interviewer to confirm that the participant is alert and communicative and then has the interviewer as 4 questions to examine his or her comprehension of the study process. Interviewers will briefly note the answers to each, provide additional teaching as noted and only continue with the interview if the participant is able to communicate acceptable answers to these four questions.

d. Discomfort or distress during the research

We do not anticipate discomfort or distress during the research study visits; however, we will make every effort to create a secure and trustworthy environment prior to conducting the interview. In addition, the potential benefit of this research outweighs the risks. Participants will be told that they do not have to answer any question they do not wish, and that this in no way will affect the level of health care they are receiving or will receive in the future. Participants experiencing mild distress during the interview will be offered a small break or to reschedule the interview tot a later date, if they desire. Participants with more serious distress will be provided the option to withdraw and provided referrals for mental health services. Participants always maintain the option to withdraw at any time, without penalty.

17. Potential Benefits of Participation

The potential benefits to the participants are substantial. Participants in all study arms have the potential to likely gain information and services that can help address their needs and aid in making healthier and more informed choices. Specifically, it will encourage become aware of their HIV and HCV status and to decrease their risk for HIV, STIs, HCV, and negative sequelae of these infections or substance use. It may also help to reduce stigma, isolation, and increase comfort levels with disclosing HIV status and same sex activity.

18. Potential Societal Impact

In addition, there are several potential benefits of this research to society including the gained knowledge of the health needs for this unique and highly vulnerable population. Importantly, it may be used in the future to help researchers and health care providers improve on existing peer navigation/mentor, linkage to care, and transitional case management interventions, through the use of mobile applications and incentives. The benefit of addressing HIV in a population that carries a disproportionate morbidity and mortality burden is substantial at both the individual and society level, and outweighs the risks.

Using both app-based mobile health technology and Peer Navigation modalities in concert will facilitate real-time interaction between consumers and service settings and between patients and peer Mentors. This will result in reductions in both undiagnosed HIV/STI/HCV and new HIV/STI/HCV infections in reentry populations and lowering their risk of morbidity and mortality as well as transmission risk to the communities and partners to whom they return following release from jails or prisons. This reduced burden of disease will lead to significant cost reductions for public health and correctional health care systems.

19. Required Additional Findings Related to Prisoner Research

Per the OHRP: **"**Prisoners are considered vulnerable because they are in a restrictive, institutional environment that provides little opportunity for making choices, earning money, communicating with outsiders, or obtaining medical care. Because their autonomy is limited, prisoners may only participate in certain categories of research, and special precautions are necessary to assure that their consent to participate is informed and voluntary." The proposed research involves minimal risk and falls under *2i of §46.306 Permitted research involving prisoners in Title 45, part 46 Protection of Human Subjects Research* -- "Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects." As indicated above, this study fits the criteria of minimal risk, none of the study-related

procedures involves more than minor inconveniences, and it is directly related to both the effects of incarceration and illicit drug use (a criminal behavior). Below, we address each of the 6 required additional findings:

1. *Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of receiving such advantages in the limited-choice prison environment is impaired:*

   Completion of the survey will have no effect on the participants' living conditions, services received or other opportunities while in custody. This will be indicated in the consent form and during the consent process. Participants will be compensated for their time in completing the interview during custody. The amount of this compensation will be $25 that will be placed on the inmates' accounts. Monies in these accounts can be used for the purchase of commissary items or refunded on release. Based on our prior experiences with research in the jails and on feedback from, Mr. Garrett Cox, former Epidemiologist, LA County Sheriff's Department, $25 is sufficient but not large enough for potential participants to be coerced into enrolling because they are unable to weigh this benefit against the potential risks of the research.

2. *The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;*

   The risks associated with completing the interview are consistent with those of non-prisoners who take part in related research. The potential risks/discomfort most likely to be associated with this study would include psychological discomfort. Several of the survey questions ask about sensitive topics such as sexual- and drug-risk behaviors, including some in-custody behaviors, and HIV status (See **Prevention Support Study Survey**). Based on prior survey/interview research with similar populations, it is *not* anticipated that the type of discomfort experienced would be severe or permanent. Participants will be aware that they do not have to answer any questions they do not want to answer and that they may stop participating in the survey or interview at any time, without any consequences. If necessary, referrals for psychological/counseling services, both within and following custody will be provided.

Another potential social, legal and informational risk is to the participants' reputation within custody, if stigmatized attitudes or behaviors or information on third parties is reported; or disciplinary action, if a breach of confidentiality occurs and evidence of a violation of jail policies is provided. Nevertheless, the data collection and storage procedures (i.e., state-of-the-art methods where all survey data storage is paperless, encrypted data storage and transfer, interviews in semi-private spaces, and the use of coded surveys) and the Certificate of Confidentiality and are designed to prevent this from happening. We will also use interviewers who are familiar with the setting and the population and train them extensively on maintaining confidentiality. Furthermore, we will work with the administrators at each jail facility to ensure inmate privacy related to the research and that they will not attempt to obtain the information collected for disciplinary or other purposes. One precaution related to this is that the jail line staff who may be involved in generating passes or escorting participants for interviews will only be informed that they are doing so for the interviewers from a particular university, not the purpose of the interviews or of the study itself. Hence, we will consistently work to ensure that the study purpose and its target population are not made know to line staff or other inmates.

3. *Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal;*

   All consenting, eligible individuals will be eligible for participation. Although, there will be instances where certain participants are not reachable, the selection process will be consistent and fair (i.e., all consenting participants will be searched periodically on the inmate locators and if found in custody during time scheduled for a follow-up interview, attempts will be made to reach them there for the survey). Nevertheless, some incarcerations may not be captured because they are very short, some people in custody may be unavailable a time of interviews, and a few may inaccessible due to LASD security measures.

4. *The information is presented in language that is understandable to the subject population;*

   The consent forms will be written at below 8th grade level and approved by the designated institutional review boards. After allowing the participant to read the consent or to have it read to

them (per their preference) the trained staff who are obtaining participants' written consent will review key information from each section of the consent. Next, they will assess all potential participants' understanding of the material by asking them questions about what the study involves and ensuring that the individuals can provided acceptable responses prior to enrolling them (See CDU **Evaluation to Sign a Consent Form for Research**). Participants who lack the capacity to understand the material or provide full informed consent will not be enrolled.

5. *Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and*

   As these are jail, rather than prison facilities, many inmates are not involved with parole boards. Study participation does not have any legal ramifications, as eligibility is not based on participation in an illegal activity. Inmates may, however, report illegal activities during the surveys, and we anticipate that most will be engaged with substance use. Hence, no collected or entered data will be linked directly to personally identifying information on individuals, steps will be taken to maintain the security of these data, and study participation and study responses will not be shared with members of the criminal justice system (including parole, probation, and custody staff members). Finally, administrators at each jail facility will agree not to attempt to obtain the information collected for disciplinary or other purposes. The consent form will clearly indicate that study participation or refusal will have no effect on the participants' charges, likelihood of conviction, sentence, or conditions of parole or probation.

6. *Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact (45 CFR 46.305(a)).*

   This study does not involve any medical treatment. Study participants will have ongoing access to services offered through LA CADA and can always access the study team to request referrals to other needed social or medical resources.

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