



**COURT SERVICES AND OFFENDER SUPERVISION AGENCY/
PRETRIAL SERVICES AGENCY FOR THE DISTRICT OF COLUMBIA
RESEARCH REVIEW COMMITTEE**

**RECOMMENDATION STATEMENT
FOR AGENCY RESEARCH**

DATE: March 30, 2011

I. RESEARCH PROPOSAL SUMMARY

Principal Researcher: Faye S. Taxman, PhD, George Mason University (GMU); Frederick L. Altice, MD, Yale University; and William B. Lawson, MD, Howard University.

Title: Seek/Test/Treat: HIV, Buprenorphine, and Criminal Justice (Project STRIDE)

Institution: GMU Center for Correctional Excellence, in conjunction with Yale University and Howard University with funding from NIH/NIDA.

Description: The purpose of this study is to conduct a placebo-controlled, randomized trial of Buprenorphine (BPN) among HIV+ for community-supervised defendants or offenders meeting DSM-IV criteria for opioid dependence. Subjects will be randomized 2:1 to BPN or placebo. The hypotheses for the project are BPN, compared to placebo, will result in:

1. Improved HIV treatment outcomes, including higher proportion initiating ART and VL<400, increased CD4 counts and retention in HIV care.
2. Improved opioid treatment outcomes, including longer time to opioid relapse and higher proportion of opioid negative urine tests.
3. Reduced drug- and sex-related HIV risk behavior.
4. Longer time to rearrest and reincarceration, lower proportion incarcerated and decreased criminal justice involvement than those receiving placebo.

The duration of the study is from January 2011 to December 2015.

CSOSA/PSA RESEARCH REVIEW COMMITTEE
REVIEW RECOMMENDATION STATEMENT

This request applies to PSA and CSOSA.

Type of Data and Analysis: The researchers propose a randomized design with a sample size of 152; with sample collection taking place from June 2011 to July-2014. A detailed description is provided in the proposal.

In implementing the research design, the researchers are requesting to:

1. Post flyers, use posters and tear-offs, and provide material in the CSOSA/PSA offices for volunteers to contact the research office for possible inclusion in the study.
2. Access to waiting rooms of CSOSA/PSA offices, including drug testing sites, where GMU/Yale/Howard research assistants could approach potential participants. This would not involve CSOSA/PSA staff providing any names; instead research staff would recruit volunteer study participants at the multiple pretrial and community corrections settings, including PSA, probation offices, and RSC and/or the residential treatment programs. The research assistants could hand out flyers or host information sessions in the waiting rooms.
3. Provide flyers and materials to CSOSA/PSA staff, which then could make them readily available to opioid users, without suggesting in any way that participation has implications for their status within the criminal justice system. The flyers would provide only basic information about the study and would not serve in any way as an explanation for the study. Instead, the information would be basic and then allow the individual person to contact the research office and make an appointment. CSOSA/PSA staff would be providing only information about the services offered at Howard University and the potential inclusion in a study.
4. Have CSOSA/PSA staff refer all opioid users to Howard University's clinic as a service provider. The PSA/CSOSA staff member could give a package to the person that has information about the service.
5. Offer information sessions at residential treatment programs that PSA/CSOSA uses for defendants/offenders under their supervision.

**CSOSA/PSA RESEARCH REVIEW COMMITTEE
REVIEW RECOMMENDATION STATEMENT**

II. RECOMMENDATION

The RRC recommendation for this study:

☐ Support ☐ Support with conditions ☒ **Do Not Support**

The RRC considers the proposed study to be non-Agency research involving human subjects as defined in Research and Evaluation Policy Statement 1201.

The RRC does not support this proposal for the reasons listed below:

Risk to CSOSA/PSA Population

In their proposal, the researchers recognize several risks associated with the proposed study, including risks inherent to the use of BPN¹, breach of confidentiality, and discomfort to participants associated with phlebotomy². CSOSA/PSA consider the risks posed by BPN to pose too much of a danger to the offender/defendant population supervised by CSOSA/PSA, for the Agency to be affiliated with it.

Appearance of Impropriety

It seems unlikely that vicarious liability will be found by allowing researchers access to CSOSA/PSA facilities, however the simple act of allowing researchers to place advertising material within CSOSA/PSA facilities and recruit test subjects from inside these facilities lends the appearance that the Agency condones their activity, if not outright endorses it. CSOSA/PSA cannot allow this perception and it is not possible to implement this process without such a perception being created. There is no precedent for this and under other circumstances, organizations would not be able to post advertising literature and recruit volunteers without CSOSA/PSA permission, lest security is notified.

Appearance That Taking Drug Is Required

Though participation in the study is voluntary and not a condition of supervised release, there is risk that it could be perceived as such by the offender/defendant depending on how it is presented by the researcher. Moreover, allowing recruiting materials related to the study to appear in

¹ Hepatotoxicity (chemically-induced liver damage), potential adverse fetal effects, drowsiness, nausea, vomiting, headaches.

² Drawing blood for testing or transfusion.

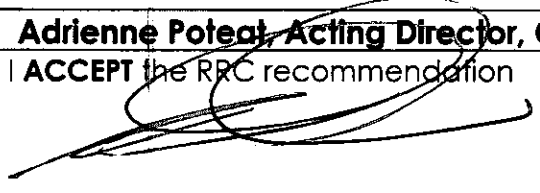
**CSOSA/PSA RESEARCH REVIEW COMMITTEE
REVIEW RECOMMENDATION STATEMENT**

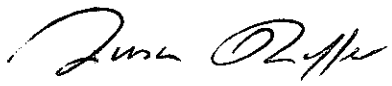
CSOSA/PSA facilities might lend an appearance of authenticity or legitimacy and convey the impression that CSOSA/PSA condone and are taking part in the study. More troubling would be if an offender/defendant – knowing that participation is voluntary – nevertheless somehow feels coerced into taking part in this study because he/she feels the terms of his/her supervised release is conditioned upon participation, or that CSOSA/PSA somehow would favor those individuals who choose to take part.

Other Considerations

CSOSA/PSA recognize that there is benefit to undertaking this study to advance knowledge about the comparative use of BPN, which potentially could improve treatment outcomes as well as provide more effective services at a lower cost. However, as proposed, there is very little – if anything – about the study that directly is consistent with CSOSA/PSA's mission.

Moreover, should an offender under CSOSA/PSA supervision fall ill during or shortly after participation in this study, it could expose CSOSA/PSA to civil liability and negative publicity. Furthermore, the very thought that CSOSA/PSA is in the practice of making the offenders/defendants it supervises available for medical research is problematic.

Adrienne Poter, Acting Director, Court Services and Offender Supervision Agency	
I ACCEPT the RRC recommendation 	I DO NOT ACCEPT the RRC recommendation
Comments:	

Susan W. Shaffer, Director, Pretrial Services Agency for the District of Columbia	
I ACCEPT the RRC recommendation 	I DO NOT ACCEPT the RRC recommendation
Comments: I have some regrets in not being able to support this study, but the appearance issues are troubling for a supervision agency where voluntary activities sometimes are not in fact seen as such by those supervised.	



Center for Advancing Correctional Excellence!
10519 Braddock Road, Ste 1904
Fairfax, VA 22030
703 993 8555 (phone)
website: <http://gemini.gmu.edu/ebct>

January 28, 2011

To: RRC Committee of CSOSA/PSA

**From: Faye S Taxman, George Mason University (ftaxman@gmu.edu)
Frederick L Altice, Yale University
William B Lawson, Howard University**

Subject: Research Protocol

Attached is a study protocol for Seek/Test/Treat: HIV, Buprenorphine, and Criminal Justice (Project STRIDE). We made revisions based on our discussion of December 6, 2010. In this memo, we address the two questions that PSA raised: 1) the use of National Institute on Drug Abuse grant dollars to provide services to offenders/defendants; and 2) the recruitment procedures for the study. We found several precedents for a federal agency to participate in studies that offer services, particularly to assess the efficacy of a service to improve offender/defendant outcomes.

Issue #1: Use of Grant Dollars to Provide Services

The STRIDE study provides access to and provision of HIV testing and substance abuse treatment services to over 250 offenders/defendants as part of a randomized controlled clinical trial. Of concern by PSA was that referring offenders/defendants to services supported by these grant funds could be interpreted as an attempt by CSOSA/PSA to augment its congressional allotment for treatment; providing study funded services would potentially increase the number of defendants/offenders that are available to access care. CSOSA/PSA raised this issue since participation in the study might increase the number of people that can access services, thus exceeding the allocated dollars for services by Congress.

First, it is the mission of both the National Institutes on Health and the Health Resources Services Agency to actively engage HIV-infected persons in care as part of its national strategy. This mission is mandated by the federal government not only for its research mission, but more importantly, for its goal for providing HIV treatment and prevention services for all persons with HIV infection as part of its Seek, Test and Treat strategy.

Second, a review of other federal agencies found that, when a study is consistent with the needs and mission of an agency, other federal agencies allow researchers to conduct a study with their clientele and/or in their facilities. This occurs even if the study provides services that exceed the current

allocation of funding for the federal agency. The federal Administrative Office of the Courts obtains federal funding for substance abuse treatment; some federal probation offices participate in research that expands services that the agency is funded to provide. Dr. Taxman has one such study funded by the National Institute on Drug Abuse (U01 DA16213) where federal probation officers are using contingency management and the grant is providing funds for the incentives used by the federal agency. Another example is the Bureau of Prisons—they have several studies that bring services to offenders that are under the control of that agency. Two studies that come to mind are a National Institute on Drug Abuse (NIDA) study as part of CJ-DATS that involves the use of buprenorphine. Another study involves augmenting care in residential reentry facilities for those offenders with mental health disorders (funded by the Jacob & Valeria Langeloth Foundation to the DC University Legal Services Group, which Dr. Taxman is evaluating). Last, Dr. Altice is involved in a multisite study funded as part of the Health Resources Service Agency's Special Projects of National Significance (SPNS) to facilitate continuity of care from jails to the community setting, including the DC jail. The DC jail has funds for services but the SPNS project expands the number and type of services provided based on the SPNS funding. The DC Jail is also participating in the Seek, Test, and Treat study by testing a computerized prevention program. Each of these agencies receives federal funds to provide treatment services as part of their normal business practices; the grant funds are viewed as allowing the agency to test new services that could improve the outcomes (either primary or secondary goals) of the agency.

As part of this submission, we provide contact information about grants that involve the Federal Bureau of Prisons and the DC jail:

Federal Bureau of Prisons

Newton E. Kendig at BOP (Medical Director)

Desk: (202) 307-3055

nkendig@bop.gov

Jody Klein-Saffron.

Human Subjects Protection Officer

Federal Bureau of Prisons

Office of Research and Evaluation

desk: 202-305-4110

jksaffran@bop.gov

DC Jail

Henry R. Lesansky, Ph.D., CCM

Health Services Administrator

D.C. Department of Corrections

1923 Vermont Ave, NW - Suite 121N

Washington, DC 20001

Desk: 202.671.2069

Fax : 202.673.2311

Henry.Lesansky@dc.gov

Also, according to budget documents submitted to Congress by CSOSA, the agency currently receives treatment funding for not quite one-third of the offenders that need substance abuse treatment services. This grant would therefore not supplant existing funding since this would expand services to offenders

with high-risk behaviors that are likely to be involved in drug use and risky behaviors that contribute to the transmission of HIV/AIDS. Similar to efforts to refer defendants/offenders to services, the study would be a referral source with its own funding. And, currently we understand that CSOSA/PSA are not currently funded to provide services offered by this grant such as medically assisted treatments for defendants/offenders with substance use disorders and for those with infected with HIV.

Issue #2 Use of federal facilities to recruit study subjects

A related concern raised by PSA was that the use of CSOSA/PSA space or personnel to advertise, recruit, and refer for free services could run afoul of regulations. The services to be provided under this grant are not being funded from a private source; instead they are funded from public (federal) grant funds that are open to anyone who meets eligibility. All of the services provided through this grant are funded from the National Institute on Drug Abuse.

In consultation with the Bureau of Prisons, they confirmed that their federal facilities are used to recruit and refer offenders into studies. This is also true for the DC Jail, the Veteran's Administration and Armed Forces, where studies are frequently conducted and clientele referred to studies. Again, each of these agencies receives federal funds to provide treatment services as part of their normal business practices.

The proposed techniques that we would like use are:

1. We would like to post flyers, use posters and tear-offs, and provide material in the PSA/CSOSA offices for volunteers to contact the research office for possible inclusion in the study.
2. We would like access to waiting rooms of CSOSA/PSA offices, including drug test sites, where GMU/Yale/Howard research assistants could approach potential participants. This would not involve CSOSA/PSA staff providing any names; instead research staff would recruit volunteers at the multiple pretrial and community correctional settings, including PTS (Pre-Trial Services), probation offices, and RSC (Re entry and Sanction Center) and/or the residential treatment programs. The research assistants could hand out flyers or host information sessions in the waiting room.
3. We would like to provide flyers and materials to PSA/CSOSA staff hand, who could then make them readily available to opioid users, without making participating in any way contingent on their status within the criminal justice system. The flyers would only provide basic information about the study and would not serve in any way as an explanation for the study. Instead, the information would be basic and then allow the individual person to contact the research office and make an appointment. PSA/CSOSA staff would only be providing information about the services offered at Howard University and the potential inclusion in a study.
4. We would like to have PSA/CSOSA staff refer to Howard University's clinic for all opioid users, as a service provider. The PSA/CSOSA staff member could give a package to the person that has information about the service.
5. We would like to offer information sessions at residential treatment programs that PSA/CSOSA uses for defendants/offenders under their supervision.

In the above referenced study in five federal probation agencies conducted by Dr. Taxman, the probation officers recruit offenders into the study by using an informed consent procedure that we trained the

officers in. The officers are involved in dispensing contingencies that are funded by the grant. The contact person at the Administrative Office of the Courts who developed an agreement with our agency:

Administration Office of the Courts

Scott VanBenschoten
Probation and Pretrial Services Administrator
Administrative Office of the U.S. Courts
Office of Probation and Pretrial Services
Desk: 202-502-1629
Cell: 202-327-1417

Scott_Vanbenschoten@ao.uscourts.gov

John Fitzgerald, Legal Counsel
Administrative Office of the U.S. Courts
Desk: 202-502-1625
John_Fitzgerald@ao.uscourts.gov

We believe that the information gleaned from this study will greatly improve the lives of defendants and supervisees as well as the citizens of DC. We appreciate your consideration of this request to work with this team on this study. We have found no statutory language that prevents a federal agency from participating in a federal study or from using federal facilities for that purpose. In fact, in many studies the research staff are provided space for the study in the federal facility. Instead we have found several precedents that other federal agencies responsible for direct service do, in fact, work with researchers on studies that are designed to assess the efficacy of a service or intervention to improve the outcomes of those involved in the justice system. Particularly with HIV/AIDS and substance abuse treatment research, federal agencies participate in studies that can have an impact on learning about new treatments or practices that are designed to improve outcomes.

As noted in our protocol there are numerous benefits for CSOSA/PSA. The advantages are:

1. Effectiveness of BPN (buprenorphine) for opioid dependent defendants/offenders
2. The comparative effectiveness of BPN with standard treatment protocols
3. The potential use of medical management for substance use disorders
4. The impact of BPN and standard substance use disorders care on criminal justice trajectories including arrests, time in jail/incarceration, outcomes from pretrial services/probation
5. The likelihood of reducing the transmission of HIV/AIDS among pretrial defendants /offenders by providing BPN and/or HIV care
6. Assisting offenders to obtain Medicaid which will increase access to health care services and not create require agency funding for the medications; and
7. The impact of criminal justice system processes on health care outcomes (including substance use disorders)

Thank you for consideration of this request. We look forward to your feedback. Please direct all questions to Dr. Faye Taxman, ftaxman@gmu.edu, 703 995 8555 (or 571 205 8282).

Seek/Test/Treat: HIV, Buprenorphine, and Criminal Justice (Project STRIDE)

Name(s) and current affiliation(s) of the researcher(s);

Frederick L. Altice, MD, Yale University
Faye S Taxman, Ph.D., George Mason University
William Lawson, MD, Howard University

Title of the study: Seek/Test/Treat: HIV, Buprenorphine, and Criminal Justice (Project STRIDE)

Purpose of the project;

- 1) To conduct a placebo-controlled, randomized trial of BPN among HIV+ for community supervised defendants or offenders (Pre-Trial Services, probation, or Re-entry and Sanction Center) meeting DSM-IV criteria for opioid dependence. Subjects will be randomized 2:1 to BPN or placebo. Data to assessed are: HIV (VL<400, CD4, retention, adherence, HIV risk behaviors), drug treatment (time to relapse, urine toxicology testing and retention) and CJS (incarceration, criminal days, involvement in other CJ activities) outcomes; and,
- 2)) To mathematically model the impact of BPN and other strategies (e.g. behavioral and adherence interventions) or co-morbidities (e.g. alcohol, drug use, mental illness, homelessness) among HIV+ persons in pretrial and community correctional settings as part of the Seek, Test, Treat, Retain (STTR) strategy.

Hypothesis for the project are BPN, compared to placebo, will result in:

1. Improved HIV treatment outcomes, including higher proportion initiating ART and VL<400, increased CD4 counts and retention in HIV care.
2. Improved opioid treatment outcomes, including longer time to opioid relapse and higher proportion of opioid negative urine tests.
3. Reduced drug- and sex-related HIV risk behavior.
4. Longer time to rearrest and reincarceration, lower proportion incarcerated and decreased criminal justice involvement than those receiving placebo.

Location of the project; Washington DC

Duration of the study; January 2011-December 2015

Research methods to be employed; Randomized Design

Sample type and size required and time frame for sample collection; Sample Size=152; sample collection from June 2011-July-2014

Agency staff and/or resources needed to support the study and description of the support needs;

Participate in design and selection of instruments, identify research questions to answer, provide administrative data, provide access to offender records on a routine basis

Indication of risk or discomfort to subjects as a result of participation;

As in all research studies, there are potential risks. We go to great efforts, however, to ensure that risks are minimized. There are additional risks with this study, particularly since it initially involves research with individuals involved within the criminal justice system and there are special protections set forth by

the Department of Health and Human Services (HHS). Specifically, the HHS requirements outlined in 45 CFR 46, Subpart C provides additional protections to prisoners involved as subjects in HHS-conducted or supported research.

Risks Associated with Buprenorphine: As with any pharmacotherapeutic intervention, there are a number of risks that must be considered. The risks associated with this trial, are reduced, however, because we are using an FDA-approved medication (Buprenorphine, BPN) for the treatment of opioid dependence. In this study, subjects randomized to BPN will be inducted using a standard escalation protocol for 5 to 7 days and maintained on a clinically appropriate dose thereafter. Many recent reports in the last several years, however, have documented that BPN poses significantly lower risk of hepatotoxicity than previously suspected but we intend to monitor these subjects regularly. The risks due to BPN are well-described and included in the package insert. The most common side effects with BPN, occurring in >2% of subjects and not associated with discontinuation of study medication, include drowsiness, insomnia, nausea, vomiting, and headache. Because BPN is a Class C medication during pregnancy, potentially causing adverse fetal effects (not been fully studied), women of child-bearing potential (WOCBP) will be counseled about and required to utilize appropriate birth control throughout the study to be included in the study.

Risks Associated with Loss of Confidentiality: As with all research, there is a risk that involves potential breaches of confidentiality. We intend to do everything possible to reduce this risk and this is one of the process measures we propose to measure. All study medication will be dispensed at Howard University that minimizes breaches in confidentiality that might occur should a subject be observed taking additional. All data will have identifiers; the list of study subjects will be maintained in a separate data base that cannot be linked to study instruments. We will further increase the protection of these subjects by obtaining a Federal Certificate of Confidentiality, particularly since they have been involved in the criminal justice system.

Risks Associated with Phlebotomy: As part of routine care, patients will undergo phlebotomy. Patients may experience discomfort or bleeding at the site.

Anticipated results.

The results are the following: 1) determination whether BPN improves the overall outcomes of defendants or offenders in the justice system; 2) determination whether BPN reduces the risky sexual and drug using behaviors; 3) determination whether BPN improve justice outcomes with fewer arrests, fewer failure to appear for trial (pretrial defendants) and few incarcerations; and 4) determination whether BPN used by Pretrial Services Agency and/or CSOSA is effective at improving treatment outcomes such as longer days drug free, improved retention in substance abuse counseling, and fewer days involved in drug market activities.

List of deliverables.

Study findings on the impact of BPN on outcomes; findings will be reported after half the sample has been involved in the trial (n=76) and after all of the findings have been reported.

Preliminary findings will be reported to PSA and CSOSA on an annual basis including:

1. Criminal Justice outcomes (i.e. number of arrests, number of convictions, days crime free, number of incarcerations) for the treatment and control group
2. Treatment outcomes (i.e. number of days in treatment, number completed treatment, number maintained BPN for one year)

The study team will make presentations to PSA/CSOSA or related agencies at the request of PSA/CSOSA.

Study Protocol

Review of the related literature

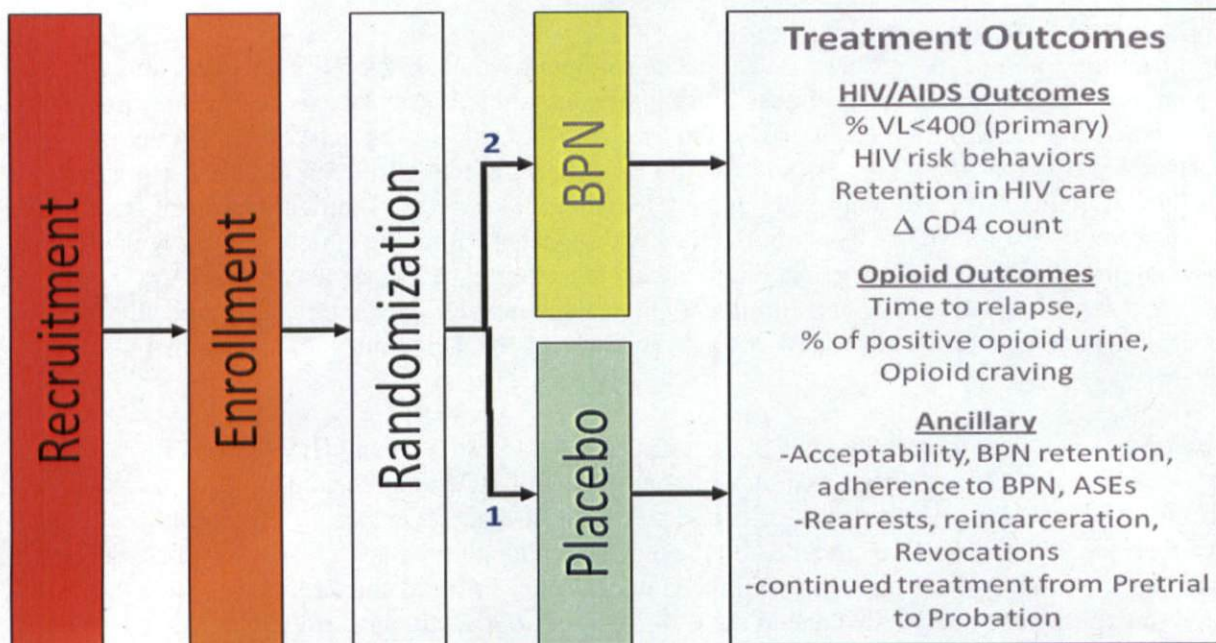
Preventing infections among core risk groups can reduce community transmission of HIV. Previous HIV testing studies have demonstrated high feasibility in prisons and jails, but extremely low detection of new HIV cases in these settings. "Front end" offenders have higher HIV risk behaviors and rates of sexually transmitted diseases, which are associated with HIV transmission. Challenges of integrating the Seek, Test, Treat, Retain (STTR) strategy early in the CJS (pretrial services and probation) result from legal system interruptions of the daily lives of offenders whose status within the system varies regularly, thereby affecting their access to or engagement in medical care. Pretrial services and community correctional agencies are not mandated constitutionally to provide medical care and there is typically no impetus to address health conditions like HIV, even if the same risk behaviors may affect criminal conduct.

Evidence-based interventions for treatment of SUDs exist, but are untested among HIV+s. RCTs confirm improved drug treatment outcomes and retention in care for HIV-uninfected people who are on methadone maintenance. Despite >40 years of experience with MM and evidence supporting its benefit, however, the CJS remains uncompelled by the evidence, though its use for HIV+s is unknown. Additionally, there are many other reasons that impede wide-scale MM implementation, including the memory of poor experiences with methadone in the CJS from the 1970s, stigma surrounding MM, its stringent regulations, safety concerns about diversion and overdose, and excessive nursing duties to remain within regulations. Methadone, compared to BPN, is likely to induce more neurocognitive impairment, a co-morbid condition that negatively impacts adherence to medications for the management of HIV/AIDS. In a RCT of BPN vs MM among HIV-uninfected jail inmates, more subjects were likely to remain on BPN than MM. In this same study, significantly more BPN subjects were linked to treatment upon release. These treatment outcomes mirror findings in RCTs of BPN and MM in community settings that confirm equivalence in drug treatment outcomes^{66, 67} and in cost-effectiveness. None of these studies, however, have been conducted among HIV+ prisoners. Preliminary Studies) and evaluated the largest, multisite study of integrating BPN treatment into HIV clinical care settings. Our group has also confirmed that there are fewer pharmacokinetic drug interactions between BPN and HAART compared to MM. The study tests the use of BPN, an evidence-based substance abuse treatment, as a conduit to and retention in HIV care among pretrial defendants and offenders, and its impact on criminal justice involvement.

Detailed description of the research method

Research Plan: Provide an orderly scientific description of the study design and research procedures as they directly affect the subjects.

Study Design



Study Design (see figure above): We propose to conduct a prospective, randomized, placebo-controlled trial of Buprenorphine (BPN) versus placebo among HIV+, opioid dependent persons within pretrial services and/or community correctional system.

Eligibility Criteria: 1. HIV+, 2. Age ≥ 18 years, 3. Currently under community correctional supervision (PRTs, Probation, Re-Entry Services), 4. Meets DSM-IV criteria for opioid dependence, 5. English or Spanish speaking, 6. Resident of Washington, DC, and 7. Eligible or have medical entitlements (Medicaid, medicare, or private insurance).

Recruitment: We will recruit from multiple pretrial and community correctional settings, including PTS (Pre-Trial Services), probation offices, and the RSC (Re entry and Sanction Center). The options for recruitment are as follows:

1. We will advertise within their offices, use posters and tear-offs, and provide flyers for anyone who is interested. The advertisements will provide the person with a contact name for the research office for possible inclusion in the study.
2. We will receive referrals of those individuals who screen to be opioid dependent by their pretrial services or community correctional supervision staff directly; if the pretrial services or community corrections officer receives permission from the offender to refer to the study; all referred people will be screened by PSA/CSOSA to be an opiate user and the agency treatment placement criteria recommends treatment for the substance use disorder. Everyone who is opiate dependent or actively using will be referred to Howard University Hospital for further medical assessment, which will include HIV testing and potentially BPN detox based on the TIP 40 recommendations.
3. We will have research staff in the waiting rooms of CSOSA/PSA offices including drug test sites where GMU/Yale/Howard research assistants could approach people in the waiting room. This would not involve CSOSA/PSA staff providing any names; instead research staff would recruit

volunteers at the multiple pretrial and community correctional settings, including PTS (Pre-Trial Services), probation offices, and RSC (Re entry and Sanction Center) and/or the residential treatment programs. The research assistants could hand out flyers or host information sessions in the waiting room.

4. The PSA/CSOSA staff could hand out flyers and information packages to opioid users. The flyers could provide information about the study. It would be up to the individual person to contact the research office and make an appointment. PSA/CSOSA staff would only be providing information at the services offered at Howard University and the potential inclusion in a study.
5. The PSA/CSOSA staff could refer to Howard University's clinic for all opioid users, as a service provider, similar to how the staff currently refer to appropriate service providers. The PSA/CSOSA staff member could give a package to the person that has information about the service.
6. The research staff can go to the residential treatment facilities that CSOSA/PSA currently use and provide information sessions at these residential treatment facilities.

All those to be identified as being opioid dependent and HIV+ will be referred to our research team from George Mason University. All referred subjects will meet with a research assistant (RA) who will conduct an initial eligibility survey and eventual enrollment. After consenting, a full baseline interview and randomization to one of two groups: TAU or BPN will occur. At any time the subject can decide to not participate. If the subject wishes to continue, then for all participants will have a urine drug toxicology performed. And female participants will have a pregnancy test done as well, as pregnancy would make the individual ineligible for the study.

All subjects will be managed in accordance with CSAT TIP 40 for the treatment of buprenorphine.(5) If urine toxicology is positive for opioids then the medical provider will assess the subject for opioid withdrawal symptoms using the Clinical Opioid Withdrawal Scale (COWS): if the COWS score is above 4, the medical staff will NOT administer study drug/placebo, but he/she will be given a Buprenorphine/naloxone (Suboxone) sublingual detoxification protocol as written in SAMHSA Tip 40 for 5-7 days, depending on clinical need and then monitored off of Suboxone and all other opioids for 3 days. Subjects who are not actively using opioids but who meet criteria for Suboxone for relapse prevention will be monitored. After all subjects are free from opioids for 3 days, the subject will then be assessed again with urine toxicology and COWS. If urine toxicology is negative and COWS is <4 then medical staff can administer induction on BPN or BPN-placebo and initiate the study treatment.

Randomization: Randomization will be 2:1 to BPN: placebo. All subjects, irrespective of study assignment, will receive standardized weekly counseling (first 12 weeks) and monthly (month 4 through 12) group relapse prevention counseling. The type of counseling will be CBT.

Study Procedures: Once consented, information gleaned from the eligibility data and baseline instrument will inform randomization. After randomization, all medications (BPN or BPN placebo) will be labeled with the subject's study number. The BPN and placebo BPN will be sent to the Howard University Investigational Drug Service (IDS). The IDS, after they learn of randomization status, will label each drug kit with a subject number and will track who is on active drug and placebo so that the investigators and those involved in patient care are blinded to which medication patients are receiving.

- a) Enrollment: Medications will be delivered from the Howard University IDS to the research site with subject ID number labeled on the kits. Both BPN and BPN-Placebo will be administered upon enrollment and with proper clinical review to assess current use and withdrawal.

Prior to the administration of the study drug/placebo it will already be known that subjects have met criteria for Opiate Dependency after initial assessment by the RA who will assess all participants in order to see if they meet criteria to be eligible for the study. This will be evaluated by asking DSM-IV criteria for opioid dependency questions regarding their 12 months prior to entry in the community correction system by utilizing a form that asks the specific criteria (Opioid Dependency Screen, ODS; created by Dr. Sandra Springer, PI) for initial assessment of history of opioid dependency prior to involvement with community correctional supervision. All participants will have a physical examination, a review of the criteria and a review of the study and a brief medical management counseling session by the study medical providers. At any time the subject can decide to not participate. If the subject wishes to continue, then for all participants will have a urine drug toxicology performed. And female participants will have a pregnancy test done as well, as pregnancy would make the individual ineligible for the study.

All subjects will be managed in accordance with TIP 40 for the treatment of buprenorphine.(5) If urine toxicology is positive for opioids then the medical provider will assess the subject for opioid withdrawal symptoms using the Clinical Opioid Withdrawal Scale (COWS): if the COWS score is above 4, the medical staff will NOT administer study drug/placebo, but he/she will be given a Buprenorphine/naltrexone (Suboxone) sublingual detoxification protocol as written in SAMHSA Tip 40 for 5-7 days, depending on clinical need and then monitored off of Suboxone and all other opioids for 3 days. Subjects who are not actively using opioids but who meet criteria for Suboxone for relapse prevention will be monitored. After all subjects are free from opioids for 3 days, the subject will then be assessed again with urine toxicology and COWS. If urine toxicology is negative and COWS is <4 then medical staff can administer induction on BPN or BPN-placebo and initiate the study treatment.

Induction onto BPN or Placebo will be performed consistent with TIP 40 protocols. We have clear documented experience inducing patients on BPN who are not actively using opioids and involved in the CJS.(6) BPN or Placebo dosing will be increased slowly until doses of 8mg to 16mg per day is achieved.

Participants will also have phlebotomy done to get monitor and assess AST, ALT, BUN, Creatine, Hepatitis C Ab, HIV viral load, and CD4. They will also be given a breathalyzer to ensure that clients are not intoxicated during the enrollment process.

- b) Monthly Research Visits: This will include monthly refills of BPN or BPN-placebo, assessment of adverse side effects, health care utilization, phlebotomy, ACASI interviews of alcohol and drug use and HIV risk behaviors, etc., and urine toxicology and pregnancy. Research staff will conduct interviews; doctors at Howard University will conduct the monthly review of adherence to the medications.

- c) Counseling visits:. All subjects, irrespective of randomization, will receive weekly (first 12 week) group counseling and then monthly (month 4 through 12) group counseling. The level of care provided would be consistent with PSA/CSOSA treatment protocol. Counseling will be on cognitive behavior therapy group counseling model. The treatment will be adopted to include reduction in HIV risk behaviors and adherence to HAART. The placebo-controlled nature of the study ensures that counselors do not know the randomization status of subjects and thereby introduce bias into their counseling sessions. Additionally, the counselor will perform urine drug toxicology for all drugs except BPN.

Data Sources:

Structured Interviews: Subjects will undergo baseline assessments and follow-up interviews. Structured interviews will include: 1) demographic information, including age, race, and gender; 2) criminal justice status including prior arrests and incarceration, types of offenses, prior probation or parole revocations, prior conditions of supervision, and perceptions of legal coercion; 3) health care status, including past medical history, current medications, adherence to antiretroviral therapy, health care utilization, previous alcohol and other drug treatment experience (12-step, counseling, pharmacotherapies, detoxification programs); 4) attitudes and beliefs about various forms of drug treatment; 5) standardized screening for mental illness, including the baseline only Mini International Neuropsychiatric Interview (M.I.N.I) to screen and diagnosis Axis I and II disorders,(16) the Brief Symptom Inventory (BSI); (17) 6) standardized measures of drug use, including determination of DSM-IV criteria for opioid dependency,(18) Addiction Severity Index (ASI) to assess drug use and severity; 7) HIV risk behaviors (using ACASI), including sexual HIV risk, drug use HIV risk and total HIV risk behavior (instrument derived from NIDA's risk behavior assessment, but has been adapted for HIV risk behavior for HIV+s, specifically event-level risk to a partner with HIV unknown or negative status. 9) HAART adherence questions in accordance with the Visual Analog Scale (VAS) and prescription monitoring via direct pharmacy refill pick-up assessments.

Washington DC CJS and Health Databases:

1. DC Pretrial Agency Administrative and Drug Test Data: DC PSA conducts standardized interviews on all PTDs, including demographics, social circumstances, and type of charge. They also conduct drug testing for all DC CJ agencies. Data sets will include historical drug testing event data (date, type of drug(s) tested positive, and status of the person (arrestee, pretrial supervision, probation, parole).. Drug test data is also available for periods of probation supervision.
2. DC Arrest Data Base: DC PSA maintains the arrest database for the DC police department (MPD and Capital Police). The database contains all arrests (date, type) and disposition including jail or prison time.
3. DC Pretrial Supervision and Probation Supervision: DC PSA and CSOSA (probation agency) use the PRISM or SMART system (respectively) for case management purposes. Data include intake date, supervision date, visit type, required conditions of release (e.g. drug testing, drug court, treatment sessions, mental health/domestic violence court), compliance with conditions of release, attendance at treatment sessions, type of warrant filed, and discharge data. The research team will have access to data from pretrial supervision and probation, which will allow the research team to model CJ trajectories and outcomes.
4. DC Regional Health Information Organization (DC RHIO): This secure health information management information system contains patient health records, which include visit dates, chronic

conditions, lab test results (CD4, viral load), visit location (e.g. office, hospital, or ER), procedures, and medications. Data files identify all subject-level information accessible through a signed medical release of information (ROI). This database has all HIV-related information for all HIV+ patients in DC who are not seen in private physician offices. Our partnership with Whitman Walker Clinic (WWC) and the DC DOH will allow us to access this data set.

5. DC Department of Health (DC DOH): As part of the partnership between NIAID and the DC DOH, HIV testing was greatly expanded starting in 2006. All HIV testing in DC, aside from private offices, are reported here. Over 90,000 HIV tests have been performed and represents all of the testing done in hospitals, ERs, community clinics and the jail.⁴⁴ The DOH maintains this name-based database that is available for all study subjects who sign a medical ROI. This database can be linked to VL and CD4 data from DC RHIO.

Laboratory Test Results: All phlebotomy information obtained after community release will be obtained through Howard University Infectious Disease Clinic and laboratory. None of the assays used are experimental and will be drawn as part of clinical care at standardized times as outlined. Tests include HIV-1 RNA testing (Amplicor 1.5, range 50 to 750,000 copies/mL); CD4 lymphocyte count using flow cytometry; liver function tests (AST/ALT, alkaline phosphatase, bilirubin). Additionally testing not done through Quest Diagnostics, but assessed by and recorded by the RA, includes the NIDA-5 rapid urine toxicology (opiates, methadone, cocaine, benzodiazepines and amphetamines), and the Alco Sensor III breathalyzer to measure Blood Alcohol levels.

Chart Review: Each subject, as part of the consenting procedures, signs for a medical release of information (ROI) to allow research staff to review their medical records and criminal justice records as well as drug and alcohol treatment, local hospitals and clinical care sites. Medical records will be retrieved to confirm self-reports of health care utilization. This information will then be used to examine the relevant impact of various components of the respective intervention and to confirm any adverse events that might occur during participation in this study.

Significance of anticipated results and their contribution to the advancement of knowledge

1. No studies have examined the impact of medically assisted treatments such as BPN on HIV risk behaviors and/or criminal justice involvement. This study will advance knowledge in this area.
2. No study has examined how HIV care has affected criminal justice involvement including arrests, incarceration, and drug use. The focus on the interface between public safety and public health can advance knowledge about the importance of addressing somatic health issues in reducing criminal conduct.
3. The public policy issues involving the use of medically assisted treatments will be explored through this study to determine whether more attention to somatic health needs will have collateral benefits in reduced risky behaviors overall.
4. The study will model the impact of providing HIV care and various SUD treatments on policy outcomes. The models will provide further information to warrant more attention to evidence based substance abuse treatment for offenders to reduce the transmission of HIV as well as to reduce drug use and other risk behaviors (STIs, etc.).

Benefits of research and/or participation to CSOSA/PSA

- 1. Most NIDA funded studies are on incarceration populations or offenders being transitioned from prison/jail to the community. Little attention has been given to pretrial defendants and/or probationers. This will provide the ability to learn about the impact of providing services in the front end.**
- 2. Other NIDA funded studies focus on case management instead of medically assisted treatments. This study will demonstrate the impact on medically assisted treatment on substance use and HIV risky behaviors.**
- 3. This study could advance knowledge about the comparative use of BPN with IOP as compared to residential treatment and IOP. This could potentially improve treatment outcomes as well as provide a more effective services at a lower cost. It will provide a local demonstration to policy makers in Washington DC about the value**

Specific resources required from the Agency

DC Pretrial Agency Administrative and Drug Test Data: DC PSA conducts standardized interviews on all PTDs, including demographics, social circumstances, and type of charge. They also conduct drug testing for all DC CJ agencies. Data sets will include historical drug testing event data (date, type of drug(s) tested positive, and status of the person (arrestee, pretrial supervision, probation, parole).

Drug test data is also available for periods of probation supervision if they change their legal status.

DC Arrest Data Base: DC PSA maintains the arrest database for the DC police department (MPD and Capital Police). The database contains all arrests (date, type) and disposition including jail or prison time.

DC Pretrial Supervision and Probation Supervision: DC PSA and CSOSA (probation agency) use the PRISM or SMART system for case management purposes. Data include intake date, supervision date, visit type, required conditions of release (e.g. drug testing, drug court, treatment sessions, mental health/domestic violence court), compliance with conditions of release, attendance at treatment sessions, type of warrant filed, and discharge data.

Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur

There is a risk of some pain/discomfort blood drawing but this is no different than the risks of the same procedures while in the hospital or in the ER. Injection site reactions including pain, tenderness, swelling, redness, bruising, itching, cellulitis, abscess, blood clot and scarring may occur. There is the possibility of additional unforeseen risks, and immediate review and follow up with the research team is important.

Those individuals in the BPN group may experience some of the side effects of the drug including nausea, headache, constipation, dizziness, nervousness, insomnia, drowsiness.

Side effects will be monitored by the principal investigators of this study who are Infectious Disease Physicians and Psychiatrist. The study nurse who will be providing the study drug/ placebo inductions and throughout the year during monthly medical follow-up meetings.

Buprenorphine is an opioid blocker and may minimize the effect of other opioid painkillers that are administered in health care settings like in the hospital or ER. Each individual in the BPN group will be given a card that says that they are receiving buprenorphine especially if you are to receive medications for pain relief. The card will also contain warnings about buprenorphine being a narcotic antagonist and instructions on what to do in the event you require pain medications. There is a real risk of opiate overdose if your healthcare provider attempts to override the blocking effects of naltrexone in order to achieve pain relief.

There is a risk of harm to an unborn fetus from buprenorphine. Women will only be able to participate if they are willing to do a monthly pregnancy tests or willing to use an adequate contraceptive method for the duration of the study.

There is also the risk from inconvenience and time spent traveling to and from the interview site.

Benefits. If part of the BPN group, the person may benefit from decreased opioid use and improved HIV health outcomes and help staying out of jail. In all cases, periodic healthcare will be provided by Howard University. The person will receive Medical Management for opioid dependence - an intervention that is designed to support patients diagnosed with opioid dependence who are starting a course of medications to help them maintain abstinence. The person will also received standardized prevention counseling. From a larger perspective, the person will be contributing to the science on how to best treat opioid dependence, in particular in HIV+ individuals within the criminal justice system and thus may help to improve health care and quality of life for other individuals in the near future.

Economic Considerations. The study will provide minimal payment in the form of gift cards for time and participation. The payments will be disbursed in the following amounts at the following time points:

\$30 on the baseline for the interview assessments completed that day. At follow-ups on weeks 4, 8, 16, 20, 28, 32, 40 & 44 you will receive \$15 for completing the interviews. At follow-ups on months 12, 24, 36, 48 you will receive \$30. \$10 for each of the five quarterly blood draws and clinical assessments since this visit may be scheduled on a separate day from the interviews.

Therefore the total amount a person can received during the study study over a 48 week (12 month) period is \$320.

Description of steps taken to minimize any potential risks or discomforts

As in all research studies, there are potential risks. We go to great efforts, however, to ensure that risks are minimized. There are additional risks with this study, particularly since it initially involves research with individuals involved within the criminal justice system and there are special protections set forth by the Department of Health and Human Services (HHS). Specifically, the HHS requirements

outlined in 45 CFR 46, Subpart C provides additional protections to prisoners involved as subjects in HHS-conducted or supported research. Additional steps involve:

1. The person will be given a voucher for transportation to Howard University to reduce the costs to the individual
2. All data forms will be deidentified with no names or official identification numbers (i.e. SSN, pretrial services number, CSOSA number, FBI number, etc); a separate subject list will be maintained on a file server at GMU that only the PIs and Project Manager will have access to
3. A toll free number will be provided for the study for subjects to report any problems with the medication or group; direct access will be provided for medical care.

Description of physical and/or administrative procedures to be followed to: 1) ensure the security of any individually identifiable data that are being collected for the project; and 2) destroy research records or remove individual identifiers from those records when the research has been completed

The research study will maintain all data files (from ACASI) on a secure server with password protection and encrypted at Yale University.

All identifier related information will be maintained at the Research Office at GMU, also on a secure server.

Description of any anticipated effects of the research project on Agency programs and operations
The agency will learn:

1. Effectiveness of BPN for opiod dependent defendants or offenders;
2. The comparative effectiveness of BPN with standard treatment protocols
3. The potential use of medical management for SUD
4. The impact of BPN and standard SUD care on criminal justice trajectories including arrests, time in jail/incarceration, outcomes from pretrial services/probation
5. The likelihood of reducing the transmission of HIV/AIDS among pretrial defendants and probationers by providing BPN and/or HIV care
6. The impact of criminal justice system processes on health care outcomes (including SUD)

Relevant research materials such as vitae, endorsements, descriptions of similar work undertaken, sample informed consent statements, questionnaires, and interview schedules

See Attachment for Consent Form

See Attachment for Questionnaires

Research Activities

Individual Activities	Study Visit (Weeks)																				
	0	1	2	3	4	5	6	7	8	9	10	11	12	16	20	24	28	32	36	40	44
Enrollment	X																				
BPN or BPN-placebo	X				X				X				X	X	X	X	X	X	X	X	
Medical	X				X				X				X	X	X	X	X	X	X	X	

Management counseling (MM)																				
LFTs	X												X			X			X	
Renal Function (BUN, Cr)	X												X			X			X	
HIV-1 RNA	X												X			X			X	
CD4 count	X												X			X			X	
Urine toxicology	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Urine pregnancy tests	X				X			X					X	X	X	X	X	X	X	X
Alcohol Breathalyzer	X				X			X					X	X	X	X	X	X	X	X
Baseline interview	X																			
HIV risk behaviors	X				X			X					X	X	X	X	X	X	X	X
Drug use	X				X			X					X	X	X	X	X	X	X	X
Health interview	X				X			X					X	X	X	X	X	X	X	X
Adverse side effects	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Substance Abuse Counseling (weekly 1-12, monthly after)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Prescription Monitoring	X					X		X					X	X	X	X	X	X	X	X

Statement indicating that copies of all deliverables will be provided to CSOSA/PSA

Study findings on the impact of BPN on outcomes; findings will be reported after half the sample has been involved in the trial (n=76) and after all of the findings have been reported.

Preliminary findings will be reported to PSA and CSOSA on an annual basis including:

1. Criminal Justice outcomes (i.e. number of arrests, number of convictions, days crime free, number of incarcerations) for the treatment and control group
2. Treatment outcomes (i.e. number of days in treatment, number completed treatment, number maintained BPN for one year)

Statement that copies of any datasets will be provided to CSOSA/PSA at the conclusion of the project.

The study will involve joining data from research interviews, CSOSA/PSA data sets, DC RHIO data sets. A copy of the deidentified data set will be provided to CSOSA/PSA after the first major paper summarizing study findings are reported.

AUTHORIZATION CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE

George Mason University

Howard University

Study Title: Seek/Test/Treat: HIV, Buprenorphine, and Criminal Justice (Project STRIDE)

Principal Investigator(s):

Frederick Altice, MD

135 College Street, Suite 323, New Haven, CT 06510

Faye S Taxman, Ph.D.

10519 Braddock Road, Fairfax VA 20030

William Lawson, MD

Howard University

Funding Source: NIH

Purpose: To determine whether Buprenorphine will help reduce relapse to opioid use and improve HIV care among opioid-dependent HIV+ individuals within the Washington, DC criminal justice system.

Invitation to Participate and Description of the Study

You are invited to participate in a research study that examines buprenorphine as a treatment for opioid dependence in HIV+ individuals within the Washington, DC criminal justice system. You are being asked to participate because: a) you have an HIV infection; b) you meet the criteria for opioid dependence; c) you are a resident of Washington, DC; d) eligible for social service entitlements and e) you are above 18yrs of age.

In order to decide if you want to be part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form provides you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed and any risks of the procedures, possible alternatives, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form. This process is known as informed consent. Agreement to meet with us and to participate further will not in any way, positively or negatively, affect your status as a prisoner or supervised offender, the medical care you receive in or out of jail, nor will it impact probation or parole, or any pending court proceedings. No information about your participation in this study will be disclosed to any criminal justice or judicial agency including pretrial services, probation or parole. If you wish to be part of this study we will ask you not to participate in any other study for the duration of your participation with us. Also, if you are currently part of another study you will not be eligible to participate in this study. Therefore, subjects can only be enrolled in one treatment study at a time.

Study Purpose

The purpose of this study is to determine whether buprenorphine, an FDA approved drug for treatment of opioid dependence in its oral formulation will help reduce relapse to opioid use in opioid dependent HIV + community supervised defendants or offenders and thus improve their health and justice outcomes. Specifically this will examine whether taking a daily buprenorphine is effective in reducing craving and relapse to opioid use and also the secondary effect on adherence to HIV medications, CD4 count, viral load and other measures of HIV + status, and reduce participation in the criminal justice system. In order to see if buprenorphine is effective in reducing opioid use, the researchers will follow all participants and schedule

regular interviews and blood draws to gather information. This will enable them to look at the presence of opioids in the subject's system and the amount of virus in the participant's blood, as well as monitor the liver for adverse side effects. The study will start the moment that you sign this consent form. The study will last for 1 year after release, with monthly prescription refills up to month 12. Laboratory tests will occur at baseline, and every 3 months. Urine toxicology tests will be done weekly for first 12 weeks, and then once a month prior to prescription refills occur.

Procedures

If you think you would like to participate in this study, you will need to give us your consent to continue this screening process. As part of this screening process, you will be asked to participate in an interview and allow a research assistant to review your medical records, including all medications prescribed and laboratory results. The interview will explore your medical, mental health, HIV risk behavior, opioid and alcohol use history, including your HIV history and your experiences with medical and mental health care.

If you are eligible to continue, you will be placed randomly into one of two groups being followed in this study. This will be done by a computer-generated program. The randomization is a 2:1 to buprenorphine versus placebo. This means you have a greater chance of being on the medication than the placebo. The entire study will last for a period of 1 year from the date of the consent being signed, medication intervention will occur every month for 12 months. Subjects in both groups will need to be interviewed for a baseline interview on the day of signing the consent form and then every month until the year is finished.

The baseline interview and quarterly interviews (months 3, 6, 9, 12) will be more extensive. You will also undergo blood draws for 1 year after release. We will monitor your HIV viral load and CD4 count and liver functions every 3 months with standard blood tests. There will be a total of 5 blood draws. Because buprenorphine may cause harm to an unborn fetus, female participants will also need to do monthly urine pregnancy tests to make sure that they are not pregnant.

In addition, whether you are in Group I or Group II, you will receive sublingual (under the tongue) medication daily. The difference between Group I and Group II is that one group will receive buprenorphine while the other group will receive a harmless but also ineffective substitute (placebo). Neither you nor the researchers will know which group is receiving buprenorphine and which group is receiving the placebo; this is called "double-blinding" and is necessary for us to obtain reliable results. Finally, regardless of which Group you are in, Medical Management (MM) counseling sessions for opioid dependence, which will be delivered by health care professionals, will be available to you. It reviews medication information including opioid dependence pharmacotherapy, lab results, opioid use status and prior counseling in addition to actively counseling the patient on opioid use. The intervention would be administered monthly by a health care professional prior to the refilling of medication prescription. Both groups will be offered weekly group standardized substance abuse treatment counseling for the first 12 weeks and then once a month for the rest of the year.

You also agree to use the services offered through this study that are appropriate for you. These services are described below.

You agree to be interviewed by a Research Assistant from George Mason University. The interview will be about your physical and mental health, use of medical care, alcohol and drug abuse and HIV risk taking behaviors. We will also obtain some locating information like your house address and telephone number in order to keep in touch with you. This information will only be shared with the study team. *No information will be shared with anyone else within the criminal justice system without your permission.* We will also take a

blood sample from you in order to take a look at your CD4 count and HIV RNA as well as your liver function, which may affect your eligibility for the study.

As part of your participation in this study, you will be asked to sign a Release of Medical Information form (ROI) including specific authorization for release of HIV, drug treatment and mental health treatment. These authorizations will allow researchers to review your medical records at your facility, including information on your lab tests, diagnoses and medications prescribed. You will also be asked to sign a release form to allow us to talk with other agencies, such as the Addiction Prevention and Recovery Administration or **HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA)** which will allow us to help coordinate your care after release. Additionally, the researchers will review your supervision and treatment program files and your official criminal justice records in administrative databases routinely used by criminal justice agencies. You decide which organizations we can talk with. Signing this second release is optional. We will not talk with any agency that you have not given us permission to speak with.

Your family members, friends or other individuals may be contacted about your whereabouts in the event that the research team is unable to locate you. These individuals will be paid a small nominal fee for providing your location or an alternate method of reaching you. These individuals will not be given any confidential information regarding your study participation or health status.

Risks and Inconveniences

There is a risk of some pain/discomfort blood drawing but this is no different than the risks of the same procedures you may receive while in the hospital or in the ER. Injection site reactions including pain, tenderness, swelling, redness, bruising, itching, cellulitis, abscess, blood clot and scarring may occur. There is the possibility of additional unforeseen risks, and immediate review and follow up with the research team is important.

If you are in the group receiving buprenorphine, you may experience some of the side effects of the drug including nausea, headache, constipation, dizziness, nervousness, insomnia, drowsiness.

Side effects will be monitored by the principal investigators of this study who are Infectious Disease Physicians and Psychiatrist. The study nurse who will be providing the study drug/ placebo inductions and throughout the year during monthly medical follow-up meetings.

Buprenorphine is an opioid blocker and may minimize the effect of other opioid painkillers that are administered in health care settings like in the hospital or ER. You must carry your study information card at all times and must always tell your provider that you are receiving buprenorphine especially if you are to receive medications for pain relief. The card will also contain warnings about buprenorphine being a narcotic antagonist and instructions on what to do in the event you require pain medications. There is a real risk of opiate overdose if your healthcare provider attempts to override the blocking effects of naltrexone in order to achieve pain relief. **In addition, it is very important to understand taking street opioid drugs (like heroin) in order to get high to override the effects of buprenorphine may increase the risks of respiratory failure and overdose. It is important to speak to the medical staff if you are actively using additional street drugs.**

There is a risk of harm to an unborn fetus from buprenorphine. If you are female and not willing to do monthly pregnancy tests or are unwilling to use an adequate contraceptive method for the duration of the

study, you will not be able to participate. If a female participant of this study is found to be pregnant, she will not receive any further doses of drug or placebo and will be referred to a high-risk obstetric clinic.

There is also the risk from inconvenience and time spent traveling to and from the interview site. The research staff members will make every effort to keep the information that you give to us safe and confidential. However, there is a minimal possibility that confidentiality may be breached unintentionally both within our laboratory and within the DOC.

Benefits

If you are part of the group receiving buprenorphine, an FDA approved drug for the treatment of opioid dependence, you may benefit from decreased opioid use and improved HIV health outcomes and help staying out of jail. In all cases, you will benefit from periodic healthcare during visits for medication monitoring and HIV care at Howard University. In addition, regardless of which group you are placed in, you will receive Medical Management for opioid dependence - an intervention that is designed to support patients diagnosed with opioid dependence who are starting a course of medications to help them maintain abstinence. This form of counseling is not currently available in the community. You will also have group standardized prevention counseling. If you decline to participate in this study, you will continue to receive community standard of care. From a larger perspective, you will be contributing to the science on how to best treat opioid dependence, in particular in HIV+ individuals within the criminal justice system and thus may help to improve health care and quality of life for other individuals in the near future.

Economic Considerations

There is no cost to you for participating in this study.

You will be given minimal payment in the form of gift cards for your time and participation. The payments will be disbursed in the following amounts at the following time points:

You will be given \$30 on the baseline for the interview assessments completed that day. At follow-ups on weeks 4, 8, 16, 20, 28, 32, 40 & 44 you will receive \$15 for completing the interviews. At follow-ups on months 12, 24, 36, 48 you will receive \$30.

You will also receive \$10 for each of the five quarterly blood draws and clinical assessments since this visit may be scheduled on a separate day from the interviews.

Therefore the total amount you will receive during your participation in this study over a 48 week (12 month) period is \$320.

Treatment Alternatives/Alternatives

You are free to drop out of this study at any time. You may obtain healthcare, treatment for opioid dependence, and case management services through standard means in the community. You may get buprenorphine or other opioid dependence treatment (methadone, naltraxone) from other providers in the community. You do not need to participate in this study to have access to buprenorphine. Buprenorphine is a treatment for opioid dependence and it is available orally from providers in the community.

Confidentiality and Privacy

You will be given a study number. All information we collect from study interviews will identify you only by this study number. Information linking your name to the study number will be kept in a file that is separate from files with your study information. Your study information will be kept on a secure server and in a locked file in a locked office. All computers and files are password protected. Your data will only be used for this study unless you give us permission to use it in other ways. Only people working on this study will have access to your information.

Any identifiable information that we get for this study will remain confidential. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

If you decide to take part in this research study, you will be required to give us information about your substance use. We will be applying for a Certificate of Confidentiality (CoC) issued by the DHHS. The CoC will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. This protection will not apply until we have obtained the CoC, which may take a few months. We will inform you when the CoC has been obtained.

Because this research is sponsored by the Department of Health and Human Services through the National Institute on Drug Abuse staff from that and other DHHS agencies may review records that identify you only for audit or program evaluation. They cannot report anything that would harm you or other research subjects.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in the research, then we may not use the CoC to withhold this information.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. Any information you give to your medical providers during this study may be entered into your medical record and could be available to insurers. If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study (5 years). After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study.

The information about your health that will be collected in this study includes:

- Research study records
- Medical records of only those services provided in connection with this Study and while you were in jail.

The information about your criminal justice status will be collected in this study includes:

- Research Study records
- Criminal justice arrests
- Jail or prison experiences

Records about your study visits will include

- Information obtained during this research regarding
- HIV / AIDS
- Opioid and alcohol Dependence
- Hepatitis infection
- Reportable infectious diseases
- Physical exams
- Urine screen results
- The diagnosis and treatment of a mental health condition
- Use and abuse of alcohol and drugs

Information about you and your health which might identify you may be used by or given to:

- Representatives from Yale University and the Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for insuring research compliance. These individuals are required to keep all information confidential. Collaborating partners at George Mason University and Howard University will also have access to the data collected.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator: Frederick L. Altice, MD of Yale University and Faye Taxman, PhD of George Mason University.
- The study sponsor : NIH
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study:

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine is required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

The sponsor will see the research information we collect about you when they come to Yale to monitor the conduct of this research study. The "Sponsor" includes any persons that work for or are hired by the sponsor to conduct research activities related to this study. For this study the sponsor includes NIH. Yale researchers will also send the sponsor your health information during the study or at the end of the study. When Yale researchers send information about you to the sponsor, they will not send information that directly identifies you such as your name, address, phone number or social security number.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

In Case of Injury

If you are injured as a result of your participation in this study, clinical care will be provided. However, you or your insurance carrier will be billed for any clinical services that are provided **outside** of the DOC. You do not give up any legal rights by signing this form.

Voluntary Participation and Withdrawal

You are free to choose not to take part in this study including not to answer any specific questions on the survey instruments. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not agree to participate. Your health care in jail/prison, your stay in jail/prison, and your release from jail/prison, pretrial supervision, or community correctional supervision will not be affected by your decision to participate or not participate in this study. You will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. You may also return to the study if you have left if it is within the year of your start date. If you sign this authorization, you may change your mind at any time, but the researchers may continue to use information collected before you changed your mind to complete the research. To withdraw, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any appointments in the future. You must also follow up your phone call by sending a written notice to revoke this authorization to the principal investigator : Frederick Altice, MD. 135 College St. Suite 323 New Haven, CT.

This authorization to use and disclose your health information will never expire unless and until you change your mind and revoke it.

The researchers may withdraw you from participating in the research if necessary.

Reasons would include:

Violent or inappropriate behavior or not following study rules.

If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors, the DOC, Yale University, George Mason, or Howard University. The contact information for **Human Subjects Review Board, Chair, George Mason University, 4400 University Drive , Fairfax, VA 22030, Telephone 703 993-4121 or HSRB@gmu.edu**

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, what is involved, and possible risks and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: _____

Signature: _____

Date: _____

Signature of Principal Investigator

Date

or

Signature of Person Obtaining Consent

Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Frederick Altice, MD At 203 737-2883 or coPI, Faye S Taxman at 703 993 8555. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688. If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/436-3650 .