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Human Research Protections
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RE: Improving Outcomes of Opioid Addicted Prisoners with Extended Release Injectable Naltrexone Before Reentry

NCT02617628

Sponsoring Agency: Patient Centered Outcomes Research Institute

DR. GEORGE E. WOODY (4413 -PS-Addictions)

This document serves as the cover letter for the attached protocol entitled: Improving Outcomes of Opioid Addicted Prisoners with Extended Release Injectable Naltrexone Before Reentry. The project began recruitment in August of 2016 and ended December 31, 2018. Please note that an approval was given for the PENN IRB Continuing Review for the submitted November 4, 2017 Informed Consent from May 17, 2019 through May 16, 2020.

Sabrina A. Poole, Psy.D.
Project Director

George E. Woody, M.D.
Principal Investigator

UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT
Informed Consent and HIPAA Authorization Form

Protocol Title: Improving Outcomes of Opioid Addicted Prisoners with Extended-Release Injectable Naltrexone (Vivitrol®) Before vs. After Reentry

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Why I Am Being Asked to Be In a Research Study

You are being asked to take part in this study because you abuse drugs. These drugs include heroin, and other opioids. If your body was (or will be) cleared from drugs in the Philadelphia Prison System (PPS), this study may help you avoid returning to opiate use when you get out.

Who Is Doing This Study and Who Pays For It?

This study will be managed by three organizations. They are the Perelman School of Medicine at the University of Pennsylvania, the Philadelphia Prison System (PPS), and NETSteps. NETSteps is a treatment program near PPS that has addiction treatment staff working in the PPS. The Patient Centered Outcome Research Institute known as PCORI will pay for it. PCORI's mission is to help patients and doctors understand what

healthcare works best in certain situations. PCORI has identified research into drug addiction and treatment as an important area.

Why Are We Doing This Study

We are doing this study to find ways to help people addicted to opioid drugs like heroin, Oxycotin, Percodan, and others stop their drug use. This study will look at giving a dose of extended-release injectable naltrexone (also called Vivitrol®) to people before or after they are released from prison. This medication blocks the effects of opiates in the body. It will not produce physical dependence. Vivitrol® blocks opioid effects for a month after a single injection. It is approved by the FDA for preventing relapse to opioid addiction. The standard of care usually given at PPS is to safely withdraw people from addicting drugs. This is followed by referral to a substance use treatment provider upon release.

Study Overview

To find out which treatment approach works best, a dose of Vivitrol® before leaving prison or after leaving prison, the research staff and the PPS administration will first describe the study to prisoners who express interest. If you continue to be interested after learning more about the study, you will be asked to read this consent and ask questions about anything you do not understand. You must also understand any risks related to being in the study. After reading this consent, you will be asked to answer a10-item questionnaire to show that you understand what you have read and what you are agreeing to do. You must answer 9 out of the 10 questions correctly. If you answer 5 out of the 10 questions on your first try, you will not be asked to join the study. If you answer 6 or more but less than 9 questions right, you will be given three more chances to answer at least 9 questions correctly. If you cannot answer 9 questions correctly, you will not be asked to join the study. Those who answer at least 9 questions correctly will be asked to sign this consent form and will be scheduled for an appointment at PPS to beginning a screening evaluation. If after these steps you become a participant in the study your involvement will last for 26 weeks (6 months).

During your first visit, after you sign the consent, the research staff will collect data that includes your name, address and other personal information. A standard blood test and a urine drug screen will be done. We will also collect an alcohol breathalyzer. We will do a physical examination. We will ask questions about your drug use, your HIV risk behaviors, psychiatric symptoms, and your overall quality of life. Opioid addicted prisoners who express interest in the study and appear to qualify will be asked to sign the consent form and go through screening. The first 200 who complete screening and appear to qualify for the study will be assigned by randomization to either receive Vivitrol® before release from prison or shortly after release from prison. The randomization is done by a computer and is much like flipping a coin.

If you are in the study and you do not have health benefits, you will be assigned a Patient Benefits Manager to help restore or obtain health benefits. The Benefits Manager assignment will happen while you are being screened. If you already have benefits, and you join the study, your continuation of these benefits will be handled by NETSteps during their standard intake process. The study will not be responsible for getting benefits for non-study persons. If you receive your first injection at PPS before you are released, the research staff will make an appointment for you to continue receiving Vivitrol ® at NETSteps after you are released. If you have been assigned to receive your first injection at NETSteps after you are released, an appointment will be set up for you at NETSteps, and the research staff will be at NETSteps for your first injection.

For all study participants, after the first injection, three more monthly injections of Vivitrol® will be offered at NETSteps. Urine and breathalyzer samples will be collected weekly, and monthly follow-up assessments will be done over the next 6 months at NET Steps in a private office dedicated to the study. You can change your mind about taking Vivitrol® after starting the study and stop taking Vivitrol® and change to another treatment at any time. Your participation is voluntary. The research staff can help you with a referral to other treatments not paid for by the study. However, your continued participation in the study by filling out the weekly and monthly

assessments is very important to us. If you go to treatment somewhere else we will ask you to continue to keep your ongoing study appointments. The information you provide at your visits will help us to see whether you relapsed or did not relapse during the study.

You should know that your participation is voluntary. You can choose whether you want to participate. You can drop out at any time. If you change your mind about being in the study and ask us not to contact you we will do so. Whatever you decide, you won't be punished or lose benefits that you would normally receive.

The federal Office of Human Research Protections, the City of Philadelphia Institutional Review Board (IRB), and the University of Pennsylvania's IRB have approved this study. All health information you provide will be confidential and available only to research staff and the IRBs noted above and kept in locked and password protected computer files which are kept in locked offices accessed only by Study staff.

STUDY DETAILS

You may hear about this study from friends, other prisoners, through a brochure, or a video that is shown to all persons through the public announcement system at the prison, or staff from the research team, NET@PPS, or a member of PPS staff may approach you. If you find any of the language or information in this consent hard to understand, please ask the research team or a study doctor to explain it. You may also discuss it with your family, friends, PPS staff, or your family doctor. If you meet all study admission criteria, want to participate, and have not been sentenced or court ordered to any other treatment, and are willing and able to come to your appointments at NET Steps after release, you will be asked to take part in the study screening.

Screening

Before you can sign the consent form, you must take the 10-item questionnaire mentioned above to make sure you understand the study. You must answer 9 of the 10 questions correctly in order to qualify for the study. If you do not answer 5 of the 10 items correctly on your first try, you cannot be in the study. If you answer 6 to 8 of the questions correctly you will be given the chance to answer the questions again. You will be given three more chances to answer at least 9 questions correctly. Those who answer 9 or more items correctly will be asked to sign this consent form and complete more screening tests. These tests are to make sure that you are healthy enough to be in the study.

If you are a female of child-bearing age, you must have a negative pregnancy test at the Screening Visit prior to getting Vivitrol®.

You cannot be in the study if you are pregnant. If you become pregnant during the study you will not be eligible to continue getting Vivitrol® since it is not approved for use during pregnancy. However, we would like to follow-up your delivery to determine if it was normal. You will be referred to other medications for opiate treatment outside the study. Although you will be receiving other treatment outside the study, we will ask you to continue your weekly and monthly study assessments.

You must also have:

1) A physical exam and blood tests (Complete Blood Count (CBC), liver test, and Chemistry Panel) to assess your health and make referrals to treatment if necessary.
2) Tests for HIV and hepatitis B and C, and a TB test to assess your health and make referrals for treatment if necessary.
3) A review of your medical history.

Baseline Evaluation

The baseline evaluation includes the following:

4) Questions about your education, work, lifetime substance use and use in the 30 days before incarceration, legal problems, social relationships, and psychiatric symptoms.

5) Questions about health services you received in the 90 days before incarceration.
6) Questions about your quality of life.
7) Questions about sexual and drug use behaviors that put you at risk for getting or spreading HIV and other infectious diseases.
8) Your opinion of any prior experience you had with naltrexone.
9) The names and address of 3 or more relatives or friends who know how to find you along with your written permission for research staff to contact them if we cannot locate you for a study assessment.
10) A urine drug test, and an alcohol breath test.
11) Repeat the urine or blood pregnancy test (females)

Randomization and Study Medication

After completing screening and baseline assessments and if you are found eligible to participate in the study you will be "randomized". You will be assigned a Patient Benefits Manager before you are released. The Benefits Manager may contact you while you are still incarcerated. Randomized means that you will be assigned to a group getting the study drug before you are released or after you are released. The process is just like flipping a coin.

Before Release Group

1) If you are put into the group" that will receive study medication before release, within several days of the time you are to be released you will be again asked about any recent opiate use and detoxification, and you will be given a "naloxone challenge" before you can receive study medication. A naloxone challenge is a short acting medication (meaning that the effects of the medication do not last that long) that is only effective through injection. The naloxone challenge will cause you to experience withdrawal if you have recently used opiates.

Therefore it is very important to tell the study physician the last time you used opiates of any kind. When you tell the study doctor or study staff about your opiate use, the study team will not disclose this information to any one at the prison.

2) We will review your urine tests, your pregnancy test (females), and your alcohol breathalyzer results. If the urine and alcohol test are negative, you will receive an injection of naloxone into the arm or buttock muscle to make sure you are no longer physically dependent. Naloxone is a pure opiate blocker that will cause severe withdrawal if you are still addicted. If you know that you have recently used opiates and are interested in the study you should tell the study doctor and research staff before taking the challenge. The study doctor and research staff may be able to determine when it will be okay for you to take the naloxone challenge without getting sick.
3) If after receiving the naloxone you show signs of withdrawal, you will be treated with clonidine and/or other non-opioid medications and have another opportunity to pass the challenge within the next several days if you wish to continue. Failure to pass the test a second time will disqualify you from study participation. The results of the challenge will be entered into your study medical records but not shared with PPS staff.
4) If you pass the naloxone you will receive an injection of 380 mgs of VIVITROL® into the muscle of your buttocks using a special needle that comes with it from the pharmacy. After VIVITROL® is injected, it lasts for a month and it cannot be removed from the body.
5) You will also be given an appointment for continuing the study at NET Steps after release.
6) If you are <u>NOT</u> released within 30 days after your first injection of VIVITROL®, and you are given a new release date, you will be asked if you are still interested in participating in the study and if you are, you will receive a second injection of VIVITROL® shortly before your new release date. This could happen several times before you are released if you are detained in PPS beyond 30 days of the injections.

After Release Group:

1) If you are in the group that will receive study medication after release, at your first visit to NET Steps you will be given a urine test, a repeat pregnancy test, and breathalyzer test. The research staff will also tell you about the naloxone challenge. If the urine and alcohol test are negative, you will receive an injection of naloxone into the arm or buttock muscle to make sure you are no longer physically dependent. If after receiving the naloxone you show signs of withdrawal, you will be treated with clonidine and/or other non-opioid medications and have another opportunity to pass the challenge within the next several days if you wish to continue. Failure to pass the test a second time will disqualify you from study participation.
2) If you pass the naloxone test you will receive 380 mgs of VIVITROL® given as an injection into the muscle of your buttocks using a special needle that comes with it from the pharmacy. After VIVITROL® is injected, it lasts for a month and it cannot be removed from the body.

Study Medication

All participants in both groups will be eligible for 3 additional monthly Vivitrol® injections at NET Steps. If staff suspects a relapse prior to the time you are to receive your next dose you will be asked to take a urine and breathalyzer test, repeat the naloxone challenge. If you relapsed and wish to continue Vivitrol®, you can do so after being detoxified and undergoing a repeat naloxone test or a clinical evaluation by the study physician. If on your next medication visit the study physician clinically evaluates that you have not relapsed and your urine screen is negative, you will not be asked to do a naloxone challenge.

All participants in both groups will be assigned a counselor and given a schedule of Study Visits for the remainder of the study. We will try to

remind you of your upcoming visits by providing you with an appointment card at the end of each visit.

The Weekly and Monthly Visits After Baseline

You will be asked to:

1) Every week you will provide a urine sample for drug testing and an alcohol breath test every week for 6 months until the end of the study.
2) Every week we will ask you to tell the doctor or clinical staff about any problems you are having with the medication or the study.
3) At visit 12 and 24 you will be asked questions about your medical history and current medical problems, education, work, substance use, legal problems, social relationships, and emotional problems.
4) At visit 12 and 24 you will be asked questions about medical services you received since your last study visit.
5) At visit 12 and 24 you will be asked questions about the current quality of your life.
6) At visit 12 and 24 you will be asked questions about HIV risk sexual behaviors and drug risk behaviors.
7) At visit 24 we will test you for HIV and hepatitis C unless these tests are known to be positive.

We understand that some of the questions asked in this study are sensitive, and you may not want to answer them. You have the right to do so. We will do our best to be sensitive to your feelings and protect the confidentiality of your answers.

Reimbursement for Time and Travel to Complete Study Assessments

You will be eligible to receive the following reimbursements for your time and travel, after your release, if you attend your study visits and complete all the assessments.

Week 1	$15.00	**Week 13**	$15.00
Signing Bonus	$30.00		

Keeping 1st week's staff scheduled appointment			
Week 2	$15.00	**Week 14**	$15.00
Week 3	$15.00	**Week 15**	$15.00
Month 1 (Week 4)	$100.00	**Month 4 (Week 16)**	$20.00
Week 5	$15.00	**Week 17**	$15.00
Week 6	$15.00	**Week 18**	$15.00
Week 7	$15.00	**Week 19**	$15.00
Month 2 (Week 8)	$20.00	**Month 5 (Week 20)**	$20.00
Week 9	$15.00	**Week 21**	$15.00
Week 10	$15.00	**Week 22**	$15.00
Week 11	$15.00	**Week 23**	$15.00
Month 3 (Week 12)	$100.00	**Month 6 (Week 24)**	$100.00

The maximum amount of reimbursement that you can receive if you complete all assessments is $660.

In order to be compensated for participation in this study, you must provide your Social Security Number.

For participants who have occasional serious issues traveling to the NETSteps clinic, the study can arrange for transport to come to pick you up to go either to the NETStep site or the University of Pennsylvania site to complete your weekly and monthly visits.

Risks or Discomforts Associated with Vivitrol®

Injection area reactions: This medication could cause injection area reactions. These reactions could include pain, tenderness, hardening of the skin where you got the injection, swelling, redness of the skin, bruising, or itchiness, but these problems usually go away in 1-3 days. Other injection area reactions may include bacterial skin infection, swelling caused by blood that collects under the skin, different kinds of pus under the skin, or unhealthy body tissue surrounding the wound, and scarring.

Unintended Opiate Withdrawal: Vivitrol® **will** cause opioid withdrawal unless the patient has been opioid-free for 7-10 days. This is why we will do a naloxone challenge prior to injecting **Vivitrol®** to make sure this will not happen.

Opioid Overdose from trying to beat the effects of **Vivitrol®**: If you attempt to beat the blocking effects of Vivitrol® by **taking extra or large amounts of opioids you could suffer an overdose that can kill you**.

Liver Injury: Another bad and serious adverse effect associated with naltrexone is liver injury. This kind of damage has almost always been associated with doses much larger than the 380-mg monthly dose used in this study. As a precaution, for safety, you cannot have liver test results more than 3 times above the upper limit of normal during screening. If you do, you cannot be in this study.

Stomach and Intestinal Problems. Stomach and intestinal problems reported in more than 10% of patients during treatment for opioid dependence have included abdominal pain, abdominal cramps, nausea, and vomiting. Loss of appetite, diarrhea, constipation, and increased thirst has been reported in less than 10% of patients. Hemorrhoids, ulcer, reflux, diarrhea, excessive gas, increased appetite, dry mouth, toothache, tooth abscess, colitis, blockage of the intestines, stomach flu, and painful boil-like swelling near the anus have been reported, but rarely.

Depression and Suicide: Thinking about suicide, attempts at suicide, and even deaths from suicides have occurred in people taking Vivitrol®, but they have been rare. The study clinical staff will monitor all participants for

depression and suicidal thoughts during the study to determine whether further treatment or referral is necessary.

A specific type of pneumonia that occurs in the lungs: There is a type of pneumonia that occurs in the lungs called "eosinophilic pneumonia" (EP). It is a disease in which white blood cell accumulates in the lungs. These cells can interfere with normal breathing. The most common symptoms include cough, fever, difficulty breathing, and sweating at night. Only one suspected case and one confirmed case have ever been found and both were cured with antibiotics and corticosteroids. The chance of this condition occurring is rare. Research subjects who develop difficult or labored breathing or low levels of oxygen in the blood will be monitored for this condition.

Pain Management: Patients in the study who may need pain medication for an injury or a medical procedure should seek alternative analgesics as opioids may not work when you are on Vivitrol®.

Reasons Not To Use Vivitrol®: If you are taking opioid analgesics; have current opioid dependence; are in opioid withdrawal; have failed a naloxone challenge; have a positive urine screen for opioids; are allergic to naltrexone, or any other components of the diluent (the substance in which the medication is mixed to help it flow); or have acute hepatitis or liver failure.

Other Risks Associated With The Study:

HIV Testing: These risks include someone finding out about your HIV positive status because of a violation of confidentiality. It is possible that you may react emotionally to this breach, and have depression or suicidal thoughts, or suicide attempts... The study clinical staff will talk with you prior to the HIV test. We will also counsel you after the HIV test to help you understand your "next steps" if you are positive.

Hepatitis B & C (HBV, HCV) Testing: Risks include violation of confidentiality and other possible problems and concerns connected with non-treatment.

Behavioral Ratings: These risks may involve violation of confidentiality or becoming anxious or embarrassed by some of the questions.

Risk of Naloxone Challenges: In people addicted to opiates, using naloxone can bring on acute withdrawal. Symptoms may include body aches, diarrhea, a rapid heartbeat, fever, runny nose, sneezing, involuntary erection or goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Other considerations include risk of worsening of preexisting heart disease in patients who are taking heart medications.

There is also the risk of your confidentiality being violated if you are found to have been using opiates while incarcerated. Although the study staff and study physicians will be careful not to release any information about your drug use or naloxone challenge results to the prison staff or administration, if you tell anyone about positive urine results when tested for the naloxone challenge and this information is told to PPS, your rights as a prisoner could be affected. If naloxone causes withdrawal, symptoms will last 20-45 minutes. Until then, you will be treated with medication and observed by the study clinical staff (doctors or nurses not connected to PPS) until the symptoms have resolved.

Risk of Pregnancy: There are no adequate and well-controlled studies of either naltrexone or Vivitrol® in pregnant women. Its effects on pregnancy, labor, and delivery are unknown. There is a high level of risk if you become pregnant while on Vivitrol®.

Women in the Study

Women with infants must agree to not breast feed. Sexually active females of child-bearing potential (except women who are no longer having menstrual cycles or have had both ovaries removed, or have had their uterus removed, or have had tubal ligation) must agree to use one of the following methods of birth control from the date they sign this informed consent until a month after their final dose of study drug:

a. Hormonal contraception (oral contraceptive, contraceptive implant, or injectable hormonal contraceptive
b. Double-barrier birth control (condom plus intrauterine device, diaphragm plus spermicide, etc.)
c. Maintenance of a monogamous relationship with a male partner who has been surgically sterilized by vasectomy.

What if New Information About Vivitrol® Becomes Available During the Study?

During the course of this study we may find out about previously unknown problems from Vivitrol® or its ingredients that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What Are the Possible Benefits of the Study?

You may not receive benefits from being in this study. There is good evidence that drugs like Vivitrol® prevent going back to drug use and that being connected to any kind of supported treatment like counseling or

medication assisted therapy improves your ability to not use drugs and your ability to reconnect to other resources in the community.

Will I Have to Pay For Anything?

You will not have to pay for any procedures or tests associated with the study.

What Happens If I Am Injured From Being in the Study?

You will be provided with an identification card stating you are in a study of Vivitrol®. You should tell your primary care provider that you are receiving Vivitrol. If you have a medical emergency, consult your study physician or primary care provider or go to the nearest emergency room. Tell the health care providers that you have received Vivitrol® in a research study being conducted by the University of Pennsylvania, and when you received your last dose of Vivitrol® or any other known medication. Ask them to call the telephone numbers listed on the study identification card for further instructions or information.

If you are injured as a result of study participation please contact Dr. Woody at 215-399-0980 Ext 112 , Dr. Yu at 215-743-6150, or Dr. Amy McNamee at NetSteps at 215-743-6150. In the event of other concerns about the study, you can call Dr. Jessica Robbins at 215-685-0869 (Philadelphia IRB and Health Center #4)**. I**n the event of injury resulting from research procedures, treatment will be provided without cost to you but the University of Pennsylvania does not plan to provide financial compensation. Your insurance will be responsible for the cost of medical care if your illness or injury is not directly related to participation in the study.

You should know that by signing this consent form you do not give up any of your legal rights. You can always ask your lawyer for advice about any issue related to your involvement in this study. You should also know that any information about child abuse or intent to harm self or others will be reported to authorities as required by law.

Notice: Information on contraband (weapons or firearms, illegal drugs found in your possession at the visit) and plans to escape will be reported. This does not include reporting positive urines for drug use while in the study.

When is the Study Over? Can I Leave The Study Before It Ends?

This study is expected to end after all participants have completed follow-up assessments. A study physician, PCORI, or one of the Human Subjects protection committees may also stop the study without your consent. Possible reasons for stopping include too many serious adverse events related to the study; new information about previously unknown adverse effects of Vivitrol® or not meeting study progress goals. Stopping the study does not require your consent but you will be informed if such a decision is made and the reason for the decision. Your participation in the study ends when you have completed all assessments at the six month visit, however, If you have not completed all of your expected visits, and you are past the 6 month visit, a study staff may call you on the telephone to ask you a series of questions about relapse and your drug use. This would be a one-time call, no compensation will be given for this call. If you express that you would not like to be called, the study will not call you.

What Information About Me May Be Used Or Shared With Others?

We will do our best to make sure that the personal information obtained during this study will be kept private. However, we cannot guarantee total privacy because your personal information may be given out if required by law. The data we collect may include information from medical records, results of physical examinations, medical history, lab tests, or protected health information such as name, address, phone numbers, social security number, and results from physical examinations and blood tests.

How Will My Protected Health Information Be Used?

Your information will be used to:

- Evaluate your response to the study medication to see which method of delivery works best (before or after release from prison)
- When reviewing your test results, including HIV status and liver tests, we use this knowledge to safely monitor your conduct in the study. We also ask information about side effects that we report directly to the IRBs involved in the study.

Who May Use and Share My Protected Health Information in the School of Medicine at the University and Outside the University?

- The study research team at the University and the NET Step research staff
- The federal Office of Human Research Protections, City of Philadelphia Institutional Review Board and the University of Pennsylvania; the Office of Human Subjects Research Protection in Washington; and members of the Patient Centered Outcomes Research Institute (PCORI) that are involved in administering the study.

How Long May the School of Medicine Use or Disclose my Protected Health Information?

Your approval for use of data that has been stripped of all personal identifiers including name, address, and telephone numbers for this study does not expire.

- Your protected health information may be held in a pass word protected database. However, the School of Medicine may not re-use or re-disclose protected health information collected in this study for a purpose other than this study unless:
    - You have given voluntary verbal or written approval
    - The study staff finds out information from you on such things as child or elder abuse, reportable communicable diseases, or possible threats to self or others
    - The study staff has reporting requirements that are state mandated, such as knowledge of communicable disease
    - Or if release of information is required by DHHS or the FDA for program evaluation or audits as required under the federal law

Can I Change My Mind About Giving Permission For Use Of My Information?

- Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What If I Decide Not To Give Permission To Use My Health Information?

- Then you will not be able to be in this research study.

***Confidentiality*:** All subject information will be kept confidential and managed according to all applicable federal and state laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) requirements. Who will have access to that information and why; who will use or disclose that information; and their rights to revoke authorization for use of protected health information has been explained in this informed consent. If you take back permission to collect or use your protected health information, the investigator retains the ability to use information collected prior to the revocation of authorization. If you take back your authorization to collect or use your protected health information, attempts will be made to obtain permission to confirm that you are living at the end of the scheduled study period.

Informed Consents with subject signatures will be kept separate from the study data. All study data will have the names of the participant removed and replaced by a study number. Source documents will be kept in a locked cabinet at the University of Pennsylvania and will include evaluation checklists, dispensing records, data from patient assessments, subject files, and laboratory test results. The IRB at the University of Pennsylvania and the Philadelphia IRB will have access to the records.

We also may be asked to give information to the Food and Drug administration, and the Study Data and Safety Monitoring Board. These organizations make sure that the study is conducted safely and ethically.

Please Note: Your Protected Health Information may no longer be protected once disclosed outside of the prison such as when you voluntarily disclose information to insurers, employers, or other third parties. Your protected health information may also no longer be protected should you discuss it with others in the prison setting. You should know that information obtained during the study can be misused if disclosed. For example, if discussed with others outside of the study, your health information, emotional condition, or current substance use could trigger conditions that could lead to the denial of privileges and inappropriately influence the deliberations of bodies such as parole boards. Upon release, such disclosures could also seriously impair your reintegration into society and subject you to discrimination as you seek community acceptance.

You should also know that if you test positive for HIV we are required to report it to the Philadelphia Department of Health. This law requires that we report your name, gender, racial/ethnic background, and the month and year you were born. The law was made to keep track of how many people in the U.S. have HIV; it also makes sure that states get money from the government to support treatment of people with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. A positive test for hepatitis C and B will also be reported.

To help us protect your privacy, we will obtain a Certificate of Confidentiality before the study starts. We will use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, a court subpoena. We can use the Certificate to resist demands for information that would identify you, except when there is a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate also cannot be used to stop us from reporting on such things as disclosure about child abuse, your intent to hurt yourself or others, or reporting, for reports required by state laws.

You should know that breaches are possible even with a certificate of confidentiality in place. If this should happen, it can increase stigma and discrimination, and increase risk of social isolation, violence, and human rights abuses from other prisoners and prison staff. For this reason, your confidentiality is important to us.

Who Can I Call With Questions, Complaints or If I'm Concerned about My Rights as a Research Participant?

You should speak to Dr. Woody at 215-746-7702, or Dr. Yu at 215-743-6150 or another member of the research team. If a member of the team cannot be reached or you want to talk to someone other than those working on the study you may contact the Office of Regulatory Affairs at the University of Pennsylvania by calling (215) 898-2614 or the Research Participant Coordinator at the Philadelphia Health System and IRB at (215) 685-0869. You may always consult your own legal advisor about your legal rights.

By signing this form you are agreeing to take part in this research study and attend all visits. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. You have been explained that your name will not appear in any publications that result from this study. Your signature shows that you understand that your participation in this study does not alter or change the regular discharge procedures or referrals from PPS. You also understand that your participation in this study will not affect your time at PPS or your eligibility for parole. Your signature also means that you are permitting the Perelman School of Medicine at the University of Pennsylvania to use the personal health information collected about you in the course of the study for research purposes as described in the consent.

A copy of this consent form will be given to you at NETSTEPS at your first post release visit.

Name of Subject (Please Print)	**Signature of Subject**	**Date**
Name of Person Obtaining	**Signature**	**Date**