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NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	Long-acting buprenorphine vs. naltrexone opioid treatments in CJS-involved adults (EXIT-CJS) S19-01450
Principal Investigator:	Joshua D. Lee MD, MSc Department of Population Health NYU School of Medicine 180 Madison Avenue, 17-14, New York, NY 10016 (646) 501-3552
Emergency Contact:	Joshua D. Lee MS, MSc (646) 501-3552

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to compare the effectiveness of extended-release buprenorphine (XR-B, Sublocade) to extended-release naltrexone (XR-NTX, Vivitrol) in helping people at release from jail or prison who have been addicted to opioid drugs (including heroin) avoid relapse to opioid use. Both extended-release buprenorphine (XR-B) and extended-release naltrexone (XR-NTX) are long-acting injections that contain enough medication to last for about one month. Extended-release buprenorphine was approved by the Food and Drug Administration (FDA) for the treatment of opioid dependence in November 2017. XR-NTX was approved by the FDA for the treatment of opioid dependence in October 2010. Extended-release buprenorphine is an opioid medication that reduces opioid withdrawal symptoms and reduces or blocks the “high” from taking heroin or other opioid drugs. Extended-release naltrexone is not an opioid medication. It blocks the effects of opioids like heroin or other opioid drugs.

This study will compare the effectiveness of these two medications, XR-B versus XR-NTX. Willing participants will be randomly assigned (like a flip of a coin) to one of these medications, which will be provided in jail or prison and during follow-up post-release. In addition, we will compare those receiving either XR-B or XR-NTX with the usual treatment that people receive in your jail or prison. You are being asked to participate in this study because you are incarcerated (in jail, prison, or another criminal justice controlled environment), have an upcoming release date, or have recent (within 6-months) contact with the criminal justice system and may be interested in taking a medication to treat your opioid dependence.

Parole boards will not take into account your participation in this study when making decisions regarding parole. Therefore, participation in this research study will have no effect on your parole.

3. How long will I be in the study? How many other people will be in the study?

We estimate that the following number of subjects will enroll (sign consent forms) in this study: At this site: up to 301 Total at all sites: 1,505

Your participation will last for approximately one year and involve 10 visits, 2 while incarcerated and 8 following release. Your first 6 community visits will occur monthly over a period of 24 weeks and then 2 more follow-up visits will occur at weeks 28 and 48. If you are recruited in the community, your first 2 visits will occur within one to two weeks of each other. Then 6 of your follow-up visits will occur monthly from weeks 1-24 and the final 2 visits will occur at weeks 28 and 48. Each of these visits will take the following amount of time:

-The initial screening visit (baseline) will take about 1-2 hours. You will find out if you are eligible for the study at this visit.

-A second visit prior to release from jail or prison will include counseling (consisting of overdose prevention and drug treatment information and treatment referral) for all groups and will take approximately 1 hour. Half of eligible participants will be assigned to receive an XR-NTX injection in the muscle of their buttock and half of eligible participants will be assigned to begin daily under the tongue buprenorphine treatment for up to several weeks until they will then receive an XR-B injection under the skin in their belly. This visit for the XR-NTX or XR-B injections will be scheduled in the 0-4 weeks prior to your planned release from jail or prison.

-If you sign up for the study in the community a second visit approximately 1 week after the initial screening visit will be scheduled. This visit is called the randomization visit. This will take approximately 1 hour of your time. At this visit, half of eligible participants will be assigned to receive an XR-NTX injection in the muscle of their buttock and half of eligible participants will be assigned to begin daily under the tongue buprenorphine treatment for up to several weeks until they will then receive an XR-B injection under the skin in their belly.

-Following release or community randomization, ALL participants will be scheduled for 8 follow-up visits at Bellevue Hospital, which will occur monthly. Both XR-NTX and XR-B injections, will be administered

once a month at these study visits. All study visits after release should take approximately 1 hour or less of your time.

4. What will I be asked to do in the study?

You may qualify for this study if you are 18 years of age or older, have a history of opioid use disorder (addiction to heroin or other opioids), are interested in medication treatment, and are currently incarcerated with a known release date or have had criminal justice involvement within the past 6 months.

If you agree to be in the study and sign this consent/authorization form, you will have testing done to make sure you are eligible and it is safe for you to participate. These tests include:

- A review of your medical and psychiatric history including history of liver disease, chronic pain requiring opioid pain control, medication allergies, and a list of all current medications you are taking.
- An evaluation including questions about your psychiatric or emotional symptoms, your drug use, problems related to your drug use, health risks, and your criminal history.
- A urine sample will be collected to test for drug use at all study visits before and after release.
- A urine pregnancy test will be administered at all study visits before and after release.
- A medical evaluation prior to treatment

We will ask you for your contact information so we can be sure to reach you to schedule visits after your release. We will also ask you for contact information for 3 people close to you. We will only contact these people if we are unable to find you using the contact information you gave us. No information about this research study or about you will be given to your contacts or any agency, including correctional or parole/probation authorities, without express written consent from you.

There are 3 possible study groups: One is the extended-release buprenorphine (XR-B) group, the second is the extended-release naltrexone (XR-NTX) group, and the third is the enhanced treatment-as-usual group with counseling (consisting of overdose prevention and drug treatment information and treatment referral).

During the initial screening visit, the research staff will make sure you are still eligible for the study. If all the tests show that you are eligible, and you agree, you will be randomly (meaning, by chance, like the flip of a coin or roll of dice) assigned to one of 2 groups: Extended-Release Buprenorphine group (XR-B) or Extended-Release Naltrexone (XR-NTX). The chances of being in each group are 50/50 (like the flip of a coin). You will be told which group you are assigned to.

Neither you nor your doctors will have control over which group you are assigned to. Both medications (XR-B and XR-NTX) are FDA-approved and available by prescription. By agreeing to be in the study you are agreeing to take whichever drug you are randomly assigned to rather than you or your doctors making a choice between the two. Both XR-B and XR-NTX will be available in jail or prison through this study.

If you are eligible for the study before the medications are available in your institution you will be invited to participant in the enhanced treatment-as-usual group. If you are eligible for the study after the

medications become available in your institution but do not want to receive either XR-B or XR-NTX, you will be invited to participate in the study in the enhanced treatment-as-usual care group. Also, if you are eligible for the study but are already on non-study methadone, buprenorphine, or naltrexone and plan on continuing these medication, you will be invited to participate in the enhanced treatment-as-usual group.

EXTENDED-RELEASE BUPRENORPHINE GROUP (XR-B): For those assigned to this group, you will receive extended-release buprenorphine (XR-B), medical management and counseling. If you are randomized to XR-B treatment, you will have one or more medical visits conducted in the weeks or months prior to your release or in the community. This will include counseling regarding drug education, relapse and overdose prevention, and opioid treatment and referrals as offered to the other groups. It will also include a medical provider visit reviewing and offering XR-B treatment.

If you agree to XR-B treatment and are not currently on daily sublingual buprenorphine (Suboxone films, buprenorphine-naloxone tablets, Subutex, buprenorphine tablet), you will have to slowly re-start daily sublingual buprenorphine up to a dose of 8mg per day (or more) for approximately seven days (or longer) prior to the first XR-B injection. This is necessary to build up your opioid tolerance before your first injection. The study and facility treatment team will help you do this carefully and slowly so that you feel as comfortable as possible.

Then, you will receive an XR-B injection to the abdomen (belly). The injection is a liquid medication in the amount of either 100 or 300 mg buprenorphine in 1.5 cc (less than 1 teaspoon) volume and will last in your body for about 30 days. The medication is stored in a small nodule (lump) under the skin of your belly where it was injected. The buprenorphine is gradually released into your body over time for a 30day period. Following release, visits at Bellevue Hospital with study physicians will offer further counseling or medication treatment referrals, the option to receive an additional XR-B injection once a month following the first injection and, continued encouragement to avoid relapses and stay on treatment. If you want to stop receiving more XR-B injections, your provider will give you counseling and referral to other treatments available. At these visits, you will be asked questions about how you are feeling and if you are experiencing any side effects from the medication and will need to provide a urine sample for drug testing (and pregnancy testing if applicable).

In the event your release date is postponed and you remain in jail or prison, the research team will try to continue providing XR-B treatment up until your new release date, although that may not be possible

You will not receive further buprenorphine injections through the study after your 6th monthly visit. However, if you wish to continue XR-B or consider other medication treatments, including daily buprenorphine or methadone treatment, the research staff will help you to find such treatment, including treatment at Bellevue Hospital, which provides all such forms of treatment.

EXTENDED-RELEASE NALTREXONE (XR-NTX) GROUP: For those assigned to this group, you will receive extended-release naltrexone (XR-NTX), medical management and counseling. If you are randomized to XR-NTX treatment, you will have one or more medical visits conducted in the weeks or months prior to your release or in the community. This will include the same counseling regarding drug education, relapse and overdose prevention, and opioid treatment and referrals offered to the other study participants. It will also include a physician visit reviewing and offering you XR-NTX treatment. XRNTX

can only be provided if you) you are not pregnant and your urine pregnancy test is negative (if appropriate). In some cases, the provider may give you a short-lasting naloxone (Narcan) injection to check if you will have opioid withdrawal when you receive XR-NTX. If you have used opioids recently, you could have withdrawal symptoms. These withdrawal symptoms could include nausea and vomiting, sweating, muscle aches, chills and other flulike symptoms.

If you do not have any withdrawal symptoms, you will receive an injection of XR-NTX to the outer upper part of your buttock. The injection is a liquid medication in the amount of 380 mg naltrexone in 4 cc volume (about 1 teaspoon) and will last in your body for about 30 days. Following release, visits with study physicians at Bellevue Hospital will offer further counseling or medication treatment referrals, the option to receive additional XR-NTX injections once a month following the first injection and continued encouragement to avoid relapses and stay on treatment. If you want to stop receiving more XR-NTX injections, your provider will give you counseling and referral to other treatments available. At these visits, you will be asked questions about how you are feeling and if you are experiencing any side effects from the medication. In the event your release date is postponed and you remain in jail the research team will make every effort to continue providing XR-NTX treatment up until your new release date, although that may not be possible.

Further naltrexone injections will not be provided by the study after completion of the final study visit. However, if you wish to continue XR-NTX or consider other medication treatments, including daily buprenorphine or methadone treatment, the research staff will help you to find such treatment, including treatment at Bellevue Hospital, which provides all such forms of treatment

ENHANCED TREATMENT AS USUAL (ETAU): For those who do not wish to take XR-B or XR-NTX and agree to be in this group, you will receive individual counseling and treatment referrals. If you agree to participate in this study, but choose to not be randomized, you will be assigned to this group. In this group you will not receive any study medication. You will be able to receive any treatments available to individuals in your jail or prison who are not in the study. Study staff at the first two visits will provide you with information on relapse and overdose prevention, treatment referrals, and navigating re-entry challenges. Following release, visits at Bellevue Hospital with study physicians will offer further counseling and/or treatment referrals and continue to encourage relapse prevention and treatment engagement. This group could also receive a form of medication treatment offered by the jail/ prison or could be referred to treatment after release.

For All Groups: You will be asked to come to the Bellevue Hospital Primary Care clinic shortly following release, with the first visit occurring about 3 weeks post-release and then every 4 weeks thereafter for a total of 6 visits over 24 weeks following your release. These 24 weeks will be considered the Treatment Phase of the study. You will be asked to give a urine sample to test for drug use at each visit. At each visit you will be asked questions about your mood, opioid cravings, quality of life, your social, legal and job status, and other treatment services you have received. After you complete the 6th visit or 24 week Treatment Phase, you will have 2 more study visits at Bellevue Hospital at weeks 28 and 52 (one-year). Between visits you may be called by staff to remind you of the upcoming visits.

The Principal Investigator and study team conducting this research study are responsible for your medical care related to the XR-B and XR-NTX treatment. Your overall health care, however, is the responsibility of your regular doctors and/or the community treatment program you subsequently enter.

Your community program is responsible for any reporting that may be required as part of agreements with probation or parole, or the courts or other branches of the criminal justice system. If during the course of the study, you have a medical emergency or require urgent medical care, the research staff will consult with the doctors treating you regarding any information important to your medical care.

We encourage you to participate in other appropriate drug treatment programs during this study. However, any treatment you receive in a drug treatment program is not part of this study, and you may continue in this study even if you do not attend or drop out of a drug treatment program. This study does not pay for any costs related to drug treatment program participation.

If Your Release Date from Jail or Prison Changes

If your previously scheduled release date changes, the study will continue to follow you in your treatment assignment until your new release date. If, however, you remain in jail and your release date becomes unknown, for instance, due to a new criminal charge, or you are transferred to NY State Dept. of Corrections for a felony conviction or parole violation, you will no longer be study eligible and would be withdrawn from the study. In this event and if you are withdrawn from the study, efforts would be made to offer you community treatment services at Bellevue Hospital upon your eventual release from jail or state prison, though such treatment would occur outside of the study and as part of your usual health care.

Any identifiable private information and/or specimen collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

The following are risks and discomforts that you may experience during your participation in this research study:

For All Groups:

Use of opioids including heroin ALWAYS puts you at risk for drug overdose and death as well as continued addiction. It is particularly risky to resume previous levels of heroin or other opioid use following ‘drug free’ time, including incarceration, which lowers our tolerance to opioids. Both the counseling and medication treatment in this study are intended to reduce the chances of your using opioid drugs at release, however, neither is known to be 100% effective, and persons returning to opioid use will be at much greater risk for harmful outcomes including overdose and death than those that do not.

If you are in the XR-B Group:

While you are being treated with a monthly buprenorphine injection, if you take small amounts of heroin or fentanyl, or other opioids, the effects will be minimized. However, if you take large amounts of heroin, fentanyl or other opioid drugs this could overpower the buprenorphine, and you could overdose and die. Buprenorphine does not block the effects of non-opioid drugs such as cocaine, tranquilizers, or alcohol, and it does not reduce the risks in using these substances.

If you use opioids after missing one of the monthly injections, your body may experience withdrawal symptoms.

Once you are being treated with buprenorphine (both the sublingual buprenorphine and XR-B), this medication may occasionally cause drowsiness, dizziness, constipation, or headaches. Additional side effects may include nausea and/or vomiting, opioid withdrawal, sweating, numbness or redness in your mouth, swollen and/or painful tongue, feeling "high," trouble paying attention, irregular heartbeat, trouble sleeping, blurred vision, and fainting. Some people taking buprenorphine may experience liver irritation. If you notice your eyes turning yellow or your urine darkening, you should tell your provider. It is important to note that some of the side effects may be opioid withdrawal symptoms for which the provider who is monitoring you can prescribe medications to reduce the discomfort. The study team will monitor your mood. If you develop significant depressive symptoms, you may be offered treatment options including antidepressant medication or referred for treatment.

It is very important that you tell the study team and providers about any other medications you are taking (either prescription or non-prescription) before beginning as well as during this study. Some medications (either prescription or over the counter) that may interact with buprenorphine include certain medications for depression or mood disorders such as Xanax (benzodiazepines), and medications to help with sleep.

Also, if you require opioids for any medical treatment once you are on buprenorphine, you will likely not have adequate pain relief from usual doses of opioid pain relievers. You should tell your treating clinician that you are participating in this study and receiving extended-release buprenorphine. The provider can treat you with non-opioid pain relief or higher doses of opioid pain medications for your condition. As a result, you may experience higher level of pain.

The extended-release buprenorphine injection (XR-B) involves possible irritation (e.g., redness, swelling, possible scarring) or infection of the skin at the injection site in your belly. In preliminary studies of a group of 848 individuals receiving extended-release buprenorphine injections, adverse events related to the injection led to stopping the injections in 4% of individuals (~34 people).

If you are in the XR-NTX Group:

While you are being treated with a monthly naltrexone injection, if you take small amounts of heroin, or other opioids, you should feel no opioid-like effects. However, if you take very large amounts of heroin or other opioid drugs, this could overpower the naltrexone, and you could overdose and die. Naltrexone does not block the effects of other drugs such as cocaine, methamphetamine, tranquilizers, or alcohol, and it does not reduce the risks in using these substances.

If you use opioids after missing one of the monthly naltrexone injections, your body may again become dependent. At that point, taking naltrexone could cause severe withdrawal, and it may not be possible to restart the naltrexone without having you detoxify from opioids. This means that amounts of heroin or other opioids that you used to take routinely could cause you to overdose, stop breathing and die. This is why it is recommended you continue in drug treatment during and after naltrexone treatment.

All medications can have side effects. Side effects from naltrexone can include trouble sleeping, anxiety, abdominal pain/cramps, nausea and/or vomiting, low energy, joint muscle pain, headaches, or symptoms of depression. It is important to note that these symptoms may represent persisting withdrawal symptoms, and the study provider who is monitoring you can prescribe medications to reduce the discomfort. The study provider will monitor your mood. If you develop significant depressive symptoms, you may be offered treatment options including antidepressant medication. Some people taking

naltrexone may experience liver irritation. If you notice your eyes turning yellow or your urine darkening, you should tell your study provider. In addition, administration of naltrexone may increase blood sugar levels, which may produce symptoms such as dizziness, increased breathing, dehydration, sedation, and localized seizures. If you experience any of these symptoms, it is important that you tell the research staff and study provider immediately. Also, if you require opioids for any medical treatment once you are on extended release naltrexone, you will likely not have adequate pain relief from usual doses of pain killers called opioids. You should then tell the treating clinician that you are participating in this study and will need non-opioid pain relief or higher doses of opioid pain medications for your condition, which you should receive only in a monitored medical setting, such as an emergency room. As a result, you may experience higher level of pain.

It is very important that you tell the study provider about any other medications you are taking or plan to take (either prescription or non-prescription including over-the-counter medications or supplements) before beginning naltrexone. There are a number of medications (either prescription or over the counter) that may interact with naltrexone such as certain antidepressants, medications for mood disorders, aspirin, and Tylenol (acetaminophen).

The extended-release naltrexone injection involves possible irritation (e.g., redness, swelling, possible scarring) or infection of the skin at the injection site. In preliminary studies of injectable naltrexone, 40 out of approximately 330 injections resulted in injection-site reactions, which have ranged from a small, painless area of hardness to pain or itching, redness, and swelling. These reactions typically improved on their own over a period of 1-3 weeks. In three cases, the swelling caused an open sore to develop, and it became infected, requiring a minor surgical procedure, antibiotic treatment and wound care. The wound healed completely over a period of approximately 3 months, resulting in a small scar on the buttock. Furthermore, it is possible that XR-NTX may involve risks to you that are not currently known.

Other Study Visit Risks/Discomforts:
There is a small chance that participants may become upset when discussing their personal history of addiction problems, criminal justice involvement, family conflict, prior trauma, or other personal issues. We will stop asking questions if you are troubled by the questions or ask to stop the interview.

6. Can I be in the study if I am pregnant or breastfeeding?

Buprenorphine and naltrexone treatment may pose risk to a fetus. You will have a pregnancy test before beginning treatment, before beginning medication and monthly thereafter to determine that you are not pregnant. The pregnancy test will be a urine dipstick test. The test is dipped in your urine sample for 10 seconds and a result is produced in 4 minutes with an accuracy of about 99%. You will be asked to use adequate birth control such as abstinence, diaphragm, condom, intrauterine device, tubal ligation (tubes tied), male partner sterilization or hormonal contraceptives throughout your treatment. If you suspect that you might be pregnant, you must inform your study physician or the research staff immediately.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will tell you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

Participating in this study, you will be taking medication that, in both groups, is known to be an effective treatment for opioid dependence. You may have a better chance of avoiding relapse to opioid abuse or dependence while on this medication than a person not taking any medication. However, entering this study does not guarantee that you will not relapse. For participants that enroll in the enhanced treatment as usual group, you may find the treatment and overdose prevention information and referrals provided helpful.

It is our hope that the knowledge gained in this study will be of benefit to others in the future, but since this research study is designed to select by chance which treatment you will receive, that treatment may not be of benefit to you. Therefore, there may be no direct benefit from agreeing to participate in this study.

9. What other choices do I have if I do not participate?

You do not have to participate in this study. If you do not participate, you are able to receive other treatments available in your jail or prison or community after release. If you decide not to be in the study, the study team will refer you to other treatment in the community.

10. Will I be paid for being in this study?

This study is sponsored by a grant from the National Institute of Drug Abuse (NIDA). Extended-Release buprenorphine (Sublocade) and Extended-Release Naltrexone (Vivitrol) are provided by the study free of charge to all participating research subjects assigned to the XR-B or XR-NTX groups.

All study-related costs associated with your being in this study will be paid through the study. However, you, the Department of Corrections (during jail incarceration), or your insurance company (after jail release) will be charged or held responsible for the costs of your routine care (the care you would have received if you were not in this study).

Payment for Participation

You will receive compensation for your participation in this study after release from prison/jail for your initial visits and thereafter once you are in the community. You will receive $50 for the first study screening visit while incarcerated and $50 if you are randomized into the study, both to be given out at your first post-release follow-up visit at Bellevue Hospital. You will receive $50 for each of the first 7 follow-up visits, and $70 for your final study visit, all at Bellevue Hospital. If you are enrolled and randomized in the community, you will receive $50 for the initial screening visit, $50 if you are randomized into the study, $50 for each of the first 7 follow-up visits, and $70 for your final study visit, all at Bellevue Hospital.

You will also have the opportunity to earn a $50 referral bonus for each eligible participant referred and successfully randomized/enrolled into this study. The maximum number of referral bonuses earned will be 6($300 max total). You must provide the person you are referring our primary research cell number and they must reach out first to our study team. Only after they are randomized/enrolled into study will you receive referral compensation via ClinCard.

Portions of the research team's salaries are being paid by this NIDA federal grant.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check, Clincard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number. If you do not have either of these numbers or are not willing to provide them, you may be in the study but will not receive any payment.

11. Will I have to pay for anything?

Any additional medical or other drug and alcohol treatment outside of the study would be considered regular, non-study care. You or your insurance carrier will be charged or held responsible for the costs of such care. You will not be responsible for the cost of your research visits.

Outside of the jails, medication-assisted opioid treatment is available free of charge to uninsured patients at Bellevue Hospital Center, and is covered under most health insurance plans including Medicaid. XRNTX is available with insurance or out-of-pocket in the community. XR-B is currently covered under NYS Medicaid plans, usually requiring a prior authorization.

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the study before it ends?

Your personal participation in the study will last approximately one year. This study is expected to end after all participants have completed all visits, and all information has been collected. This study may

also be stopped or your participation ended at any time by your physician or the study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. If you do decide to withdraw your consent, we ask that you contact Dr. Joshua Lee and let him know that you are withdrawing from the study. His mailing address is 180 Madison Avenue, Room 1714, New York, NY 10016. If you wish to withdraw your Authorization as well you must contact Dr. Lee in writing.

Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.

The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study and may be asked to return for a final check-up.

14. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI,” and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality

To help protect your privacy, the researchers will obtain a Certificate of Confidentiality from the National Institutes of Health. With this certificate, the researchers cannot be forced to disclose the information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and 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 and your involvement in the research. If an insurer, employer or other person obtains your written consent to receive research information, then the researcher may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant of the research project under the following circumstances: the present danger of child abuse, suicide, and/or homicide.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?

All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries as well as NYS Prescription Monitoring Data (I-STOP/PMP Registry Data), HIV-related information (which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV), and HCV related information.

Data will be also be stored at the University of Chicago, which has been funded to manage the data collected by this and similar studies. To protect your confidentiality, information that could be used to directly identify you (e.g., your name, address, date of birth, social security or medical record number) will be stored separately from your other data and will not be shared with anyone other than the local

researchers conducting this study. The National Institutes of Health require that the data collected in this study are shared with other researchers so that the data may have the greatest scientific value. For that reason, the University of Chicago will make data (without direct identifiers) available to researchers at other institutions, who agree to use those data for scientific research only (data will not be shared for commercial or other purposes). Your data will be used for statistical analyses, monitoring and safety, and results will be reported on groups of people only—never on individuals. All reasonable efforts will be made to prevent an individual study participant from being identified.

Who may use and share information in connection with this study?

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institute of Drug Abuse (NIDA)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research (New York State and New Jersey Department of Corrections and NYC-area correctional facilities and Bellevue Hospital Center, as well as Yale, Dartmouth, OHSU-UCLA; Rutgers; and Friends Research Institute)
- Health+Hospitals Corporation personnel responsible for the support or oversight of the study at Bellevue Hospital

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?

Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries

for future research conducted by NYULMC or its research partners. _____ Subject Initials

17. Optional permission to be contacted for future research

I authorize the principal investigator and his or her co-investigators to contact me about future research on alcohol and/or drug-use within the NYUSM's Department of Population Health provided that this future research is approved by the original IRB of record and that the principal investigator and coinvestigators are affiliated with the research protocol. If I agree, then someone from Dr. Lee's research staff might contact me in the future and he or she will tell me about the new research that is being done. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

☐ I agree to be contacted by the Principal Investigator or Co-Investigators of the research study titled: (Long-acting buprenorphine vs. naltrexone opioid treatments in CJS-involved adults).

☐ I **do not** want to be contacted by the Principal Investigator or Co-Investigator of the research study titled: (Long-acting buprenorphine vs. naltrexone opioid treatments in CJS-involved adults).

_____

Signature of participant Date

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care at any of the NYUSOM facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you must join in any study.

18. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

19. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date