Document Coversheet

Study Title: Integrated Outpatient Treatment of Opioid Use Disorder and Severe Injection Related Infections

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	7/11/2024
NCT Number:	NCT04677114
IRB Number	60903
Coversheet created:	5/7/2025

IRB Approval
7/11/2024
IRB # 60903
IRB3

KEY INFORMATION FOR B-OPAT: BUPRENORPHINE PLUS OUTPATIENT PARENTERAL ANTIBIOTIC THERAPY STUDY

We are asking you to choose whether or not to volunteer for a research study about combining treatment for opioid use disorder (OUD) with treatment for severe infections from injection drug use. We are asking you because you are currently hospitalized at the University of Kentucky, have a severe infection (like endocarditis – infection in the heart, osteomyelitis – infection in the bone, septic arthritis – infection of the joint(s), or bacteremia – infection in the blood), and may have OUD and be eligible for treatment with buprenorphine (e.g. Suboxone® or generics, Sublocade®). This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Many patients with medical problems similar to yours, such as endocarditis (or the other infections above) and OUD, stay in the hospital to finish intravenous (IV) antibiotic therapy, which may be six weeks or longer. Patients with these infections, but who do not have OUD, often get to leave the hospital earlier to finish their IV antibiotics at home through a catheter that stays in the arm for several weeks (called a PICC). The purpose of the study is to see if it is just as safe or better to finish antibiotics at home OR to finish them in the hospital if treatment for the opioid use disorder and the infection both start in the hospital. Everyone in the study will receive standard clinical treatment for OUD with buprenorphine and counseling AND standard IV antibiotics to treat their infections, but half of the patients will finish their IV antibiotics at home and other half will finish them in the hospital. Everyone continues to receive standard OUD treatment when they leave the hospital. It will be up to chance (like flipping a coin) whether you finish your antibiotics at home or at the hospital. Your study participation starts when you are in the hospital and continues for 6 months after discharge. Some patients may be in the hospital for ~2 weeks but others may be hospitalized for longer so the total time in the study will vary – the total time is the time in the hospital PLUS 6 more months after you leave the hospital.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer for this study if you think you would be interested in receiving treatment for opioid use disorder with buprenorphine and also completing antibiotic treatment for your infection at home through a PICC. If you qualify to participate in this study and decide to volunteer, whether you are able to complete antibiotics at home will be decided by chance as part of the study process. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might choose not to participate in the study if you do not want treatment for OUD with buprenorphine, or if you live more than 1 hour drive from Lexington, KY because you will need to come to frequent appointments as part of being in the study. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

If you do not choose to participate in this study, you can still receive treatment for OUD with buprenorphine. For a complete description of alternate treatment/procedures, see the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Laura Fanucchi, MD of the University of Kentucky, Department of Medicine at 859-323-1982 or laura.fanucchi@uky.edu

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You should not take participate in this study if you are younger than 18 years old, currently a prisoner, currently pregnant, or if you live more than a 60-minute drive from Lexington, KY because you will need to come to frequent appointments as part of participating in this study. If you have never used opioids, you should not participate. You should not participate if you do not want opioid use disorder treatment with buprenorphine or if you would not want to complete IV antibiotic treatment at home with a PICC.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at UK Medical Center while you are still hospitalized and the UK Center on Drug and Alcohol Research (CDAR) after you are discharged. The first research visit in the hospital will likely take 2 hours, and subsequent weekly research visits in the hospital will likely take 30 minutes until you are discharged. After leaving the hospital, you will need to come to CDAR at 845 Angliana Avenue weekly for research study visits. You will need to come 12 times during the study. Each of those visits will take about 1 hour. After these 12 weeks, you will then come to CDAR once monthly for 3 months for research follow up, and these visits will take about 1 hour. If you are also receiving treatment for opioid use disorder at the UK First Bridge Clinic (also located at 845 Angliana Ave), some of your research visits can be scheduled on one of your clinic appointment days. This will happen if, by chance, you are in the group of study volunteers that is discharged to complete IV antibiotics at home, or if you are referred by your primary clinical team in the hospital. The total amount of time you will be asked to volunteer for this study is approximately 20 hours over the next 7-8 months, depending on the duration of your hospital stay. See the Appendix for detailed table of the study timeline.

WHAT WILL YOU BE ASKED TO DO?

If you volunteer to participate in the study, you will be assigned by chance to one of two groups. You have a 50/50 chance of being assigned to each group. Both groups receive the same medical treatment for OUD in the hospital and complete the same research assessments. The main differences between the two groups are that one group (called B-OPAT) will be discharged from the hospital about 2-3 weeks earlier than the other group because they will complete IV antibiotic therapy at home through a peripherally inserted central catheter (PICC) line. A PICC line is a long catheter that goes into a deep vein in your upper arm and can stay in place for several weeks. It is covered by a sterile dressing that must be kept clean and changed weekly by a nurse or similar medical personnel. The B-OPAT group will receive ongoing treatment for OUD at the UK First Bridge Clinic in Lexington, KY after discharge. If you are assigned by chance to the second group (called Treatment As Usual (TAU)), your primary team in the hospital will determine where your antibiotic treatment will be completed. It is likely that if you are in the TAU group, you will be asked to stay in the hospital to complete IV antibiotic therapy. You will also be offered ongoing treatment for OUD after discharge, which may occur at the UK First Bridge Clinic if you choose. Both groups will complete six months of research follow-up after discharge from the hospital.

Your participation in the study starts right after the informed consent process and involves both medical treatment for OUD and research assessments. The medical treatment for OUD will include buprenorphine therapy. This is standard medical treatment for OUD and not an experimental treatment. You will be started on buprenorphine as soon as it is safe to do so. The research team will work closely with the clinical team taking care of you in the hospital to determine the best time to start buprenorphine. If you have already been started on buprenorphine by your inpatient team at the time of informed consent, you can still participate in the study. If, by chance, you are assigned to the B-OPAT group, the outpatient IV antibiotic therapy will be arranged by the team taking care of you in the hospital as a critical part of your care. The research team will work closely with the hospital team to make sure everything is set up for you to receive IV antibiotics at home.

The first research visit after informed consent is longer than the others and will probably take around two hours. During this first visit you will be asked to answer questions about your health, behavior and drug use. At every research visit you will also be asked to give a urine sample which will be tested for several types of legal and illegal drugs (like pain medications, heroin, methamphetamine). None of the results of any of these tests, including the urine drug test, will be given to or shared with anyone not on the research team. The results of the urine drug test will not affect your ability to continue to participate in the study. Additional research visits while you

are still in the hospital will happen once weekly and will probably take less than one hour. At these visits you will repeat several of the assessments done in the initial visit. A list of the research assessments is included in the Appendix.

After discharge from the hospital, weekly research visits continue for both groups, and take place at CDAR at 845 Angliana Ave., Lexington, KY. If you are in the B-OPAT group, you will be asked to come to CDAR 1-2 times weekly for standard opioid use disorder treatment where you will receive bup/nx prescriptions, counseling, and a urine drug test for a total of 12 weeks after hospital discharge. The weekly research assessment and urine sample can be done on the same day as one of your clinic treatment visits. If you are in the TAU group, you will also be asked to come to CDAR weekly for research visits and urine samples. If you cannot come to CDAR for research visits, we will complete as many assessments as possible over the phone or by HIPPA-compliant video call.

After the 12-week post-discharge period, both groups will be asked to come to CDAR once per month for 3 months for research assessments and to give a urine sample. Also, approximately 15 participants in each group will be asked if they are willing to participate in an additional interview about their experiences in the study. We will give you additional information about that interview if you are invited.

For subjects of childbearing potential only: If you become pregnant during the study, we will refer you to UKHealthCare PATHWAYS program, which provides prenatal opioid addiction treatment with buprenorphine, counseling, and support groups. You may continue to participate in the research assessments as part of this study. Please call Laura Fanucchi, MD at 859-323-1982 or 859-330-0194 (pager) if you become pregnant.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Risk of treatment group assignment: If by chance you are assigned to the B-OPAT group, you will receive between 1 – 4 weeks of IV antibiotic therapy as an outpatient with a peripherally-inserted central catheter (PICC). This is a standard method of providing long-term treatment of intravenous antibiotics in a home environment. The risks of receiving IV antibiotics at home include problems with the PICC such as infection and blood clots, as well as antibiotic-related problems, such as kidney damage, muscle damage, or allergic reaction, depending on the antibiotic you are receiving. If you are in the B-OPAT group, you will have home health set up to assist with PICC dressing changes, or we will change your dressing for you on a weekly basis during one of your clinic visits. You will also be seen in the infectious disease clinic for monitoring which is standard clinical care. If you are in the TAU group, you will likely also receive a PICC, as they are commonly utilized in the hospital setting to minimize the need for frequent needle sticks for blood draws or peripheral IV catheter placement. You will also be receiving antibiotics for treatment of your infection, and the risks of antibiotic-related problems are the same. There are serious risks if you inject any drugs into your PICC – these risks may include fatal overdose, reinfection with bacteria in your blood, bones or heart, and blockages of the PICC where it would need to be removed. We do not know if people are more or less likely to inject drugs into their PICC in either one of these groups. The buprenorphine treatment is provided in both groups because it has been shown to decrease craving, drug use and withdrawal; but it will be up to you to decide NOT to inject drugs into your PICC. If you want to inject drugs into your PICC, you should not participate in this study.

Risk of treatment for opioid use disorder with buprenorphine: Buprenorphine is an opioid and is an FDA-approved medication for treatment of opioid use disorder, and is not an experimental treatment. Many previous studies show that treatment of opioid use disorder with buprenorphine is effective to help people enter remission and recovery from opioid use disorder and reduces the risk of overdose death. There are some risks of buprenorphine treatment that are listed in the Appendix.

Risk of behavioral assessments: During the screening process and during research assessments, it is possible that you may feel uncomfortable answering personal questions about your health, psychiatric and drug use history. You may stop answering questions at any point.

Risk of loss of confidentiality: There is the risk that others may see your Protected Health Information (PHI). The following PHI will be collected as part of this project: names (individual, employer, relatives, etc.), address, telephone number, dates (birth, admission, discharge), medical record numbers, psychiatric and physical health history, drug use history, results from psychiatric and physical health assessments, and data from experimental

measures. We will make every effort to keep private all research records that identify you to the extent allowed by law. However, there is a very small risk that a breach in confidentiality may occur (<1/1000). If this occurs, it may cause problems such as embarrassment and emotional stress.

There is always a chance that any medical treatment can harm you. The research procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, volunteers in clinical trials involving buprenorphine have benefited from receiving the medication because those studies demonstrated decreased drug use and reduced risk of overdose death. If by chance you are assigned to the B-OPAT group, you may also benefit from being able to leave the hospital earlier than you otherwise would have if you were not participating in the study. Your willingness to take part, however, may help doctors better understand and/or treat others who have your condition.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, the alternative is to continue receiving treatment for opioid use disorder and for the infection while you are in the hospital, and you will be provided follow-up options after discharge.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have, like OUD and the infection, including antibiotics. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

Buprenorphine treatment is standard clinical care for OUD that Medicaid, Medicare and commercial insurances cover. If Medicaid is your insurer, you will not have any copays. However, if you have another insurance, you may have deductibles and copays. If you have no insurance, you will be billed for medical care that you receive.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. Therefore, these costs will be paid by the sponsor, National Institute on Drug Abuse (NIDA). There are no additional costs to you to participate in the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. All documentation that contains protected health information (PHI) is kept apart from research data. Files will not contain your name or identifying information. You will be assigned a unique identifying number if you decide to participate in this study. Some data will be collected using an application called REDCap, which stores data on a secure web server located behind a firewall on UK's network. All other electronic files will be stored on the HIPAA-compliant Center on Drug and Alcohol Research (CDAR) server that is located in the data center of the UK hospital and is behind the firewall. Access to the CDAR server and to the REDCap application is password protected and only assigned staff are granted access. Any laptops used for data collection will be encrypted. The specific files are also password-protected. All personal identifiers are encrypted when the data are uploaded.

All written documents, will be stored in locked cabinets at the Center on Drug and Alcohol Research at 845 Angliana Avenue. Paper documents that contain PHI will be stored separately from research data. Offices are locked and building entry is protected by badge access. Key access will be limited to study personnel.

You should know that in some cases we may have to show your information to other people.

For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else.

To ensure the study is conducted properly, officials of the Food and Drug Administration, the National Institutes of Health, and of the University of Kentucky may look at or copy pertinent portions of records that identify you.

Certificates of Confidentiality (CoC):

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or intent to kill yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. Stopping buprenorphine treatment of opioid use disorder abruptly is not recommended as opioid withdrawal is likely, and the risk of overdose is higher without medication. If you decide to leave the study early, we will work with you to help you continue buprenorphine treatment or other substance use disorder and medical treatment if you desire

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may possibly take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

Though it is unlikely to occur, if you believe you are hurt or if you get sick because of something that is due to the study, you should call Laura Fanucchi, MD at 859-323-1982 or 859-330-0194 (pager) immediately; or Michelle Lofwall, MD at 859-323-6774 or 859-330-1908 (pager). Dr. Fanucchi or Lofwall will determine what type of treatment, if any, that is best for you at that time.

If you are still in the hospital and have a concern about your health not related to the study, please press your call button. If you are out of the hospital and having a life-threatening emergency, please call 911.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

If you get hurt or sick while you are participating in the study, but from a reason not related to the study (e.g. you need additional medical treatment related to OUD or your infection), these costs will be covered by your insurance company, Medicare, or Medicaid. You will be responsible for these costs if you do not have insurance.

Though we do not anticipate that you will get hurt or sick from a reason related to the study (e.g. emotional distress related to answering personal questions about your substance use), medical costs related to your care because of study-related harm will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive payments for research visits that start while you are in hospital and continue for 6 months after you leave the hospital. These research visits are not clinical care visits. The first research visit is the initial assessment for the study and happens in the hospital. You are paid $50 for this and this first payment will be in cash. After discharge for the first three months, you will receive $25 for each short outpatient research assessment visit (weeks 1-3 of each outpatient month 1-3), and $50 for each longer monthly outpatient research assessment visit (weeks 4, 8, and 12). You then receive $50 for each follow-up visit (months 4, 5, and 6), and $250 as a bonus if all research visits are completed. These are paid as checks at the time of assessment completion. If your assessment visit is not completed in person, we will mail you a check. The total amount you could receive for taking part in this study is $850, which includes the $25 you already received for completing the screening assessment. Assistance with transportation expenses to attend visits related to study participation may be provided.

With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will not provide you with individual research results.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to two times per year.

Do you give your permission to be contacted in the future by Dr. Laura Fanucchi or a member of the research team regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials** _____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 120 people to do so.

The National Institute on Drug Abuse is providing financial support for this study.

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

If you become incarcerated after enrolling in the study, we will attempt to collect study measures by phone, video-call, or in-person visits to the jail, prison, or home incarceration setting if possible. We will make every effort to continue to pay you for research assessments as outlined above. If we are not able to, we will attempt to pay you for any visits completed while you are incarcerated upon your release. Your participation in the study will not impact parole determinations.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent, Once you give your permission to have your de-identified information stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information, results of physical exams, blood tests, X-rays, and other diagnostic and medical procedures related to the study, as well as medical history, Medicare Health Insurance Claim Numbers (HICN), and Social Security Numbers (SSN).

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK Hospital
- National Institutes of Health
- Food and Drug Administration
- Center for Clinical and Translational Science (CCTS)
- Collaborating researchers at Weill Cornell Medical College
- Your primary physician will be contacted if the researcher, in the course of the project, learns of a medical condition that needs immediate attention.

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Laura Fanucchi, MD, 845 Angliana Ave., Lexington, KY 40508 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

Appendix: Study Visits and Assessments

Assessment	What is it for?
Addiction Severity Index (ASI) – Lite	Asks about drug and alcohol use, medical and psychiatric history, employment, and legal history.
Mini Neuropsychiatric Interview (MINI) v 5.0	Asks about mental health and substance use.
PROPr	Asks about health-related quality of life.
Brief Pain Inventory (BPI)	Asks about pain.
Clinical Opiate Withdrawal Scale (COWS) and Subjective Opiate Withdrawal Scale (SOWS)	Asks about withdrawal symptoms.
Visual Analogue Scale	Asks you to rate current cravings and withdrawal.
Timeline Follow Back (TLFB)	Helps us understand recent details of drug use, as well as recent healthcare visits, and interactions with the legal system.
Locator form	Provides several methods for us to be able to reach you.

	Timeline of what you will be asked to do						
	Enrollment	Inpatient		After Discharge			Follow Up
		Initial	Weekly	Weeks 1-4	Weeks 5-8	Weeks 9-12	Month 4-6
B-OPAT							
Research Assessment Visits	Screening Consent (1 hr)	1x (2 hrs)	1x per week (30 mins)	1x per week (Wks 1-3, 5-7, 9-11: 30 mins) (Wks 4, 8, 12: 1 hr)			1x per month (1 hr)
OUD Treatment		Yes		Clinic visits 2x weekly		1x per week	
Infection Treatment	Per your inpatient team			Outpatient with PICC			
TAU							
Research Assessments	Screening Consent (1 hr)	1x (2 hrs)	1x per week (30 mins)	1x per week (Wks 1-3, 5-7, 9-11: 30 mins) (Wks 4, 8, 12: 1 hr)			1x per month
OUD Treatment		Yes		Treatment arranged by inpatient team			
Infection Treatment	Determined by your inpatient team						

Appendix: Risks

Buprenorphine: Buprenorphine is an opioid and is an FDA-approved medication for treatment of opioid use disorder.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Opioid withdrawal – anxiety, runny nose or eyes, goosebumps, sweating, abdominal pain	It may occur if bup/nx is given too soon after a another opioid like heroin, or oxycodone is taken.	Uncomfortable but not dangerous	It can be treated with supportive medications and will stop on its own with time.
Headache, constipation, difficulty sleeping	It occasionally occurs	Uncomfortable, but not dangerous	Your dose may need to be adjusted
Sleepiness, euphoria	It occasionally occurs	Can be dangerous with over-sedation and in combination with other drugs like benzodiazepines	Your dose will be reduced. You will be advised to avoid driving or operating heavy machinery if you feel sedated.
Slow breathing rate, low blood pressure, heart problems	It is uncommon, but a risk when bup/nx is combined with other sedating drugs like benzodiazepines and alcohol	Can be very serious or even fatal.	It is extremely unlikely with bup/nx alone.
Liver injury	Very uncommon	Usually mild	Bup/nx may need to be stopped, but this is unlikely
Allergic reaction	Extremely uncommon	Mild to very severe and possibly fatal	Most allergic reactions are safely treated with medications and stopping the drug.

You may experience opioid withdrawal if you stop taking buprenorphine. To make sure this doesn't happen, the doctor may ask you to gradually reduce the amount of medication you are taking, if you want to stop taking the medicine.

The Food and Drug Administration has recently written that all opioids (this would include buprenorphine) may have additional risks and interactions with other medications. For instance, opioids can interact with certain medicines that increase the effects of serotonin, a chemical in the brain. These medications include antidepressants and migraine medicines, and the interaction causes a serious central nervous system reaction called serotonin syndrome. Symptoms of serotonin syndrome include: agitation; hallucinations; rapid heart rate; fever; excessive sweating; shivering or shaking; muscle twitching or stiffness; trouble with coordination; and/or severe nausea, vomiting, or diarrhea. If you develop these symptoms you should seek medical attention. Taking opioids may also lead to a rare, but serious condition called adrenal insufficiency in which the adrenal glands do not produce adequate amounts of the steroid hormone, cortisol, particularly during stressful conditions. You should seek medical attention if you experience symptoms of adrenal insufficiency such as nausea, vomiting, loss of appetite, fatigue, weakness, dizziness, or low blood pressure.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendices: Study Visits and Assessments; Risks**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject**	_____ **Date**
_____ **Printed name of research subject**	
_____ Printed name of [authorized] person obtaining informed consent and HIPAA authorization	_____ Date