Document Coversheet

Study Title: Behavioral Effects of Drugs Inpatient 44 Neurobehavioral Mechanisms of Opioid Choice

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Consent and Authorization to Participate in a Research Study

KEY INFORMATION FOR BEHAVIORAL EFFECTS OF DRUGS: INPATIENT (44)

We are asking you to choose whether or not to volunteer for a research study about the behavioral, neural and physiological effects of opioids. 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?

This experiment is studying the choice to take intravenous remifentanil during magnetic resonance imaging (MRI). Remifentanil is an FDA-approved opioid used for anesthesia that is in the same family as fentanyl but is much shorter acting. By doing this study, we hope to learn about how different interventions influence brain activity when making opioid use decisions. Your participation in this research will consist of two outpatient sessions (about 4-6 hours total) and a 17-day inpatient stay.

During two initial outpatient visits to one of our laboratories, you will be asked to complete a series of tasks, which will take about 4-6 total hours across the two outpatient visits. During these sessions, you will also be acclimated to the MRI scanner. If you are comfortable in the MRI scanner, you will be invited to complete an inpatient study lasting approximately 17 days that will include 6 experimental sessions inside the MRI scanner and 1 session outside of the scanner (i.e., 7 inpatient sessions). Because you are physically dependent on opioids, you will receive oral capsules up to six times per day to prevent withdrawal during your inpatient admission. These capsules will contain an opioid such as hydromorphone, oxycodone, morphine or hydrocodone, though sometimes they could also contain placebo (a blank, no drug). The length of your inpatient stay could vary to avoid testing on the weekends.

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

You are not a patient receiving medical treatment and will not receive any direct benefits from this study. However, the knowledge gained will contribute to a better understanding opioid use decisions. If you are seeking treatment, please notify one of the investigators now and they will make the necessary referral.

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

Risks of participating include 1) your protected health information (PHI) might be seen by unauthorized individuals, 2) embarrassment in disclosing sensitive personal information, 3) discomfort and/or dissatisfaction due to the study procedures, 4) side effects of MRI, 5) side effects of the opioid drugs and withdrawal from placebo maintenance doses, and 6) side effects of needle insertion. For a complete description of risks, refer to 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?

The investigators in charge of this study are Joshua Lile, Ph.D. and Michael Wesley, Ph.D. of the University of Kentucky, Department of Behavioral Science. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study their contact information is: 859-323-6034 (Dr. Lile) and 859-323-1332 (Dr. Wesley).

If you have any questions, suggestions or concerns 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 participate if you have a history of, or current, serious physical disease (e.g., respiratory disease [asthma, COPD, sleep apnea], impaired cardiovascular functioning, seizure disorder or CNS tumors) or serious psychiatric disorder. You should also not participate if you are younger than 18 or older than 50, if you have contraindications for MRI scanning (e.g., pacemaker, metal implants, claustrophobia, or any other implanted medical device), or if you have uncorrected vision or hearing problems. Lastly, you should not participate if you are seeking treatment for your drug use, are currently in treatment for your drug use, or are currently in successful remission from your drug use.

If you are female, you should not participate if you are pregnant or plan on becoming pregnant during your participation in this experiment. You must be using an effective form of birth control (e.g. birth control pills, surgically sterilized, IUD, cervical cap with a spermicide, condoms or abstinence), and you must be willing to take pregnancy tests to ensure you are not pregnant during the study. Should one of these tests show that you are pregnant, your participation will be ended immediately. If you are female, you should not participate if you are lactating or breast feeding a baby.

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

The research procedures will be conducted at the University of Kentucky Clinical Research Unit (CRU) Psychopharmacology of Addiction Laboratory (PAL), Neurobehavioral Systems Laboratory (NSL) and the Magnetic Resonance Imaging and Spectroscopy Center (MRISC). You will need to come to one of our outpatient laboratories (PAL or NSL) for about 4 hours across two outpatient laboratory visits (qualification visits and scanner acclimation). If you are comfortable in the MRI scanner, you could be invited to complete an inpatient study lasting up to 17 days, during which time you will be asked to complete 1 sessions that will be conducted at the CRU and 6 sessions that will be conducted at the MRISC. Each of those sessions will last about 2-3 hours. Further study days might be scheduled if needed to avoid testing on the weekends. An example schedule is provided in Appendix A.

WHAT WILL YOU BE ASKED TO DO?

During two initial outpatient visits to one of our laboratories, each lasting about 2 hours, you will be asked to complete a series of tasks and will be acclimated to the MRI scanner. If you are comfortable in the scanner, you could be invited to participate an inpatient phase lasting up to 17 days.

If you participate in the inpatient study phase, on your admission day, you will arrive at the PAL or NSL at a scheduled time (e.g., 8:00 AM) and complete urine drug and breath alcohol screens and field sobriety test. In some cases, you could be observed by a same-sex staff member when you provide a urine sample, but you will be notified before this occurs. If you pass the urine and breath screening (note that testing positive for certain substances is permitted) and the field sobriety test, you will be escorted to the CRU, where you will be evaluated by a physician and admitted. During the time you participate, you must abstain from using any illicit substances, alcohol, and caffeine. Because you are physically dependent on opioids, upon admission, you will begin receiving oral doses of an opioid, approximately every 4 hours (six times per day) to help prevent withdrawal. You might need to be awakened while sleeping to take these doses.

Prior to the first session, you will have a midline catheter placed in a vein in your arm. A nurse from the UKHealthCare Vascular Access Team (VAT) will first insert a needle into your arm, which will be replaced by an intravenous (IV) catherter approximately 3-5 inches long. The midline catheter permits longer-term (up to 30 days) IV access. Your consent for study participation applies to the initial insertion of the midline catheter and any re-insertion deemed necessary by the study physicians and/or hospital policy. Removal of the IV midline catheter will occur upon completion of the last experimental session or when deemed necessary by the study physicians and/or hospital policy. In addition, a second IV access point will be needed for a single session, so a standard peripheral catheter will be placed prior to the session and removed immediately after. Please note that a standard peripheral catheter might also be used instead if any issues are encountered with the midline catheter. A standard peripheral catheter would remain in your arm for a shorter period of time (around 3 days) and might need to be replaced on a regular schedule according to hospital policy or if it comes out of your arm.

During your inpatient stay, you will complete one session in your hospital room and six sessions at the MRISC that involve MRI scanning. MRI is a method for recording brain structure and activity. It involves lying down on a padded platform that is loaded into the circular center of the MRI machine. For those sessions, you will be escorted to the MRISC and instructed to remove all jewelry and other metal-containing objects before entering the scanner. While in the scanner, you will be asked to lie still as images of your brain are acquired. During much of the time in the scanner (approximately 30-50 minutes), you will be performing a choice task. In three of the scanning sessions, both

choice options could reward you with money. In one of these scanning sessions, the choice task will include individualized drug images. Before participating in the MRI sessions, you will be asked to select 40 images from a database of pictures that best represents your preferred route of opioid use and associated paraphernalia, which will be used in the task. During three of the scanning sessions, you will be making a series of choices that could reward you with money or intravenous solution. This intravenous solution could contain the opioid remifentanil or placebo (a blank, no drug). You can earn additional money based on the decisions you make while completing the choice tasks. You will also complete a two-part session on one day that will not be conducted in the scanner. In the first part, you will complete a choice task with money as possible reward for the two options, and in the second part, you will have the opportunity to choose between two intravenous solutions that could contain placebo or remifentanil.

During admission to the inpatient unit, we will collect data concerning your physiological status, your mood and your performance on various laboratory tasks at regular intervals. That is, we will record your breathing rate, expired CO_2, pupil diameter, blood oxygen saturation, heart rate and blood pressure. We will also ask you to answer various questionnaires about your mood and drug effects, and any opioid withdrawal signs and/or symptoms you might be experiencing. You must agree to complete these assessments and tasks to the best of your ability and at the scheduled times.

The capsules you will receive will contain hydromorphone, oxycodone, morphine, hydrocodone or placebo (a blank, no drug). The IV solutions you will receive will contain remifentanil or placebo. The drugs and doses to be administered are approved by the Food and Drug Administration (FDA), though not for this experimental purpose. You will take all doses under supervision of the nursing staff at the CRU.

You must agree to follow the general rules of the CRU and share in the routine responsibilities of keeping the unit and yourself neat, clean and orderly. You will be provided a detailed list of the CRU rules before being admitted as an inpatient. You should understand that during the time that you spend on the CRU that you will not be allowed to leave the unit unsupervised, nor will you be allowed to have visitors. You will be allowed to use your mobile device (e.g., phone, tablet), except during study activities.

Since the CRU is in a UK HealthCare (UKHC) controlled location, its policies on contraband and weapons also apply. Certain tobacco products and flame or ignition sources not stored in permitted locations, deadly weapons, forbidden drugs or equipment used to produce, conceal, or consume them, other illegal items or substances, and alcohol for consumption by mouth (Restricted Items), are not allowed in the CRU. By signing this consent, you agree that (a) the researchers and others associated with the study may notify people within UKHC, the UK Police Department, and others should any of the Restricted Items be suspected or found and they may share the information associated with those items with those others, and (b) your possible involvement with discovered illegal Restricted Items may be used any action, suit, or proceeding, or be used as evidence, and you may be removed from UK property.

There will be urine checks, breathalyzers and room searches on a random schedule for evidence of unauthorized drug or alcohol use. If a urine screen or breathalyzer shows that you used other drugs or alcohol, or you have them in your possession, you will be dropped from the study, and will lose a substantial portion of the money you might have earned.

During your inpatient enrollment, you will not be permitted to drink caffeinated beverages, but decaffeinated coffee and soft drinks will be made available to you. You will not be allowed to smoke or use other tobacco/nicotine products during the experimental sessions, which will last between 2-4 hours. Use of these products is permitted during non-session times when staff are available to escort you to the designated smoking area.

When you are not participating in experimental sessions, we will provide you with recreational activities (television, reading material, music, arts and crafts, video games or board games). For your enjoyment, you will be allowed to use certain items that we purchase. These items may include, but are not limited to, portable radios, video movies and games, puzzles, games, books, and magazines. If you use any of these materials, and ruin them or do not return them, the price of the item will be deducted from your payment. When you come to the inpatient unit, you should not bring any valuable items with you.

You will be discharged from the CRU on the day following your last experimental session. On the day of, and the day prior to, discharge, you will receive doses of Suboxone, which will help relieve opioid withdrawal after you leave the hospital. If you want to try to stop using illicit opioids while on the Suboxone, we will help you to identify a treatment program. You must have some withdrawal signs before you get the first dose so that it does not produce side effects. You have the option of refusing Suboxone induction and will be asked to sign a form acknowledging the risks associated with this refusal. You will also be given a Narcan® overdose rescue kit when you are discharged.

After you are discharged from the study, you will come in weekly to receive remaining payments in increments of up to $500. At that time, you will also complete a basic follow up in which we will ask you about your drug use, conduct physiological assessments and test your urine for the presence of drugs.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is a risk that personal information that identifies you might be viewed by unauthorized people. However, 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. The measures taken to protect your confidentiality are described below.

There is a risk that you might experience embarrassment from disclosing sensitive personal information. You may refuse to answer any questions that we ask, though refusal to answer certain questions might impact your ability to continue in the study.

You might experience discomfort or dissatisfaction due to study procedures. If you experience discomfort or dissatisfaction, you may discuss this with the study staff or investigators and may decide to discontinue your participation in this study. If you decide to withdraw from the study early, however, you will not receive any of the completion allowance described below.

While in the MRI scanner you may become too hot or too cold, in which case you may ask for an adjustment of room temperature or a blanket. Some people may become nervous or feel claustrophobic while in the scanner. A small number of people experience a sense of dizziness or vertigo while in the scanner due to the magnetic field. Although rare, you could experience nerve tingling or twitching. If any of these issues occur and disturb you, you may ask to be withdrawn and you will be withdrawn immediately. More information is provided below in Appendix B.

Opioid agonists produce side effects that include nausea, vomiting, headache, dry mouth, itchiness, drowsiness, sweating, dizziness, stimulation, sleepiness, lightheadedness, restlessness, a feeling of well-being, talkativeness, difficulty urinating, constipation and non-clinically-significant respiratory depression. It is likely that you will experience one or more of these less serious side effects. More serious side effects may include allergic reaction, skeletal muscle rigidity and clinically significant respiratory depression. It is unlikely that you will experience these more serious side effects. The clinical staff providing medical oversight for this study is prepared to intervene if these more serious side effects occur. More information is provided below in Appendix C.

During your participation, you might experience some opioid withdrawal. These symptoms include nausea, vomiting, teary eyes, runny nose, loose stool, stomach cramps, shakiness, anxiety/irritability, increased heart rate, sweating/chills, restlessness, and body aces/discomfort. If you are experiencing signs or symptoms of opioid withdrawal, during non-session times, certain over-the-counter medications will be made available to you to manage diarrhea, constipation, nausea and pain.

You will need to have midline or peripheral IV catheter inserted into your arm. These procedures are associated with a risk of bruising, blood clotting, soreness, infection, bleeding, pain and irritation from the insertion of a needle or catheter. These risks are minimal since standard sterile procedures will be used. There is also a risk of feeling light headed or fainting. The likelihood of this happening is uncertain and will vary across subjects.

There is always a chance that any medical treatment can harm you. The research treatments/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?

You are not a patient receiving medical treatment and will not receive any direct benefits from this study. However, the knowledge gained will contribute to a better understanding of the effects of opioid drugs and consequences of their long-term use. If you are seeking treatment, please notify one of the investigators now and they will make the necessary referral.

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

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

Participating in this research study will not cost you anything, except for costs associated with traveling to and from the research facility.

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. Your name, address and social security number will be listed on the receipt for payment that you receive, as required by the Internal Revenue Service; but no information about your participation in this research project will be released. You cannot participate in this research if you withhold your social security number.

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. We will store all paper records containing information that identifies you in

a locked storage area accessible only to study personnel, and all electronic records will be stored on password-protected devices (e.g., computer).

You should know however, that there are some circumstances in which we might have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused, if you pose a danger to yourself or someone else, or if you have certain communicable diseases. In addition, officials of the University of Kentucky, the National Institutes of Health or the FDA may look at or copy pertinent portions of records that identify you. We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

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 harm to 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. By signing this consent you agree that your healthcare providers and associated staff affiliated, contracted with, or with access to records of the University of Kentucky (UK) may see your information from research studies and consider and use that information in the course of medical care and related activities.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can discontinue your participation in this study at any time. You will not be treated differently if you decide to stop taking part in the study. If you decide to leave the study early, however, you will not receive any of the completion allowance described below. Please note that if you agree to complete the optional intravenous dosing session during screening and this session is scheduled, and then you decide to leave the study after the second MRI scanning session but before the intravenous dosing session, then you will not receive any of the completion allowance described below.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if: 1) failure to adhere to the rules of the research facilities, 2) if you verbally or physically assault another volunteer, patient or staff member, 3) if your behavior is disruptive to other ongoing studies, 4) if your behavior is disruptive to the other volunteers, patients, research staff or medical staff, 5) failure to comply with the alcohol, drug, and food restrictions, 6) failure to comply with the pregnancy restrictions, 7) failure to complete a scheduled session, 8) failure to perform the tasks and procedures to the best of your ability, 9) if you leave the study against the advice of the principal investigator or the medical doctors. If you are discharged from the study for any of these reasons, you will not receive the completion allowance described below.

The medical doctors on this project can terminate your participation if they do not feel that it is medically safe for you to continue. In addition, the federal agency paying for the study might choose to stop the study early for a number of scientific reasons. If your participation is terminated for medical reasons or because the study is stopped, you will receive the completion allowance for each of the sessions you completed.

Abrupt discontinuation of the daily medication doses could lead to the emergence of opioid withdrawal. If your participation is discontinued early, you will be asked to stay in the hospital long enough to receive the Suboxone doses and will receive a Narcan® kit upon discharge.

Data collected up to the point of discontinuation will remain in the study database.

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

You may not take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You may not take part in another study while you are enrolled in this study.

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

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Lon Hays, M.D., M.B.A. at (859) 323-6021 x 79015 or Danielle Anderson, M.D. at (859) 562-2356 immediately. You

can also call 911 in the case of an emergency. Dr. Hays or Dr. Anderson will determine what type of treatment, if any, is best for you at that time. The medical costs related to your care and treatment because of research related harm will be your responsibility.

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.

Medical costs related to your care and treatment because of study-related harms will be your responsibility. A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

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 be paid for your participation in this experiment. You will earn $30 for completing each of the two outpatient sessions, and another $30 completion allowance for each of these sessions if you finish the entire study. You will also receive $60 for each day that you reside on the CRU. If you complete all of your scheduled experimental sessions, you will be paid a completion allowance of $60 for each of the days you resided at the CRU. For example, if you complete the study and stayed on the inpatient unit for 17 days, you would earn a minimum of $2160. You will also be able to earn additional money by completing the choice tasks.

If you make more than a total of $600 by participating in research projects, the University of Kentucky will report your earnings to the appropriate state and federal government agencies (i.e., Internal Revenue Service [IRS]). It is your responsibility to determine how these earnings might affect your personal financial situation. A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

Your earnings will be given to you in a series of separate payments. The first payment will be given to you on the day of your discharge. The remaining payments will be given to you once per week following your discharge. Due to University of Kentucky accounting policies, checks cannot be written for more than $500, so your payments will be given to you in amounts of up to $500 until you have received all of the money you are owed. When you come back for your payments, we will survey you about your drug use since we last saw you. You will also need to provide a breath sample negative for alcohol when you return for your payments. If you come to the PAL with a breath sample positive for alcohol, your payment will be withheld until you can provide a breath sample negative for alcohol. We will not pay you additional money (other than the portion of the completion bonus you are receiving) when you come back for your payments and provide follow-up information.

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. There is a slight possibility that during a research project, an investigator could discover something that could affect health of you or your family. For example, there is a possibility that the MRI scan might reveal a structural brain abnormality that you were not aware of. If this occurs, the finding will be reviewed by the study physicians, Drs. Hays and Anderson, and we will notify you of the incidental finding and provide medical referrals if warranted. At that time, you can choose to receive or refuse the result or finding.

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health?

☐ **Yes** ☐ **No** **Initials**_____

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Joshua Lile, Ph.D., or Michael Wesley, Ph.D., 465 E. High St. Suite 204B, Lexington, KY, 40507.

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.

Do you give your permission to be contacted in the future 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 18 people to do so at the University of Kentucky.

The National Institute on Drug Abuse is providing financial support and/or material 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.

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 data collected in this study. This means that no link or code to your identity will be kept. After we remove all identifiers, the data 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 or samples stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

AUTHORIZATION TO USE OR DISCLOSE YOUR INDENTIFIABLE 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 (information about your race, gender, socioeconomic status, and age)
- Results of physical examinations related to the study
- Results of psychiatric screening tests related to the study
- Results of questionnaires and study procedures related to the study
- Results of blood tests and urine screens related to the study
- Medical history related to the study

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- UK Hospital;
- UK Investigational Drug Service (IDS);
- UK Center for Clinical and Translational Science (CCTS)
- The United States Food and Drug Administration;
- The US National Institutes of Health;
- UK Healthcare and their representatives;
- Health systems outside of UK for which you have a patient relationship

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 would 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: Joshua Lile, Ph.D. or Michael Wesley, Ph.D. at 465 E. High St. Suite 204B, Lexington, KY 40507 to inform them 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 A. Example Study Schedule*

Day	Table 1. Schedule
Pre-Admit 1	Behavioral qualification.
Pre-Admit 2	Behavioral qualification + scanner acclimation.
1	Admission to the CRU. Begin maintenance capsules (0800, 1200, 1600, 2000, 0000 and 0400 h).
2-7	Maintenance continues through 7-day acclimation phase.
8	Behavioral data collection session (before 1200 dose) in hospital room. IV solution choice session (after 1200 dose) in hospital room. Maintenance continues.
9	Experimental session: money vs. money choice task in MRI scanner. Maintenance continues.
10	Experimental session: money vs. IV solution choice task in MRI scanner. Maintenance continues.
11	Experimental session: money vs. IV solution choice task in MRI scanner. Maintenance continues.
12-13	Weekend
14	Experimental session: money vs. IV solution choice task in MRI scanner. Maintenance continues.
15	Experimental session: drug cued money vs. money choice task in MRI scanner. Maintenance continues.
16	Final maintenance dose administered at 0800. Experimental session: money vs. money choice task in MRI scanner. Suboxone administered once withdrawal emerges after the session is complete.
17	Suboxone administered. Discharge

***Note the order of the experimental sessions could vary.**

Appendix B: Risks of MRI

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Feeling too hot or cold	It occasionally occurs	It will not impact your overall health	Yes
Feeling nervous or claustrophobic	It is uncommon	It will not impact your overall health	Yes
Dizziness or vertigo	It is uncommon	It will not impact your overall health	Yes
Nerve tingling or twitching	It is rare	It will not impact your overall health	Yes

Appendix C: Possible Drug Side Effects

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Nausea, vomiting, headache, dry mouth, itchiness, drowsiness, sweating, dizziness, stimulation, sleepiness, lightheadedness, restlessness, a feeling of well-being, talkativeness, difficulty urinating, constipation, low blood pressure, low heart rate and non-clinically-significant respiratory depression	It is likely you will experience one or more of these side effects	Moderately serious, though these side effects will not impact your overall health	Yes
Skeletal muscle rigidity, including chest wall rigidity	It is uncommon	Very serious though it will not impact your overall health	Yes
Allergic reaction	It is rare	Moderately serious, but it will not impact your overall health	Yes
Clinically significant respiratory depression	It is rare	Very serious though it will not impact your overall health	Yes

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendix with example schedule; Appendix with table of possible side effects**

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 person obtaining informed consent and HIPAA authorization**	_____ **Date**
_____ **Signature of Principal Investigator or Sub/Co-Investigator**	