Document Coversheet

Study Title: Modulation of Drug Intake: Evaluation of Opioid and Cannabinoid Interactions on Drug Self-Administration

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KEY INFORMATION FOR

MAIN STUDY CONSENT:

STUDY 2: MARIJUANA AND OPIOID SELF-ADMINISTRATION

You are being invited to take part in a research study about the effects of marijuana and intranasal opioids on mood and behavior. You are being invited to take part because you have experience with marijuana and opioids and have expressed interest in the study.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

By doing this study, we hope to learn more about how marijuana and opioids influence your mood, physiological responses (heart rate, breathing) and your behavior, including drug taking behavior. Your participation in this research will include approximately 1-4 screening visits (about 4 hrs each); if you qualify for the study, you will be asked to live at the UK Hospital for approximately 6.5 weeks. If you decide to participate, you will not be allowed to leave the hospital and will not be allowed to have visitors during your stay.

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

You may choose to participate to earn extra money. However, there is no direct benefit to you for taking part in this study. Your willingness to take part may help us understand marijuana and opioid interactions.

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

You may not have the time necessary to participate. If you participate, you will have to live at the UK Hospital for approximately 6.5 weeks. Please let us know if this is a concern. There are also risks and side effects associated with marijuana and opioids – a full list of these effects are listed in the detailed portion of the consent form.

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 person in charge of this study is Shanna Babalonis, Ph.D. of the University of Kentucky, Department of Behavioral Science and Center on Drug and Alcohol Research. If you have questions, suggestions, concerns regarding this study or you want to withdraw from the study her contact information is: **(859) 257-1881.**

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?

If you are not ages 18-50, you will not be allowed to take part in this study. If you are seeking treatment for drug abuse, you should not take part in this study; please tell us now and we will help you find treatment. You will not be allowed to participate if you are physically dependent on opioids (you get sick when you stop using). You will not be allowed to participate if the medical staff thinks that giving you the study drugs could be dangerous to your health. If you have any serious medical problems (e.g., a history of heart problems, breathing problems, head trauma, epilepsy or seizures), you will not be allowed to participate in this study. If you decide that you do not want to participate or do not think the study will fit your schedule, you should not take part.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

If you are selected to participate, you will live at the UK Hospital in the CCTS Inpatient Unit. During your stay, you will participate in 20 sessions. Two of these sessions are qualification sessions and will last approximately 4 hrs each. The other 18 sessions will last approximately 8 hrs and you will participate in about 2-3 sessions per week. You will be given a calendar that will list the date of each session. On your days off from session, you can read, watch movies, and engage in recreational activities, but you will not be permitted to leave the hospital or have visitors.

WHAT WILL YOU BE ASKED TO DO?

If you agree to be in the study, we will ask you to do the following things:

1. Once you are medically cleared for the study, you will live at the UK Hospital for about 6.5 weeks. You will be transported by staff members to the Straus Research Facility for each session. You will stay at the Straus Facility for approximately 8 hrs on session days. Once session is completed, you will be transported back to the UK Hospital.

2. You will need to follow the inpatient unit rules for the duration of your stay. If you do not follow the rules, you will be discharged from the study – you will not receive a payment bonus if you are discharged for breaking rules.

Some examples of these rules are:

- You will not be allowed to have any visitors, but you will be able to make phone calls
- You will be allowed to smoke cigarettes, but only under supervision of the CCTS nursing staff
- No sexual behavior or sexual intercourse for the duration of the study
- No drug or alcohol use; you cannot use any drugs that are not given to you as part of the study

3. After you are admitted to the inpatient unit, we will show you the session room where testing will take place. We will teach you how to use the computer and show you the kinds of questions you will be asked and tasks you will need to complete. You will have plenty of time to ask questions about how to perform any of the tasks. You will also receive a placebo marijuana to practice the vaporized smoking procedure. You will have plenty of time to practice before the sessions begin.

4. There are a total of 20 sessions. Two of these sessions are qualification sessions – these sessions help us determine if you will qualify for the rest of the study. If you qualify, you will complete 18 experimental sessions.

5. During the qualification sessions, you will receive an intranasal dose (a snorted drug) of either an opioid drug, (for example: hydromorphone, oxycodone, morphine, or hydrocodone), or you will receive placebo (an inactive substance) and you will receive vaporized marijuana or placebo. Each of these qualification sessions will last approximately 4 hours. After you complete these sessions, you will be informed whether you qualify to continue with the rest of the study. If you do not qualify, you will be discharged. If you qualify to continue, you can continue with the rest of the study.

6. After the qualification session, there are 18 experimental sessions. You will receive a calendar of the dates of each session. An example calendar is provided below.

Sample Study Calendar:

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Sat.
Week 1				*Admission*	Qualification Session	Qualification Session	
Week 2		**Sample Session**		**Self Admin Session**		**Self Admin Session**	
Week 3		**Sample Session**		**Self Admin Session**		**Self Admin Session**	
Week 4		**Sample Session**		**Self Admin Session**		**Self Admin Session**	
Week 5		**Sample Session**		**Self Admin Session**		**Self Admin Session**	
Week 6		**Sample Session**		**Self Admin Session**		**Self Admin Session**	
Week 7		**Sample Session**		**Self Admin Session**		**Self Admin Session**	*Discharge*

7. There are two types of sessions during the main study: Sample Sessions and Choice Sessions. During Sample Sessions, you will receive a drug dose and you will be instructed to pay close attention to the drug effects because you will have the opportunity to earn that same drug dose during the two Choice Sessions later in the week (usually on Wednesday and Friday).

8. During the Sample Session, you will receive one drug dose – either an intranasal opioid dose (an active opioid or placebo) or a vaporized marijuana dose (active marijuana or placebo). Each sample session will last approximately 8 hrs. You will need to remember how the drug made you feel during the Sample Session in order to decide if you would like to work for the drug.

9. Later in the week during Self-Administration Sessions (Wednesday and Friday), you will be given the opportunity to work – by clicking a computer mouse – for the same dose that you were given on Monday. You can work for the drug dose, money or neither – it is your choice.

10. We will ask you 7 times whether you want to work for money or drug and you will make a choice each time. After each choice, you will be working for $1/7^{th}$ of the total dose available or $1/7^{th}$ of the available money.

11. If you want to receive the total Sample dose, you would need to choose to work for drug during each of the 7 trials. If you want to receive the total amount of money ($21), you would need to choose to work for money during each of the 7 trials. You can also select to work for some drug and some money.

12. If you choose drug, you will get the amount of drug that you have chosen when your seven choices are complete. If you choose money, it will be added to your earnings.

13. The length of the Self-Administration Sessions is standardized (approx. 6 hrs). You will not be able to leave session early if you choose not to work for drug or choose to work for very little. Regardless of your choice, you will remain in the session area for the full amount of time.

14. On Self-Administration Sessions, you will be given a drug before you start working for your dose or money. This is a pre-treatment dose (either a vaporized marijuana dose or an intranasal dose) – this is only a pre-treatment dose – you will not be working to earn this dose. You will be working for the drug that you sampled during the Sample Session.

15. Throughout the study, the vaporized marijuana dose will contain a dose of active marijuana or it will be a placebo. You will vaporize the dose according to our instructions. If you are not able to follow our instructions, you will be discharged.

16. Throughout the study, you will also receive intranasal drug doses – these doses will contain an active dose of an opioid (for example: hydromorphone, oxycodone, oxymorphone, hydrocodone) or placebo (a blank/inactive dose). We will ask you to snort the powder through a straw. If you are not able to follow our instructions, you will be discharged.

17. During sessions, we will measure how you respond to each test drug by measuring things like your heart rate, blood pressure, temperature, oxygen saturation, pupil diameter, and respiration rate. We will also ask you questions about how you are feeling. For example, we may ask you if you are feeling high, if you like the drug effects or if you are feeling sick. We will also ask you to complete tasks that measure your coordination, have you estimate time intervals, and look at blinking lights to test your eyes – this test will not harm your vision. The sample sessions will last approximately 8 hrs; the self-administration session will last approximately 6 hrs.

18. During session, you may engage in activities such as reading, as long as these activities do not interfere with the study or any of the scheduled tasks or questionnaires.

19. On days when you are not in session, you will be asked to fill out several questionnaires each day. For example, we will ask you about how you feel, whether you feel tired or have an upset stomach. The nurses will measure your vital signs (heart rate, blood pressure, etc.) several times every day. You will also give breath and urine samples every day, which will be tested for drugs and alcohol; women will be tested for pregnancy. Use of drugs or alcohol that are not given to you as part of the study is forbidden and will result in your dismissal from the study.

20. If you are female, you will be tested regularly to see if you are pregnant. If the test is positive, you will be notified, discharged from the study and referred for treatment. If you become pregnant at any time during the study (during screening, during the study, in the time between study discharge and your follow-up appointment, anytime in the 30 days after you leave the study), you will need to notify the study investigator (Dr. Babalonis) or the study physician (Dr. Lofwall) as soon as possible: **Shanna Babalonis, Ph.D. (859) 257-1881; Michelle Lofwall, M.D. (859) 323-9321**

By signing this consent form you are agreeing to practice an effective method of birth control (e.g., oral contraceptives, intrauterine device, diaphragm, condom) for the entire study duration (prior to study admission through 30 days after completion).

21. After you complete all of the sessions, you will be discharged from the inpatient unit. We will ask you to complete a follow-up appointment approximately 2-4 weeks after you complete the study. We will ask you about your drug use and health. You will be paid $25. The follow-up appointment may be conducted over the phone or in person at the Robert Straus Behavioral Research Facility.

22. At any point, if you decide that you want to seek treatment for your substance use, we will assist you in finding treatment.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks and discomforts of this study are related primarily to the drugs given to you and the experimental procedures. We have carefully selected the doses to minimize the risk of serious side effects.

The likely risks of receiving marijuana include feeling high/intoxicated, euphoria, increased hunger and thirst, perceptual changes, anxiousness, panic-like reaction, lightheadedness/dizziness, performance impairment, drowsiness, orthostatic hypotension, resting increases or decreases in blood pressure, increased heart rate, red/bloodshot eyes, dry mouth, sleepiness, concentration difficulties, faintness, restlessness, confusion, loss of coordination, shakiness, stomach upset, headache, paleness, flushing, sweating, slurred speech, and fatigue. There is also a chance that marijuana could cause a lung infection due to microbes on the plant – we have taken precautions to decrease these chances of this happening.

The likely risks of receiving opioids include dizziness, stimulation, restlessness, a feeling of well being, talkativeness, itchiness, nausea, vomiting, decreased breathing, headache, constipation, dry mouth, sweating, sleepiness, drowsiness, and light-headedness. The risks of decreased breathing after administration of opioid drugs is related to the dose administered. We have carefully selected the doses to minimize the chance of decreased breathing.

During this study, you will be snorting powder through a straw. Snorting drugs can irritate the nasal tissue and potentially give you a nosebleed. You have experience with snorting opioid drugs so you are probably familiar with the sensations.

We will watch you carefully throughout your participation to minimize the chance of any serious reactions.

We do not have any plans to draw your blood after the screening is completed. However, if you were to get sick or hurt during the study, we may need to conduct a blood draw. There are risks related to blood draws including soreness, bruising, pain, infection, possible fainting, and bleeding. It is possible that we will have to try more than once to draw blood.

We will obtain an ECG once per week while you are enrolled in the study. An ECG is painless; however, the electrodes may feel cold when first applied. In rare cases, some people may develop a rash or irritation where the patches were placed.

Exposure to drugs may have harmful effects on a fetus or a newborn, and you will not be allowed to participate in the study if you are pregnant, planning to become pregnant or breastfeeding during the study, or if you cannot use an appropriate contraception method.

We will make every effort to keep private all research records that identify you to the extent allowed by law. However, there is a risk that a breach in confidentiality may occur. 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 medications/treatments/procedures in this study are no different. In addition to risks described in this document, you may experience a previously unknown risk or side effect. We will do everything we can to keep you from being harmed.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. However, if you take part in this study, you may help us learn more about the effects of marijuana and opioids when taken together.

WHAT WILL IT COST YOU TO PARTICIPATE?

The study procedures and medications will be provided to you at no cost.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by law. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. We will collect your social security number; this is required in order for you to participate.

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. Your name will be kept separate from the information that you give, and these two things will be stored in different places under lock and key. Information collected electronically will be stored on password-protected computers.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

You should know that there are some circumstances in which we may 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 or if you pose a danger to yourself or someone else. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under certain circumstances including: abuse or neglect, harm to self or others, or diagnosis of certain communicable diseases (including but not limited to, hepatitis C, HIV, or tuberculosis), which will be reported to the State Health Department along with your full name as required by law.

Officials of the Food and Drug Administration, National Institutes of Health, and the University of Kentucky may look at or copy pertinent portions of records that identify you.

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.

The investigators conducting the study may need to remove you from the study. This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- they 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.

If you stop the study because of side effects from the medication or another health-related reason, we will follow-up with you by telephone or request that you come visit us so we can see how you are doing.

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 should discuss this with the investigator 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?

If you believe you are hurt or if you get sick because of something that is done during the study, you should call Michelle Lofwall, M.D. **(859) 323-9321**. Dr. Lofwall will determine what type of treatment, if any, is best for you at that time.

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. That cost will be your responsibility. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study. The medical costs related to your care and treatment because of research 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 payment for your participation. You will receive $60 per night that you stay in the hospital. If you complete the study, you will receive an additional $60 for every night of your stay ($120/night if you complete). However, you will not receive this bonus if you are dismissed from the study, do not qualify after the qualification session is completed, or if you choose to quit the study before completion. For example, if you complete the study and stay 45 nights (the number of nights will vary slightly for each person), you would earn $5,400 for the inpatient stay.

You will also receive and additional $25 for your follow up appointment scheduled for 2-4 weeks after your discharge from the study.

We will provide your earnings to you via check(s). The maximum amount of each check is $500. You will receive your first check at discharge. We will mail you the remainder of the checks. We will mail you $500 per check per day until you are fully paid. We will mail the checks to the address that you provide us.

For example, if you complete the study and earn $5,400, you will receive $500 on the day of discharge and then will receive ten checks in the mail: nine $500 checks (9 x $500 = $4,500) and one $400 check (total of $4,900 in mailed checks). It will take approximately 2 weeks for you to receive all 10 checks. Alternatively, you are permitted to visit our office to pick up a check in-person during normal business hours Monday-Friday (closed on weekends, holidays).

Study payments are considered taxable income reportable to the Internal Revenue Service (IRS). You will be asked to complete a W-9 form which includes your name, address and Social Security number. 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?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?

This study is funded by the National Institutes of Health/National Institute on Drug Abuse.

A description of this clinical trial will be available on www.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.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION OR SPECIMEN(S):

There is a possibility that data/tissue/specimens/blood collected from you may be shared with other investigators in the future. If that is the case, the data/tissue/specimen/blood will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued. After removal, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

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:

Name, address, date of birth, weight, gender, social security number, results of physical exams, blood tests, urine tests related to the study, and ECG results.

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 (only when required by law)
- University of Kentucky representatives
- UK HealthCare and their representatives
- UK Hospital
- The National Institutes of Health and/or its divisions
- The Investigational Drug Service (IDS) at the University of Kentucky
- Food and Drug Administration
- Center for Clinical and Translational Science (CCTS)
- Health systems outside of UK for which you have a patient relationship

If you are a woman and you become pregnant anytime during the study or within 30 days after discharging from the study, you must inform Dr. Lofwall or Dr. Babalonis – they must then report the outcome of your pregnancy to the Sponsor (and/or the FDA).

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:

- You will send a written letter to Dr. Babalonis to inform her of your decision. Her address is:
  Shanna Babalonis, Ph.D.
  845 Angliana Avenue
  Lexington, KY, 40508
- 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).
- You may not be allowed to participate in the study.

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.

INFORMED CONSENT SIGNATURE PAGE

You are a participant or are authorized to act on behalf of the participant. This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

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

_____	_____
Signature of research participant	**Date**
_____	
Printed name of research participant	
_____	_____
Printed name of person obtaining informed consent/ HIPAA authorization	Date
_____	
Signature of Principal Investigator or Sub/Co-Investigator	