Document Coversheet

Study Title: Behavioral Effects of Drugs (Inpatient): 42 (Cocaine and Zolmitriptan)

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KEY INFORMATION FOR (BED)(IN)(42)(COCAINE AND ZOLMITRIPTAN)

Now that you have completed screening under our general screening protocol (IRB # 44379), we are asking you to choose whether or not to volunteer for a research study about how a study medication, zolmitriptan, impacts the effects of cocaine. We are asking you because it currently appears that you qualify to participate. 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?

By doing this study, we hope to learn the effects of zolmitriptan (a medication used to treat migraines) on the subjective (how you feel) and physiological (how your body reacts) effects of cocaine. We are also interested in determining whether zolmitriptan impacts whether you like the drug and want to take it again. Your participation in this research will last about 34 days. The research procedures will be conducted in the Clinical Research Unit (CRU) at the University of Kentucky Medical Center. During the time you participate, you must agree to participate as an inpatient on the CRU. You will be asked to reside on the CRU over approximately one month and complete 1 practice session, 1 medical safety session and 12 experimental session days. The purpose of this research is to gather information on the safety and effectiveness of zolmitriptan on the behavioral, subjective, and physiological effects of cocaine. These two drugs are Food and Drug Administration (FDA) approved but are being tested for research purposes.

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

Understand that you are not a patient receiving medical treatment and that you will not receive any direct benefits from this study. However, the knowledge gained will contribute to a better understanding of the nature of effects of these drugs and may result in improved therapeutic treatments for patients taking these drugs. If you are seeking treatment, please notify the investigator now and he will make the necessary referral. For a complete description of benefits, refer to the Detailed Consent.

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

The primary risks to participation are those specifically related to the ingestion of the study drugs. Two types of risk are associated with the administration of these drugs to human volunteers. First, the drugs under study occasionally produce side effects. Second, there is a slight risk that habituation or tolerance will develop. If you develop habituation or tolerance to the medications administered in the study, the effects of these medications would be decreased if they were administered to you at therapeutic doses. There are also possible side effects related to insertion of the needle used to deliver the study drug: cocaine. These include soreness, bruising, pain, infection, possible fainting, and bleeding. For a complete description of risks, refer to the Detailed Consent and/or Appendix. If you do not want to be in the study, there are no other choices except not to take part in the study.

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 chose 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 William W. Stoops, Ph.D., of the University of Kentucky, Departments of Behavioral Science, Psychiatry, and Psychology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: 859-257-5388

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 participate if you have a history of serious physical disease, current physical disease, impaired cardiovascular functioning, phenylketonuria, high blood pressure, chronic obstructive pulmonary disease, history of epilepsy or seizure, diabetes, current or past histories of serious psychiatric disorder. You should not participate if you have a history of other significant medical problems. You should not participate if you are taking monoamine reuptake inhibitors (including SSRIs), monoamine oxidase inhibitors, or cimetidine. If you are taking any of those medications just mentioned, you should discuss this with the research staff before agreeing to participate.

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 have ever been addicted to drugs or alcohol, you should discuss this with the research staff before agreeing to participate.

If you are a 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 a pregnancy test before being accepted into the research study. You will also be required to take a pregnancy test prior to each experimental session. Should one of these tests show that you are pregnant, your participation will be terminated 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 in the Clinical Research Unit (CRU) at the University of Kentucky Medical Center. During the time you participate, you must agree to participate as an inpatient on the CRU. You will be asked to reside on the CRU over approximately one month and complete 1 practice session, 1 medical safety session and 12 experimental session days (14 sessions total). The practice and experimental session will take about 8 hours to complete. The medical safety session will take about 5 hours to complete. The total amount of time you will be asked to volunteer is 34 days over the next month.

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 make telephone calls.

WHAT WILL YOU BE ASKED TO DO?

Before participating in this research study, it will be necessary for you to have a physical and psychiatric examination. The psychiatric examination information will not be inserted in your medical file and will take approximately 20 minutes. During the time you participate, you must agree to participate as an inpatient on the CRU for approximately one month or until we successfully complete up to a maximum of 14 sessions. During the time you participate, you will not be able to use any illicit substances, alcohol, and caffeine. It is important that you realize that you will have to have a caffeine-free diet while you reside in the hospital. A nurse from the UKHealthCare Vascular Access Team (VAT) will insert a needle into your arm. The needle will be removed and a long intravenous (IV) catheter (approximately 3 – 5 inches), called a midline catheter. The placement of this midline catheter would allow for longer-term IV access (e.g., 30 days) to receive fluids (i.e., saline) and IV cocaine. Your consent for study participation applies to the initial insertion of the midline catheter and to any re-insertion deemed necessary by the study physicians and to hospital policy. Please note that if the midline catheter needs to be removed or if an unforeseen event prevents administration of IV cocaine (e.g., saline leaking during a session) that a peripheral catheter may be inserted in your arm. This type of catheter is a small tube that allows for IV access, and

it will remain in your arm for several days at a time (e.g., 2 – 3 days). The peripheral catheter will be replaced on a regular schedule according to hospital policy. It may be necessary to re-insert the peripheral catheter more frequently if it comes out of your arm.

The first session day will be a “practice” session day to make you familiar with the various tasks and procedures of the experiment. The placement of the IV midline catheter will occur after completion of this first “practice” session. The second session will be a “safety” session to be sure that you will not react badly to the drug doses to be administered in the study. During the “safety” session, you will be asked to take three drug doses at 60-min intervals. The remaining experimental sessions will occur in blocks of 3 experimental sessions, separated by at least 5 maintenance days. During experimental sessions, you will sample a drug dose in the morning and then have the opportunity to choose between the sampled drug and money during 5 additional trials that will occur throughout the day. Session days will last approximately 8 hours each. During the sessions we will collect data concerning your heart function and temperature, mood, and performance on various laboratory tasks. That is, we will record your heart rate, blood pressure, and temperature. We will also repeatedly ask you to answer various questionnaires about how you feel and about what kind of drug effect you feel. Completing the behavioral and physiological measures poses no hazard or risk greater than those experienced in daily life, but the drug administered in the study pose a risk as described below. You must agree to complete these questions and to do the tasks to the best of your ability and at the scheduled times. During the days and times that you are not participating in an experimental session, you will be free to engage in approved recreational activities. 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. As mentioned above, if a peripheral catheter needs to be used, it will be removed upon completion of the last experimental session or when deemed necessary by the study physicians and/or hospital policy.

During your participation, you must not use any drug except those administered in the experiment. There will be urine checks and breathalyzers daily 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. If you are dropped from the study because you used other drugs or alcohol, or had them in your possession, you will lose a substantial portion of the money you might have earned.

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.

During the time that you spend on the CRU we will provide you with standard hospital meals. When you are not participating in the daily 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 do not return them or ruin them, you should understand the price of the item will be deducted from your payment. When you come to the CRU, you should not bring any valuable items with you. You will have the opportunity to use study earnings to purchase certain items (e.g., extra snacks, personal health items) that are not provided to you.

Daily experimental procedures. On your admission day, you will arrive at the Psychopharmaology of Addiction Laboratory at 8:00 AM. We will then conduct a urine drug screen and field sobriety test. If you pass the urine screen and the field test, at approximately 9:00 AM you will be escorted to the CRU, where you will be admitted. You will then complete a "practice" session to familiarize you with the experimental routine. The second session will be a "safety" session in which you will be asked to take all of the drug doses available in future sessions. In the remaining experimental sessions, you will sample a drug dose in the morning and then have the opportunity to choose between the sampled drug and money during 5 additional trials that will occur throughout the day. Session days will last approximately 8 hours each. You should understand that you will not be allowed to smoke during the experimental session which will last approximately 8 hours. You will be discharged from the CRU on the day following your last experimental session. We have included a table in the Appendix to help you better understand the study protocol. This table is meant to serve as an example. To avoid conducting experimental sessions on weekend days (Saturday and Sunday), your stay may be extended. Thus, your participation may be longer than 33 days.

Drugs and Drug Administration. During the experiment you will receive infusions of a drug solution through the IV midline or peripheral catheter (if needed) in your arm. The solution will contain cocaine or will contain only saline. You will also be given a medication by mouth twice per day: 7:00 AM and 7:00 PM. These capsules could contain placebo (no drug) or a drug indicated for migraines, zolmitriptan (Zomig®). The two active study drugs could be given alone or in combination at any given time during study participation. For example, receiving placebo capsules and saline solution. The order in which the drug doses will be tested will be randomly determined. Only Dr. Stoops and the Investigational Drug Service will have access to dose conditions.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The laboratory tasks and subjective-effects questionnaires present no risks exceeding those of everyday experience. The primary risks to participation are those specifically related to the ingestion of the study drugs. Two types of risk are associated with the administration of these drugs to human volunteers.

First, the drugs under study occasionally produce side effects. These are outlined in the Appendix. We will monitor for these side effects daily while you reside on the CRU. If you feel you are experiencing any of these side effects, you should tell the nursing staff or physician. In addition, study participation may involve risks that are currently unforeseeable. **You should understand that the combination of the drugs administered in the study may increase the frequency or severity of drug side effects.**

Second, there is a slight risk that habituation or tolerance will develop. If you develop habituation or tolerance to the medications administered in the study, the effects of these medications would be decreased if they were administered to you at therapeutic doses.

Some medications administered in this study have been linked to rare reports of sudden death. Patients taking this medication that have died most often had undiagnosed personal heart related problems or a family history of heart problems. **We will screen you for heart problems using an electrocardiogram and by screening both you and your immediate family's medical history. You should NOT participate in this research if you know of any heart related problems for yourself or your immediate family.**

A separate risk of the research is the risk related to putting in the IV midline or peripheral catheter. These include soreness, bruising, pain, infection, possible fainting, bleeding or a blood clot, and malposition of the IV midline or peripheral catheter.

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?
We do not know if you will get any benefit from taking part in this study. Understand that you are not a patient receiving medical treatment and that you will not receive any direct benefits from taking part in this study. However, if you take part in this research study, the knowledge gained will contribute to a better understanding of the nature of effects of these drugs and may result in improved therapeutic treatments for patients taking these drugs. If you are seeking treatment, please notify the investigator now and he 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. The clinical laboratory tests, physical examination and psychiatric screen described above will be paid for by a grant from the sponsor: National Institute on Drug Abuse (NIDA).

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. 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. It is possible, though, that the doctors may order extra medications unrelated to study participation (e.g., hydrocortisone cream if you develop a rash) that would be billed to you. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

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 your responsibility. Your insurer, Medicare, or Medicaid may agree to pay for the costs. However, a co-payment or deductible may be needed from you. The amount of this co-payment or deductible may be costly.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?
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 [NIH]) or agency auditing the research (Food and Drug Administration [FDA], Center for Clinical and Translational Sciences, Clinical Services Core [CCTS]);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

If suspected or actual Restricted Items are associated with you, we may notify UKHC, UK Police, and others about it and the circumstances involved. 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. 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:

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

If you are terminated for any of these reasons, it will be deemed that you did not complete all of your scheduled experimental sessions and you will not receive the completion allowance described below. The study medications will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons.

You should also understand that the medical doctors on this project, Lon R. Hays, MD, M.B.A., Kevin W. Hatton, M.D., and Danielle M. Anderson, M.D., can terminate your participation if they do not feel that it is medically safe for you to continue. If your participation is terminated for medical reasons, you will receive the $60/session completion allowance for each of the experimental sessions you completed.

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/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?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Kevin Hatton, M.D. at (859) 218-0365, Lon R. Hays, M.D., M.B.A. at (859) 323-6021 x 79015 or Danielle M. Anderson, MD at (859) 562-2356 immediately. The physicians will determine what type of treatment, if any, is best for you at that time. 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.

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 $60 for each day that you reside on the CRU, including weekends even though sessions do not occur on weekends. If you complete all of your scheduled experimental sessions, you will be paid a completion allowance of up to 60 for each of the days you resided at the CRU. You will also have the opportunity to choose to receive money instead of drug doses during the experimental sessions. If you complete the entire study, you may earn approximately $4,320, depending on the number of days you reside on the CRU and how many times you choose to receive money instead of drug.

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue 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. You should understand that by participating in this research study, the University of Kentucky will report your earnings to the appropriate state and federal government agencies (i.e., IRS). You should further understand that it is your responsibility to determine how these earnings might affect your personal financial situation.

You should also understand that 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. For example, if you resided on the CRU for 33 days and completed all experimental sessions you would earn up to $4,320. Your first and remaining payments would be for up to $500 and would be given to you on the day you leave the CRU and every week there after until you have received all of the money you have earned. It could take up to 7 weeks to receive all of your study payments. 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 Psychopharmacology of Addiction Laboratory 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 this information.

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

If the investigators on this project, William W. Stoops, Ph.D., Joshua A. Lile, Ph.D., Lon R. Hays, MD, M.B.A., Kevin Hatton, M.D., and Danielle M. Anderson, M.D. learn of new information in regard to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study. If you choose not to continue, you will not lose any of your earnings. That is, you will receive the completion allowance for each of the experimental sessions you completed.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

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? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or 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 William W. Stoops, Ph.D. 465 E. High Street, Suite 204B, Lexington, KY 40507, phone number: (859) 257-5388.

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 *2 – 3* times per year.

Do you give your permission to be contacted in the future by *William W. Stoops, Ph.D.,* regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?
This research is supported by a grant from the National Institute on Drug Abuse (NIDA [DA052203]).

If you volunteer to take part in this research, you will be one of about 20 to do so at the University of Kentucky.

The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?
Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

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. This form describes how researchers may use your information. Please read it carefully.

Your health information will be used and/or released (disclosed) for the following research study: Behavioral Effects of Drugs (Inpatient): 42 (Cocaine and Zolmitriptan).

You allow William W. Stoops, Ph.D., and his research staff at the University of Kentucky to create, access, use and release your health information for the purposes listed below.

Your health information that may be used and released includes:

- Demographic information (information about your race, gender, weight, height, socioeconomic status, educational attainment, emergency contacts, and age)
- Results of physical examinations related to the study
- Results of psychiatric screening tests related the study (psychiatric screening tests include the Beck Depression Inventory, a Psychiatric History Questionnaire, Attention Deficit Hyperactivity Disorder screens, Brief Symptom Inventory, Drug Abuse Screening Test, Michigan Alcohol Severity Test, Alcohol Use Disorder Identification Test, Fagerstrom Test for Nicotine Test, Computerized Structured Clinical Interview for DSM-5, Adverse Childhood Experiences Questionnaire and a Suicide Screening)
- 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
- If you become pregnant anytime during the study or within 30 days after stopping the study drug, you must inform the study doctor. The study doctor must then report the outcome of your pregnancy to the Sponsor and FDA.

Your health information will be used for:
- A study coordinated by William W. Stoops, Ph.D., examining the effects of stimulant drugs. Your protected health information is necessary to conduct this line of research, as well as to meet legal, institutional, and accreditation requirements.

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity,
- University of Kentucky Medical Center, Investigational Drug Service, Center for Clinical and Translational Sciences, Clinical Services Core, and Clinical Research Organization,
- The Food and Drug Administration (FDA),
- The National Institute on Drug Abuse (NIDA)

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 will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the 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)
- Eligibility for benefits (if applicable)

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

- You will send a written letter to: William W. Stoops, Ph.D. 465 E. High Street, Suite 204B, Lexington, KY 40507 to inform him 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).
- You will not be allowed to participate in the study.

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 Timeline

WHAT WILL YOU BE ASKED TO DO?

Day	Details
0	Admission to the CRU
1	Practice Session. You will be familiarized with the experimental session tasks during this session. IV midline catheter placed in arm after Practice Session.
2	Medical Safety Session. You will receive the IV doses to be tested in this study separated by 60 minutes and then complete questionnaires and physiological assessments.
3-8	Medication maintenance (includes weekend). Oral dose administered twice daily 0700 and 1900 h (7:00 AM and 7:00 PM, respectively.
6-8	Experimental sessions 1-3. During experimental sessions you will complete 1 sample and 5 choice trials to receive portions of the sampled drug or money. You will also complete questionnaires, computerized tasks, and physiological assessments.
9-16	Medication maintenance (includes weekend).
14-16	Experimental sessions 4-6. Details are the same as for days 6-8.
17-24	Medication maintenance (includes weekend).
22-24	Experimental Sessions 7-9. Details are the same as for days 6-8.
25-32	Medication maintenance (includes weekend).
30-32	Experimental Sessions 10-12. Details are the same as for days 6-8. IV midline catheter removed after Experimental Session 12.
33	Discharge.

Appendix: Risks

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible Risk or Side Effect of cocaine	How often has it occurred?	How serious is it?	Can it be corrected?
nervousness, restlessness, faintness, irritability, shaking, nausea, headache, flushing, sweating, performance impairment, rash, blurred vision, difficulty sleeping, loss of appetite changes in heart rate or blood pressure	These can occur occasionally. Nearly all subjects enrolled in similar studies in our laboratory experience at least some of these side effects.	Somewhat serious	These side effects are likely to decrease over time as the medications clear from your system.
stroke, seizure, heart attack, death	These are extremely uncommon. No subjects enrolled in similar studies in our laboratory have experienced these side effects.	Very serious	No

Possible Risk or Side Effect of zolmitriptan	How often has it occurred?	How serious is it?	Can it be corrected?
sleepiness, sleep walking, dry mouth, nausea, pain/pressure in neck or throat, drowsiness, weakness, warmth, redness or mild tingling under the skin, increased heart rate and increased blood pressure.	These can occur occasionally.	Somewhat serious	These side effects are likely to decrease over time as the medications clear from your system.
Chest pain, sudden lateral numbness or weakness, sudden headache, confusion, problems with vision, speech or balance, dizziness, severe stomach pain, hematochezia, serotonin syndrome and cyanosis	These are extremely uncommon. No subjects enrolled in similar studies in our laboratory have experienced these side effects.	Very serious	These side effects are likely to decrease over time as the medications clear from your system.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendices of Risks and Study Procedures**

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** _____ **Signature of Principal Investigator or Sub/Co-Investigator**