Combined Consent and Authorization to Participate in a Research Study

Sedative-Anxiolytic Effects on Simulated Driving Performance

Main Study Consent

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study that will examine the effects of sedative and anti-anxiety medications on a variety of measures. You are being invited to take part in this research study because you are between the ages of 18 and 50, you are in good health, and you are not a regular tobacco user. If you volunteer to take part in this study, you will be one of about 24 to complete the study at the University of Kentucky.

WHO IS DOING THE STUDY?

The person in charge of this study is Sharon Walsh, Ph.D. of the University of Kentucky, Center on Drug and Alcohol Research. The study physician will be Michelle Lofwall, M.D. of the University of Kentucky. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

By doing this study, we hope to learn about the persistence of effects of sedative and anti-anxiety medications, such as on driving ability.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

If you are under the age of 18 years old or older than 50 years of age, you will not be allowed to participate in this study. If you use nicotine products regularly, you should not participate. If you are pregnant, breastfeeding, or planning on becoming pregnant, you should not participate. If you have a serious health condition, you should not participate in the study.

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

The research procedures will be conducted at the Center on Drug and Alcohol Research (CDAR) Building and the Center for Clinical and Translational Science (CCTS), a research unit located in the University of Kentucky Hospital. There will be a total of six experimental sessions over the next two months for which you will need to arrive in the afternoon, stay overnight at the UK hospital and leave the following day in the afternoon. There will also be one to three practice sessions (2 – 4 hours each) to familiarize you with the experimental tasks.

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, we will schedule 1-3 practice sessions for you. During these practice sessions, we will show you the experimental tasks that you will complete during study sessions. The practice sessions will last 2 – 4 hours, and after you have completed them, we will inform you if you have been selected to continue in the study.

2. After the practice sessions are complete, we will arrange a schedule of visits for you (an example schedule is below). You will be required to stay overnight at the UK hospital on 6 separate occasions and take part in experimental sessions the day of and the day after each overnight stay.

Sunday	*Monday*	*Tuesday*	*Wednesday*	*Thursday*	*Friday*	*Saturday*
	Session 1 PM (stay overnight)	Session 1 AM (leave ~3PM)	Wash out	Wash out	Session 2 PM (stay overnight)	Session 2 AM (leave ~3PM)
Wash out	Wash out	Wash out	Session 3 PM (stay overnight)	Session 3 AM (leave ~3PM)	Wash out	Wash out
Wash out	Session 4 PM (stay overnight)	Session 4 AM (leave ~3PM)	Wash out	Wash out	Wash out	Session 5 PM (stay overnight)
Session 5 AM (leave ~3PM)	Wash out	Wash out	Wash out	Session 6 PM (stay overnight)	Session 6 AM (leave ~3PM)	

3. For the evening (PM) part of overnight sessions, you will be required to report to the CDAR building in the early afternoon. We will arrange for you to be picked up or you can have a friend drop you off, but it is important that you arrive on time for each session. You will not be allowed to drive yourself home the next day. You will be asked to give an observed breath and urine sample for alcohol, drug, and pregnancy testing. You will drive a scenario on the driving simulator and answer some questions about your mood and how well you performed the simulation. There may be other tests of your vision, memory or balance. After this, you will be escorted to the inpatient unit, where you will spend the night. You will be given dinner that must be finished by 8:30 PM.

4. At ~11:30PM, a nurse will give you a capsule to swallow. This capsule will contain a sedative drug (like Ambien or Lunesta), an anti-anxiety drug (like Valium or Xanax), or a placebo (an inactive substance- e.g. a sugar pill). The study staff will not know which drug you will receive on which session. After you take the study drug, you should attempt to sleep. You may be asked to wear a wrist monitor (e.g. FitBit) to track your quality of sleep.

5. In the morning, you will be escorted to the CDAR building, where you will receive breakfast. You will then complete the morning (AM) part of the session. You will receive another capsule to swallow. This capsule will contain a sedative/anti-anxiety drug or a placebo (an inactive substance- e.g. a sugar pill). The study staff will not know which drug you will receive on which session. You will complete several scenarios on the driving simulator, answer computer questionnaires about your mood, how well you slept, if you feel impaired, etc. There may be other tests of your vision, memory or balance. We will also monitor your vital signs (e.g. blood pressure, respiration rate, pulse).

6. During one of your sessions, we will ask you to complete a DXA scan. This is a non-invasive x-ray scan that will measure your body fat percentage. The only medical reason you should not complete a DXA scan is if you are pregnant. We will test females for pregnancy prior to the scan. You will need to arrive approximately an hour early on the day we schedule this scan.

7. Once data collection is complete, we will assess your level of impairment with a field sobriety test and you will be given transportation home.

8. If you are pregnant, you cannot participate in this study. If you are a woman who could have children, it will be necessary to have a urine (or serum) test to see if you are pregnant before you start this study. If you are a sexually active male or female, you must agree to take precautions to avoid the possibility of impregnation because it is not known how these drugs will affect an unborn child. If you are a woman and become pregnant during the course of the study, you must notify the Principal Investigator of this fact as soon as possible. You can reach the Principal Investigator at 859- 257-6485.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks of this study are primarily related to the drugs given to you and the experimental procedures. The side effects of receiving sedative drugs include sedation, nausea, vomiting, headache, sweating, light-headedness, sleepiness, dry mouth, dizziness, constipation, motor impairment, short-term memory loss, allergic reactions, and abdominal pain.

There is also some risk that completing the driving simulator tasks may have some side effects. They include headache, nausea, dizziness, motion sickness, and vomiting.

There is always a chance that any medical treatment can harm you, and the investigational treatment in this study is no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect. We will tell you if we learn anything new that could change the risks of the study.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. Your willingness to participate may help doctors and public health officials to understand how sedative and anti-anxiety medications affect individuals.

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 benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive. As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or grade in a class.

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?

The study medication and procedures are provided at no cost to you.

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. Your name, social security number, and address

may 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 project will be released.

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.

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

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

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

You may 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 also discuss with the investigator before you agree to participate in another research 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 Michelle Lofwall, MD at 859-257-9321 immediately. Dr. Lofwall will determine what type of treatment, if any that 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. 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 taking part in this study. You will receive $25 for each practice session prior to being accepted into the study. You will receive your payment at the end of each visit. There will be one to three practice sessions.

You will receive a base pay of $100 per overnight visit regardless of whether or not you complete all the sessions. Additionally, you will receive a performance-based completion bonus for each driving scenario of $5. In order to receive the performance bonus, you must obey the rules of the road and follow all directions given to you by the study staff for the driving simulations.

If you complete all 6 sessions, you will receive a completion bonus of an extra $50 per overnight session ($300). You will not receive this bonus if you decide not to complete the study or are dismissed due to not following directions.

If you complete all sessions and finish all of the drives on time, your total earnings (excluding screening and practice sessions) will be about $1,080 ($600 for sessions, $300 completion bonus, $180 driving performance bonus). After each session, you will receive payment for that session day ($100) plus any on-time driving bonuses earned during that session. The completion bonus will be paid to you after your final session.

If you make more than $600 by participating in research projects, the University of Kentucky will report your earnings to the appropriate state and federal government agencies (for example, the Internal Revenue Service). You should further understand that it is your responsibility to determine how these earnings might affect your personal financial situation.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Dr. Walsh, at 859-257-6485. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

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

If the researcher learns of new information in regards 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.

POTENTIAL FUTURE USE

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by Center on Drug and Alcohol Research staff members regarding your willingness to participate in future research studies about drug or alcohol use?

☐ **Yes** ☐ **No** _____**Initials**

WHAT ELSE DO YOU NEED TO KNOW?

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

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

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

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

- Demographic Information
- Social Security Number
- Results of physical exams, blood tests, other diagnostic and medical procedures
- Personal medical history

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.
- UK Hospital.
- The National Institute on Drug Abuse.

- Investigational Drug Service (IDS).
- Center for Clinical and Translational Science (CCTS).

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 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) collect or release your health information (revoke the authorization). If you revoke the authorization:

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

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

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

You are the subject. You have read this information, and you will receive a copy of this form after it is signed.

_____ _____
Signature of research subject Date

_____
Printed name of research subject

_____ _____
Name of [authorized] person obtaining informed consent/HIPAA authorization Date

_____
Signature of Principal Investigator or Sub/Co-Investigator