INFORMED CONSENT IN-PERSON SCREENING - Adderall

Project Title: **Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device: Study 1**

Principal Investigator: Timothy Brown

Research Team Contact: Timothy Brown, (319) 335-4785

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are between the ages of 18 and 40 years, with a valid driver's license for two years, drive a minimum of 5,000 miles per year, and are in good health.

The purpose of this research study is to explore the usefulness of the Mobile Alertness Memory Profiler (M-AMP) assessment in detecting the effect of certain drugs on driving performance. The M-AMP is an inexpensive, non-invasive assessment that assesses alertness, attention, and memory. This study will evaluate the M-AMP assessment by comparing this measure before and after subjects have taken Adderall, a stimulant usually taken by prescription.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 26 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for three visits, one screening visit, approximately 45 minutes in length and two study visits that will be separated by 2-7 days and will last approximately 5-6 hours in length, starting at 8:00 AM.

WHAT WILL HAPPEN DURING THIS STUDY?

Visit 1 (Screening Visit)

Upon arrival at NADS, study staff will verbally review this document with you, answer any questions you may have about the study, provide you time to read this document and, if you agree to participate, obtain your written consent. You will receive a copy of this signed Informed Consent Document.

First you will be asked to provide a urine sample for a drug screen test. If you are female, the urine sample will also be tested for pregnancy.

If your drug screen test or pregnancy test comes back positive, your test results will remain confidential. However, you will be ineligible to continue in the study.

If you continue to be eligible to participate in the study, you will be asked to complete a questionnaire about general demographic information, your driving record, driving behavior, and driving history. If you are eligible to continue, you will be asked to drive two short 5-8 minute practice drives on the simulators. After your drives, you will be asked to complete a questionnaire about how you feel. A medical professional will then conduct a physical and psychological evaluation. If you continue to be eligible to be in the study, study staff will set up an appointment for your next two study visits. You will then be asked to arrange for third party transportation to and from NADS on both study visit days. In the event that you are unable to arrange for third party transportation, taxi transportation will be arranged for you by study staff at no cost to you.

Visits 2 and 3 (Study Visits)

For these visits, you will be asked to consume either Adderall or an Adderall placebo. You will receive both study drugs, but you will be randomly assigned to the order in which you receive them. You will have a 50/50 chance of receiving Adderall at the first visit and the placebo at the second and vice-versa. This means that the order in which you receive the study drug will be determined purely by chance, like flipping a coin.

You will be instructed to minimize caffeine usage in the 24 hours preceding your visits.

- No caffeine within two hours of going to bed the night before your visit
- No more than one 8 ounce cup of caffeinated beverage no later than 6 AM the day of your visit.

You will also be asked to refrain from alcohol for the 24 hours preceding each visit, and to get between seven and nine hours of sleep the night before each visit.

For these visits, you must continue to meet study eligibility. You will be asked to provide a urine sample for a urine drug screen test and a pregnancy test for females. If your drug screen test or pregnancy test comes back positive, your test results will remain confidential. However, you will be ineligible to continue in the study.

If you continue to be eligible to participate in the study, your height and weight will be measured and recorded, and you will be asked to complete a questionnaire about your sleep habits in the last 24 hours and your food intake within the last 4 hours. If you remain eligible to continue, you will be fitted with an EEG monitoring device. This device is a non-intrusive wireless recording device that is worn on your head. It wirelessly records brain activity for nine channels as well as data about electrical activity from your heart and head movement data. It uses leads that will be applied to various locations on your head using a gel to attach them to your scalp. There will also be a lead that research staff will attach to your chest to monitor ECG activity. You will then complete a 45 minute Mobile Alertness Memory Profiler (M-AMP) Assessment which involves three tests.

1. The first is a multiple choice vigilance task that requires you to identify a predetermined target from amongst three objects.
2. The second task is divided into an eyes open task and an eyes closed task. The eyes open task requires you to press a button each time an image appears on the screen. The eyes closed task requires you to press a button each time you hear an auditory tone.
3. The third task is an image recognition task in which you will be presented a set of images and then asked to indicate whether images from another set were in the original set you were shown.

A medical professional will obtain an individual blood sample of 4mL (less than a teaspoon).

You will then be escorted to the driving simulator and asked to drive for 35 minutes. The drive consists of urban, freeway, and rural roadways**.**

You will be asked to complete questionnaires about your current sleepiness level before and after the study drive, and questionnaires about how you feel after the drive and your experience driving the simulator.

After completing the questionnaires, you will be escorted back to the prep room where you will be provided either the Adderall or Adderall placebo with a glass of water. After thirty minutes you will complete another Mobile Alertness Memory Profiler (M-AMP) Assessment. After the assessments, a medical professional will obtain an individual blood sample of 4 mL(less than a teaspoon) for a laboratory test. The collected blood sample will be used only for study purposes; to assess how quickly the medication was metabolizing. Next you will again be escorted to the driving simulator for another 35 minute drive followed by the same set of questionnaires. After completing the drive and the questionnaires, you will be escorted back to the prep room where you will complete a final Mobile Alertness Memory Profiler (M-AMP) Assessment. Then the EEG monitoring device will be removed from your head, the medical professional will obtain a third individual blood sample of 4 mL(less than a teaspoon), and you will be transported home.

You may skip any questions that you do not wish to answer on the questionnaires.

Blood/Data Storage for Future Use

As part of this study, we are obtaining blood samples from you. We would like to study your blood in the future, after this study is over.

The tests we might want to use to study your blood may not even exist at this time. Therefore, we are asking for your permission to store your blood so that we can study them in the future. These future

studies may provide additional information that will be helpful in understanding the effects of Adderall, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your blood, but decide in the future that you would like to have it removed from future research, you should contact Dr. Timothy Brown at 319-335-4785. However, if some research with your blood has already been completed, the information from that research may still be used.

Video Recording

All driving trials will be recorded on video.

The simulator contains sensors that measure vehicle operation, vehicle motion, and your driving actions. The system also contains video cameras that capture images of you while driving (e.g., driver's hand position on the steering wheel, forward road scene). These sensors and video cameras are located in such a manner that they will not affect you or obstruct your view while driving. The video cameras are over-the-shoulder cameras and will not capture or record your face unless you turn around to look back at the cameras. The cameras will record the forward visual scene. The information collected using these sensors and video cameras are recorded by research staff for analysis, and may be used as described in the Confidentiality section below. Access to the videos will be restricted to members of the research team and will be maintained with the engineering data to support future analysis of the data.

Future Studies

We will keep on file your name and information about you, including birth date, contact phone numbers, and the annual mileage you drive each year. In the future, we may contact you to see if you would be willing to complete questionnaires, interviews, or drives for future studies. Agreeing to participate in this study does not obligate you to participate in future studies. You would be asked to give a separate consent for any future studies.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks, indicated below, from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate being associated with this study.

One risk involves the possibility of discomfort associated with simulator disorientation. This can occur as a consequence of driving the simulator. Previous studies with similar driving intensities and simulator setups produced few disorientation effects. When effects were reported, they were usually mild to moderate and consisted of slight uneasiness, warmth, or eyestrain for a small number of participants. These effects typically last for only a short time, usually 10-15 minutes, after leaving the simulator. You may quit driving at any time if you experience any discomfort.

If you ask to quit driving as a result of discomfort, you will be allowed to quit at once. You will then be

escorted to a separate room where you can sit and rest. A beverage and snack will be offered. A trained staff member will determine when you will be allowed to leave. If you show few or no signs of discomfort, you will be transported home.

If you experience anything other than slight effects, a follow-up call will be made to you 24 hours later to ensure you're not feeling ill effects.

Adderall also presents a risk for side effects. The risks for taking a single dose of Adderall are:

- Cardiovascular problems (ie heart attack, stroke, hypertension and arrhythmia).
- Aggression
- Psychosis/ mania
- Hallucinations.

The risk of blood sampling is pain, tenderness, bruising, or bleeding at the needle puncture site, and transient lightheadedness or dizziness. Placement of indwelling venous catheters poses a risk of infection or thrombophlebitis, increasing with duration of placement.
Some people may find the use of the EEG gel unpleasant as it needs to be washed out of the hair after the procedure is complete.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, society might benefit from this study because the information might provide a better understanding of how to detect drugs being used by drivers. This may allow the development and refinement of new technologies that could minimize drugged driving-related crashes in the future.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you, if you proceed past the screening visit. If you do, you may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

If you agree to participate in this study, you will be paid $275 if you complete all study visits and procedures. If you withdraw or your participation ends, your compensation will be pro-rated as follows:

Visit 1 (Screening)	$ 25
Visit 2	$ 115
Visit 3	$ 135
Total (complete all visits)	$ 275

In the event that you fail to meet the study criteria at any visit (e.g., the drug screen, pregnancy screen, sleep requirements, and alcohol/caffeine restrictions) you will be paid only $10 for the visit.

WHO IS FUNDING THIS STUDY?

The National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH) is funding this research study. This means that the University of Iowa is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent described in this document and permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- Representatives of Advanced Brain Monitoring involved in the research
- Auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

You will be assigned a study number which will be used instead of your name to identify all data collected for the study. The list linking your study number and your name will be stored in a secure location and will be accessible only to the researchers at the University of Iowa. All records and data

containing confidential information will be maintained in locked offices or on secure password protected computer systems that are accessible to the researchers, the study sponsor, and its agents. It is possible that persons viewing the video data may be able to identify you. If we write a report or article about this study, we typically describe the study results in a summarized manner so that you cannot be identified by name.

The **engineering data** collected and recorded in this study (including any performance scores based on these data) will be analyzed along with data gathered from other participants. These data may be publicly released in final reports or other publications or media for scientific (e.g., professional society meetings), regulatory (e.g., to assist in regulating devices), educational (e.g., educational campaigns for members of the general public), outreach (e.g., nationally televised programs highlighting traffic safety issues), legislative (e.g., data provided to the U.S. Congress to assist with law-making activities), or research purposes (e.g., comparison analyses with data from other studies). Engineering data may also be released individually or in summary with that of other participants, but will not be presented publicly in a way that permits personal identification, except when presented in conjunction with video data.

The **video data** (video image data recorded during your drive) recorded in this study includes the forward visual scene and all in-vehicle audio including your voice (and may include, in some views, superimposed performance information). Your face will not be recorded. Video and in-vehicle sounds will be used to examine your driving performance and other task performance while driving. Video image data (in continuous video or still formats) and associated audio data may be publicly released, either separately or in association with the appropriate engineering data for scientific, regulatory, educational, outreach, legislative, or research purposes (as noted above).

The **simulator data** are captured and stored on hard drives located within a limited access area of the NADS facility. Access to simulator data is controlled through permissions established on a per-study basis.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we ask you to contact Kayla Smith 319-335-4672 as soon as you decide not to participate.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen if you fail the drug screen, for females, if you are pregnant while participating, or if you do not meet the requirements for the study. Additionally, your participation may end if you fail to operate the research vehicle in accordance with the instructions provided or if there are technical difficulties with the driving simulator.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Timothy Brown, (319) 335-4785. If you experience a research-related injury, please contact: Dr. Timothy Brown (319) 335-4785.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 04/04/14.

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)