

## INFORMED CONSENT DOCUMENT

**Under the Paperwork Reduction Act, a federal agency may not conduct or sponsor, and a person is not required to respond to collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control number. The OMB Control Number for this information collection is 2127-NEW (expiration date: MM/DD/YYYY). The average amount of time to complete the informed consent is 20 minutes. All responses to this collection of information are voluntary. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden send them to Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Washington, DC, 20590.**

**Project Title: In-Vehicle Drowsy Driving Detection and Alerting**

**Principal Investigator: John Gaspar, 319-335-4776**

**Research Team Contact: Rose Schmitt, 319-335-4666**

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 a male between the ages of 21-30, have had a valid driver's license for at least two years, drive a minimum of 10,000 miles per year, and are in good general health.

The purpose of this research study is to evaluate procedures designed to detect and minimize the effects of drowsy driving.

### **HOW MANY PEOPLE WILL PARTICIPATE?**

Approximately 120 people will take part in this study 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 require 2 visits. The first is a 60 minute daytime screening visit. The second visit is an overnight study visit that could last approximately 9 hours and begins at 11:00 PM.

## **WHAT WILL HAPPEN DURING THIS STUDY?**

### **Visit 1 (Daytime 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 obtain your written consent. You will receive a copy of this signed Informed Consent Document. Next, you will be asked to show your driver's license to confirm you have a valid U.S. driver's license and then fill out a payment form. We will also ask you to fill out a video release form. A video release form that requests edits to your person and voice so that you are not identifiable will also be available upon request.

You will then be asked to provide a breath alcohol measurement. Next, you will be asked to watch an overview presentation of the simulator cab. You will then be escorted into the simulator, provided with an overview of the simulator cab, and asked to drive a 15-minute practice drive in order for you to become comfortable with driving the simulator. After your drive, you will be asked how you feel. If you are eligible to continue, an appointment time for your study visit will be scheduled. You will also receive an activity monitor (Fitbit Flex), charging device, and activity log. Study staff will review instructions for wearing the monitor, charging the monitor, and completing the activity log.

Your study visit will begin at 11:00 PM and last up to 9 hours. After staff confirm your study visit date and review the instructions for wearing your activity monitor and completing your activity log, you will be free to go.

### **Visit 2 (Overnight Study Visit)**

The day of your study visit, you will be asked to be awake by 8:00 AM and refrain from sleep until your study visit begins at 11:00 PM. No napping will be permitted. You will also need to refrain from caffeine beginning at 1:00 PM the day of your study visit. In addition, you will be asked to begin wearing your activity monitor at 8:00 AM the day prior and keep it on until the beginning of the study visit. You will also complete an activity log. Before wearing the device, you should be sure it is charged (you will be shown how to tell this at your screening visit).

On the day of your visit, you will be asked to arrive at the National Advanced Driving Simulator at 11:00 PM. We ask that you have finished your dinner when you arrive. Transportation to and from your appointments can be arranged if you are unable to make arrangements yourself. You may ask a friend or relative to drive you to the visit. You will not be allowed to drive yourself.

After your arrival, staff will collect your activity wrist monitor and activity log. While data are collected from your monitor, you will be asked to complete a survey about your sleep and food intake over the last 24 hours. Next, you will be asked to complete a breath alcohol test. If your participation is ended, you will be paid for your time and effort, and transported home.

You will be asked to complete a questionnaire about your current sleepiness level every 30 minutes and again just prior to your drive. You will then be escorted into the simulator. Eye tracking calibration procedures will be conducted. You will then drive for approximately 4 hours. Your drive will consist of freeway roadways. You may stop driving at any time if you require a break. During any breaks, you will be asked to complete a survey that asks you about your current sleepiness level and why you chose to

take a break. You may take as long of a break as you need. You will be allowed to nap, consume caffeine, exercise, or engage in other activities during this break to assist you in staying awake. Caffeine consumption will be limited to one 8-oz cup of coffee, however. After your study drive, you will complete a questionnaire about how you feel and a post-drive survey that asks about your drive and how it relates to the real world. At the completion of your visit, staff will finalize your payment voucher and transportation will be arranged to take you home. You will be asked to avoid driving until you are well rested.

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

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 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.

**WHAT ARE THE RISKS OF THIS STUDY?**

You may experience one or more of the following risks 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, we will provide transportation 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.

An experimenter will ride with you in the simulator to ensure your safety while you drive.

Drowsy driving is dangerous, and participants need to refrain from driving until sufficiently rested.

**WHAT ARE THE BENEFITS OF THIS STUDY?**

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the information gathered might benefit society by obtaining a better understanding of how drowsy driving impairs

specific driving performance.

**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. 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. Your social security number is obtained for payment purposes only; it will not be retained for research purposes. If you wish to be paid via direct deposit, please be sure to bring your bank information so that you are able to provide this on your payment form.

If you agree to participate in this study, you will be paid up to \$150 if you complete all study visits and procedures. In the event that you fail to meet the study criteria (e.g., breath alcohol test, sleep requirements, and activity level requirements), you will be paid only \$5 for the study visit. In addition, you have the potential to earn rewards for completing the study drive in under 3.25 hours, as well as the potential for penalties if you depart the lane (more than half of your vehicle departs the road surface onto the shoulder) or crash. The following table shows this information.

Visit 1 (Screening)	\$ 15
Visit 2 (Study) Starting Amount	\$ 85
Visit 2 (Study) Rewards	\$ 1 per minute under 3.25 hours, up to \$ 50
Visit 2 (Study) Penalties	- \$85 for road departure or crash
Total (complete all visits)	Up to \$ 150

If you decide to withdraw your participation early, your pay will be pro-rated at \$15 per hour of participation.

**WHO IS FUNDING THIS STUDY?**

The National Highway Traffic and Safety Administration (NHTSA) is the study sponsor and is funding this research study. This means that the University of Iowa is receiving payments from them 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 NHTSA for conducting this study.

**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
- Auditing departments of the University of Iowa
- The study sponsor, NHTSA

- The University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

You will be assigned a study number that 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 simulator 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. If presented in conjunction with video data, the image of the participant's face will be masked or blurred to prevent personal identification.

The **video data** (video image data recorded during your drive) recorded in this study includes your video-recorded likeness and all in-vehicle audio including your voice (and may include, in some views, superimposed performance information). 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 and restricted to members of the research team.

### **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 will not 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 Rose Schmitt at 319-335-4666 as soon as you decide not to participate.

### **Can Someone Else End my Participation in this Study?**

Under certain circumstances, the researchers or NHTSA might decide to end your participation in this

research study earlier than planned. This might happen if you do not meet the activity 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. John Gaspar, (319) 335-4776. If you experience a research-related injury, please contact: Dr. John Gaspar, (319) 335-4776.

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, Iowa, 52242, (319) 335-6564, or e-mail [irb@uiowa.edu](mailto: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://research.uiowa.edu/hso>. 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.

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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: 10/26/18.

\_\_\_\_\_  
(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)