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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 a 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 xxxx-xxxx (expiration date: xx/xx/xxxx). The average amount of time to complete the informed consent is estimated to be 15 minutes. All responses to this collection of information are voluntary. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Washington, DC, 20590.

Project Title: Examining Distraction and Driver Monitoring Systems to Improve Driver Safety – Track A: Distraction

Principal Investigator: Timothy Brown, 319-335-4785

Research Team Contact: Rose Schmitt, 319-335-4066

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 18 years of age or older, hold a valid U.S. driver's license with no restrictions other than vision correction, you drive at least once weekly or at least 2,000 miles per year, have no need for special equipment to help you drive, are comfortable and willing to engage in distracting tasks, and are in good general health.

The purpose of this study is to identify how various inputs for driver monitoring systems impact the ability of the system to assess driver states (such as distracted or drowsy). Driver monitoring systems are a vehicle safety system used to assess the driver's alertness or attentiveness using sensors. These sensors

track the driver's face (e.g., where you are looking or position of your head). For this study, we are interested in learning about the capabilities of driver monitoring systems to detect driver distraction.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 120 people will take part in the overall study (Track A: Distraction & Track B: Drowsiness and Distraction while Drowsy) at the University of Iowa. We anticipate that 60 people will take part in this Track A (distraction) study.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will require one visit to the University of Iowa Driving Safety Research Institute (DSRI), home of the National Advanced Driving Simulator (NADS), that will last approximately 2 hours.

WHAT WILL HAPPEN DURING THIS STUDY?

Upon arrival at the University of Iowa Driving Safety Research Institute (DSRI) in the University Research Park, a research team member will verbally explain the purpose and procedures involved in the study and will answer questions you may have about participation. If you agree to participate in the study, you will sign the consent document electronically and will receive a copy of this signed form. Once you sign the consent document, the research team will keep your demographic and driving responses from the online eligibility questionnaire as data.

Next, you will complete a payment form and provide your driver's license so that a research team member can confirm its validity (by checking expiration date). Then, you will provide a breath alcohol measurement by blowing into a breathalyzer. You must have a reading of 0.000% to continue in the study. After this, a research team member will take a picture (digital image) of your face to obtain Red Blue Green (RGB) values of your skin tone and take measurements of your facial shape and height (both standing and seated). The digital image will not be kept as data; the research team will only keep the digital image until the values obtained are verified.

After these measurements, you will watch a PowerPoint presentation that gives you an overview of the purpose of the study, the simulator cab, the drives you will complete in the simulator, and information about any distracting tasks the research team may ask you to do while in the simulator. During your drive, the research team might request that you add or remove layers of clothing, such as a sweater, jacket, hat, scarf, shawl, sweatshirt, etc.

After responding to any questions you may have, a research team member will escort you into the simulator. You will drive the NADS-1 with motion. The NADS-1 contains a full-size vehicle cab in an enclosed dome with the driving environment projected on the walls around the vehicle. Once seated in the vehicle cab, you will position yourself in the driver's seat and make adjustments as needed so that you may drive comfortably. A research team member will conduct calibration procedures for the driver monitoring system once you are situated in the driver's seat. You will complete two drives. The first

drive will allow you to become familiar with the simulator and will take approximately 20 minutes. After the drive, you will complete a short questionnaire about how you feel and you will rate your current sleepiness level. This consists of a single question rated on a 10-point scale. If you feel okay, you will complete the study drive, which takes approximately 60 minutes. This drive will include periods of attentive and distracted driving. During periods of distracted driving, you will engage with tasks that lead to different levels of distraction with various effects to your driving performance. This allows us to assess how well the DMS assesses your driver state. You will again complete a short questionnaire about how you feel and rate your current sleepiness level after the study drive.

After exiting the simulator, a research team member will answer any questions you may have about your visit and ask if you are interested in the Track B (drowsiness) study. If yes, the research team member will add your name to a contact list. After this, your visit will be complete.

Data Storage for Future Use

As part of this study, we are obtaining driving performance, audio/video, digital image, and questionnaire data from you. We would like to study your driving patterns and responses in the future, after this study is over. Other qualified researchers who obtain proper permission may gain access to your data for use in approved research studies that may or may not be related to the purpose of this study. This process could occur without additional informed consent from you.

These future studies may provide additional information that will be helpful in understanding how driving performance or driver monitoring system assessment varies among individuals, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your driving performance, audio/video, digital image, and questionnaire data will be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. There are no plans to provide financial compensation to you should this occur.

Your driving performance and questionnaire data, and values obtained from the audio/video or digital image sources, will be stored *without* your name or any other kind of link that would enable us to identify which sample(s) are yours. Therefore, if you give permission to store your driving performance and questionnaire data, as well as values obtained from the audio/video and digital image sources, it will be available for use in future research studies indefinitely and cannot be removed. The audio/video and digital images will not be available for future studies as they will only be retained through study closure.

Once this study is over, your data will be moved to the DSRI data repository. Your data will be stored *without* your name or any other kind of link identifying which sample(s) are yours. Other researchers could gain access to this data via Data Use Agreements or similarly termed documentation, but the data is not placed in any publicly available central repository or other national repository sponsored by Federal agencies.

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Audio/Video Recording or Photographs

One aspect of this study involves taking a digital image (photograph) of your face so we can obtain RGB values of your skin tone for analysis. By participating in this study, you consent to this digital image. Study investigators supervise access to this data but may release it as required by law.

Digital video/audio recorders (cameras) placed in the simulator will record all of your drives so that we can view your face, see your interactions with the vehicle displays, and see your view of the scene in front of you. The placement of the cameras will allow the researchers to record the simulator controls and your response to driving events.

The simulator contains sensors that measure vehicle operation, vehicle motion, and your driving actions.

The sensor and camera placement will not affect you or obstruct your view while driving. The information collected using these sensors and cameras are recorded for analysis by research staff and used as described in the "WHAT ABOUT 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.

A possible risk of driving the simulator is discomfort associated with simulator disorientation. Some individuals in driving simulator studies report feeling uncomfortable during or after the simulator drive. These feelings are usually mild to moderate and consist of slight uneasiness, warmth, or eyestrain. These effects typically last for only a short time, usually 10-15 minutes, after leaving the simulator. You should notify the researcher any time you experience these feelings. You may quit driving at any time if you experience any discomfort.

If you ask to quit driving because of discomfort, you may quit immediately. A research team member will escort you to a room, ask you to sit and rest, and offer you water and a mint. For your safety, a trained staff member will determine when you may leave the DSRI facility. If you show few or no signs of discomfort, you can leave in your vehicle. DSRI can help you arrange transportation if you feel you are unable to drive home. If you experience anything other than slight effects, a DSRI staff member will call to follow-up with you 24 hours later to ensure you are not feeling ill effects.

Trained researchers will monitor your safety while driving in the simulator. A research team member will ride with you, and other researchers will communicate with you via intercom if necessary.

There is a risk of loss of confidentiality of your data. Measures in place to protect your confidentiality are indicated in the "WHAT ABOUT CONFIDENTIALITY" section later in this document.

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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 information gained will provide important insight into driver monitoring systems to assess driver state.

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 receive $30 per hour for being in this research study with a $10 minimum. If you fail to meet study eligibility criteria, you will receive only $5 for the visit. You will need to provide your address so the University of Iowa can mail a check to you. If you wish to be paid via direct deposit, please be sure to bring your bank information (routing and account number) so you can provide this on your payment form. You will still need to provide your address if you choose direct deposit in case the direct deposit fails and a check is required.

WHO IS FUNDING THIS STUDY?

The National Highway Traffic Safety Administration (NHTSA) is funding this research study. This means that the University of Iowa is receiving payments from NHTSA 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 permitted by law. However, it is possible that other people such as those indicated below will 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. These people include

- federal government regulatory agencies,
- auditing departments of the University of Iowa,
- the study sponsor or its agents, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies).

To help protect your confidentiality, we will assign a study number to you which the research team will use instead of your name to identify all data collected for the study. This includes data generated from your digital image, questionnaire data, and engineering data. The research team will store the list linking your study number and your name in a secure location. Only a small group of researchers at the

University of Iowa have access to this list. All records and data containing confidential information are maintained in locked offices or on secure password-protected computer systems that are accessible to the researchers, the study sponsor, and its agents. Study documents are identified by subject number only, except the Informed Consent Document. This is identified by your last name and first initial and stored in a separate digital folder than other study documents. The research team will destroy the digital records of informed consent six years after the study closes. If we write a report or article about this study, or share the study data set with others, we describe the study results in a summarized manner so that you cannot be identified by name.

The research team will store your **digital image (photograph)** on a secure password-protected device until transfer to a secure bit-locked hard drive accessible only to the research team. The data is stored on the hard drive until the research team completes analysis of your digital image and verification of the output. After verification, a research team member will delete your digital image.

The research team will analyze the **engineering data** collected and recorded in this study (including any performance scores based on these data) along with data gathered from other subjects. The research team, sponsor, or its agents may publicly release these data 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). The above-listed parties may release the engineering data individually or in summary with that of other subjects, but will not present the data publicly in a way that permits 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). The research team will use the video and in-vehicle sounds to examine your driving performance and other task performance while driving.

The **simulator data (the combined engineering and video data)** is captured and stored on hard drives located within a limited access area of the DSRI facility. Access to simulator data is controlled through permissions established on a per-study basis.

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 are unable to complete the study procedures, you will receive $30 per hour of participation with a $10 minimum. If you drop out due to feeling ill in the simulator, we will follow the procedures above in the "WHAT ARE THE RISKS OF THIS STUDY?" section for your safety.

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 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 **Timothy Brown (319-335-4785) or Rose Schmitt (319-335-4666)**. If you experience a research-related injury, please contact **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://hsro.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.

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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): _____

_____ _____
(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)