

Study Introduction + Consent for Eligibility Questionnaire

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Thank you for your interest in our study!

The purpose of this research 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) accurately and reliably. You will be driving on the NADS-1 simulator with motion. There are two studies, referred to as Track A and Track B. Track A will evaluate distraction only and Track B will evaluate both drowsiness alone and distraction while drowsy. A subset of people will be asked to complete both tracks. Track A will be completed first. Information for both tracks is provided below.

You will be required to come to our facility, the University of Iowa Driving Safety Research Institute (DSRI), home of the National Advanced Driving Simulator (NADS), located on Oakdale Blvd. to participate. You are responsible for arranging your own transportation to and from study visits; DSRI will not be arranging any transportation. For the drowsiness study (Track B), you will not be allowed to drive, bike, or walk yourself after the visit ends and DSRI will be offering reimbursement of \$35 per trip (\$70 total) to cover transportation expenses for this visit. We ask that you refrain from recreational drugs and alcoholic beverages within 24 hours of any study visit.

Track A (Distraction Study):

This track involves one study visit lasting approximately 2 hours. At this visit, we will review and sign the informed consent document, have you

complete a payment form, verify your driver's license validity, and take a breath alcohol (BrAC) measurement (must be 0.000% to be eligible to continue). We will take a picture of your face to obtain skin tone data, take facial shape and height (both standing and seated) measurements, and then you will watch a training presentation. You will be escorted into our NADS-1 simulator and complete a familiarization drive of about 20 minutes. After this we will ensure you are feeling well enough to continue in the study. You will then complete a study drive of approximately 60 minutes. You will complete a rating of your current sleepiness level before and after your study drive. After your drive, you will again be asked how you are feeling and your visit will be complete.

If you complete the study visit and all study procedures, you can earn up to \$60 for your time and effort. If you withdraw from the study or your participation ends (e.g., due to simulator issues or protocol non-compliance), your compensation will be pro-rated at a rate of \$30/hour. You will receive a minimum of \$10 if you meet eligibility criteria at the visit. If you fail to meet study eligibility criteria at the visit, you will receive only \$5 and be sent home.

Track B (Drowsiness and Distraction while Drowsy Study):

This track involves one study visit lasting approximately 9 hours. The visit will start at either 5:15 p.m. or 6:45 p.m. The time of your visit will be given to you in advance so that you know when to arrive at the facility. At this visit, we will review and sign the informed consent document, have you complete a payment form, and verify your driver's license validity. We will also take a picture of your face to obtain skin tone data and take facial shape and height (both standing and seated) measurements.

Your eligibility to complete the study visit will be determined at the visit. You will need to be sure you are awake by 7:00 a.m. the day of your study visit. You must refrain from sleep, including naps, until you arrive for your study visit. You must also avoid stimulation such as aerobic exercise or caffeine after 1:00 p.m. the day of your study visit. We will collect a breath alcohol measurement at the start of the visit and ask you to complete a questionnaire about your sleep and food intake for the past 24 hours to ensure your continued eligibility.

You will receive instructions regarding driving the NADS-1 simulator and the study drives at your visit. You will be asked to complete one familiarization drive of approximately 20 minutes and three study drives each of

approximately 60 minutes. The first drive will occur while you are still alert and not experiencing signs of drowsiness. The next two drives will begin once you are showing signs of drowsiness and have been awake for at least 14 hours. We will have you wait a number of hours to ensure you are showing signs of drowsiness. You will complete several sleepiness ratings before and after your study drives, as well as during the waiting period (approximately every 30 minutes for 3-4 hours). We will also be asking you how you are feeling to ensure you are well enough to continue driving between each drive. You will again be asked how you are feeling after your final drive. After this, your visit will be complete. You will not be permitted to walk, bike, or drive yourself home after this visit and will need to arrange your own transportation to and from the visit.

You may also bring things to do for use during the waiting period. During this time, you will not be able to do stimulating activity such as consume caffeine or exercise, but you could bring a book, knitting, an electronic device for movies or music, etc.

If you complete the study visit and all study procedures, you can earn up to \$340 for your time and effort. You will receive up to \$270 for completing the study visit with an additional \$35 per trip (\$70 total) to reimburse for transportation expenses to and from the overnight study visit. If you withdraw from the study or your participation ends, your compensation will be pro-rated at a rate of \$30/hour. You will receive a minimum of \$10 if you meet study eligibility criteria at the visit. If you fail to meet study eligibility criteria at the visit, you will receive only \$5 and be sent home.

General Information:

As part of this eligibility questionnaire, we are asking you some demographic and driving questions. In order to ask these only once (and not ask again at your study visit(s)), we will be keeping your responses to these questions if you enroll into Track A, Track B, or both. This means that if you sign an informed consent document at a study visit, we will be keeping your demographic and driving responses as data. No other responses to this eligibility questionnaire will be kept, and we will only be keeping the demographic and driving responses as data if you sign a consent document. If you do not sign a consent document, we will not keep your data. This block of questions is specifically highlighted in the questionnaire so that you know which responses will be kept.

If you are not interested in this research, exit this questionnaire early, or are determined not eligible, we will not ask for your name or any other information that would identify you. If you are determined potentially eligible, you will be asked to provide your contact information so that a researcher may contact you to set up a study appointment. There is no compensation for completing this eligibility questionnaire. Compensation for the study visits is as described above.

We will keep your information secure and confidential. However, federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research.

We encourage you to ask questions. If you have any questions about the research study itself, please contact Rose Schmitt (319-335-4666, dsri-recruit@uiowa.edu). 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.

Are you interested in participating in this
research study? Yes No

If Yes:

Thank you. Several criteria must be met for participation in this study. You will be asked several questions to determine your eligibility. We ask that you respond honestly to all questions. You will not be allowed to skip any questions because we need these answers to be able to determine your initial eligibility for the study. If at any time you do not wish to continue, simply close your browser window. If you do not meet criteria at certain points while taking this questionnaire, you will receive a message stating you do not meet criteria and you will not be able to continue the questionnaire.

We will be collecting personal and health information as part of this eligibility screening. This information will only be kept until this study is complete. Researchers have access to this data until it is deleted.

We will also be collecting demographic and driving information that will be kept as data if you enroll into the study, as described in the study information on the previous page. This information will only be kept if you enroll into the study, otherwise it will only be kept until this study is complete. Researchers have access to this data until it is deleted.

No personal identifiable information will be released to the public.

Do you still wish to continue? By selecting "yes", you are consenting to provide us information for screening purposes and to keep your demographic and driving data if you enroll into the study. (If selecting "yes", you may need to click "Next Page" on the next page to continue to the questions.)

Yes No

If No:

We appreciate the time you took to read about our research and to consider participating. There are no additional questions. Press "Next Page" to exit the questionnaire.

If you have any questions about the research that may affect your interest, please email dsri-recruit@uiowa.edu (refer to study "WDDMS") and a researcher will gladly speak with you. A phone call can be set up via this email address if that is preferred.

If you would like to be added to our registry for future research, or if you are in the registry and would like to update your information, you can visit drivingstudies.com to fill out a submission form.

Thank you!

Eligibility Questions

Thank you. The following questions will ask you some basic eligibility questions that apply to both Track A and Track B. Please respond honestly.

	Yes	No
Can you attend one visit to DSRI that lasts approximately 2 hours? (Track A specific)	<input type="radio"/>	<input type="radio"/>
Are you comfortable with and willing to engage in distracting tasks such as reaching into the backseat, interacting with a screen over your shoulder, interacting with the touchscreen in the center console of a vehicle, interacting with a cell phone (for calls or emails), or other similar tasks?	<input type="radio"/>	<input type="radio"/>
Do you agree to abstain from alcohol use and recreational drug use in the 24 hours prior to your appointment(s)?	<input type="radio"/>	<input type="radio"/>
Do you go to sleep and wake at approximately the same time every day?	<input type="radio"/>	<input type="radio"/>
Do you have normal or corrected-to-normal (via surgery, glasses, contacts, hearing aids, or similar) vision and hearing?	<input type="radio"/>	<input type="radio"/>
Do you possess a valid U.S. Driver's License?	<input type="radio"/>	<input type="radio"/>
Have you been a licensed driver for at least 2 years?	<input type="radio"/>	<input type="radio"/>
In a typical year, do you drive at least once weekly or at least 2000 miles per year?	<input type="radio"/>	<input type="radio"/>

Do you have any of the following restrictions listed on your driver's license? Check all that apply.

- Intermediate License (Restriction Y in Iowa) or similar
- No interstate or freeway driving (Restriction Q in Iowa) or similar Maximum speed of 35 mph (Restriction R in Iowa) or similar
- No driving when headlights required (Restriction G in Iowa) or similar None of the above

We need some individuals to participate in both Track A and Track B. To ensure that we enroll some individuals who are eligible for both tracks, the following questions will ask you some eligibility questions more specific to Track B.

	Yes	No
Can you attend one visit to DSRI beginning at 5:15 p.m. or 6:45 p.m. and lasting approximately 9 hours overnight?	<input type="radio"/>	<input type="radio"/>
Do you agree to abstain from sleep beginning as early as 7:00 a.m. the day of your study visit (this includes no napping)?	<input type="radio"/>	<input type="radio"/>
Do you agree to abstain from stimulation such as aerobic exercise or caffeine after 1:00 p.m. the day of your study visit?	<input type="radio"/>	<input type="radio"/>
Do you agree to abstain from driving for the day following your overnight study visit?	<input type="radio"/>	<input type="radio"/>
Do you agree to arrange for transportation home from the overnight study visit? You will not be allowed to drive, bike, or walk yourself home.	<input type="radio"/>	<input type="radio"/>

Sleep Patterns

The following questions ask you about your sleep patterns. Your answers will determine if you continue to meet the study qualifications. We need people with a variety of levels and patterns of sleep, so there are no right or wrong answers. Please respond as honestly and accurately as you can.

Considering your own "feeling best" rhythm, at what AM time would you get up if you were entirely free to plan your day?

5:00 AM - 6:30
 6:30 AM - 7:45
 7:45 AM - 9:45 AM
 9:45 AM - 11:00 AM
 11:00 AM - 12:00 PM

During the first half-hour after you've woken in the morning, how tired do you feel?

Very tired
 Fairly tired
 Fairly refreshed
 Very refreshed

At what time in the evening do you feel tired and as a result in need of sleep?

8:00 PM - 9:00 PM
 9:00 PM - 10:15
 10:15 PM - 12:45 AM
 12:45 AM - 2:00 AM
 2:00 AM - 3:00 AM

At what time of the day do you think you reach your "feeling best" peak?

5:00 AM - 8:00
 8:00 AM - 10:00
 10:00 AM - 5:00 PM
 5:00 PM - 10:00 PM
 10:00 PM - 5:00 AM

One hears about "morning" and "evening" types of people. Which ONE of these types do you consider yourself to be?

Definitely a "morning" type
 Rather more a "morning" than an evening type
 Rather more an "evening" than a "morning" type
 Definitely an "evening" type

Demographic and Driving Questions

If you are eligible and sign a consent document for Track A, Track B, or both, your responses to the following questions will be kept as data. This is so we don't have to ask you these questions both here and again at your study visit(s). If you do not meet criteria for the study or if you do not sign a consent document at a study visit, these responses will not be kept as data. By continuing, you consent to allow us to keep this information as described. None of this information will be released publicly. If you have any questions about how this information may be used, you can contact us at

What is your age?

What is your sex?

Male Female

Are you Hispanic or Latino?

Yes
 No

For example: Mexican, Puerto Rican, Cuban, Salvadoran, Dominican, Guatemalan, etc.

How do you identify with respect

to race? Please select all that apply.

- American Indian or Alaska Native
- Native Asian or Asian American
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Other
- Prefer Not to Respond

It is important that we enroll individuals with a variety of skin types to test the ability of the driver monitoring system sensors to detect everyone.

THE FITZPATRICK SKIN TYPE SCALE



Please select which Type most closely matches your face, specifically your cheeks.

Type 1 Type 2 Type 3 Type 4 Type 5 Type 6

How often do you drive?
Please select the most appropriate category.

- Less than once weekly
 At least once
 weekly At least
once daily

How many years of driving experience do you have?

Due to pre-existing health conditions, some people are not eligible for participation in this study. We need to ask you some health-related questions to further determine your eligibility. Responses are required so that we may best determine your eligibility to be scheduled for an appointment. Responses to these health questions and the rest of the questions on the questionnaire are not kept as data.

Do you have an active tumor, or have you had a stroke in the past 6 months?

Yes No

(If you can answer "yes" to any of these questions, please mark "yes")

OR

Do you have any of the following lingering symptoms from a stroke, tumor, head injury, or infection?

- Vision impairment (blurring, loss, or double vision)
- Weakness or numbness in arms, legs, or face
- Trouble swallowing or slurred speech
- Coordination issues or loss of control
- Trouble walking, thinking, remembering, talking, or understanding

OR

Are you currently receiving any radiation and/or chemotherapy treatment, or have you received any radiation and/or chemotherapy in the last six months?

OR

Have you been diagnosed with a serious illness where the condition is still active or has lingering effects? Examples include (but not limited to) cancer, Crohn's disease, Hodgkin's disease, Parkinson's disease, Huntington's disease, Lou Gehrig's disease (ALS), Alzheimer's, multiple sclerosis, or any condition requiring radiation or chemotherapy treatments.

Do you experience any daytime drowsiness?

Yes No

This can be the result of sleep apnea, narcolepsy, sleep habits, mental health, etc.

Have you recently (past 72 hours) had any inpatient or outpatient procedures done that required the use of anesthesia?

Yes No

Are you, or is there any possibility that you are pregnant? Yes No Not Applicable

Have you ever been diagnosed with seizures or epilepsy? Yes No

Have you had a seizure in the past 12 months? Yes No

Have you experienced any pain from neck or back injuries within the last year? Yes No

Is it a current or chronic neck or back injury? Yes No

Do you have any mobility issues that would make climbing down a short ladder or walking on a narrow walkway without assistance difficult for you to perform safely? Yes No

In the event normal exiting of the simulator is not possible (e.g., rare instances such as power outage or fire), you would need to climb down a short ladder and walk on a narrow, grated walkway to the nearest exit location.

Do you require the use of any special equipment to help you drive, such as pedal extensions, hand brake or throttle, spinner wheel knobs, seat cushion, booster seat, or other non-standard equipment? Yes No

Medications, Supplements, or Herbal Remedies

Are you currently taking any prescription or over-the-counter medications, supplements, or herbal remedies? Yes No

Have you been taking any of the medications, supplements, or herbal remedies for less than 6 months or do any of them cause daytime drowsiness or make you drowsy? Yes No

Please tell us which medications, supplements, or herbal remedies you have been taking for less than 6 months, cause daytime drowsiness, or make you drowsy. _____

Please use this space for any comments you would like to add about your responses to any of the health questions. _____

Do you have Ménière's Disease or any inner ear, dizziness, vertigo, or balance problems?

Yes No

Note:

Ménière's Disease is a problem in the inner ear that affects hearing and balance. Symptoms can be low-pitched roaring in the ear (tinnitus), hearing loss that may be permanent or temporary, and vertigo.

Vertigo is a feeling that you or your surroundings are moving when there is no actual movement, described as a feeling of spinning or whirling and can include sensations of falling or tilting. It may be difficult to walk or stand and you may lose your balance and fall.

Do you experience discomfort or motion sickness when using an electronic device (such as a cell phone) as a passenger in a moving vehicle?

Yes No Unsure

A moving vehicle can include, but is not limited to, a passenger vehicle (such as a sedan, truck, SUV, van) or a transit vehicle (such as a bus).

Please describe your discomfort or motion sickness while trying to use an electronic device as a passenger. Please include how or when this occurs and _____ the severity.

This questionnaire is designed to measure your experience with different visual display or entertainment devices and if they ever caused discomfort.

Visual display or entertainment devices include Movie Theatre or Cinema, Smartphones & Tablets with movies or games, Video Games, Virtual Reality Glasses or Head Mounted Displays, Simulators, Large Public Moving Display Advertising or Information Screens.

Please answer these questions solely with respect to your experiences during adulthood (older than 18 years) and ignore childhood experiences.

How often have you experienced each of the following symptoms when using any of these devices?

	Never	Rarely	Sometimes	Often
Nausea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/> Headache	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/> Dizziness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/> Fatigue	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/> Eye-Strain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/>				

Have any of these symptoms stopped you using any of these devices or made you avoid viewing such displays? Never Rarely Sometimes Often

If you have answered stopped or avoided, please list the devices or displays that you avoid:

Please use this space for any comments you would like to add about your responses to any of the questions (e.g., situations that may cause motion sickness, more information about a diagnosis, mobility concerns, etc.).

Eligibility Questionnaire

If deemed ineligible by background scoring logic, prospective subject will see this message.

Thank you for your interest in our study. Unfortunately, it appears you are not eligible at this time. You may still qualify for future research with the Driving Safety Research Institute. If you would like to be added to our registry for future research, or if you are in the registry and would like to update your contact information, you can visit drivingstudies.com to fill out a submission form.

If you have any questions about your eligibility, please email dsri-recruit@uiowa.edu (refer to study "WDDMS") and a researcher will gladly speak with you. A phone call can be set up via this email if that is preferred over email contact. Thanks again!

Eligibility Questionnaire

If deemed potentially eligible for the study by background logic, prospective subject will see the following.

Thank you for your responses! A research team member will contact you if you are eligible to continue or if there is a need to follow up on a response. If you wish to contact a researcher directly, please email dsri-recruit@uiowa.edu and reference "WDDMS" and a researcher will get in touch as soon as possible.

Be sure to add dsri-recruit@uiowa.edu to your contact list or safe senders group so you don't miss any emails from us.

If you'd like us to contact you to participate, please enter your contact information below.

Please note that by providing contact information, you are linking your name and contact information to your questionnaire responses. This is required to verify eligibility for our study. If you do not provide a name or contact information, your responses will not be associated with you in any way, but we will be unable to verify eligibility to participate or contact you to participate.

Preferred or Chosen First Name

You will be addressed by this name in communications from us.

Legal First Name

Legal Last Name

Email Address

This is the primary contact method.

Primary Phone Number

When might we call

you?

You will be called at this number if your email address bounces back as undeliverable, if we have a last-minute appointment available that might work for you, if we need to cancel your appointment on short notice, or if you are running late to your appointment.

If you have any comments regarding your contact information, please note those in the space provided.

Have you ever gone by another name?

For example, if your name is Kathryn, have you ever preferred to go by Katie? Have you ever had a different last name?

This allows us to look you up in our registry and check your participation history to confirm you haven't done a related study that might exclude you from participation. Please note potential other names in the space provided, if you are comfortable doing so.

prior study participation does not necessarily exclude you

Please indicate which days and times would work best for the approximately 2-hour Track A appointment. Note that this would be appointment start time. We will do our best to

accommodate one of your choices.	8 a.m. to 11 a.m. 8:30 p.m.	11:30 a.m. to 4:30 p.m.	4:30 p.m. to
Monday	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tuesday	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wednesday	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Thursday	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Friday	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate which days might work best for the approximately 9-hour Track B appointment. Note that the two times listed are the two appointment start times. We will do our best to accommodate one of your choices.

	5:15 p.m.	6:45 p.m.
Monday	<input type="checkbox"/>	<input type="checkbox"/>
Tuesday	<input type="checkbox"/>	<input type="checkbox"/>
Wednesday	<input type="checkbox"/>	<input type="checkbox"/>
Thursday	<input type="checkbox"/>	<input type="checkbox"/>
Friday	<input type="checkbox"/>	<input type="checkbox"/>
Saturday	<input type="checkbox"/>	<input type="checkbox"/>
Sunday	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate any dates that you know will NOT work for a study visit through (date to be entered once data collection window confirmed)