

IVDDA Phone Screening Procedures

For a participant to be eligible for a study they must meet **ALL** of the following criteria:

- ◆ Be able to participate when the study is scheduled
- ◆ Meet all inclusion criteria
- ◆ Pass the phone health screening questions

Instructions to the experimenter are in normal text.

Portions to be read aloud to potential participant are in bold.

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). Public reporting for this collection of information is estimated to be approximately 15 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. 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.

Overview

The purpose of this research study is to evaluate procedures designed to detect drowsy driving.

Study Information, Time Commitment, and Compensation:

This study involves one screening and one study visit. The first visit will be a screening appointment that will last approximately 60 minutes and will determine if you are eligible to be in the study. If you are eligible, the next visit will be scheduled and will take place beginning at 11 PM and last up to 9 hours.

You must come to the University Research Park for both visits to participate. If you do enroll into the study, arrangements will be made for your transportation to your residence from the National Advanced Driving Simulator at the end of the study visit, either through transportation you arrange or a taxi paid for by the NADS. We can also arrange transportation to the study visit, if needed, or you can be dropped off. You will not be allowed to drive yourself home at the end of the study visit. You can either arrange transportation or the NADS will pay for a taxi. You are responsible for your own transportation for the screening visit.

We ask that you not drink alcoholic beverages within 24 hours of these visits, not drink caffeine after 1 PM the day of your study visit, and to refrain from using recreational drugs within 30 days of your scheduled visits. Your eligibility to complete each visit will be determined at each visit.

Participation involves signing a consent form, wearing an activity monitoring device such as a FitBit, and completing an activity log. You will need to begin wearing your activity monitoring device and completing your activity log by 8 AM the day prior to your study visit and wear the device until your study visit begins. You will need to be sure you are awake by 8 AM the day of your study visit and refrain from sleep, including naps, until you arrive for your study visit. You will also complete several

questionnaires before and after your study drives. You will receive instructions regarding driving the simulator and the study drives at your visits. We will collect a BAC at the start of each visit to help ensure your continued eligibility. The practice drive, conducted at your screening visit, will last 15 minutes. The study drive, conducted at the study visit, will last 4 hours. All drives occur in our NADS-1 simulator with motion.

Compensation

If you complete all study visits and procedures, you will be paid up to \$150 for your time and effort. If you fail to meet study criteria, you will be paid only \$5 for the visit. If you withdraw from the study visit early or your participation ends, you will earn \$15 for each hour of participation.

For Visit 1, the screening visit, you will earn \$15.

For Visit 2, the study visit, you can earn up to \$135 - \$85 base pay with the potential for rewards and penalties. You can earn \$1 for each minute under 3.25 hours you complete the study drive, and be penalized \$85 for any road departures or crashes.

- **Are you still interested in participating?**
 - If YES, continue with Inclusion Criteria
 - IF NO, thank them and explain that they do not fit the criteria for this study.

Inclusion Criteria ~ General Questions

Overview

Before this list of questions is administered, please communicate the following:

- **You must meet several criteria to participate in this study. I need to ask you several questions to determine your eligibility.**

Proceed to Closing if an answer does not meet study criteria.

- 1) **Do you possess a valid U.S. Drivers' License?** *Must answer yes.*
- 2) **How long have you been a licensed driver?** *Must be at least 2 years.*
- 3) **What restrictions do you have on your license?** *Must be free from any restrictions except for vision.*
- 4) **How many miles do you drive per year?** *Must drive at least 10,000 miles per year.*
- 5) **Do you require any special equipment to help you drive such as pedal extensions, hand brake or throttle, spinner wheel knobs or other non-standard equipment?** *Must be able to drive without special equipment.*
- 6) **What is your age?** *Must be between 21 and 30.*

General Questions Inclusion Criteria is met – proceed to Specific Questions
Inclusion Criteria

Inclusion Criteria ~ Specific Questions

Proceed to Closing if an answer does not meet study criteria.

- 1) **How far do you live from University of Iowa Research Park, which is North of the Coral Ridge Mall?** *Must live within a 30-minute drive from the facility*
- 2) **Could you attend two study visits, one lasting 60 minutes and one beginning at 11 PM and lasting up to 9 hours overnight?** *Must answer yes.*
- 3) **Can you wear an activity monitor beginning 8 AM the day before your study visits and wear the monitor until arrival?** *Must answer yes.*
- 4) **Can abstain from sleep beginning at 8 AM the day of your study visit (this includes no napping)?** *Must answer yes.*
- 5) **Can you refrain from caffeine after 1 PM the day of your study visit?** *Must answer yes.*
- 6) **Can you abstain from driving for the day following your study visit?** *Must answer yes.*
- 7) **Do you go to sleep and wake at approximately the same time every day?** *Must answer yes.*

8) Do you believe that you have might have obstructive sleep apnea? *Must answer that they have no reason to believe they have OSA.*

9) Have you participated in any drowsy-driving related studies before? *Must answer no.*

10) Because we are conducting a study to determine how sleep impacts driving performance, the following questions ask you about your sleep patterns. Your answer will determine if you continue to meet the study qualifications.

Administer Morning/Evening Phone Screening Questionnaire on next page

Morning/Evening Phone Screening

Research assistant will read the following statement over the phone:

Because we are conducting a study to determine how sleep impacts driving performance, the following questions ask you about your sleep patterns. Your answer will determine if you continue to meet the study qualifications. We need participants 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.

1. Considering your own “feeling beat” rhythm, at what time would you get up if you were entirely free to plan your day?
 - 5:00 AM-6:30 AM—5 points
 - 6:30 AM-7:45 AM—4 points
 - 7:45 AM-9:45 AM—3 points
 - 9:45 AM-11:00 AM—2 points
 - 11:00 AM-12:00 PM—1 point

2. During the first half hour after you’ve woken in the morning, how tired do you feel?
 - Very tired—1 point
 - Fairly Tired—2 points
 - Fairly refreshed—3 points
 - Very refreshed—4 Points

3. At what time in the evening do you feel tired and as a result in need of sleep?
 - 8:00 PM - 9:00 PM—5 points
 - 9:00 PM - 10:15 PM—4 points
 - 10:15PM - 12:45 AM—3 points
 - 12:45 AM- 2:00 AM —2 points
 - 2:00 AM- 3:00 AM—1 point

4. At what time of the day do you think you reach your “feeling best” peak?
- 5:00 AM – 8:00 AM – 5 points
 - 8:00 AM – 10:00 AM – 4 points
 - 10:00 AM – 5:00 PM – 3 points
 - 5:00 PM – 10:00 PM – 2 points
 - 10:00 PM – 5:00 AM – 1 point
5. One hears about “morning” and “evening” types of people. Which ONE of these types do you consider yourself to be?
- Definitely a “morning” type—6 points
 - Rather more a “morning” than an evening type—4 points
 - Rather more an “evening” than a “morning” type —2 points
 - Definitely an “evening” type—0 Points

Scores 12 and above include in study and proceed to General Health Exclusion Criteria (page 3 Phone screening procedures)

Scores 11 and below will not be included in study, proceed to Closing (page 6 Phone Screening Procedures)

Specific Inclusion Criteria is met – proceed to General Health Exclusion Criteria

General Health Exclusion Criteria

Overview

Before administering this list of questions, please communicate the following:

- 1 Because of pre-existing health conditions, some people are not eligible for participation in this study.**
- 2 I need to ask you several health-related questions before you can be scheduled for a study session.**
- 3 Your responses are voluntary and all answers are confidential.**
- 4 You can refuse to answer any questions**
- 5 No responses will be recorded.**

- Exclusion criteria are provided below each question.
- If a participant fails to meet one of the following criteria, proceed to the Closing

1) Have you been diagnosed with a serious illness?

- *Cancer (receiving any radiation and/or chemotherapy treatment within last 6 months)*
- *Crohn’s disease*
- *Hodgkin’s disease*
- *Parkinson’s disease*

2) Do you have Diabetes?

- *Type I Diabetes - insulin dependent*

- *Type II – **Uncontrolled** (Type II Diabetes accepted if controlled (medicated and under the supervision of physician))*

3) Do you suffer from a heart condition such as disturbance of the heart rhythm or have you had a heart attack or a pacemaker implanted within the last 6 months?

- *History of ventricular flutter or fibrillation*
- *Systole requiring cardio version (atrial fibrillation may be acceptable if heart rhythm is stable following medical treatment or pacemaker implants)*

4) Have you ever suffered brain damage from a stroke, tumor, head injury, or infection?

- *A stroke within the past 6 months*
- *An active tumor*
- *Any symptoms still exist*

5) Have you ever been diagnosed with seizures or epilepsy?

- *A seizure within the past 12 months*

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

- *Meniere's Disease*
- *Any recent history of inner ear, dizziness, vertigo, or balance problems*

7) Do you have migraine or tension headaches that require you to take medication daily?

- *Any narcotic medications*

8) Do you currently have a drug dependency, anxiety disorder, ADHD, claustrophobia, or untreated depression?

- *Untreated depression*
- *Agoraphobia, hyperventilation, or anxiety attacks*
- *ADHD (treated and untreated)*
- *Dependency or abuse of psychoactive drugs, illicit drugs, or alcohol*

9) Are you currently taking any prescription or over the counter medications?

- *Sedating medications or drowsiness label on medication **UNLESS** potential participant indicates they have been on the medication consistently for the last 6 months **AND** states they have **NO** drowsiness effects from this medication*
- *Stimulant medication **UNLESS** potential participant indicates they have been on the medication consistently for the last 6 months **AND** states they have **NO** drowsiness effects from this medication*

10) Do you experience any kind of motion sickness?

- *One single mode of transportation where intensity is high and present*
- *More than 2 to 3 episodes for mode of transportation where intensity is moderate*

or above

- *Severity and susceptibility scores rank high*

11) Have you experienced any pain from neck or back injuries within the last year?

- *Any current skeletal, muscular or neurological problems in neck or back regions*
- *Chronic neck and back pain*
- *Pinched nerves in neck or back*
- *Back surgery within last year*

12) 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?

- *Make note to ensure extra staff on hand, does not rule participant out*

Closing

MEETS ALL CRITERIA

Instructions:

- **Refrain from drinking alcohol and taking any NEW prescription or over the counter drugs for the 24 hours preceding your driving session. If you do need to take a new medication 24 hours preceding your driving session, please call us. Ibuprofen, Tylenol, aspirin, and vitamins are acceptable to take prior to driving session.**
- **Bring Driver's License with you to appointment.**
- **We ask that cell phones and pagers be turned off or left home or in your car outside as they are not allowed while participating in the driving study.**
- **Request the following of all participants:**
 - **Wear flat shoes to drive in**
 - **No hats worn or gum chewing allowed while driving**
 - **Refrain from wearing artificial scents (perfume or cologne) as some staff are allergic to scents**
- **You will be required to wear a seat belt while driving.**
- **The front door will be locked when you arrive for your study visits, so please come to the door at your appointment time. Someone should be in the lobby waiting to let you in. If they had to step away for a moment, they will return as soon as possible.**
- **Please call (319) 335-4666 if you are unable to make this appointment and need to reschedule as soon as possible. We prefer 24-hour notice. Please leave a message if you receive voicemail and a staff member will return your call.**
- **Please bring your calendar or schedule so we can plan your visits.**

Provide directions, explain where to park and ask them to check in at the front desk inside the main entrance.