

Study Documents

Driver Monitoring of Inattention and
Impairment Using Vehicle Equipment
(DrIIIVE) –

Track B: Assess Potential
Countermeasures for Drowsy Driving
Lane Departures

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1 APPENDIX B: ADVERTISEMENT

Advertisement Wording

Adults ages 21-34 are invited to participate in a driving simulation study evaluating procedures designed to detect and mitigate drowsy driving. Must have normal sleep patterns, live within 30 minute drive of University of Iowa Oakdale Campus/ Research Park, and have not participated in any driving simulation studies regarding distraction or alcohol and driving conducted at the National Advanced Driving Simulator. 3 visits total (Two overnight visits from 7pm to 6am). Drug and pregnancy screen completed at some visits. You will be paid for your time and effort. For more information, call 319-335-4719 or www.drivingstudies.com Mention study name "Drowsy".

2 APPENDIX C: ADVERTISEMENT EMAIL

Email Script

Subject: Participants invited for driving study



The National Advanced Driving Simulator at The University of Iowa Oakdale Campus/Research Park is inviting adults to participate in a driving simulation evaluating procedures designed to detect drowsy driving.

Who can be part of this study?

- Adults ages 21-34
- Live within 30 minute drive of University of Iowa Oakdale Campus / Research Park
- Have normal sleep patterns
- Have not participated in any driving simulation studies regarding distraction or alcohol and driving conducted at the National Advanced Driving Simulator
- Able to attend 3 study visits (Two overnight visits from 7pm to 6am)
- Drug and pregnancy screen completed at some visits

If you meet the above criteria and are interested in participating, please visit:

www.drivingstudies.com

Email: nads-recruit@uiowa.edu

Call: 319-335-4719

Mention study name: "Drowsy"

If you do participate in the study, you will be paid for your time and effort. Even if you don't qualify to participate in this study, please forward this message to anyone you know who does!

3 APPENDIX D: ADVERTISEMENT FLYER

Adults ages 21-34 are invited to participate in a driving simulation study evaluating impact of drowsiness on driving performance. Must have normal sleep patterns and live within 30 minute drive of UI Oakdale Campus/Research Park

3 visits total (Two visits from 7pm to 6am). Drug and pregnancy screen completed at some visits.

You will be paid for your time and effort.

For more information, call 319-335-4719

or visit www.drivingstudies.com

Mention study name: "Drowsy"



4 APPENDIX E: ADVERTISEMENT ON DRIVINGSTUDIES.COM



Drowsy Driving Mitigation

The National Advanced Driving Simulator at The University of Iowa Research Park (formerly the Oakdale Campus) is inviting adults to participate in a driving simulation evaluating procedures designed to detect and mitigate drowsy driving.

Requirements:

- Adults ages 21-34
- Live within 30 minute drive of University of Iowa Oakdale Campus / Research Park
- Have normal sleep patterns
- Have not participated in any driving simulation studies regarding distraction or alcohol and driving conducted at the National Advanced Driving Simulator
- Able to attend 3 study visits (Two visits from 7pm to 6am)
- Drug and pregnancy screen completed at some visits

For more information:



recruit@nads-sc.uiowa.edu



319-335-4719

5 APPENDIX F: PHONE SCREENING

DRIIVE Phase 2 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.

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 3 study visits. The first visit will be a screening appointment which will be approximately 1 ½ hours in length and will determine if you are eligible to be in the study. If you are eligible, the next 2 visits will be conducted over a 2 week period of time and will take place overnight beginning around 7 pm and lasting up to 11 hours.

Each of the three visits requires you to come to the University Research Park (formerly the Oakdale Campus) 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 overnight visits. You will not be allowed to drive yourself home at the end of the overnight visits.

We ask that you not drink alcoholic beverages within 24 hours of these study visits, not drink caffeine 12 hours prior to your visit, and to refrain from using recreational drugs 30 days of your scheduled visits. Additionally, we will be conducting urine drug screens at some visits and for females; a urine pregnancy test will be completed for some study visits. Your eligibility to complete each visit will be determined at each visit.

Participation involves signing a consent form, wearing an activity monitoring device which is similar to wearing a watch, and completion of an activity log. 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.

Compensation

If you complete all study visits and procedures you will be paid \$250 for your time and effort.

If you withdraw from the study or your participation ends your compensation will be prorated:

Visit 1 \$10

Visit 2 \$100

Visit 3 \$140

If you fail to meet study criteria you will be paid only \$5 for the visit.

- **Are you still interested in participating?**
 - If YES, continue with Inclusion Criteria
 - If NO, ask if he/she would like us to keep him/her in our recruitment database for consideration of future participation.
 - IF NOT interested in future studies and wish to be removed from database
 - Make note regarding deletion
 - Reason if given

Inclusion Criteria ~ General Questions

Overview

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

- There are several criteria that must be met for participation in this study. I will 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) How old are you?

Must be between the ages of 21 and 34.

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) Are you able to attend two study visits after 7 pm and stay overnight without sleeping?

Must answer yes.

- 3) Are you able to refrain from caffeine after 12pm on the day of the overnight visit?

Must answer yes.

4) Are you able to abstain from driving for the day following your overnight drive?

Must answer yes.

5) Do you go to sleep and wake at approximately the same time every day?

Must answer yes.

6) Have you no reason to believe that you have might have obstructive sleep apnea?

Must answer yes that they have no reason to believe they have OSA.

7) 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 Survey

Must meet criteria specified in attachment.

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:

- **Because of pre-existing health conditions, some people are not eligible for participation in this study.**
 - **I need to ask you several health-related questions before you can be scheduled for a study session.**
 - **Your responses are voluntary and all answers are confidential.**
 - **You can refuse to answer any questions**
 - **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) If the subject is female:

- **Are you, or is there any possibility that you are pregnant? Or, are you currently breast feeding?**
 - *If there is ANY possibility of pregnancy*
 - *If breast feeding.*

2) 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*
- *Currently receiving any radiation and/or chemotherapy treatment*

3) 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))*

4) 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)*

5) 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*

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

- *A seizure within the past 12 months*

7) 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*

8) Do you currently have a sleep disorder such as sleep apnea, narcolepsy, or Chronic Fatigue Syndrome?

- *Sleep Apnea*
- *Narcolepsy*
- *Chronic Fatigue Syndrome*

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

- *Any narcotic medications*

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

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

11) 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 consistency 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 consistency for the last 6 months AND states they have NO drowsiness effects from this medication*
- *Omega3 2000mg daily for six weeks or more*

12) 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*

13) 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*

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 allergic to scents**
- **You will be required to wear a seat belt while driving.**
- **If your appointment is before 8am or after 5pm, the front door will be locked, doors 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) 335-4719 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 they receive voicemail and a staff member will return your call.**
- **Please bring your calendar or schedule so we can plan your overnight visits.**

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

DOES NOT MEET CRITERIA:

- **Inform participant that they may qualify for a future study and ask if they wish to remain in our database to be called for future studies.**
- **If participant is not in our database, ask if they would like to be considered for future driving research studies, if yes, fill out NADS database form.**

6 APPENDIX G: MORNING/EVENING PHONE SCREENING

Morning/Evening Phone Screening

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 best" 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 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 a "evening" than a "morning" type —2 points
 - Definitely a "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)

7 APPENDIX H: INFORMED CONSENT

INFORMED CONSENT DOCUMENT

Project Title: Driver Monitoring of Inattention and Impairment Using Vehicle Equipment

Principal Investigator: Timothy Brown

Research Team Contact: Dawn Marshall, 319-335-4774

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, the risks and benefits of the study, and 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 21-34, with 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 60 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 3 visits. The screening visit will take up to 1 ½ hours, and two night-time study drive visits which could last up to 11 hours each.

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 then obtain your written consent. You will receive a copy of this signed Informed Consent Document. Then you will be asked to provide a urine sample at which point a urine drug screen test will be performed to look for illegal drugs like PCP, morphine, cocaine, marijuana, etc. Female subjects' urine specimen will additionally be tested and screened for pregnancy. Then you will be asked to sit quietly and rest for 5 minutes prior to a staff member taking your blood pressure and heart rate. Your participation in the study will end if your

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drug screen test is positive, your blood pressure and/or heart rate do not meet the study requirements, and if female, you test positive for pregnancy. Results from the drug screen, blood pressure, heart rate, and for females, pregnancy test will remain confidential and your eligibility status will be documented as either a "yes" or "no." No other information will be recorded. Then you will be asked to complete a breath alcohol test. If you fail to meet study criteria, you will be paid for your time and effort.

If you meet study criteria, you will then be asked to watch an overview presentation of the simulator cab, and staff will train you on an in-vehicle task involving changing CD tracks. Next, you will be escorted into the simulator, provided with an overview of the simulator cab, and asked to drive a 5-8 minute practice drive in order for you to become comfortable with driving the simulator. If you are eligible to continue, appointment times for the next two study visits will be scheduled.

Regarding the next two study visits, both will begin in the evening and continue throughout the night. After staff confirms your next two study visits and reviews the instructions for receiving and wearing your activity monitor and completing your activity log, you will be free to go.

Visits 2 & 3 (Nighttime/Overnight Visits)

Two days prior to each of these visits you will receive an activity wrist monitor that will record your activity and sleep. You will also complete an activity log.

On the day of each of the overnight visits you will be asked to arrive at the National Advanced Driving Simulator between 5:00 and 7:00 pm. We ask that you have finished your dinner when you arrive. You may drive yourself to these visits, but you will not be allowed to drive yourself home at the end of the overnight visits. You may ask a friend or relative to drive you to the visit. If you prefer transportation by taxi or shuttle will be arranged.

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.

If you continue to meet study criteria, a drowsiness mitigation system you may experience while driving will be demonstrated to you. You will be escorted to a large waiting room with the other participants. Here, you will be provided with various activities (e.g. internet, movies, games) while you are waiting to drive. While you are waiting, you will not be allowed to converse with other participants. Staff will monitor you while waiting. You will be asked to complete a questionnaire about your current sleepiness level every 30 minutes prior to your drive. One hour preceding your first drive, you will be escorted to a private room where you will be asked to complete a test to measure your current sleepiness level. This test will last 10 minutes. You will complete the test again 10 minutes prior to your drive.

You will then be escorted into the simulator. Eye tracking procedures will be conducted, and you will be asked to complete a brief test and a questionnaire about your current sleepiness level. You will then drive for approximately 45 minutes. Your drive will consist of 3 segments, the first two are 10 minutes in length and include urban and freeway roadways. The third segment is a rural roadway and will be

approximately 25 minutes long. After your study drive, you will be asked to complete a task to test your current sleepiness level, questionnaires about your current sleepiness level, and a questionnaire about how you feel. At the completion of your second visit, your next visit will be confirmed and transportation will be arranged to take you home. You will be asked to avoid driving until you are well rested.

After completion of the third 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 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.

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 relating the data from this study to future studies. Agreeing to participate in this study does not obligate you to participate in future studies. You will 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.

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

As all of the participants for the evening drives will be waiting in a single room, it is possible that you may know or be known by another participant. Interactions between participants while waiting will be minimal.

Drowsy driving is dangerous, and participants need to refrain from driving until they are 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 and the effectiveness drowsiness mitigations. This, in turn, may allow the development of new technologies that could minimize drowsy 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. 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 \$250 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)	\$ 10
Visit 2 (Overnight)	\$ 100
Visit 3 (Overnight)	\$ 140
Total (complete all visits)	\$ 250

In the event that you fail to meet the study criteria (e.g., the drug screen, pregnancy screen, breath alcohol test, and activity level requirements) you will be paid only \$5 for the visit.

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 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.
- No compensation for treatment of research-related illness or injury is available from the University of Iowa unless it is proven to be the direct result of 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,
- 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 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). Additionally, the video data may be shared with researchers at the University of Wisconsin, Madison.

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 Dawn Marshall 319-335-4774 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 fail the drug screen, for females, if you are pregnant while participating, or 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. 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, Iowa, 52242, (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://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.

FOR IRB USE ONLY
APPROVED BY: IRB-02
IRB ID #: 201008800
APPROVAL DATE: 02/04/15
EXPIRATION DATE: 02/04/16

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: 02/04/16 .

(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)

8 APPENDIX I: VIDEO RELEASE FORM

CONSENT FOR RELEASE OF VIDEO IMAGE AND AUDIO DATA

I, the undersigned, have agreed to participate in a research study to be conducted at the University of Iowa entitled "Driver Monitoring of Inattention and Impairment Using Vehicle Equipment – Drowsiness Mitigation". The purpose of the study is to evaluate procedures designed to detect and mitigate drowsy driving. As part of the informed consent form I have signed for that study, I have agreed to allow the University, the study sponsor, and those acting pursuant to its authority, to record and use for research purposes video image data (including my video-recorded likeness) and audio data (including my voice), as well as, in some views, superimposed performance information (referred to below as "the Recording"). This Consent for Release of Video Image and Audio Data pertains to the following non-research purposes the University, the study sponsor, and those acting pursuant to its authority propose for my video image data (in continuous video or still formats) and associated audio data, either separately or in association with the appropriate engineering data:

- 1) Public release for regulatory purposes (e.g., to assist in regulating devices);
- 2) Public release for educational purposes (e.g., to assist with educational campaigns for members of the general public);
- 3) Public release for outreach purposes (e.g., to nationally-televised programs highlighting traffic safety issues);
- 4) Public release for legislative purposes (e.g., to assist the U.S. Congress with law-making/rule-making activities).

Engineering or simulator data may also be released individually or in summary with that of others participating in the study, but will not be presented publicly in a way that permits personal identification, except when presented in conjunction with video image data.

I hereby authorize the University of Iowa, the study sponsor, and those acting pursuant to its authority, to use my recorded video image and audio data, with or without related engineering or simulator data, for the non-research purposes specified above.

I transfer and assign to the University of Iowa and the study sponsor any right, title, and interest I may have in and to the Recording, including the copyright, and in and to all works based upon, derived from, or incorporating the recorded data.

I irrevocably waive any right to inspect, edit, or approve said Recording in any of its forms.

I irrevocably release the University of Iowa and the study sponsor, and any of their employees, agents, and assigns, from any and all claims that I may have at any time arising out of, or related to, the Recording or use of the Recording, including, but not limited to, any claims based on the right of privacy, libel, or defamation.

Name of Participant

Signature of Participant

Date

9 APPENDIX J: SLEEP AND FOOD INTAKE SURVEY

Study: DRIIVE
Participant: _____
Visit: _____

Sleep and Food Intake Survey

As part of this study, it is useful to collect information about your sleep and food, alcohol, and caffeine intake. Please read each question carefully. If something is unclear, ask the researcher for assistance. Your participation is voluntary and you have the right to omit questions if you choose.

- 1) On a typical _____, when do you normally go to bed? _____AM/ PM
- 2) On a typical _____, when do you normally wake up? _____AM/ PM
- 3) What time did you go to sleep last night? _____ AM/PM
- 4) What time did you wake today? _____ AM/PM
- 5) In total, how many hours did you sleep last night? _____
- 6) Do you feel that you got enough sleep? No Yes
- 7) Did you take a nap today?
 No
 Yes, times? _____
- 8) When did you eat your last meal? _____AM/PM
 - a) What did you eat at that meal?

- 9) Have you had anything to eat since your last meal?
 No
 Yes, when? _____AM/PM
 - a) What did you eat? _____

10) Have you had any nicotine in the last 24 hours?

- No
- Yes, when? _____ AM/PM
 - a) How many cigarettes did you smoke? _____
 - b) How much chewing tobacco did you use? _____
 - c) Other forms of nicotine? (type and frequency) _____

11) Have you had any caffeine in the last 24 hours?

- No
- Yes, when? _____ AM/PM
 - a) How many cups of coffee did you drink? _____
 - b) How many cans of caffeinated soda did you drink? _____
 - c) Other forms of caffeine? (type and frequency) _____

12) Have you had any alcohol in the last 24 hours?

- No
- Yes, when? _____ AM/PM
 - a) How many cans of beer did you drink? _____
 - b) How many glasses of wine did you drink? _____
 - c) How many mixed drinks did you consume? _____
 - d) How many shots of alcohol did you consume? _____

13) Have you taken any prescription or over-the-counter medications in the past 24 hours?

- No
- Yes, Explain what was taken, how much was taken and when it was taken.

10 APPENDIX K: WELLNESS SURVEY

STUDY: Drive Track B
PARTICIPANT: _____
VISIT: _____
DATE: _____

WELLNESS SURVEY

Directions: Circle one option for each symptom to indicate whether that symptom applies to you right now.

1. General DiscomfortNone.....Slight.....Moderate..... Severe
2. FatigueNone.....Slight.....Moderate..... Severe
3. HeadacheNone.....Slight.....Moderate..... Severe
4. Eye StrainNone.....Slight.....Moderate..... Severe
5. Difficulty FocusingNone.....Slight.....Moderate..... Severe
6. Salivation IncreasedNone.....Slight.....Moderate..... Severe
7. SweatingNone.....Slight.....Moderate..... Severe
8. NauseaNone.....Slight.....Moderate..... Severe
9. Difficulty ConcentratingNone.....Slight.....Moderate..... Severe
10. **"Fullness of the Head"None.....Slight.....Moderate..... Severe
11. Blurred VisionNone.....Slight.....Moderate..... Severe
12. Dizziness with Eyes OpenNone.....Slight.....Moderate..... Severe
13. Dizziness with Eyes ClosedNone.....Slight.....Moderate..... Severe
14. **VertigoNone.....Slight.....Moderate..... Severe
15. ***Stomach AwarenessNone.....Slight.....Moderate..... Severe
16. Burping.....None.....Slight.....Moderate..... Severe
17. Vomiting.....None.....Slight.....Moderate..... Severe
18. Other _____None.....Slight.....Moderate..... Severe

* Fullness of the head is an awareness of pressure in the head.

**Vertigo is experienced as loss of orientation with respect to vertical upright.

***Stomach awareness is a feeling of discomfort which is just short of nausea.

11 APPENDIX L: REMINDER CARD

Visit 2: Date _____

Visit 3: Date _____

Arrive between 5:00 and 7:00 PM for both visits

Start wearing Activity Monitor (watch) _____

Begin using Activity Log _____

- No alcohol 24 hours prior to appointment
- No caffeine after 12:00 noon on day of visits
- No new prescription or over the counter meds 24 hours prior to visits
- Must be awake by 7:00 AM for both visits and no naps before appointments
- Minimum of 6 hours of sleep night before both visits

12 APPENDIX M: ACTIWATCH INSTRUCTIONS

Actiwatch Wearing Instructions

1. Fit the Actiwatch to the wrist of your non-dominant arm, similar to a wristwatch.

(If you write with your Right hand, put the Actiwatch on your Left wrist)

- Tighten the watchband so that the Actiwatch will not move around on your wrist.



2. WEAR Actiwatch at all times. This includes:

- Showering
- Sleeping/ napping
- Rain
- Playing sports
- Exercise



3. REMOVE Actiwatch **ONLY** if:

- You will be swimming.
- The Actigraph will be submerged under water.



4. If you must remove the Actiwatch

- Please place the Actiwatch in a safe and secure location.
- Please begin wearing the Actiwatch again as soon you can.

5. Handling and Care

- Please treat the Actiwatch with care, as if it is your own property.
- Normal wear and tear is expected and will not cause problems with the Actiwatch.
- Extreme impact to the Actiwatch or other extreme conditions should be avoided, if possible.



6. If you suspect that the Actiwatch is damaged or not working, please contact Dawn by phone (319-335-4774) as soon you can.

13 APPENDIX N: ACTIVITY LOG

Subject ID: _____

ACTIVITY LOG INSTRUCTIONS TO PARTICIPANT

You will use this log to document your activity in the days preceding your study visits. You are asked to record the following types of information:

- About your sleep
- About your food and beverage consumption
- About your activities throughout the day

Asleep column: place an X in the time slots for when were asleep. To do this, place an X in the log at the time you lay down to sleep. When you awake, place another X.

Activity column: provide brief comments about what you were doing during that time frame. For example if you went to the gym, write gym. Also record if you wake up during the night and for how long you are awake. You should complete this column when you complete the activity.

Food/beverage column: Provide brief comments about what food and beverages you consumed throughout the day. Please make special note of anything that you eat or drink that contains caffeine or alcohol. You should complete this column when you complete the meal/snack.

Items with caffeine include: coffee, soda, tea, energy drinks, energy bars, vitamin water, food containing chocolate, candy

Alcohol items include: beer, wine, liquor/spirits

Pages 2-3 provide you with an example of how to complete your log.

Be specific, but try to keep your answers as brief as possible. If you have questions about completing your activity log, please contact **Dawn Marshall at (319) 335-4774**.

REMEMBER:

Refrain from consuming any alcohol 24 hours prior to ALL your driving sessions.

After 12:00 pm on the day of your overnight visits, restrict beverage intake to water. This does not include Vitamin Water which contains caffeine.

Refrain from taking naps on the day of your overnight visit.

Subject ID: _____

Activity Log Example:

DATE: 02/25/2013

Time		Asleep	Activity	Food/Beverage
12:00-12:15	AM	X		
12:15-12:30	AM	X		
12:30-12:45	AM	X		
12:45-1:00	AM	X		
1:00-1:15	AM	X		
1:15-1:30	AM	X		
1:30-1:45	AM	X		
1:45-2:00	AM	X		
2:00-2:15	AM	X		
2:15-2:30	AM	X		
2:30-2:45	AM	X		
2:45-3:00	AM	X		
3:00-3:15	AM	X		
3:15-3:30	AM	X	Woke up	
3:30-3:45	AM	X		
3:45-4:00	AM	X		
4:00-4:15	AM	X		
4:15-4:30	AM	X		
4:30-4:45	AM	X		
4:45-5:00	AM	X		
5:00-5:15	AM	X		
5:15-5:30	AM	X		
5:30-5:45	AM	X	Woke up	
5:45-6:00	AM	X		
6:00-6:15	AM	X		
6:15-6:30	AM	X		
6:30-6:45	AM		Gym	20 oz. PowerAde
6:45-7:00	AM			Energy Bar
7:00-7:15	AM			
7:15-7:30	AM			
7:30-7:45	AM		At work	
7:45-8:00	AM			
8:00-8:15	AM			
8:15-8:30	AM			
8:30-8:45	AM			
8:45-9:00	AM			12 oz. Latte Starbucks
9:00-9:15	AM			
9:15-9:30	AM			
9:30-9:45	AM			
9:45-10:00	AM			
10:00-10:15	AM			
10:15-10:30	AM			
10:30-10:45	AM			
10:45-11:00	AM			
11:00-11:15	AM			
11:15-11:30	AM			
11:30-11:45	AM			
11:45-12:00	AM/PM		Lunch	Chocolate cake, turkey sandwich, Chips,

Time		Asleep	Activity	Food/Beverage
12:00-12:15	PM			16 oz. Pepsi
12:15-12:30	PM			
12:30-12:45	PM			
12:45-1:00	PM		At Work	
1:00-1:15	PM			
1:15-1:30	PM			
1:30-1:45	PM			
1:45-2:00	PM			
2:00-2:15	PM			
2:15-2:30	PM			
2:30-2:45	PM			Snickers Bar
2:45-3:00	PM			
3:00-3:15	PM			
3:15-3:30	PM			
3:30-3:45	PM			
3:45-4:00	PM			
4:00-4:15	PM			
4:15-4:30	PM			
4:30-4:45	PM		Drinks	2 Red Bull and Vodka
4:45-5:00	PM			
5:00-5:15	PM			
5:15-5:30	PM			
5:30-5:45	PM			
5:45-6:00	PM		Making Dinner @ home	
6:00-6:15	PM			
6:15-6:30	PM			
6:30-6:45	PM		Eating Dinner	1 Glass of wine
6:45-7:00	PM			Lasagna
7:00-7:15	PM		Watching TV	Salad
7:15-7:30	PM			
7:30-7:45	PM			
7:45-8:00	PM			
8:00-8:15	PM			2 scoops Coffee ice cream
8:15-8:30	PM			
8:30-8:45	PM		Reading in Bed	
8:45-9:00	PM			
9:00-9:15	PM			
9:15-9:30	PM	X		
9:30-9:45	PM	X		
9:45-10:00	PM	X		
10:00-10:15	PM	X		
10:15-10:30	PM	X		
10:30-10:45	PM	X		
10:45-11:00	PM	X		
11:00-11:15	PM	X		
11:15-11:30	PM	X		
11:30-11:45	PM	X		
11:45-12:00	PM	x		

Activity Log

Date: _____

Subject ID: _____

Time		Asleep	Activity	Food/Beverage
12:00-12:15	AM			
12:15-12:30	AM			
12:30-12:45	AM			
12:45-1:00	AM			
1:00-1:15	AM			
1:15-1:30	AM			
1:30-1:45	AM			
1:45-2:00	AM			
2:00-2:15	AM			
2:15-2:30	AM			
2:30-2:45	AM			
2:45-3:00	AM			
3:00-3:15	AM			
3:15-3:30	AM			
3:30-3:45	AM			
3:45-4:00	AM			
4:00-4:15	AM			
4:15-4:30	AM			
4:30-4:45	AM			
4:45-5:00	AM			
5:00-5:15	AM			
5:15-5:30	AM			
5:30-5:45	AM			
5:45-6:00	AM			
6:00-6:15	AM			
6:15-6:30	AM			
6:30-6:45	AM			
6:45-7:00	AM			
7:00-7:15	AM			
7:15-7:30	AM			
7:30-7:45	AM			
7:45-8:00	AM			
8:00-8:15	AM			
8:15-8:30	AM			
8:30-8:45	AM			
8:45-9:00	AM			
9:00-9:15	AM			
9:15-9:30	AM			
9:30-9:45	AM			
9:45-10:00	AM			
10:00-10:15	AM			
10:15-10:30	AM			
10:30-10:45	AM			
10:45-11:00	AM			
11:00-11:15	AM			
11:15-11:30	AM			
11:30-11:45	AM			
11:45-12:00	AM/PM			

Activity Log

Date: _____

Subject ID: _____



Time		Asleep	Activity	Food/Beverage
12:00-12:15	PM			
12:15-12:30	PM			
12:30-12:45	PM			
12:45-1:00	PM			
1:00-1:15	PM			
1:15-1:30	PM			
1:30-1:45	PM			
1:45-2:00	PM			
2:00-2:15	PM			
2:15-2:30	PM			
2:30-2:45	PM			
2:45-3:00	PM			
3:00-3:15	PM			
3:15-3:30	PM			
3:30-3:45	PM			
3:45-4:00	PM			
4:00-4:15	PM			
4:15-4:30	PM			
4:30-4:45	PM			
4:45-5:00	PM			
5:00-5:15	PM			
5:15-5:30	PM			
5:30-5:45	PM			
5:45-6:00	PM			
6:00-6:15	PM			
6:15-6:30	PM			
6:30-6:45	PM			
6:45-7:00	PM			
7:00-7:15	PM			
7:15-7:30	PM			
7:30-7:45	PM			
7:45-8:00	PM			
8:00-8:15	PM			
8:15-8:30	PM			
8:30-8:45	PM			
8:45-9:00	PM			
9:00-9:15	PM			
9:15-9:30	PM			
9:30-9:45	PM			
9:45-10:00	PM			
10:00-10:15	PM			
10:15-10:30	PM			
10:30-10:45	PM			
10:45-11:00	PM			
11:00-11:15	PM			
11:15-11:30	PM			
11:30-11:45	PM			
11:45-12:00	PM			

14 APPENDIX O: STANFORD SLEEPINESS SCALE

Study: DRIVE

Participant: _____

Visit: _____

Form Number: _____

Date: ___ __

SLEEPINESS SCALE

Degree of Sleepiness	Scale Rating
Feeling active, vital, alert, or wide awake	1
Functioning at high levels, but not at peak; able to concentrate	2
Awake, but relaxed; responsive but not fully alert	3
Somewhat foggy, let down	4
Foggy; losing interest in remaining awake; slowed down	5
Sleepy, woozy, fighting sleep; prefer to lie down	6
No longer fighting sleep, sleep onset soon; having dream-like thoughts	7
Asleep	X

15 APPENDIX P: RETROSPECTIVE SLEEPINESS SURVEY

Study: DRIIVE
 Participant: _____
 Visit: _____
 Form Number: _____
 Date: ____

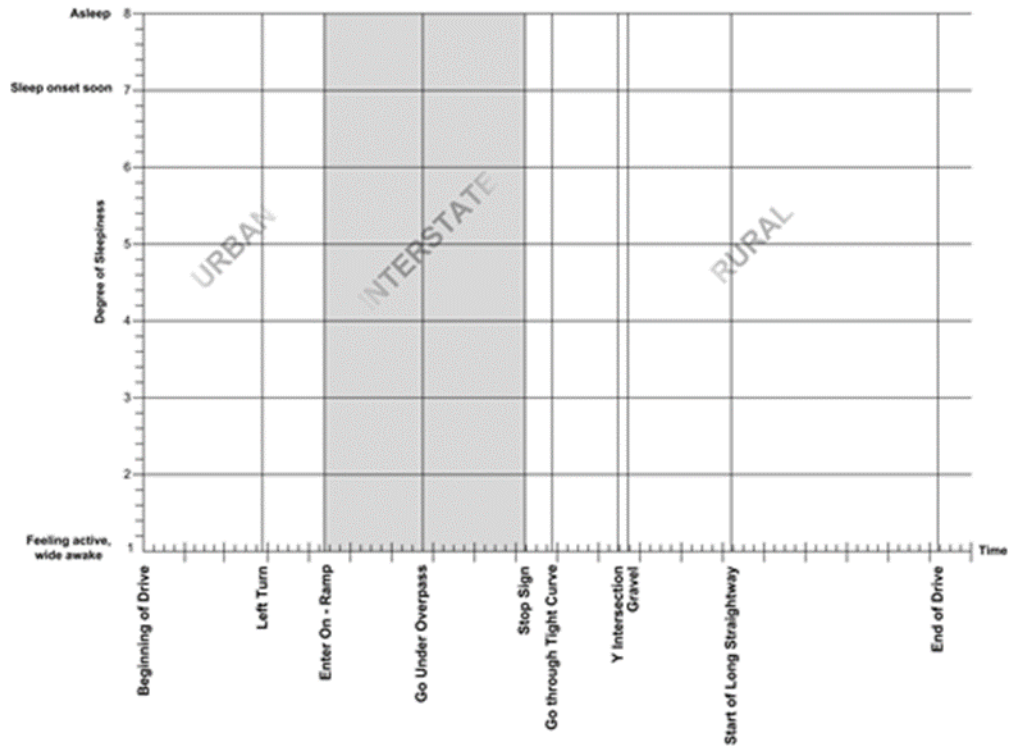
Degree of Sleepiness	Scale Rating
Feeling active, vital, alert, or wide awake	1
Functioning at high levels, but not at peak; able to concentrate	2
Awake, but relaxed; responsive but not fully alert	3
Somewhat foggy, let down	4
Foggy; losing interest in remaining awake; slowed down	5
Sleepy, woozy, fighting sleep; prefer to lie down	6
No longer fighting sleep, sleep onset soon; having dream-like thoughts	7
Asleep	8

- Please rate your degree of sleepiness as you began to drive: _____
- Please rate your degree of sleepiness at the left turn in the urban environment: _____
- Please rate your degree of sleepiness on the on-ramp to the interstate: _____
- Please rate your degree of sleepiness at the interchange on the interstate: _____
- Please rate your degree of sleepiness at the stop sign on the off-ramp from the interstate: _____
- Please rate your degree of sleepiness as drove through the sharp curve the rural environment: _____
- Please rate your degree of sleepiness as you passed the service station at the Y-intersection: _____
- Please rate your degree of sleepiness at the start of the gravel road: _____
- Please rate your degree of sleepiness at start of the long straight away: _____
- Please rate your degree of sleepiness just before you were told to stop: _____

Study: DRIIVE
 Participant: _____
 Visit: _____
 Form Number: _____
 Date: ____

Degree of Sleepiness	Scale Rating
Feeling active, vital, alert, or wide awake	1
Functioning at high levels, but not at peak; able to concentrate	2
Awake, but relaxed; responsive but not fully alert	3
Somewhat foggy, let down	4
Foggy; losing interest in remaining awake; slowed down	5
Sleepy, woozy, fighting sleep; prefer to lie down	6
No longer fighting sleep, sleep onset soon; having dream-like thoughts	7
Asleep	8

Draw a line between the ratings to indicate your level of sleepiness for the times between the points of interest that are listed.



16 APPENDIX Q: DEBRIEFING STATEMENT

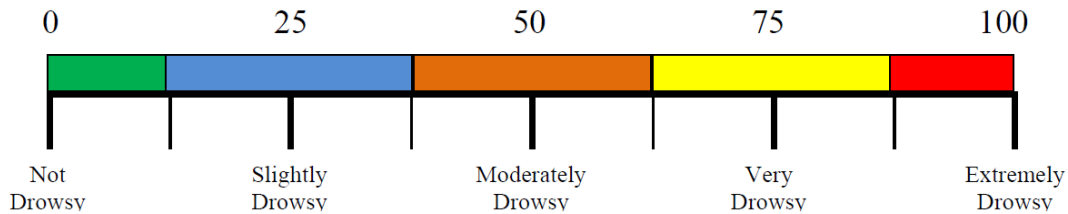
DrIVE Debriefing Statement

When is it safe to drive again?

At the time you will be transported home from completing this study visit, you will have been deprived of sleep for 20 or more hours. Although you could legally drive, we ask you to wait until you have had a full 8 hours of sleep before driving to ensure you are well rested and safe.

Please do not tell anyone about the details of your drive until May 2015. It is important that everyone arrive for their appointment with the same information. Telling someone what happens during the drive may change the way they drive and greatly compromise our ability to collect the data we need.

17 APPENDIX R: OBJECTIVE RATING OF DROWSINESS SCALE



Five Levels of Drowsiness

From Wierwille and Ellsworth (1994).

- **Not Drowsy (1):** A driver who is not drowsy while driving will exhibit behaviors such that the appearance of alertness will be present. For example, normal facial tone, normal fast eye blinks, and short ordinary glances may be observed. Occasional body movements and gestures may occur.
- **Slightly Drowsy (2):** A driver who is slightly drowsy while driving may not look as sharp or alert as a driver who is not drowsy. Glances may be a little longer and eye blinks may not be as fast. Nevertheless, the driver is still sufficiently alert to be able to drive.
- **Moderately Drowsy (3):** As a driver becomes moderately drowsy, various behaviors may be exhibited. These behaviors, called mannerisms, may include rubbing the face or eyes, scratching, facial contortions, and moving restlessly in the seat, among others. These actions can be thought of as countermeasures to drowsiness. They occur during the intermediate stages of drowsiness. Not all individuals exhibit mannerisms during intermediate stages. Some individuals appear more subdued, they may have slower closures, their facial tone may decrease, they may have a glassy-eyed appearance, and they may stare at a fixed position.
- **Very Drowsy (4):** As a driver becomes very drowsy, eyelid closures of 2 to 3 seconds or longer usually occur. This is often accompanied by a rolling upward or sideways movement of the eyes themselves. The individual may also appear not to be focusing the eyes properly, or may exhibit a cross-eyed (lack of proper vergence) look. Facial tone will probably have decreased. Very drowsy drivers may also exhibit a lack of apparent activity, and there may be large isolated (or punctuating) movements, such as providing a large correction to steering or reorienting the head from a leaning or tilted position.
- **Extremely Drowsy (5):** Drivers who are extremely drowsy are falling asleep and usually exhibit prolonged eyelid closures (4 seconds or more) and similar prolonged periods of lack of activity. There may be large punctuated movements as they transition in and out of intervals of dozing.

