Supporting Statements: Part B
Examining Distraction and Driver Monitoring Systems to Improve Driver Safety
OMB Control Number: *2127- New*

Abstract:[1]

The National Highway Traffic Safety Administration (NHTSA) is seeking approval for this new information collection request (ICR) to allow NHTSA to conduct a study on driver monitoring systems (DMS). DMS refers to in-vehicle technology that can detect driver state and interact with the driver through the human-machine interface (the user interface that connects the driver to the vehicle). NHTSA is proposing to conduct a study to improve NHTSA's understanding of the differences in approaches to state detection and the potential safety impacts of DMS. The study involves two tracks: Track A and Track B. The voluntary study would involve recruiting licensed drivers for a simulated driving study and the following information collections: (1) a online eligibility questionnaire to determine eligibility for participation and appointment reminder confirmation process; (2) informed consent forms for participation; (3) breathalyzer measurements prior to participation in the study; (4) facial shape and height measurements; (5) Track A study drives; and (6) Track B study drives. The objective of this simulator driving study is to assess the ability of DMS to assess driver states (e.g., distracted, drowsy) and understand how differences in DMS impact the ability of a system to reliably assess different driving states. This study will add to the state of knowledge by experimentally collecting data to support a full assessment of the factors associated with DMS and the modeling of driver state based on sensor data.

Response to this collection of information is voluntary and is a one-time collection. Respondents are generally healthy individuals aged 18 and older. Efforts will be made to enroll a diverse age sample that broadly represents the age of the driving population and includes those at greater risk of crashing (e.g., less than 25 years of age and greater than 65 years of age). Additional efforts will be made to enroll individuals with diverse skin tones, oversampling those who rate themselves higher on the Fitzpatrick Skin Type Scale. The study will be reviewed and approved by the University of Iowa Institutional Review Board (IRB) before any data collection procedures begin.

[1] The Abstract must include the following information: (1) whether responding to the collection is mandatory, voluntary, or required to obtain or retain a benefit; (2) a description of the entities who must respond; (3) whether the collection is reporting (indicate if a survey), recordkeeping, and/or disclosure; (4) the frequency of the collection (e.g., bi-annual, annual, monthly, weekly, as needed); (5) a description of the information that would be reported, maintained in records, or disclosed; (6) a description of who would receive the information; (7) the purpose of the collection; and (8) if a revision, a description of the revision and the change in burden.

B. JUSTIFICATION

B.1 Describe the potential respondent universe and any sampling or other respondent selection to be used.

Respondents will be licensed drivers, ages 18+, in Eastern Iowa and surrounding areas willing to travel to the University of Iowa Research Park to participate in a driving simulation study. The University of Iowa Driving Safety Research Institute (DSRI), home of the National Advanced Driving Simulator (NADS), currently has a registry of approximately 7000 individuals who have already expressed interest in participating in driving research studies. Registry members have been recruited through community events, email campaigns, participant referrals or word of mouth, and print, radio, and television advertisements. Individuals are also invited to the registry after completing a study at DSRI. Members of the registry primarily reside in Iowa and Illinois, though there are individuals from as far away as California. Being affiliated with a university also gives DSRI access to international students, staff, and faculty, which will aid in the recruitment of diverse skin tones. From the registry, potentially eligible individuals (those who meet initial age and gender criteria via registry query) will be contacted via email. We plan to primarily recruit using email to the DSRI registry. This includes approximately 450 individuals aged 18-25, 5200 aged 26-64, and 1400 aged 65+. If insufficient interest exists from the registry, DSRI can pursue University of Iowa Mass Mail, posted advertisements, STAR Registry (older adults), community organizations such as senior centers, social media advertisements, and word of mouth to increase the pool of potential subjects. Individuals will be selected based on ability to meet study timeline and generally in order of response.

Eligibility requirements include meeting age criteria, ability to attend visits of specified length, driving requirements such as a valid license for at least two years and driving at least once weekly or 2000 miles annually, consistent sleep patterns and not showing evidence of being a “night” person (go to sleep later than midnight and awake after 7:00 a.m.), ability to adhere to study protocol, and general health requirements put in place for the safety of subjects and research staff.

Enrolling a representative sample of adults is important. The online eligibility questionnaire supports efforts toward a representative sample by asking questions related to ethnicity, race, and skin type. We also are collecting information related to how often the individual drives and how many years of driving experience they have. DMS are potentially very sensitive to factors such as skin tone and height. Skin type is collected during the online eligibility questionnaire (using the Fitzpatrick Scale) to assist with enrolling a diverse sample in this regard. Researchers will obtain a digital image to collect RGB values to assess skin tone at the study visit(s) as well. Additionally, height (both standing and seated) is collected as part of the measurements. The research is conducted in a motion simulator. Given this, efforts must be taken to ensure individuals who could be put at risk unnecessarily are not enrolled. The online eligibility questionnaire screens out those with the greatest risk of issues in the simulator (pregnancy, seizures or epilepsy with episode in past year, neck or back injury, or mobility concerns (due to procedures required in the event of emergency)), as well as for serious illness that likely also would mean an individual is not driving (e.g., lingering symptoms from a stroke or head injury). The sample must also be able to adequately see and hear to be able to follow protocol and must

not experience daytime drowsiness since one purpose of the study is to test ability of the DMS to assess drowsiness and obtaining baseline driving without the presence of drowsiness is necessary for this. Balance and vertigo issues are excluded due to the nature of driving in the simulator.

B.2 Describe the procedures for the collection of information.

Individuals who previously have expressed an interest in participating in driving studies with DSRI will be contacted by email through the DSRI subject registry. Potential subjects will complete an online eligibility questionnaire (FORM A) to determine their eligibility to participate in Track A, Track B, or both. Each respondent deemed eligible and who agrees to participate will receive a confirmation email after scheduling. The email will include the date and time of their study visit as well as logistical information such as directions and parking. It will also include a contact email address and phone number in case of cancellation or questions and remind subjects that they must refrain from alcohol and recreational drug use (e.g., cannabis) in the 24 hours prior to any study visit. Reminder emails with a link to a page of instructions and reminders for the visit (FORM B Appointment Reminder Confirmation Process) will be sent approximately 24 hours prior to the appointment. This ensures the subject's eligibility has not changed and checks that they are not feeling ill and therefore likely to cancel or have affected performance at the visit.

For Track A, upon arrival at the DSRI in the University of Iowa Research Park, a research team member will verbally explain the purpose and procedures involved in the study and answer questions about participation. Subjects will be asked to sign the consent document approved by the University of Iowa Institutional Review Board electronically (FORM C). Subjects will be asked to provide a breath alcohol measurement by blowing into a breathalyzer and must have a reading of 0.000% to continue in the study. After this, a research team member will take measurements of facial shape and both standing and seated height, as well as take a digital image of the subject's face so that RGB values can be obtained for assessment of skin tone variability. Subjects next will be asked to watch a PowerPoint presentation that gives an overview of the purpose of the study, the simulator cab, the drives to be completed in the simulator, and information about any distracting tasks they may be asked to do while in the simulator. During this drive, they may be asked to add or remove layers of clothing, such as a sweater, jacket, hat, scarf, shawl, sweatshirt, etc. This is to see if this affects the ability of the DMS to assess driver state.

After any questions have been answered, subjects will be escorted into the simulator. They will be driving the NADS-1 with motion. The NADS-1 contains a full-size vehicle cab in an enclosed dome with the driving environment projected on the walls around the vehicle. Subjects will be asked to position themselves in the driver's seat and make adjustments as needed so they are able to drive comfortably. Calibration procedures for the driver monitoring system will be conducted once situated in the driver's seat. Subjects will complete two drives. The first drive will allow subjects to become familiar with the simulator and will take approximately 20 minutes. After the drive, subjects will be asked how they feel and be asked to rate their current sleepiness level (FORM D). This consists of a single question rated on a 10-point scale. If they feel ok, they will complete the study drive, which takes approximately 60 minutes. This drive will include periods of attentive and distracted driving. During periods of distracted driving, subjects will engage

with tasks that lead to different levels of distraction with various effects to driving performance. This allows for assessment of how well the DMS assesses driver state. Subjects will again be asked how they feel and rate their current sleepiness level after the study drive. After exiting the simulator, a member of the research team will answer any questions subjects may have about their visit and ask if they are interested in the Track B study. If yes, their name will be added to a contact list for that study. After this, the Track A distraction visit will be complete.

For Track B, on the day of the study visit, subjects are to be awake by 7:00 a.m. and refrain from sleep (i.e., no naps) until the study visit begins at either 5:15 p.m. or 6:45 p.m. Each night, there will be two subjects (one at each scheduled visit time). Subjects will need to refrain from stimulation such as aerobic exercise or caffeine beginning at 1:00 p.m. Subjects must also refrain from alcohol and recreational drug use (e.g., cannabis) in the 24 hours prior to the study visit. Subjects will be asked to have finished dinner and any snacks by the time they arrive. However, if this isn't possible, subjects may eat during the waiting period that begins roughly 2 hours into the visit. Subjects must agree to not drive, bike, or walk themselves home from DSRI and to make other arrangements for a designated sober driver to take them home or be transported home via a taxi or ride-share. DSRI will be providing compensation to aid with these expenses.

Upon arrival to DSRI, a research team member will verbally explain the purpose and procedures involved in the study and answer questions about participation. Subjects will be asked to sign the consent document approved by the University of Iowa Institutional Review Board electronically (FORM E). After this, subjects will be asked to complete a questionnaire about their sleep and food intake over the last 24 hours (FORM F) and to provide a breath alcohol measurement by blowing into a breathalyzer. Subjects must meet all criteria to proceed in the visit. If they have taken any naps, if they have consumed caffeine after 1:00 p.m., if they have a breath alcohol reading greater than 0.000%, or if they have consumed alcohol or a recreational drug within the past 24 hours, they will not be allowed to participate in the study. If participation is ended, subjects will be asked to obtain their ride home. If they remain eligible, a research team member will take measurements of facial shape and both standing and seated height, as well as take a digital image of the subject's face so that RGB values can be obtained for assessment of skin tone variability. Subjects then will be asked to watch a PowerPoint presentation that gives an overview of the purpose of the study, the simulator cab, the drives to be completed in the simulator, and information about any distracting tasks they may be asked to do while in the simulator. During this drive, they may be asked to add or remove layers of clothing, such as a sweater, jacket, hat, scarf, shawl, sweatshirt, etc. This is to see if this affects the ability of the DMS to assess driver state.

After any questions have been answered, subjects will be escorted into the simulator. They will be driving the NADS-1 with motion. Subjects will be asked to position themselves in the driver's seat and make adjustments as needed so they are able to drive comfortably. Calibration procedures for the driver monitoring system will be conducted once situated in the driver's seat. Subjects will complete two drives. These drives occur while they are still alert and not showing any signs of drowsiness. The first drive will allow subjects to become familiar with the simulator and will take approximately 20 minutes. After the drive, subjects will be asked how they feel and be asked to rate their current sleepiness level (FORM D). This consists of a single question rated on a 10-point scale. If they feel ok, they will complete the first study drive, which takes

approximately 60 minutes. Subjects will again be asked how they feel and rate current sleepiness level after the study drive, then exit the simulator.

If subjects feel able to continue, they will begin a waiting period anticipated to last 3 to 4.5 hours. They will be asked to complete a questionnaire about current sleepiness level approximately every 30 minutes during this time. The next drive cannot start until subjects are showing signs of drowsiness and have been awake for at least 14 hours. Subjects will be asked to remain awake until the study drive and be told they can watch movies, work, play games, knit, read, etc., but cannot consume caffeine or exercise. If subjects are engaging with screens (e.g., watching a movie), they will be asked to put the screen away and sit quietly or switch to a less stimulating activity roughly 30 minutes prior to the anticipated drive start time.

When it is time to begin the second drive, subjects will be escorted into the simulator. If necessary, calibration procedures for the DMS will be conducted once situated in the driver's seat. Subjects will complete a rating of their current sleepiness level, then drive for approximately 60 minutes. After this, they will complete a rating of their current sleepiness level, be asked how they feel, then be allowed a restroom and stretching break. After this short break (5-10 minutes), they will again be escorted into the simulator. Subjects will complete a rating of current sleepiness level, then drive for approximately 60 minutes. After this, they will complete a rating of current sleepiness level, be asked how they feel, and exit the simulator. One of these drives will assess drowsiness alone, and one of these drives will assess drowsiness with distraction. During periods of distracted driving, subjects will engage with tasks that lead to different levels of distraction with various effects to driving performance. The order of these drives will be counterbalanced across subjects so that half will complete the drowsiness drive first and half will complete the drowsiness with distraction drive first. After exiting the simulator, a member of the research team will answer any questions that subjects may have about their visit. They will be instructed to obtain their ride home and be asked to avoid driving until well-rested. Subjects will be required to sign a release agreement prior to leaving the DSRI facility that states the mode of transport home (subjects cannot drive, bike, or walk) and that they agree to not drive until well-rested (FORM G).

The final sample will consist of 68individuals, 28 participating in Track A only, 28 participating in Track B only, and 12 participating in both Track A and Track B. The respondents will be age 18+ and divided appropriately by gender. Efforts will be made to enroll a diverse age sample that broadly represents the age of the driving population and includes those at greater risk of crashing (e.g., less than 25 years of age and greater than 65 years of age). Although there are no fixed requirements, target enrollment will be 25% aged 18-25, 25% aged 65+, and 50% between the ages of 25 and 65. Additional efforts will be made to enroll individuals with diverse skin tones, oversampling those who rate themselves higher on the Fitzpatrick Skin Type Scale. The 68 consented subjects will complete a Track A study visit lasting two hours, a Track B study visit lasting approximately nine hours, or both .

B.3 Describe methods to maximize response rates.

Participation in the study is voluntary. Response rate will be maximized by initially contacting only individuals who have previously expressed interest in driving research. Subjects will be

offered $30/hour as compensation for completing all study procedures. This rate of pay is comparable to the current national average hourly wage but was chosen based on our experience. Anything less than $20-$25 per hour would likely result in failure to recruit enough subjects to provide adequate statistical power.

In addition to compensation, several methods will be used to maximize response rates, including:

- Completing recruiting and screening electronically for respondent convenience.
- Sending a visit confirmation email including the scheduled date and time, directions, pertinent study information, and a contact email address and phone number in case of cancellation or questions.
- Sending reminder emails within 24 hours of the scheduled study appointment to boost show rate and help alleviate schedule misunderstandings or forgetfulness.

B.4 Describe any tests of procedures or methods to be undertaken.

The instruments planned for this study have been used extensively in prior studies, both government- and industry-funded, and refined for ease of completion and question comprehension.

- The Karolinska Sleepiness Scale (KSS, FORM D, NHTSA Form 1719) is a validated instrument (Åkerstedt T, Gillberg M. Subjective and objective sleepiness in the active individual. *Int J Neurosc*. 1990;52:29–37. doi: 10.3109/00207459008994241.) that has been used in several industry- and NIH-sponsored studies at DSRI. This was also used as part of the "Development and Evaluation of Protocol for Evaluating the Potential for a Drug to Impair Driving" study sponsored by NHTSA for which the University of Iowa DSRI was a sub-contractor to Acclaro.
- The Sleep and Food Intake (SFI, FORM F, NHTSA Form 1720) has been used as part of NHTSA-sponsored research as well as NIH-funded clinical trials at DSRI. It has also been used in industry-sponsored research with a drowsiness focus.
    - "Driver Monitoring of Inattention and Impairment Using Vehicle Equipment (DrIIVE)"
        - U.S. DOT Docket No. NHTSA-2012-0179
    - "Advanced Vehicle-Based Countermeasures for Alcohol-Related Crashes"
        - DTNH22-06-D-00043-0002
    - "Advanced Countermeasures for Multiple Impairments"
        - DOT HS 811 886)
    - "Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device"
        - Sponsored by NIDA as a sub-contractor to Advanced Brain Monitoring
        - Federal Register Docket Number 2013-23972

- The online eligibility questionnaire (FORM A, NHTSA Form 1718) has been used since 2017 in industry- and government-funded trials and was based off phone-screening procedures used for well over a decade. The version for this collection has been substantially trimmed to include only the most necessary health questions for subject safety and ability to complete study tasks.

Additionally, a small pilot study (nine or fewer subjects) will be conducted to assist with refining study scenarios and DMS testing. The engineering data from the simulator will be reduced to provide summary measures of driving performance. Questionnaire responses will be used to determine eligibility and subject state. To balance having a diverse testing sample with understanding how detection changes within an individual between states, a hybrid within-between testing approach will be used with the aim of having some of the subjects complete both tracks while other subjects participate in only one of the tracks. This allows for consideration of both within- and between-subjects variability to maximize the benefits of both design approaches. The within-subject component allows for the consideration of how individual drivers experience the different states and how that is manifest in the data used by the DMS. The between-subject component allows for consideration of more individuals and, therefore, increases variability in the sample to better assess how sensors handle that individual variability. Combining them in this hybrid approach with a reasonable target for overlap in the sample eliminates the burden of having to oversample in Track A to account for attrition while still maintaining some within-subject exposure to all the driver states. Data analysis at DSRI is most often conducted using R or SAS. However, more complex methods of analysis, such as machine learning models, can be performed directly on raw data or reduced data either within MATLAB or in R or Python.

B.5 Provide the name and telephone number of individuals consulted on statistical aspects of the design.

- Thomas Fincannon, Ph.D., Research Psychologist, National Highway Traffic Safety Administration, Office of Vehicle Safety Research, Human Factors/Engineering Integration Division NSR-310, 202-366-8851
- Timothy Brown, Ph.D., Senior Technical Program Manager, The University of Iowa, 319-335-4785
- John Gaspar, Ph.D., Senior Technical Program Manager, The University of Iowa, 319-335-4776
- Justin Mason, Ph.D., Associate Researcher, The University of Iowa, 319-467-1614
- Amy Benedick, PMP, Senior Study Director, Westat, 240-314-2816