

DEPARTMENT OF TRANSPORTATION

INFORMATION COLLECTION SUPPORTING STATEMENT

Recruitment of Human Subjects for Driver Monitoring of Inattention and Impairment Using Vehicle Equipment (DrIIVE)

Part A. Justification

- 1. Explain the circumstances that make the collection of information necessary. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

Subchapter V of Title 49 of the United States Code (U.S.C.) authorizes the Secretary of Transportation to conduct “motor vehicle safety research, development, and testing programs and activities, including activities related to new and emerging technologies that impact or may impact motor vehicle safety.” 49 U.S.C. § 30182. Pursuant to Section 1.95 of Title 49 of the Code of Federal Regulations (CFR), the Secretary has delegated this authority to the National Highway Traffic Safety Administration (NHTSA).

Data from the National Highway Traffic Safety Administration show that approximately 34,000 fatal vehicle crashes occur every year in the United States. In 2011, the National Highway Traffic Safety Administration reported 29,757,000 fatal vehicle crashes in the United States. A large proportion of these crashes are caused by one of three factors: 9,878 alcohol intoxication, 709 drowsy, and 3,331 distracted cases. In an effort to understand potential mitigation strategies, NHTSA has contracted with the University of Iowa’s National Advanced Driving Simulator (NADS) to develop and evaluate vehicle-based algorithms to detect impairment and inattention. Any information requested for collection will be used to aid in the implementation of the algorithm(s) to detect impaired driving.

NHTSA has been conducting research to assess the potential of vehicle-based technologies in mitigating impairment related crashes by using driver state monitoring to implement potential countermeasures for impaired and distracted driving. This involves the development, refinement, and evaluation of algorithms for detecting three types of impaired driving (distracted, alcohol impaired, and drowsy).

NHTSA proposes an experimental driving simulator study to develop algorithms for detecting impaired driving. This study will measure the ability of subjects to maintain lane position and vehicle speed relative to the posted speed limit while either drowsy or distracted by a secondary task while driving a driving simulator. NHTSA is requesting clearance to collect voluntary information from subjects to determine their eligibility to participate and remain in the driving simulator study.

- 2. Indicate how, by whom, and for what purpose the information is to be used. Indicate the actual use the agency has made of the information received from the current collection.**

The National Advance Driving Simulator group (NADS) at the University of Iowa and the University of Wisconsin will conduct the proposed study under an Indefinite Delivery Indefinite

Quantity (IDIQ) with NHTSA. There are six instruments that will be used for the study: two screening questionnaires for recruitment and four instruments to determine if the subject has followed the instructions for the study. Prior to participation in the study candidate subjects will be asked questions over the phone using the **(1) Recruitment Questionnaire** and **(2) Morning Evening Questionnaire**. Both questionnaires will be used to prescreen the subject based on the eligibility criteria listed below. Candidate subjects will be asked questions about their driving habits, general health, sleeping/waking habits and caffeine consumption. The general health questions will be used to screen out individuals that may incur harm while in the simulator, such as those with back or neck injuries. The questions about sleeping/waking habits and caffeine consumption will be used to determine if their regular habits make them a good fit for the study schedule requirements.

Individuals must meet the criteria listed below to be eligible to participate in the observational experiments:

- 21-34 years or older at the time of the study
- Possess a valid US driver's license
- Licensed driver for two or more years
- Drive at least 10,000 miles per year for the past two years
- Restrictions on driver's license limited to vision
- Does not use any special equipment to drive, such as pedal extensions, hand brake or throttle, spinner wheel knobs, or other non-standard equipment that would limit interpretation of accelerator pedal, brake pedal, or steering inputs.
- No participation in similar studies
- Have had a minimum of 6 hours of sleep the night before their visit
- Were awake by 7:00 am
- Have taken no naps
- No caffeine after noon
- Have a BAC of 0.00% if they have consumed alcohol in the past 24 hours
- No new medications that cause drowsiness or are stimulating

Responses to **(1) Recruitment Questionnaire** and **(2) Morning Evening Questionnaire** will only be used to identify eligible subjects for this study and will not be kept nor analyzed. Candidates who are selected for the study will be scheduled for a study visit to participate in the driving simulator. Individuals that do not meet the eligibility requirements listed above would be excluded because they may introduce too much variability and mask the effects of the independent variables which are the principal focus of the observational experiments.

During the study visit, the subjects will provide their **(3) Pre-visit Activity Log** with information on their daily activities and the **(4) Pre-Drive Sleep and Intake Questionnaire** with questions about their sleep and food and beverage intake in the 24-hours preceding their appointment. This information will be used to confirm that subjects have complied with study requirements regarding number of hours of sleep, morning wake time, and napping and caffeine consumption in the 24 hours prior to their study visit. Compliance to these directions are necessary to effectively producing drowsiness.

If subjects continue to meet study requirements, they will be asked to complete **(5) PreDrive and Post-Drive Stanford Sleepiness Scale** every 30 minutes until their simulator drive session. This single rating response is collected to confirm that the subjects' drowsiness level is increasing as the time for their simulator drive approaches. This data will be used to assure the team that the experimental manipulation was effective and thus the vehicle measures (i.e. lane keeping and steering) collected can be used to develop the algorithm.

After the subject has completed their simulator drive, they will be asked to complete the **(6) Retrospective Sleepiness** scale indicating his/her drowsiness level at various points during his/her simulator drive. This post drive scale will be used to help the researchers better understand the data and refine the algorithm. For example, if a person has rated their condition on a particular section of their drive as low on the **(6) Retrospective Sleepiness** scale, yet the algorithm has triggered an alert, this event will be categorized as a false alarm. This information will support the development of algorithms to detect impaired driving, e.g. driving while distracted or drowsy.

The Stanford Sleepiness Scale (SSS) is a standard scale that documents level of sleepiness^a. The Retrospective Sleepiness Scale was derived as part of previous drowsiness and driving protocol and is based on the Stanford Sleepiness Scale. All other questionnaires were internally developed to confirm inclusion and exclusion criteria are met, compliance with protocol instructions, and to aid in the understanding of experimental data and are not intended for statistical analysis.

In summary, the information to be collected will be used to:

- (a) Screen for individuals meeting the eligibility criteria for the study.
- (b) Confirm experimental manipulations are effective.
- (c) Questions regarding drowsiness will allow the researchers to further amend and refine the algorithms, if necessary.

3. Describe whether the collection of information involves the use of technological collection techniques or other forms of information technology.

Subjects will be recruited primarily via emails but also using flyers or informational sessions. Individuals interested in the study will contact the NADS recruiting coordinator and complete an eligibility questionnaire by phone, email, or in person. The use of automated, electronic,

^a Hoddes, E., Dement, W. and Zarcone, V. The development and use of the Stanford Sleepiness Scale (SSS). *Psychophysiol.*, 1972, 9: 150.

mechanical, or other technological collection techniques or other forms of information technology is fundamental to the proposed collection of information. NHTSA and NADS have sought and will continue to seek automated means to reduce the collection burden, reduce errors, and increase efficiency. NADS utilizes <https://uiowa.qualtrics.com> which has met rigorous security requirements, including those of HIPAA, for this electronic collection. _

4. Describe efforts to identify duplication. Show specifically why any similar information cannot be used.

The information collected during participant recruitment is specific to a particular individual to determine that individual's eligibility to participate in experiment. Therefore, similar information collected from other individuals is not relevant or applicable. The agency is also not aware of any other sources of this information. The current project is an extension of previous impaired driving research projects described in the following reports: DOT HS 811 547, DOT HS 811 358, and DOT HS 811 886. Previous protocols are leveraged to the extent possible to maintain comparability of driving performance comparability across projects.

5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.

This collection of information involves individuals and does not involve small businesses or other small entities.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently.

If the information is not collected, NHTSA will not be able to conduct the studies because the agency would be unable to schedule participants for the study. The agency would be unable to confirm whether participants meet the criteria for eligibility for the study. Further, the post sleepiness information was not collected it would affect the ability to explain and use the results as they relate to the development of the drowsy and distracted driver algorithm.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the guidelines set forth in 5 CFR 1320.6.

The information collection is consistent with the guidelines set forth in 5 CFR 1320.6.

8. Provide a copy of the Federal Register document soliciting comments on extending the collection of information, a summary of public comments responding to the notice, and a description of the agency's actions in response to the comments. Describe efforts to consult with persons outside the agency to

obtain their views.

A Federal Register Notice published on January 16, 2013 (Vol. 78, No. 11 / Wednesday, January 16, 2013) (pp. 3496 - 3497)) soliciting public comments for 60 days. An electronic version of this notice is attached. The comments period closed on March 18, 2013. One set of comments was received from Delphi which expressed support for the line of research, recommended the inclusion of the automotive industry in the process, and offered its expertise in the development of these systems as the program moves forward.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

Respondents will not receive any compensation for responding to this information collection. Respondents who are selected to participate in the observational experiments will be compensated for the time spent participating in the experiments but will not receive any additional compensation for responding to the information collection. Respondents who are not selected to participate will not receive any compensation.

Participants are paid for their time and effort to attend study visits, not per protocol procedure such as a questionnaire.

Participants will be paid \$250 if they complete all study visits and procedures. If they withdraw or their participation ends, their compensation will be pro-rated as follows:

Visit 1 (Screening)	\$ 10
Visit 2	\$ 100
Visit 3	\$ 140
Total (complete all visits)	\$ 250

In the event that they do not meet the study criteria (e.g., the drug screen, pregnancy screen, breath alcohol test, and activity level requirements) they will be paid only \$5 for the visit. No compensation is available prior to attending the Visit 1 (screening visit) because prior to this point they have not been officially enrolled in the study by providing informed consent.

10. Describe any assurance of confidentiality provided to respondents.

Regarding the confidentiality issue, we plan to revise the supporting statement to include the following statement, which does not promise confidentiality and is similar to what was included in the supporting statement for the Quiet Cars information collection: “The NADS Center will provide each participant with an informed consent form that explains to subjects that the University of Iowa, the University of Wisconsin, and NHTSA will protect all personally identifying data and information collected in connection with this study to the extent provided by

law. In order to maintain privacy, subjects will be assigned a study number which will be used instead of their name to identify all data collected.”

11. Provide additional justification for any questions on matters that are commonly considered private.

The screening questionnaire conducted over the phone has questions about topics that are commonly considered private, such as general health information. The answers to all of the screening questionnaires will be used to ensure individuals meet eligibility requirements prior their enrollment in the study. The information will not be retained after review or used for the results of the research report. Inquires about general health history are collected as a safety precaution to exclude participants who may have a condition that would prove a danger at any time to his or herself. Additional screening questions, such as sleeping/waking habits and caffeine consumption will also be used to determine that the individuals continue to meet study requirements as this information affects the level of drowsiness individuals experience. This information will only be used for determining eligibility, however, the records will not be retained nor analyzed for the study.

12. Provide estimates of the hour burden of the collection of information on the respondents.

Table 1: Estimated Burden Hours

	Number of Respondent	Frequency of Responses	Number of Questions	Estimated Individual Burden	Total Estimated Burden Hours	Annualize Cost to respondents^b
1- Recruitment questionnaire	168 ^c	1	26	10 minutes (0.167 hours)	28.00	\$652.96
2- Morning Evening Questionnaire	96	1	5	5 minutes (0.083 hours)	8.00	\$186.56
3-Pre-Visit: Activity Log	96	2	1	45 minutes (1.500 hours)	144.00	\$3,358.08

^b Estimated based on the mean hourly rate for Massachusetts (all occupations) is \$26.32 as reported in the May 2011 Occupational Employment and Wage Estimates, Bureau of Labor Statistics. http://www.bls.gov/oes/oes_dl.htm

^c This includes 96 subjects and an additional 75% to account for the extra number of individuals that may take the eligibility questionnaire in order to get the 96 subjects needed. The 75% is an estimate and is based on experience with similar studies.

4-Pre-Drive: Sleep and Intake Questionnaire	96	2	13	3 minutes (0.100 hours)	9.60	\$223.87
5-Pre-Drive and Post- Drive:: Stanford Sleepiness Scale	96	22	1	1 minutes (0.367 hours)	35.20	\$820.86
6-Post-Drive: Retrospective Sleepiness Scale	96	2	13	7 minutes (0.233 hours)	22.40	\$522.37

Number of Respondants:

It is estimated that we will contact 168 individuals for the phone-screening portion of the study. It is estimated that 96 individuals will be enrolled to obtain the desired completed data sets.

Estimated Burden on Respondants:

For the individuals who only complete the phone screening, the burden will be approximately 10 minutes.

For subjects who participate in the study, it is estimated that burden will be 71 minutes.

Please note that the burden reported here is lower than in the 60 Day Notice because questions have been removed.

13. Provide estimates of the total annual cost to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Question 12 or 14).

There are no additional costs to respondents or record keepers.

14. Provide estimates of annualized cost to the Federal government.

The costs of this information collection are included in an Indefinitely Delivery Infinite Quantity awarded to the University of Iowa, National Advanced Driving Simulator (NADS), which

includes analysis and report preparation. The specific cost to collect the information (recruitment) is estimated as: (220 hours) (\$33.56/hours)^d = \$7383.20. There are no other costs to the government.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

There is no program change of burden hours to NHTSA's overall burden hour total.

16. For collections of information whose results will be published, outline plans for tabulation and publication.

Personal information will not be published. An exact publication date has not been established but would occur no sooner than Quarter 3 of Fiscal Year 2013 through Quarter 1 of Fiscal Year 2014.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that the display would be inappropriate.

NHTSA and the University of Iowa, NADS are not seeking such approval.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.

There are no exceptions.

^d Estimated average hourly rate for researcher/recruiter coordinator.