DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-*2023-0026*]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Examining Distraction and Driver Monitoring Systems to Improve Driver Safety

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for approval of a new information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) summarized below will be submitted to the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden. This document describes a new collection of information for which NHTSA intends to seek OMB approval titled Examining Distraction and Driver Monitoring Systems to Improve Driver Safety. A Federal Register Notice with a 60-day comment period soliciting comments on the following information collection was published on July 14, 2023. Four comments were received during the comment period. This 30-day notice includes a summary of those comments, responses to the comments (no changes to the study are expected as a result of the comments), and an update to the estimated burden hours from the 60-day notice.

DATES: Comments must be submitted on or before [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at www.reginfo.gov/public/do/PRAMain. To find this particular information collection, select "Currently under Review – Open for Public Comment" or use the search function.

FOR FURTHER INFORMATION CONTACT:

For additional information or access to background documents, contact: Thomas Fincannon, Office of Vehicle Safety Research, Human Factors/Engineering Integration Division NSR-310, West Building, W46-447, 1200 New Jersey Ave, SE, Washington, DC 20590; thomas.fincannon@dot.gov

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted OMB.

Title: Examining Distraction and Driver Monitoring Systems to Improve Driver Safety

OMB Control Number: New

Form Numbers: NHTSA Form 1718 Online Eligibility Questionnaire, NHTSA Form 1719 Karolinska Sleepiness Scale, NHTSA Form 1799 Appointment Reminder Confirmation Process, NHTSA Form 1720 Sleep and Food Intake, NHTSA Form 1721 End of Visit Release

Agreement, NHTSA Form 1730 Track A Consent Form, and NHTSA Form 1731 Track B Consent Form Track B.

Type of Request: New information collection

Type of Review Requested: Regular

Length of Approval Requested: Three years from date of approval

Summary of the Collection of Information:

NHTSA proposes to collect information from the public as part of a study to improve NHTSA's understanding of the differences in approaches to driver state detection and the potential safety impacts of 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). For example, a DMS that detects drowsiness may display an icon on the dashboard, such as a coffee cup, accompanied by a sound to alert the driver that drowsiness is present.

This study contains two tracks to assess DMS, and subjects may participate in Track A, Track B, or both. This allows for a balance between understanding how driver state detection changes within a diverse testing sample and within an individual across driver states. The overall sample will contain 80 data sets. Each track will have 40 completed data sets. Thus, the total sample size is anticipated to be 68 subjects and will include subjects that completed Track A only (n = 28), Track B only (n = 28), and those that completed both tracks (n = 12). Track A will evaluate the ability of the DMS to assess distraction and Track B will evaluate the ability of the DMS to assess both drowsiness alone and distraction while drowsy.

NHTSA proposes to collect information from licensed drivers about their age, sex, driver license status, sleep and driving habits, and general health history to determine eligibility for the

study. Those interested in participating will be asked about their ability to adhere to various requirements of the protocol (e.g., abstain from caffeine) and availability for a study appointment. Those who participate in the study will come to the University of Iowa Driving Safety Research Institute (DSRI), home of the National Advanced Driving Simulator (NADS). Both tracks involve a consent process, breath alcohol measurement, facial shape measurement, standing and seated height measurement, training presentation, a familiarization drive in the driving simulator, and sleepiness ratings before and after each study drive as well as approximately every 30 minutes during a waiting period. Both tracks also involve taking a digital image of the face so that researchers can obtain RGB values to assess skin tone variability. Track A only involves one study drive that occurs while the subject is alert and distracted. In Track B, subjects will be asked about their sleep and food intake (to confirm they have not consumed caffeine since 1:00 p.m., that they were awake by 7:00 a.m., and that they have consumed no other substances that could influence driving) prior to an overnight driving session that involves three study drives. The first drive occurs while alert. The next two drives are counterbalanced and will occur while drowsy (at least 14 hours awake and having sleepiness ratings indicating drowsiness) and while drowsy and distracted. Simulator data will be used to evaluate the ability of the DMS to assess driver state.

Respondents will volunteer for the study by responding to an internet ad or via solicitation for volunteers from the DSRI subject registry. Only potential subjects in the registry meeting inclusion criteria will be contacted. Respondents will be asked a series of questions to determine eligibility to participate in the study. The questionnaire covers both Track A and Track B so respondents don’t have to complete the questionnaire more than once and so researchers can ensure a subset of respondents meet criteria for both tracks. Criteria for both studies are

largely the same; differences are related to ability to attend visits of a specified length, willingness to adhere to different protocol elements, and sleep habits (needed only for Track B). A research team member will answer all questions the respondent may have and schedule eligible respondents who wish to participate for a session at the DSRI.

Description of the Need for the Information and Proposed Use of the Information:

NHTSA was established by the Highway Safety Act of 1970 (Pub. L. No. 91-605, §202(a), 84 Stat. 1713, 1739-40). Its mission is to reduce the number of deaths, injuries, and economic losses resulting from motor vehicle crashes on our nation's highways. To further this mission, NHTSA conducts research as a foundation for the development of traffic safety programs.

In 2013, NHTSA published the final version of the Visual-Manual NHTSA Driver Distraction Guidelines for In-Vehicle Electronic Devices. In the decade since, vehicle technologies and interfaces have evolved and a substantial amount of new research on the topic of driver distraction has been conducted. As a result, NHTSA requires a rigorous and thorough review to update the current state of knowledge on driver distraction, attention management, and distraction/risk assessment. Driver monitoring systems (DMS) are currently deployed in many production vehicles. Current production systems use different data sources, including driver-facing cameras, vehicle inputs (e.g., steering wheel torque), driving performance (e.g., lane departures), and other measures (e.g., time on task). Future production systems are also likely to use physiological sensors (e.g., heart rate) as tools to identify driver state more accurately. DMS could play a variety of roles in vehicles, including detecting and alerting drivers to distraction, drowsiness, or impairment, and then adjusting the vehicle technology to meet the needs of the driver or providing support in particular situations. It is important for NHTSA to be

able to discern the differences in approaches to state detection to understand the potential safety impacts of DMS. This requires a comparison of various sensor approaches to driver state monitoring and the development of a test protocol for different DMS methodologies. The overall objective is to develop and deliver a methodology that will assess the ability of DMS to accurately determine driver state by collecting data to support a full assessment of the factors associated with DMS and modeling driver state based on sensor data in a driving simulator.

60-Day Notice:

A Federal Register notice with a 60-day comment period soliciting public comments on the following information collection was published on July 14, 2023 (88 FR 45269). Four comments and one email were received in response to that notice. During the public comment period for the 60-day notice, NHTSA received four comments and one email. The first comment requested collection of data regarding circadian effects as related to school start times. This would involve subjects under the age of 18 and are not related to driver monitoring systems and is out of scope of the planned research project. The second comment expressed a dislike for driver monitoring systems as expressed the opinion that DMS are a disciplinary tool rather than a safety tool. NHTSA respectfully disagrees with this opinion and believes DMS may be able to improve motor vehicle safety.

One email from Alliance for Automotive Innovation asked if the research was in response to Sec. 24209 of the Infrastructure Investment and Jobs Act, 2021 (H.R. 3684; Pub. L. 117-58, enacted on November 15, 202 and commonly referred to as the Bipartisan Infrastructure Law or BIL). NHTSA responded by email to the Alliance for Automotive Innovation and noted that this project does include elements that were funded by the IIJA/BIL legislation. The email response also encouraged submission of comments to regulations.gov and noted that NHTSA

would provide responses to comments in a 30-day notice published in the Federal Register (this document).

Two of the comments received were relevant to the burden and design of the study. The following summarizes the points brought up in those comments and NHTSA's response.

The American Academy of Sleep Medicine (AASM) commended NHTSA for planning the current information collection. They found the assessment of both drowsiness and distraction while drowsy to be a progressive and necessary step in determining the utility of DMS as a tool for road safety.

The AASM commented that self-reported sleepiness may not always reflect an individual's true level of sleepiness and recommended the inclusion of other objective measures of alertness, such as electroencephalography (EEG) or the psychomotor vigilance task (PVT) to strengthen the accuracy of collected drowsiness data. **Response:** The research team has used both EEG[1] and PVT[2] as part of prior drowsy driving research. We included the review of this data as part of preliminary steps in this research study. Specifically, we found a strong relationship between the Observer Rating of Drowsiness (ORD) and the Karolinska Sleepiness Scale (KSS) ($r = 0.682$, $p < 0.001$) and weak relationships between ORD and Psychomotor Vigilance Task (PVT) prior to the drive ($r = 0.150$, $p < 0.001$) and after the drive ($r = 0.244$, $p < 0.001$). Based on our prior published research, the inherent value of adding EEG is limited, but there are substantial

[1] Brown, T., Johnson, R., & Milavetz, G. (2013). Identifying Periods of Drowsy Driving Using EEG. Annals of Advances in Automotive Medicine, 57, 99. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3861841/; Brown, T., Lee, J., Schwarz, C., Fiorentino, D., McDonald, A., Traube, E., & Nadler, E. (2013). Detection of Driver Impairment from Drowsiness. 23rd International Technical Conference on the Enhanced Safety of Vehicles, Seoul, South Korea.; Brown, T., Lee, J., Schwarz, C., Fiorentino, D., & McDonald, A. (2014). Assessing the Feasibility of Vehicle-Based Sensors to Detect Drowsy Driving. (DOT HS 811 886). Washington, DC: National Highway Traffic Safety Administration Retrieved from http://www.nhtsa.gov/DOT/NHTSA/NVS/Crash%20Avoidance/Technical%20Publications/2014/811886-Assess_veh-based_sensors_4_drowsy-driving_detection.pdf

[2] McDonald, A. D., Lee, J. D., Schwarz, C., & Brown, T. L. (2018). A Contextual and Temporal Algorithm for Driver Drowsiness Detection. Accident Analysis & Prevention.

increases to the burden (e.g., application/cleanup & driver distraction) that do not outweigh this benefit. Depending on the EEG system, applying the EEG to the participant's scalp can range from 45 minutes to 120 minutes. The EEG may also interfere with the driver and cause additional distraction, discomfort, or prevent them from becoming immersed in the driving scenario, further reducing ecological validity. Recently, other researchers have investigated the associations between KSS, ORD, vehicle-based measures, and metrics from electrooculogram (EOG) and EEG[3]. KSS was associated with ORD, standard deviation of lateral position (SDLP), percentage of eyelid closure over the pupil over time (PERCLOS), EEG alpha power, EEG theta power, and percentage of time with slow eye movement. Interestingly, measures from the physiological sensors (i.e., EEG and EOG) displayed only weak and moderate associations. Given these considerations, we maintain that the KSS will produce sufficiently accurate data to support the goals of the data collection while minimizing participant burden. The KSS will be used to determine when drivers have achieved a certain level of drowsiness and thus, they will begin the drowsy drive. We anticipated participants will complete the KSS nine times prior to the drive. Drowsiness will be defined based on a combination of the participant being awake for a minimum of 14 hours and the KSS. The KSS will not be administered during the drive as this may influence driver's levels of drowsiness. Drowsiness during the drive will be captured by measures derived from eye closures over the course of the drive (e.g., PERCLOS). Given that each approach to measuring drowsiness comes with inherent flaws, we are using a combination of measures to infer drowsiness based on a sleepiness scale to bookend drowsiness during the drive and use of eye measures (i.e., PERCLOS) to elucidate changes in drowsiness levels during the drive.

[3] Uchiyama, Y., Sawai, S., Omi, T., Yamauchi, K., Tamura, K., Sakata, T., Nakajima, K., & Sakai, H. (2023). Convergent validity of video-based observer rating of drowsiness, against subjective, behavioral, and physiological measures. PLoS one, 18(5), e0285557.

The AASM recommended that the information collection include an assessment of possible sleep disorders during the online eligibility questionnaire and advised excluding individuals with untreated sleep disorders from the study. Additionally, AASM recommended that the data collection include a measure of participant sleep quality in order to quantify contributing factors to drowsiness and driving performance; they suggested use of a participant sleep log and/or a three-day reporting of bedtimes, waketimes, estimate of the amount of time to fall asleep, number of awakenings, estimate of the amount of time awake during the awakenings, and daytime sleeping times and duration. **Response:** The proposed study procedures will capture wake and sleep time for the day preceding the study visit. We are not aware of any validated sleep log, and as additional measures would increase burden to participants, we have proposed to only ask targeted items that are known to influence drowsiness (i.e., wake time and sleep time) and can be used to provide measures for the analysis (i.e., hours of sleep and continuous time awake). The items that we ask participants are extracted from sleep logs and are variables that we could include in our statistical models. Since the sleep logs are not validated, we selected specific items, rather than using the entire log, as this reduces participant burden. Given that the focus of this research is on the manifestation of drowsiness (i.e., for the purpose of determining validity of DMS assessment) while driving in the general driving population, we did not propose collecting subjective evaluation of sleep quality in subjects which might be better addressed by NIH funded research, nor do we plan to exclude participation based on sleep disorders given that an estimated 9 to 15% of individuals have ongoing sleep disorders. A DMS will need to detect distraction and drowsiness, regardless of individual health conditions, and exclusion of these drivers could hinder the external validity of findings from this research. The presence of daytime drowsiness regardless of source will be collected using self-reported sleepiness via the KSS.

The AASM also requested clarification on how the data obtained from the study would be protected, particularly as it related to prevention of consequences for participants who are distracted while driving. The AASM also asked whether a certificate of confidentiality would be provided. **Response:** The study has received approval from the University of Iowa Institutional Review Board, which requires us to protect the participants' anonymity. Respondents' performance in the driving simulator will be deidentified and separated from any personally identifiable information. Certificates of confidentiality are generally not sought unless we are collecting data that would put the participants at legal risk, which is not the case in this study.

The National Association of Mutual Insurance Companies (NAMIC) commented that the use of the Fitzpatrick Skin Type Scale in the online eligibility questionnaire, which requires participants to self-rate, negates the uniformity of the scale. Further, NAMIC questions why the study intends to oversample participants who are rated higher on the scale (e.g., darker skin types). **Response:** The proposed self-rating of an applicant on the Fitzpatrick Skin Type Scale will be used to inform our study stratification and data collection logistics. The scale will be used to objectively quantify their skin pigmentation upon consenting and enrolling our study by a single rater. Additionally, the RGB values for skin tone will be captured during the visit via visual processing to provide an objective metric with greater gradation.

NAMIC also requested additional clarification on which driver monitoring system(s) will be used in the study. **Response:** The team will implement a sensor suite to provide the same types of signals available to a variety of types of DMS including vehicle and driver data. DSRI has existing relationships with technology suppliers that will be leveraged to provide necessary data. We do not propose to evaluate the algorithms from any technology suppliers, but instead focus on the utility of the underlying signals in detection.

Both AASM and NAMIC commented on the importance of recruiting participants from a large audience to ensure a sample that is representative and generalizable to a larger driving population. NAMIC noted their concerns related to the limited location (noting a 30-mile radius around Iowa City, IA), number of participants, and participant selection process. **Response:** A power analysis was conducted to estimate the sample size needed for the study. We agree that generalizability is important and must be balanced with the experimental aims of the research. Given that the research method utilizes a one-of-a-kind driving simulator, recruitment must be focused in the geographic area where it is housed. The plan is to maximize diversity of the sample within the limits of the proposed sample size through robust recruitment utilizing the existing registry which includes thousands of potential participants that includes the Cedar Rapids-Iowa City, IA CSA; Davenport-Moline, IA-IL CSA; Waterloo-Cedar Falls, IA MSA; Dubuque, IA MSA; Ottumwa, IA USA; Fort Madison-Keokuk, IA-IL-MO USA; Burlington, IA-IL USA; and Marshalltown, IA USA in addition to the surrounding rural areas. To expand the diversity of the overall sample, areas outside of Iowa City are being included in the recruitment approach. Additionally, participants who are not in the registry are not excluded from participating. No participants are excluded due to location so long as they are able to arrange safe transportation to/from the facility for the overnight visit. Prior research has shown that this can be done effectively, particularly when the study includes within-subject comparisons, which is one reason why we are including a subset of the sample in both tracks. As Iowa is less ethnically diverse than the US population overall, targeted recruitment will be performed to promote a more balanced sample based on the Fitzpatrick Skin Type Scale, which is also a crucial variable to include when assessing the capabilities of DMSs. The proposed self-rating of an applicant on the Fitzpatrick Skin Type Scale will be used to inform our study stratification and data collection logistics.

Affected Public:

Individuals aged 18+ from Eastern Iowa and the surrounding areas who have volunteered to take part in driving studies will be contacted for participation. They will be randomized evenly by sex, though some imbalance will be permitted to be inclusive of individuals who do not identify on the binary. 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.

Estimated Number of Respondents: Varies by individual information collection. See Table 1 below.

Frequency: Varies by individual information collection. See Table 1 below.

Annual Number of Responses: 626

Estimated Annual Burden Hours: 175 hours

The estimated annual burden for the study is 175 hours. Table 1 provides estimates for the burden calculation across the study.

Table 1: Annual Burden Estimates

Study Component	Annual Number of Respond-ents	Frequency of Response	Annual Responses	Time per Response	Cost Per Response $32.36/Hour)	Annual Estimated Burden (Rounded)	Annual Opportunity Costs (rounded)
Online Eligibility Questionnaire (Form 1718)	200	1	200	10 min	$5.39	33 hrs	$1078
Appointment Reminder Confirmation	35	1.15	40	5	$2.70	3 hrs	$108

Process (Form 1799)							
Breathalyzer Measurement	28	1.16	32	3	$1.62	2 hrs	$52
Facial Shape and Height Measurement	27	1.15	31	7	$3.78	4 hrs	$117
Karolinska Sleepiness Scale (Form 1719)	27	8.43	228	1	$0.54	4 hrs	$123
Track A Informed Consent (Form 1730)	16	1	16	15	$8.09	4 hrs	$129
Track A Study Drive (includes Training Presentation, Familiarization Drive and Study Drive)	16	1	16	81.25	$43.82	22 hrs	$221
Track B Informed Consent (Form 1731)	16	1	16	15	$8.09	4 hrs	$129
Sleep & Food Intake (Form 1720)	16	1	16	5	$2.70	1 hr	$43
Track B Study Drive (includes Training Presentation, Familiarization Drive, Wait Time, Study Drives)	45	1	45	388.38	$209.47	97 hrs	$3142
End of Visit Release	16	1	16	2	$1.08	1hr	$17

Agreement (Form 1721)							
Total Burden			626			175 hrs	$5,159

Estimated Total Annual Burden Cost: $0

The respondents are not expected to incur any reporting or recordkeeping cost from the information collection. The only costs associated with any of the information collections is the cost for travel to and from DSRI, which is associated with each of the study drives. We estimate that 83 respondents will travel to DSRI for each of the two tracks, though 13 respondents will travel for both tracks resulting in 96 round trips. We expect most subjects to be traveling locally, within 30 miles from the test facility. Maximally, we estimate a round trip distance from subjects' starting destination to DSRI to be 60 miles. The standard mileage rate for business-related driving in 2023 is 65.5 cents per mile driven, or $39.30 for 60 miles driven. Therefore, we estimate the maximum travel costs associated with Track A Study Drive to be $1,886 (48 respondents × $39.30 = $1,886.40). We estimate that the total transportation costs will be higher for subjects in Track B, who will not be permitted to walk, bike, or drive when leaving the test facility. Previous overnight studies conducted at DSRI have shown that $70 compensation for transportation expenses was sufficient to limit subject attrition and offset costs of third-party transportation. Accordingly, we estimate the travel costs associated with Track B Study Drive to be $3,360 (48 respondents × $70 = $3,360). The total costs for this ICR are estimated to be $5,246 ($1,886 + $3,360). These transportation costs are offset by subject compensation. For subjects in Track B, who will not be permitted to walk, bike, or drive when leaving the test facility, an additional $70 will be provided to offset the costs of finding alternative

transportation. Table 1 provides an estimate for the opportunity cost of the collection; however, there is no direct cost to the respondents for this collection.

PUBLIC COMMENTS INVITED: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

AUTHORITY: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29A.

Issued on *[INSERT DATE]*

Cem Hatipoglu
Associate Administrator, Vehicle Safety Research

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