

## **Information Collection Request Supporting Statements: Part A**

### **Driver Alcohol Detection System for Safety Field Operational Test OMB Control No. 2127-0734**

#### **Abstract:<sup>1</sup>**

This is a request to the Office of Management and Budget (OMB) for review and approval of a renewal with modification of currently approved information collection request (ICR) titled “Driver Alcohol Detection System for Safety - Field Operational Test (DADSS-FOT).” This ICR is for a voluntary information collection to evaluate breath-based sensor technologies that are integrated into research vehicles. The purpose of the information collection is to collect information to provide a greater understanding of the performance of both breath- and touch-based sensors with actual dosed passengers using the technology under varying environmental conditions. Although the sensors will undergo significant laboratory testing, it is necessary to evaluate their function in real-world environmental conditions to ensure that they will be operational for all possible conditions. This ICR is for the collection of data from human subjects to allow NHTSA to perform real-world testing. The primary component of this information collection is the collection of sensor data during a Field Operational Test (FOT) involving human subjects; however, demographic information about participants and post-test information will be collected as well. The objectives of the FOT are to: (1) Determine the effectiveness of the DADSS sensors in a real-world driving environment; (2) Analyze DADSS breath- and touch-based sensors in real-world driving scenarios; and (3) Obtain technical data to further refine the DADSS Performance Specifications that will ultimately be used for system design and product development. Respondents are voluntary participants that will be accepted for inclusion based on a pre-screening interview to ensure they are able to consume alcohol. For the study, NHTSA intends to collect data from a total of 480 uniquely individual participants to collect a minimum of 312,000 data points through their participative rides/drives. NHTSA has already collected data from 62 participants and will need to collect data from an additional 418 individuals .. The respondent selection interviewing is a one-time data collection and the respondents have the opportunity to participate in the FOT up to 60 times within the study; however, for the 62 individuals that have participated, they have participated an average of 2.13 times. In accordance with DOT policy on research involving human subjects, this study has been reviewed and approved by a Health and Human Services-approved Institutional Review Board before data collection began. Recipients of the respondent information are the data analysts and researchers

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<sup>1</sup> 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) if the information collection involves approval by an institutional review board, include a statement to that effect; (8) the purpose of the collection; and (9) if a revision, a description of the revision and the change in burden.

and the data are used initially to assess whether to include the respondent in the study and later to assess the functionality of the in-vehicle equipment. During the FOT, the only data collected from the human subjects will be measurement data from sensors on the vehicle, which will be recorded and used by the data analysts and researchers. This information collection is under request for extension and both the annual burden hours and the total annual burden cost have been revised based on the study experience up to August 31, 2021. The original ICR reported a total 2-year burden estimate of 115,830 hours (annual burden of 57,915 hours) and a total 2-year cost of \$2,256,847.50 (annual cost of \$1,128,423.75). These were estimates of maximum burden to the public based on the assumption that each individual participant would choose to participate the maximum 60 times. With adjustments made to time, response rate, and participation level, burden calculations have been updated. The burden is therefore no longer based on maximum participation of 60 times per individual participant, rather the average number of times individuals have chosen to participate thus far in data collection. The updated burden estimate is an *annual* burden of 3,249 hours. The annual burden cost associated with this ICR extension is zero other than the time spent participating. In addition, the respondents are compensated at an hourly rate above the opportunity cost.

## **A. Justification**

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

### Background

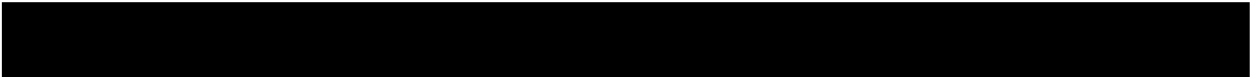
Transportation safety is the Department of Transportation's (DOT's) top strategic priority. Drunk driving is an act that compromises the safety of motorists on the nation's highways resulting in human injury and fatality as well as substantial economic burden. In 2019, 10,142 people were killed in alcohol-impaired driving crashes (i.e., crashes in which at least one driver had a BAC of .08 g/dL), accounting for 28 percent of all traffic-related deaths in the United States involving an estimated 9,598 alcohol-impaired drivers.<sup>2</sup> Despite increased knowledge and messaging, the problem of driving under the influence has not changed. These data demonstrate the human toll inherent to drunk driving. According to Department of Justice data, there were over 700,000 DUI arrests in 2019 and based on self-reported data from the 2012 Behavioral Risk Factor Surveillance System (BRFSS) survey, there were an estimated 121 million alcohol-impaired driving episodes annually.<sup>3,4</sup>

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<sup>2</sup> Department of Transportation (US), National Highway Traffic Safety Administration (NHTSA). Traffic Safety Facts 2019 data: alcohol-impaired driving. Washington, DC: NHTSA; 2015 [cited 2021 Sept 14].

<sup>3</sup> Federal Bureau of Investigations, Crime Data Explorer. <https://crime-data-explorer.app.cloud.gov/pages/explorer/crime/arrest> [cited 2021 Sept 14]

<sup>4</sup> Jewett A, Shults RA, Banerjee T, Bergen G Alcohol-impaired driving among adults-United States, 2012. MMWR Morbidity and Mortality Weekly Report. 2015;64(30):814-17. Available at URL <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6430a2.htm>



This illustrates that only a small percentage of driving under the influence can be policed. At present, there are breath-based ignition interlocks installed in vehicles of individuals who have previously been convicted of alcohol-related driving incidents. However, this technology is part of a punitive system that only applies to a small proportion of individuals deemed at risk for repeat offenses and in localities that require these devices. Currently, there is no technology that will detect a driver's blood alcohol concentration (BAC) in the vehicle commercially available to the general public and for use in a non-punitive manner. If such a technology could become available and able to prevent drunk driving across the general driving population, that technology would have the potential to prevent thousands of deaths and injuries in motor vehicles. Any such technology must be transparent to the driver, highly reliable, and accurate. An analysis of the National Highway Traffic Safety Administration's (NHTSA) Fatality Analysis Reporting System (FARS) estimates that if driver BACs were no greater than 0.08 percent, approximately 70% of alcohol-impaired road user fatalities occurring in 2010 would have been prevented. Therefore, developing noninvasive, in-vehicle alcohol detection technologies is deemed imperative for improving transportation safety and an important objective for DOT.

The Automotive Coalition for Traffic Safety (ACTS) began research, funded in part by NHTSA, in February 2008 to try to find potential in-vehicle approaches to the problem of alcohol-impaired driving. Members of ACTS comprise motor vehicle manufacturers representing approximately 99 percent of light vehicle sales in the U.S. This cooperative research partnership, known as the Driver Alcohol Detection System for Safety (DADSS) Program, is exploring the feasibility, the potential benefits of, and the public policy challenges associated with a more widespread use of non-invasive technology to prevent alcohol-impaired driving. The 2008 cooperative agreement between NHTSA and ACTS for Phases I and II outlined a program of research to assess the state of detection technologies that are capable of measuring blood alcohol concentration (BAC) or Breath Alcohol Concentration (BrAC). The 2008 cooperative agreement and a subsequent 2013 cooperative agreement support the creation and testing of prototypes and subsequent hardware that could be installed in vehicles.

Specifically, the 2013 cooperative agreement calls for research vehicles to be built, some of which will include breath-based alcohol detection systems and others will include touch-based alcohol detection systems. The sensors are to be integrated into a vehicle in a manner that does not significantly alter the appearance of the vehicle interior. The purpose of the research vehicle is to evaluate the potential implementation and integration of both breath- and touch-based sensor technologies. Although the sensors will undergo significant laboratory testing, it is necessary to evaluate their function in extreme real-world environmental conditions to ensure that they will be operational for the harshest conditions that the sensors will encounter.

The sensor-equipped research vehicles are used to gather data regarding sensor validity and reliability, as well as assess the real-world use of the sensors with human participants in varying environmental conditions. These are the first vehicles ever to be equipped with systems designed to be unobtrusive that can measure driver alcohol levels. As such, it represents the first opportunity for researchers to gain an understanding of the use of the sensors in the operational context for which they were designed. Data collected from the study's Field Operational Test

(FOT or DADSS FOT) will be used to further refine the DADSS Performance Specifications and evaluate subsystem/sensor performance.

### DADSS FOT and Data Collection

A key to the establishment of effective in-vehicle alcohol detection systems is an understanding of real-world use of the technology. The DADSS FOT will provide a greater understanding of the performance of both breath- and touch-based sensors with actual drivers using the technology under varying environmental conditions.

The objectives of the DADSS FOT are to:

- Determine the effectiveness, as compared to the standardized breathalyzer, of the DADSS sensors in a real-world driving environment.
- Analyze DADSS touch- and breath-based sensors in real-world driving scenarios.
- Obtain technical data to further refine the DADSS Performance Specifications for the DADSS System that will ultimately be used for vehicle design and development.

Objective data are collected and analyzed in this task utilizing a data acquisition system (DAS) built into the test-vehicles. Objective data obtained are based on observable episodes, undistorted by emotion or personal bias of the FOT participants. Objective data consists of numerical and video data that capture host vehicle states and maneuvers, surrounding traffic, system operation, and driver behavior.

The human component of the information collection pertains to the human test subjects participating in the study. This information collection obtains information about each human subject in screening interviews, orientation testing, and post-drive interviews. Screening interviews determine eligibility in the study and assurance of safety of participants given the consumption of alcohol. Orientation testing involves verification of information and eligibility as well as COVID-screening. Post-drive interviews assess functionality of the sensor-systems from the human-interaction perspective.

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

ACTS has contracted with KEA Technologies, Inc. (hereinafter referred to as “KEA”) to administer the DADSS FOT and analyze its results. The investigators currently performing this study are Dr. Abdullatif (Bud) Zaouk and Dr. George Bahouth. In accordance with DOT policy on research involving human subjects, this study has been reviewed and approved by a Health

and Human Services-approved Institutional Review Board before data collection began.<sup>5</sup> The study leads and an approved team of researchers are collecting and analyzing data.

The data collected from the DAS during the DADSS FOT is for the purpose of validating the DADSS prototype sensors under varying environmental conditions. The use of human participants in the DADSS FOT is for the operation of the vehicle and to have participants testing the sensors with and without alcohol in their systems so that the sensors' performance may be evaluated. As a result, the research team has relied on a convenience sample of participants. Participant recruitment has been and will be conducted by KEA and its subcontractors using web-based and other forms of advertisements to reach volunteers.

During the study, KEA employees and paid volunteer participants both drive test vehicles and serve as human passengers, with or without alcohol in their systems. KEA and its subcontractors recruit volunteer participants for the study and, in so doing, administer a progressive series of initial screenings: a telephone interview with a screening to ensure that individuals can consume alcohol safely, followed by a criminal background check to verify driving and criminal history questions answered during the initial screening (to ensure that potential voluntary participants will not endanger KEA's drivers or ACTS's valuable vehicles) which is performed independently of the telephone interview and is not included in respondent burden. The criminal background check requires that the contractor collect social security numbers, which are purged once the background check is complete, prior to the start of the FOT. This information is for the recruitment of participants and used for recordkeeping purposes.

Once a respondent is deemed eligible for participation in the study, the research team contacts the respondent, indicates eligibility, and initiates contact for the orientation phase of the study. At orientation, the respondent participates in further validation of eligibility which also includes some wait time while screening tests are completed. Orientation also includes instruction for the vehicle use and further dosing as necessary for participation in the study. The information collected from respondents and shared with respondents is used in order to perform the FOT.

During the FOT, The DADSS test cars are equipped with a reference sensor, a certified, traditional breathalyzer, from SmartStart as well as the DADSS breath- and touch-based prototype sensors. Each DADSS vehicle is equipped with an automatic data collection system (DAS) which records sensor, vehicle, and participant data without requiring any input from the

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<sup>5</sup> In December 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the Commission) issued a report which included a recommendation that Federal agencies engaged in research involving human subjects adopt the pertinent regulations of the Department of Health and Human Services. These regulations, specified in 45 CFR, Part 46, deal with requirements for protection of human research subjects. In response to the Commission's recommendation, in March 1982, the Chairman of the Federal Coordination Council for Science, Engineering and Technology appointed an Ad Hoc Committee for the Protection of Human Research Subjects. The Ad Hoc Committee, composed of representatives of affected departments and agencies, developed a Model Policy which applies to research involving human subjects that is conducted, supported, or regulated by Federal departments and agencies. This policy is based on Subpart A of 45 CFR, Part 46. On January 8, 1984, the Secretary of Transportation agreed to implement the Model Policy without exception.

participants. Both the driver and passenger sides of the vehicle are equipped with the breath-based alcohol-detection sensors and the reference and touch-based sensors are shared.

The vehicle drivers are not permitted to consume alcohol under any circumstances; only alcohol-free measurements will be obtained from the driver. The passenger is asked to consume two differing amounts of alcohol. Assignment of the driver and passenger roles is alternated so that no given participant is required to consume alcohol every test day. The DADSS FOT examines the operation of the DADSS system in test cars to verify that the DADSS breath- and touch-based sensors record data from vehicle occupants accurately and reliably. The study also examines vehicle occupants in their physical position in their seats by recording video data. The study requires physical verification of the participant's three-dimensional (3-D) position in the space so that position may be correlated with sensor data from the breath-based sensors as well as height and weight data collected from the demographic interview. Video verification is also required to correlate touch-based sensor interaction with the data collected from those sensors in the event that there are data artifacts and/or anomalies.

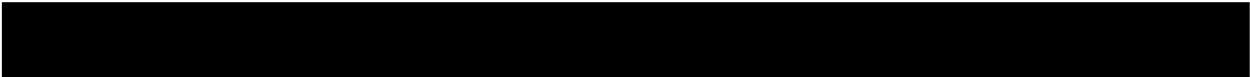
Following the FOT drive experience, the research team asks the participants a set of questions to determine user-interface, difficulties, and general experience during the drive. The participants who received alcohol dosing are then monitored to allow BrAC to drop to a safe level before being released for the day and are provided safe transportation to exit the facility. Protocol ensures that adequate time elapses between the end of a test day and the beginning of the next test day, so that a drinking passenger's BrAC returns to 0.00% before assuming the role of the driving participant on the next day. In the event that the driver becomes incapacitated or unable to continue driving, the DADSS research team arranges for any necessary medical services as well as a tow truck and transportation for both study participants. The post-drive information collection is conducted through a post-drive interview with the respondents.

The objective driving data including sensor performance along with ergonomic and demographic data will be analyzed and compiled in a thorough technical report to NHTSA and ACTS. The report will serve as a basis for further refinement of the DADSS Performance Specifications. The report will also disseminate the results of the evaluation of subsystem/sensor performance.

NHTSA is currently collecting information in this manner for the study, but has not analyzed the data, as the data collection is ongoing. Extension of the study is necessary due to COVID-related delays which paused data collection for a period of time and during development of new COVID precautions.

**3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burden.**

Data collection from the human subjects is performed by person-to-person interview. The research team has not developed electronic reporting of human subject responses. This person-



to-person interview and recording is for the initial screening interview, orientation, and post-drive interview.

During the drive-time of the FOT, sensor data is automatically captured and stored by the data acquisition system requiring no action on the part of the study participants except to breathe into or touch the sensors.

**4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

NHTSA, ACTS and the KEA research team are unaware of other research conducted currently or in the past that could be used to fulfill the research objectives of evaluating non-invasive alcohol detection technologies. The scope of this project examines:

- real-world validity and reliability of non-invasive alcohol detection technologies; and
- driver operation of those non-invasive alcohol detection technologies.

Real-world operational verification of these sensors is an integral part of the development and refinement of non-invasive alcohol detection technologies. The results of the DADSS FOT will serve as a basis for further refinement of the DADSS Performance Specifications. The study will evaluate subsystem/sensor performance and verify of the adequacy of the user interface.

With respect to the human subject data collection, as there have not been, nor any planned, studies of this nature, there are no alternative studies or data collection efforts that have the necessary information for recruitment for the study. The questionnaire for screening and orientation are unique to this study. Additionally, it is essential to interview human subjects post-drive to gather their unique experience in the test-vehicle.

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

This information collection does not impact small businesses or other small entities.

**6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

NHTSA and its research team believe that, to meet its research objectives, this study collects data at the lowest frequency possible based on the methods of the study developed to establish appropriate statistical strength.

Recruitment of participants occurs only once, requiring a single collection for the initial screening. The full orientation with in-vehicle instruction occurs for the first FOT-drive for each respondent and if that respondent chooses subsequent drives, full orientation will only occur

again if the time between drives calls for reinforcement of instruction. Orientation screenings occur for each drive to ensure safety of the respondent.

To ensure that the research team collects the least amount of data possible, the Intraclass Correlation Coefficient (ICC, a value between 0 and 1) can be computed to analyze the validity of breath- or touch-based sensors versus a reference category.

Based on ICC calculations and adding a margin of error for possible sensor failure (as described more in depth in Part B of the submission), original design called for approximately 2600 observations per 10 test conditions for four (4) tests of technology is required to assess the performance of the DADSS sensors. This study will utilize 30 test vehicles and 480 paired test participants. As described in Part B item 1 of this ICR, this study requires a minimum of 312,000 data points given the target number of test conditions, the technology being tested and the anticipated sensor failure rates. A total of 480 unique test participants is needed to complete data collection for this study. This is a key measure of necessity for the study along with the requisite 312,000 data points.

- 7. Explain any special circumstances that would cause an information collection to be conducted in a manner:**
- a. requiring respondents to report information to the agency more often than quarterly;**
  - b. requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
  - c. requiring respondents to submit more than an original and two copies of any document;**
  - d. requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
  - e. in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
  - f. requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
  - g. that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
  - h. requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no special circumstances related to this information collection.

- 8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public**



**comments received in response to that notice and describe actions taken by the agency in response to the comments. Specifically address comments received on cost and hour burden. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format, and on the data elements to be recorded, disclosed, or reported.**

NHTSA published a notice in the Federal Register with a 60-day public comment period to announce the extension to the currently approved information collection on December 30, 2021 (86 FR 74427). NHTSA received one comment in response to this notice. Mothers Against Drunk Driving (MADD) “supports NHTSA’s request for an extension of the information collection.” They further urge action to help meet the deadline mandated in the advanced technology provisions of the Infrastructure Investment and Jobs Act calling for the Agency to mandate that drunk and impaired driving prevention technology become standard equipment in all new passenger motor vehicles. MADD recognizes the timing of completion of NHTSA efforts and “adherence to the deadline mandated in the law is vital to the lives of the American public.” NHTSA has responded to this comment in the 30-day Federal Register notice with recognition of the comment; however, no changes to the burden or study are necessary to address the comment.

NHTSA recognized errors in three rows of a table presented in the 60-day notice and has corrected them in the 30-day notice, but the totals calculations were not affected.

NHTSA published a notice in the Federal Register with a 30-day public comment period to announce the extension to the currently approved information collection on March 15, 2022 (87 FR 14613).

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

Participants in this study will be compensated for their time spent on-site at the testing location, including orientation, testing, post-test interview, and potential recovery time. In a previous FOT with similar information collection and driving responsibilities, EuroFOT, respondents were compensated for their on-site time. Compensation is based on a 2.5% per annum cost of living adjustment (COLA), over the \$18/hour rate from the EuroFOT in 2013-2014. Thus, hourly compensation for on-site participation for this study is \$19.50. Participants will be paid weekly for their participation.

Monetary compensation for voluntary subjects (not the KEA employees) participating in the information collection is considered essential for the reasons listed below:

*Availability and time burden:* This study imposes burden on voluntary test participants by requiring them to ride in or drive test vehicles in varied environmental conditions during specific times of day. This study also requests that voluntary respondents provide personal information

such as driving history and other personal classifications. Monetary compensation will provide incentive to potential voluntary participants to provide the personal information that is required for screening purposes and to ensure the safety of KEA employees and these valuable test vehicles during the course of this study.

*Data quality:* Compensating voluntary participants will significantly increase their willingness to participate, thus improving the likelihood of obtaining the target number of voluntary participants to an extent beyond that possible if we did not compensate the participants.

*Complex study design:* The research is a correlational study and will require more than just a few participants to obtain the target number of data points. Compensation will increase the likelihood of obtaining and retaining the target number of participants and substantially reduce the likelihood of attrition.

The compensation for this collection has been reviewed by an IRB and deemed appropriate for participation without over-compensation that would lead to coercion of participation.

**10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.**

All information collected will be kept strictly anonymous to the extent that anonymity can be protected by law (e.g., DOT has the right to access all the data collected in the study). A researcher from the project team will always handle the demographic and vehicle data, including video. No personally identifiable information (PII) will be co-located with demographic data. A unique participant ID number will be generated for all participants linking their demographic and driving data. A link between the participant ID number and PII is, however, needed to track participation and compensate participants.

Data from driving records and criminal backgrounds will not be retained after verifying the participants' verbal responses during the recruitment interview. All other data collected from eligible participants, including the demographic data, health screening assessments, and the in-vehicle data, will be stored in a password-protected, encrypted database on a firewalled server at a KEA-affiliated location. The data will be associated with a participant ID (not the identity (e.g., name) of the participants) but maintained separately from study data. A second password-protected, encrypted database, accessible only by the Principal Investigator and a KEA accounts payable accountant, will contain the participant ID and the participant contact information so that payment for participation can be made. Video data will also be deleted within seven (7) years of the conclusion of the study.

Participants will be given a consent form to sign during orientation that notifies them of the confidentiality of their information as participants in this study.

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly**

**considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.**

This study collects information regarding voluntary participants’ background including their driving record and verification of a lack of criminal history. As noted above, although not required by NHTSA, ACTS and KEA and their subcontractors perform a criminal background check to ensure that voluntary participants in the study will not harm either the KEA employees with whom they are paired during the study or the costly vehicles themselves. Although not required by DOT, the background check is necessary for the following items due to the nature of the study: be 21 years of age, have a valid U.S. or Canadian Driver’s License, have no more than one (1) driving infraction and/or conviction on their driving record for the previous three years, be free of any criminal conviction in their past including criminal driving offenses, and be willing to work at least five (5) days per week for 12 consecutive weeks during a three-month data collection cycle.

The orientation will collect information on COVID vaccination status and participants will be required to take a COVID rapid test to ensure a negative result. This information is collected to maintain the utmost safety for the participant and the research staff. The orientation phase also collects information about gender, height, weight, sex, and ethnicity because BrAC is known to vary based on these variables.<sup>6</sup> The screening at each pre-drive orientation involves collection of health status (including drug screening and pregnancy test) and related information; however, this information will not be retained and only used to screen for eligible participants and to ensure safety.

**12. Provide estimates of the hour burden of the collection of information on the respondents and estimates of the annualized labor cost to respondents associated with that hour burden.**

Information collection and burden for both the direct collection from the participants and the on-site time commitment of the participants is updated in this extension approval request based on experience with the study to date. Table 1 includes the estimated burden hours and cost for the currently approved collection and is provided for reference.

**Table 1. Original Estimated Respondent Information and Associated Burden – Current Approved Collection**

<b>Instrument</b>	<b>Number of Individuals</b>	<b>Frequency of Responses</b>	<b>Number of Questions</b>	<b>Estimated Individual Burden</b>	<b>Total Estimated Burden Hours</b>	<b>Total Cost of Burden Hours over 24-month study period</b>
Eligibility/ Demographic	600	1	32	15 min	150 hr	\$ 1,087.50*

<sup>6</sup> Cederbaum A, Alcohol metabolism, 2012. Clin Liver Dis. 2012;16(4):667-85.

Interview						
Orientation	480	1	N/A	1 hr	480 hr	\$ 9,360.00**
Test-day questions	480	Once per each day of the FOT	8 (test-day questions)	10 min/day for 60 days	4,800 hr	\$ 93,600.00**
FOT	480	650 tests per participant		3.83 hr/day for 60 days	110,400 hr	\$ 2,152,800.00**
TOTAL					115,830 hr	\$ 2,256,847.50

\* Interviewees will not be compensated for the eligibility/demographic interview, but we calculate the estimated burden hour cost to the public using the prevailing Federal minimum wage rate of \$7.25/hour.

\*\*Participants in the FOT will be compensated \$19.50 per hour for their time in the orientation and the FOT study and this rate was used to calculate their burden hours.

The total estimated burden hours associated with the study was 115,830 hours. Estimated total burden cost totaled \$2,256,847.50. The study was planned for 24 months and thus the annual burden associated with this study was estimated at \$1,128,423.75 This may have been erroneously entered as the \$2 million figure for the annual burden cost instead of averaging that figure over two years.

When NHTSA originally obtained clearance for this ICR, the agency did not expect to need to renew the collection. Instead, it was expected that the data collection would have been completed within the three-year clearance period. However, COVID-19 delayed the research effort, necessitating this request for extension. Accordingly, NHTSA is submitted revised burden estimates based on the portion of the planned data collection that, as of August 31, 2021, still needs to be completed. Updates include adjustments to numbers of screenings, duration associated with information collection, and frequency of data collection of various phases of the study. It is estimated that data has been collected for one quarter of the study, thus the burden calculations presented pertain only to the collection remaining participants and the time expected to collect the remaining information.

As of August 31, 2021, collection is complete for 62 participants of the necessary 480 participants. The calculations for burden follow a similar row-structure as was presented in Table 1 and are shown in Tables 2 and 3. Table 2 has additional sub-rows to more specifically distinguish between direct collection from respondents and burden based on time-commitment only. Also note that Table 2 columns are slightly different than Table 1.

**Table 2. Revised Estimated Respondent Information**

Instrument	# Respondents	Frequency	Number of Responses	Duration
Eligibility/Demographic Interview	2,787	1	2,787	30 min (0.5 hrs)
Orientation				
Full Orientation	418	1	418	1 hour
Health Screening Only	234	2	468	30 min (0.5 hrs)
FOT	418	2.13	890	5 hours
Test-Day Interview	418	2.13	890	Included in FOT

**Table 3. Complete Estimated Burden Hours and Associated Opportunity Costs**

<b>Instrument</b>	<b>Number of Responses</b>	<b>Number of Respondents</b>	<b>Duration</b>	<b>Estimated Burden Hours</b>	<b>Cost per hour</b>	<b>Estimated burden hour cost</b>
Eligibility/Demographic Interview	2,787	2,787	30 min (0.5 hrs)	1,393.5 hrs	\$15.34	\$21,376.29
Full Orientation	418	418	1 hour	418 hours	\$15.34	\$6,412.12
Health Screening Only	468	234	30 min (0.5 hrs)	234 hours	\$15.34	\$3,589.56
Field Operational Test	890	418	5 hours	4,452 hours	\$15.34	\$68,293.68
Total (covering a 24-month period)				6,497.5 hours (6,498 hours)		\$99,679.32
<b>Estimated Annual Burden</b>				<b>3,249 hours</b>		<b>\$49,839.66</b>

**Table 3a. Annual Estimated Burden Hours and Associated Opportunity Costs**

<b>Instrument</b>	<b>Average Number of Responses/Year</b>	<b>Average Number of Respondents /Year</b>	<b>Duration</b>	<b>Estimated Burden Hours</b>	<b>Cost per hour</b>	<b>Estimated burden hour cost</b>
Eligibility/Demographic Interview	1,393.5	1,393.5	30 min (0.5 hrs)	696.75 hrs	\$15.34	\$10,688.15
Full Orientation	209	209	1 hour	209	\$15.34	\$3,206.06
Health Screening Only	234	117	30 min (0.5 hrs)	117 hours	\$15.34	\$1,794.78
Field Operational Test	445	209	5 hours	2,225.85 hours	\$15.34	\$34,144.54
<b>Estimated Annual Burden</b>				<b>3,249 hours</b>		<b>\$49,839.66</b>

The changes for this extension approval and updates to the remaining burden hours and associated opportunity costs are as follows.

- **Eligibility/Demographic Interview.** As of August 31, 2021, 62 participants had been successfully recruited and participated in the FOT. Successful recruitment involved a screening of 420 individuals, thus a 15 percent recruitment rate. The total number of participants necessary for the study is 480. With 418 respondents to be recruited at a rate of 15 percent of those going through the initial eligibility screening, the research team would need to screen 2,787 individuals. This recruitment rate of 15 percent is lower than the estimated 75 percent recruitment rate estimated for the original ICR. Frequency of this screening remains at one per respondent, but the duration of the interview is averaging 30 minutes as opposed to the original estimation of 15 minutes. The estimated burden for this eligibility/demographic interview is 1,393.5 hours. The median hourly wage for the Southwest Virginia non-metropolitan area is \$15.34 per hour for all

occupations which serves as the opportunity cost per hour. The associated estimated opportunity cost is \$21,376.29.

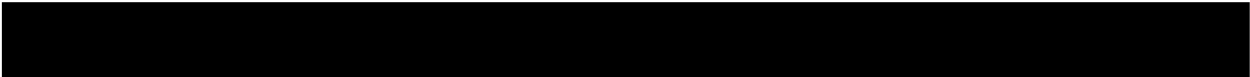
- Orientation. Each eligible respondent is now a participant in the study and arrives on-site for the orientation. As previously mentioned, full orientation involves the health screenings as well as in-vehicle instruction. Each of the remaining 418 participants will go through the full orientation. This full orientation lasts 1 hour. The estimated burden associated with this is 418 hours. Thirty-five of the 62 respondents (56%) that have participated have returned to participate in the study again, with the average returns at three times. Thus, 56 percent of the 418 (234 participants) are expected to need to go through the health screening portion of the orientation another two times. This health screening portion of orientation is 30 minutes. The burden hours calculated for health screenings only is 234 hours. The hourly opportunity cost remains at \$15.34, thus the estimated opportunity cost across the study for the full orientation is \$6,412.12 and for the health screening is \$3,589.56.
- FOT. Based on the experience of that data collected through August 31, 2021, 62 participants were involved in data collection. Twenty-seven participants only participated once, the remaining 35 participated an average of 3 times each, thus an average of 2.13 drives for the 62 participants. The average duration of the pre-drive, drive, and post-drive recovery is 5 hours. This is separate from the time during orientation. For the remaining 418 participants, they are estimated to participate 2.13 time, with a five-hour commitment during the FOT. The total burden hours is 4,452. The hourly opportunity cost remains at \$15.34, thus the estimated opportunity cost for the FOT across the study is 68,293.68.
- Test-Day Questions. These questions were counted separately on the initial ICR. However, the question responses are collected during the post-drive recovery time and included in the average time for participants in the FOT portion of the study. Therefore, there is no need to calculate additional burden hours or cost for this element of data collection.

The total burden for the remaining data collection is 6,497.5 hours, rounded up to 6,498 hours. The research team expects the data collection to take 24 months. This is longer than initially estimated due to observed difficulty in recruitment. The estimated annual burden hours for the remaining study is 3,249 hours and the estimated annual opportunity cost is \$49,839.66.

**13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. Do not include the cost of any hour burden already reflected in the response provided in question 12.**

There are no additional costs to respondents beyond those associated with the hourly burden presented above, which are not to be included in this section.

**14. Provide estimates of annualized costs to the Federal government. Provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.**



Costs to the Federal Government involve contract costs for implementation of the study. Of the total \$6,954,763, 20% is paid for by ACTS and 80% is paid for by NHTSA. The total cost to the Federal government over an estimated total of 52 months (extended by 2 years from original timeframe due to COVID delays and difficulty recruiting) is therefore, \$5,563,810, and the approximate annual cost to the Federal government is \$1,283,956. This is the cost of the entire study.

**15. Explain the reasons for any program changes or adjustments reported on the burden worksheet. If this is a new collection, the program change will be entire burden cost and number of burden hours reported in response to questions 12 and 13. If this is a renewal or reinstatement, the change is the difference between the new burden estimates and the burden estimates from the last OMB approval.**

Given this is an extension request, some changes to the burden have been made. Calculations for this extension were totaled and averaged over what is expected to be an additional two years of data collection based on the delay from COVID-19 restrictions as well as challenges in recruiting participants.

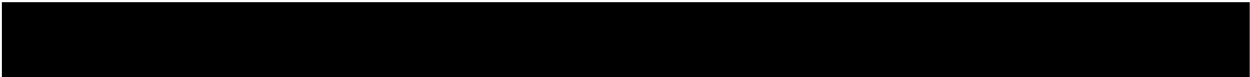
Estimates of respondents, time, and frequency have been updated in response to the data collection up to this point. Based on current response rates (15% compared to the original estimate of a 75% response rate), estimates of the number of individuals necessary for contact for recruitment has been increased.

The experience of the research team has also led to a change in the timing for both the eligibility/demographic interview has increased. The timing for orientation has been separated into the amount of time necessary for a full orientation and the amount of time necessary for completion of the health screening portion of the orientation for those returning participants.

Additionally, estimates of the number of times a unique respondent returns to participate in the study has been adjusted based on the experience of those respondents thus far.

The final change is that the original burden hours were calculated at 115,830 but that was the total number of hours, not the hours averaged over the two years of the study. The updated estimated annual burden hours are 3,249. The annual burden cost has been changed to zero, as there is no additional cost associated with participation and respondents are compensated for their time.

**16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions as applicable.**



Data from this collection is to be used internally within the DADSS program to further advance the technology. NHTSA does not plan for a publicly-available published report based on this study.

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

No such approval is being requested. The expiration date for the information collection will be shared with the respondents at the orientation.



**18. Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions." The required certifications can be found at 5 CFR 1320.9.<sup>7</sup>**

No such exception to the certification statement is being requested. A statement similar to the following shall be provided to the participants: *Paperwork Reduction Act Statement: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2127-0734. The purpose of the information collection is to collect information to provide a greater understanding of the performance of both breath- and touch-based sensors with actual dosed passengers using the technology under varying environmental conditions. The primary component of this information collection is the collection of sensor data during a Field Operational Test (FOT) involving human subjects; however, demographic information about participants and post-test information will be collected as well. The objectives of the FOT are to: (1) Determine the effectiveness of the DADSS sensors in a real-world driving environment; (2) Analyze DADSS breath- and touch-based sensors in real-world driving scenarios; and (3) Obtain technical data to further refine the DADSS Performance Specifications that will ultimately be used for system design and product development. We estimate that it will take approximately 30 minutes to one hour to complete the orientation and up to 5 hours to complete the FOT. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Room W45-205, Washington, DC, 20590.*

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<sup>7</sup> Specifically explain how the agency will display the OMB control number and expiration date and inform potential respondents of the information required under 5 CFR 1320.8(b)(3): the reasons the information is planned to be and/or has been collected; the way such information is planned to be and/or has been used to further the proper performance of the functions of the agency; an estimate, to the extent practicable, of the average burden of the collection (together with a request that the public direct to the agency any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden); whether responses to the collection of information are voluntary, required to obtain or retain a benefit (citing authority), or mandatory (citing authority); the nature and extent of confidentiality to be provided, if any (citing authority); and the fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.