Department of Transportation Office of the Chief Information Officer

Supporting Statement
Driver Alcohol Detection System for Safety Field Operational Test

INTRODUCTION

This is a formal request to the Office of Management and Budget (OMB) to review and approve a new National Highway Traffic Safety Administration (NHTSA) information collection request (ICR) titled "Driver Alcohol Detection System for Safety - Field Operational Test (DADSS-FOT)."

Part A. Justification

1. CIRCUMSTANCES THAT MAKE COLLECTION OF INFORMATION NECESSARY

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 2014, 9,967 people were killed in alcohol-impaired driving crashes, accounting for nearly one-third (31%) of all traffic-related deaths in the United States.[1] Also in 2014, over 1.1 million drivers were arrested for driving under the influence of alcohol or narcotics.[2] However, that is only one percent of the 121 million self-reported episodes of alcohol-impaired driving among U.S. adults each year.[3]

These statistics demonstrate the human toll and economic cost inherent to drunk driving. They also show 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 who are at risk for repeat offenses. Currently, there is no commercially available technology that will detect a driver's blood alcohol concentration (BAC) non-intrusively in the vehicle. To reach and prevent drunk driving across the larger population, it is necessary to have alcohol detection technology that is transparent to the driver as well as being 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

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[1] Department of Transportation (US), National Highway Traffic Safety Administration (NHTSA). Traffic Safety Facts 2014 data: alcohol-impaired driving. Washington, DC: NHTSA; 2015 [cited 2016 Feb 5]. Available at URL: http://www-nrd.nhtsa.dot.gov/Pubs/812231.pdf

[2] Department of Justice (US), Federal Bureau of Investigation (FBI). Crime in the United States 2014: Uniform Crime Reports. Washington (DC): FBI; 2015 [cited 2016 Feb 5]. Available at URL https://www.fbi.gov/about-us/cjis/ucr/crime-in-the-u.s/2014/crime-in-the-u.s.-2014/tables/table-29

[3] Jewett A, Shults RA, Banerjee T, Bergen G Alcohol-impaired driving among adults-United States, 2012. MMWR Morbi Mortal Wkly Rep. 2015;64(30):814-17. Available at URL https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6430a2.htm

alcohol–impaired road user fatalities occurring in 2010 would have been prevented. Therefore, developing noninvasive, in-vehicle alcohol detection technologies is 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 that will include both a breath- and touch-based alcohol detection sensor. 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. Therefore, simulator and test-track environments are not appropriate for the proposed study.

The research vehicles will be used to gather data regarding sensor validity and reliability, as well as the assess the real-world use of the sensors with human participants in varying environmental conditions. These will be the first vehicles ever to be equipped with systems designed to be unobtrusive that can measure driver alcohol levels. As such, it will represent 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) (called the DADSS-FOT hererafter) will be used to further refine the DADSS Performance Specifications and evaluate subsystem/sensor performance.

A key to the establishment of effective in-vehicle alcohol detection systems is an understanding of real-world use of the technology. This study will be initiated to 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 will be collected and analyzed in this task utilizing a data acquisition system (DAS). Objective data obtained will be based on observable episodes, undistorted by emotion or personal bias of the FOT participants. Objective data will consist of numerical and video data that capture host vehicle states and maneuvers, surrounding traffic, system operation, and driver behavior. Subjective data collected will include obtaining background information on participants before participation in the FOT and at the conclusion of each FOT day.

2. HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED

ACTS has contracted with KEA Technologies, Inc. (hereinafter referred to as "KEA") to administer the DDASS-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 will be reviewed and approved by a Health and Human Services approved Institutional Review Board before data collection begins.[4]

The data collected from the DADSSFOT is only for the purpose of validating the DADSS prototype sensors under varying environmental conditions. It is <u>not</u> being conducted for the purpose of validating the sensors with varying subgroups of the population (e.g., gender or race). Those types of evaluations are the subject of tightly controlled laboratory studies beyond the scope of the DADSS-FOT. Therefore, the use of human participants in the DADSS-FOT is only 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 is not constrained to a representative sample of participants for the DADSS-FOT. and may rely on a convenience sample of participants. Participant recruitment 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 will both drive test vehicles and, with or without alcohol in their systems, serve as human passengers. KEA and its subcontractors will recruit volunteer participants for the study and, in so doing, will administer a

[4] 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.

progressive series of screenings: a telephone interview, followed by 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). 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.

The DADSS-FOT will require 480 driver/passenger participants either to drive or ride as passengers in DADSS test vehicles provided by KEA over the course of a 24-month period. Each participant pair will be assigned to one (1) of 30 test vehicles for a three-month period, five (5) days per week and for four (4) hours per day. Participants will test the DADSS vehicles in 10 different geographic/temperature conditions. Participants will be asked questions each day of the DADSS-FOT regarding the logistics of each test day.

The DADSS test cars will be equipped with a reference sensor, the ACS Alcolock L3 Interlock, as well as the DADSS breath- and touch-based prototype sensors. Each DADSS vehicle will be equipped with an automatic data collection system (DAS) which will record sensor, vehicle and participant data without requiring any input from the participants. Both the driver and passenger sides of the vehicle will be equipped with the breath-based alcohol-detection sensors and the reference and touch-based sensors will be shared.

The vehicle driver will not be permitted to consume alcohol under any circumstances; only alcohol-free measurements will be obtained from the driver. The passenger will be asked to consume two differing amounts of alcohol, approaching BrAC of 0.02-0.03% and 0.04-0.05%, respectively. The design of the passenger user interface was designed to accommodate the perceptual and the information processing limitations associated with a BrAC at the maximum dosage (0.05%) so that errors in user interface issues due to alcohol consumption would be mitigated.

Assignment of the driver and passenger roles will be alternated so that no given participant will be required to consume alcohol every test day. The test protocol will ensure 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 will arrange for any necessary medical services as well as a tow truck and transportation for both study participants.

The DADSS-FOT will examine 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 will also examine 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. Information regarding participant occupation is collected because occupation can be correlated

with skin thickness on the fingers, a variable known to affect the performance of the touch-based prototype sensors. Information regarding gender and Body Mass Index (BMI) (a ratio of height to weight) is also collected because BAC varies by these factors.

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.

3. EXTENT OF AUTOMATED INFORMATION COLLECTION

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. EFFORTS TO IDENTIFY DUPLICATION

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.

5. EFFORTS TO MINIMIZE THE BURDEN ON SMALL BUSINESSES

Participation in the DADSS-FOT is completely voluntary. As described above, participants in the DADSS-FOT will be recruited from a pool of eligible drivers. These individuals' job for the length of their participation in this study will be either to ride in or drive a DADSS test vehicles and answer standard questions at the start and end of each test day. Since the study is voluntary, participating in this study will present no burden to any small business.

6. IMPACT OF LESS FREQUENT COLLECTION OF INFORMATION

NHTSA and its research team believe that, to meet its research objectives, this study collects data at the lowest frequency possible within a single ICR approval based on the methods of the study described below and through statistical estimation of the data required to address the goals of the study. 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. The ICC indicates how closely the instruments correlate in their measurements, where 0 = no correlation and 1 = full correlation.

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), 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, who will alternate as drivers and passengers in the test vehicles. This study will be conducted once over a twenty-four (24) month period. As described in Part B item 1 of this document, this requires 312,000 data points given the target number of test conditions, the technology being tested and the anticipated sensor failure rates. The number of tests required per participant is 650. For a 4-hour test day, that is equivalent to 11 tests per day per participant, a feasible number of required tests. To minimize the potential for participant attrition, the research team is limiting participation to three-month intervals. Participants will be expected to drive (or ride) approximately 4 hours per day and no more than 20 days per month.

Regarding recruitment, the research team designed the progressive screening process to ensure that staff rules out ineligible interviewees early in process, so as not to unnecessarily take up these individuals' time.

7. SPECIAL CIRCUMSTANCES

There are no special circumstances related to this information collection. Participants are expected to obey all applicable control laws. The cost associated with the DADSS-FOT test vehicles, including liability insurance, is fully covered by ACTS.

8. COMPLIANCE WITH 5 CFR 1320.8

NHTSA published a notice in the Federal Register with a 60-day public comment period to announce this proposed information collection on Nov 23, 2016, 81FR84690 (NHTSA-2016-0120).

NHTSA published a notice in the Federal Register with a 30-day public comment period that announced this information would be sent to OMB for approval on August 8, 2017, 82FR37163 (NHTSA 2017-0070).

9. PAYMENT OR GIFTS TO RESPONDENTS

Members of the research team were part of EuroFOT[5], a study with similar scope and participant responsibilities to the DADSS-FOT that tested different vehicle components. The EuroFOT study paid participants $18 per hour during 2013-2014. Allowing for a 2.5% per annum cost of living adjustment (COLA), the hourly rate for the DADSS-FOT study will be $19.50 per hour for all participant activities. Participants will be paid weekly. for their participation.

[5] The EuroFOT was a field operational test conducted by a Tier 1 automotive supplier and the methods and results of the study are proprietary and not available for public review. Members of the research team were part of the EuroFOT study and are able apply lessons learned from the study design to the present effort.

[redacted]

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. Compensation for this time and burden is justified. 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.

10. ASSURANCES OF CONFIDENTIALITY

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 identifible 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 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.

11. JUSTIFICATION FOR COLLECTION OF SENSITIVE INFORMATION

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. This requires collection of social security numbers from potential participants. Social security numbers will be deleted from study records following background verification. 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. Voluntary participants are not employees because they will only be participating for a short period of time in order to get the sample size (#of people) needed for testing the devices.

The study also collects video data to verify the physical position of the individual in the test cars. This data will be used to verify if there are any anomalies with how the individual operated the alcohol sensors. The study collects information about gender, height, weight, sex, and ethnicity because BrAC is known to vary based on these variables.[6] The screening process involves collection of health status and related information; however, this information will not be retained and only used to screen for eligible participants.

12. ESTIMATES OF BURDEN HOURS FOR INFORMATION REQUESTED

A total of 480 drivers will be recruited for the DADSS-FOT study. It is estimated that 600 drivers (25% more individuals than the target number of the sample) will need to be contacted in order to obtain 480 eligible drivers for participation in the study.

The eligibility/demographic interview is estimated to take 15 minutes. The DADSS-FOT orientation session is expected to take approximately one (1) hour. The estimates of burden hours for the participants, including the time taken for the test days are presented in Table 1 below.

Table 1. Estimated Burden Hours

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

[6] Cederbaum A, Alcohol metabolism, 2012. Clin Liver Dis. 2012;16(4):667-85.

[redacted]

*** 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.**

13. ESTIMATES OF TOTAL ANNUAL COSTS TO RESPONDENTS

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. All participants will be paid for their time at a rate of $19.50 per hour. Potential recruits who are determined to be ineligible for participation will not be compensated for the completed portion of the eligibility interview.

14. ESTIMATE OF COST TO THE FEDERAL GOVERNMENT

The estimate of costs for the entire 28-month study period is $6,954,763, with an approximate annual cost totaling $3,477,382. The method utilized in this calculation was a bottom-up cost estimate based on the target sample size. The relevant sample size was then divided across the number of cars available to determine the number of samples needed per car and consequently the number of participants required to provide the number of samples to satisfy the study requirements. The total number of participant labor hours estimated for this study is 115,830. The unburdened cost of participant labor is $2,255,760.

The 28-month estimate also includes the labor costs research personnel, study coordinators, and labor associated with recruitment and oversight of the DADSS-FOT. Additionally, the estimate includes operational expenses such as fuel, vehicle, sensor and software maintenance, as well as communication costs (e.g., wifi and cellular 4g). These costs are based on thirty (30) vehicles and average approximately $13,333/vehicle. The unburdened study operations cost is $400,000 over the 28-month study period.

The collection of this information requires analysis by staff to determine the performance of the sensors to further refine the DADSS Performance Specifications that will ultimately be used for system design and product development. The analysis cost includes statistical design and analysis, database management, data manipulation and reporting. The unburdened cost of the study analysis is $492,966.

KEA has an overhead and general administrative burden of 1.21% totaling $3,806,037. 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 28 months is therefore, $5,563,810, and the approximate annual cost to the Federal government is $2,781,905.

15. EXPLANATION OF PROGRAM CHANGES OR ADJUSTMENTS

This is a new data information collection for the DADSS, which will result in a program change of an additional 115,830 burden hours added to NHTSA overall total.

16. PUBLICATION OF RESULTS OF DATA COLLECTION

[redacted]

Data analysis will occur staggered with the data collection activities, with analysis commencing two months after data collection begins. Data analysis will involve regular inspection of sensor, participant video and subjective data to verify its integrity before it will be submitted for the proposed statistical analysis. Statistical analysis is expected to be completed by Month 26 of the study and used as input into the draft report on Month 27 of the study. The results of this information collection will be documented in a final technical report to be delivered to and maintained by NHTSA by Month 28 of the study.

Table 2. Study Timeline

FOT Study Activity	Months from OMB Approval
Pre-FOT Platform Development	Month 1 – Month 6
Participant Recruitment	Month 1 – Month 6
FOT Data Collection	Month 6 – Month 19
Data Analysis	Month 9 – Month 26
Draft Report	Month 27
Final Report	Month 28

17. APPROVAL FOR NOT DISPLAYING THE EXPIRATION DATE OF OMB APPROVAL

No such approval is being requested.

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT

None.