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Supporting Statement

Older adults comprise an increasing proportion of the driving population, but some older drivers develop symptoms of dementia that may impair their ability to drive safely. Many older adults continue to drive following a diagnosis of early dementia or mild cognitive impairment (MCI). While most agree that people with advanced dementia cannot drive safely, the level of cognitive impairment that is inconsistent with safe driving has not been established. State driver licensing agencies strive to differentiate between potentially risky older drivers who should undergo license review and potential revocation and those of similar age who are able to drive safely and so pose no undue risk to themselves or other drivers. The purpose of this research effort is to document differences in driving performance and driving habits between participants with MCI, as determined by recognized clinical methods, and control participants matched on age and sex who do not meet MCI criteria. Data collected through the study will include clinical measures of participants' cognitive and sensory skills; measures of driving performance as demonstrated during a driving evaluation conducted by a driving rehabilitation specialist (DRS); and driving exposure based on data collected using instrumentation that will be installed in participants' vehicles for approximately one month. Findings will provide valuable information to medical professionals and others who provide guidance to older adults and their families regarding an older adult's ability to drive safely, as well as to licensing agencies, regarding the relationship between age-related cognitive impairment and the ability to drive safely.

A. Justification

The National Highway Traffic Safety Administration (NHTSA) of the U.S. Department of Transportation (USDOT) is seeking approval from the Office of Management and Budget (OMB) to conduct a qualifying interview with prospective participants in a study about the consequences of early stage dementia and mild cognitive impairment (MCI) on driving habits, driver performance and safety entitled, *Mild Cognitive Impairment and Driving Performance*, and to conduct the study described above.

A.1. Explain the circumstances that make the collection of information necessary. Identify any Legal or 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.

a. Circumstances making the collection necessary

NHTSA was established to reduce the number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. As part of this statutory mandate, NHTSA is authorized to conduct research as a foundation for the development of motor vehicle standards and traffic safety programs.

Older adults comprise an increasing proportion of the driving population. The independent mobility that driving confers improves older adults' access to the goods and services they need, and enhances their ability to take part in community and family activities that support quality of life. Driving cessation has been associated with decreased mobility, and consequently

poorer quality of life. However, early stage dementia and mild cognitive impairment (MCI), conditions markedly more prevalent with advancing age, can undermine driver performance and safety. Driving habits may also change in ways that increase risk for MCI drivers and other road users.

While most agree that people with advanced dementia cannot drive safely, the level of MCI- or dementia-related impairment that is inconsistent with safe driving has not been established. Further, the research literature includes little information about effects of MCI on performance of specific driving tasks. Thus, medical care providers and driver licensing agency personnel have inadequate information to support guidance to older adults with MCI or dementia regarding continued driving. Improving the understanding of changes in driving behaviors associated with MCI-related functional decrements will help older adults and their families, as well as health care professionals, licensing agencies, and others who provide guidance to older adults regarding driving safety to know when the risks associated with the person continuing to drive outweigh the individual's mobility needs. The findings from this study also will help clinicians to identify and intervene when a client with dementia begins to exhibit potentially risky driving behaviors.

NHTSA proposes a quasi-experimental driving performance and exposure study to document differences in functional abilities, driving performance and driving exposure between participants with MCI, as determined by recognized clinical methods, and control participants matched on age and sex who do not meet MCI criteria, and relationships between specific functional and driving evaluation measures. Data collected through the study will include:

1. Driving evaluation: Measures of driving performance as demonstrated during a professional evaluation conducted by a driving rehabilitation specialist (DRS);
2. Functional skills (cognitive and sensory) as measured using clinically recognized instruments (see Appendix B for descriptions and justifications of these instruments; and
3. Driving exposure measures based on data collected using instrumentation installed in participants' own vehicles for approximately one month of naturalistic data collection.

NHTSA is requesting clearance to collect voluntary information from potential participants to determine their eligibility to participate in this study, as well as the other measures described above.

b. Statute authorizing the collection of information

Title 23, United States Code, Chapter 4, Section 403 (Attachment 1) gives the Secretary authorization to use funds appropriated to carry out this section to conduct research on all phases of highway safety and traffic conditions; and to conduct research, training, and education programs related to older drivers (See 23 U.S.C. 403(a)(1), 23 U.S.C. 403 (a)(7)).

A.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.

This is a new collection of information. Respondent compliance is voluntary.

TransAnalytic, LLC will conduct this study under an Indefinite Delivery Indefinite Quantity (IDIQ) contract with NHTSA. A single questionnaire will be used for this study, a screening questionnaire for recruitment. NHTSA intends to recruit potential participants through referrals from Driver Rehabilitation Specialists (DRSs) of drivers suspected of having some degree of cognitive impairment by the State of Virginia Department of Motor Vehicles (VA DMV). The DRS will provide a toll-free contact number that drivers can use to learn more about the NHTSA research study. A comparison group of drivers matched on age and sex who have not been diagnosed with cognitive impairment will also be recruited, either by contacting individuals who participated in other studies and gave their consent to be contacted about future research opportunities or by posting notices describing the research opportunity at Area Agency on Aging Senior Centers. People interested in participating will contact a designated staff member through the toll-free number to enroll. Prior to participation in the study candidate participants will be asked questions over the phone using the **Mild Cognitive Impairment and Driving Performance Questionnaire**. This questionnaire will be used to prescreen each potential participant based on the eligibility criteria listed below. Candidate participants will be asked about their age, driver license status, general health, access to a car to use in the study and whether the car had been adaptive controls, and their driving exposure.

Individuals must meet the following criteria to be eligible to participate in the study:

1. Age 60 or older at the time of data collection;
2. Currently licensed to drive;
3. Drive at least three trips per week;
4. Do not have adaptive equipment installed in the vehicle (e.g., hand controls)
5. Have no medical condition of such severity as to interfere with safe driving; have not had a medical professional recommend driving cessation;
6. Intend to be in the data collection area during the data collection interval (e.g., do not plan an extended trip during the naturalistic data collection interval).

Responses to the **Mild Cognitive Impairment and Driving Performance Questionnaire** will only be used to identify eligible participants for this study and will not be kept nor analyzed. Candidates who are selected for the study will be scheduled for study visits to complete evaluations of functional and driving performance, and for installation and later removal of naturalistic driving data collection devices in their vehicles. Those who do not meet eligibility requirements listed above would be excluded because they may introduce too much variability into the data and mask effects of independent variables which are the principal focus of the study. Those who meet eligibility requirements and agree to participate in the study will complete study activities as described above.

Response is strictly voluntary.

A.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 information technology. Also describe any consideration of using information technology to reduce burden.

To collect this qualifying information, NHTSA will engage in a telephone call that a driver, who has responded to an invitation, has placed to a staff member on the research team. No automated, electronic, mechanical, or other technological collection techniques are planned to obtain this information. Telephone interview is the least burdensome method to contact participants in this case.

Where appropriate, functional and driving performance measures will be automated; driving exposure data collection will all be automated using unobtrusive data collection devices installed in the participant's vehicle; thus, instrumentation will be largely invisible to the participant.

A.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.

To qualify for this study drivers must engage in a specified amount of driving (trip frequency) and meet other study inclusion criteria. There is no source of this information other than direct inquiry to the participant. The single direct telephone conversation proposed in this application is not only an efficient means of acquiring the necessary qualifying information; it also permits the driver to ask any questions he/she may have about study participation. Similarly, there is no source of information regarding these drivers' functional abilities, driving performance and exposure, or about the relationship between MCI and driving performance and exposure.

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

The collection of information does not involve small businesses except insofar as the data will be collected by a small business contractor to NHTSA.

A.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.

The population of older drivers is expanding. With advancing age comes a greater prevalence of dementia and other types of cognitive impairment that can interfere with the capability to drive safely. NHTSA has a responsibility to provide guidance to State driver licensing agencies, as well as to physicians, DRSs, and other health caregivers who advise older adults regarding about when to transition from or to cease driving. The planned study will provide the evidence NHTSA needs to develop such

guidance; but, such evidence must be obtained from properly qualified older drivers who represent the population of interest. Qualification of participants for inclusion in the study and collecting data described above is essential to the development of needed, reliable evidence-based guidance regarding the relationship between age-related cognitive declines, including those associated with MCI, and the ability to drive safely.

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

No special circumstances require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.6.

A.8. Provide a copy of the FEDERAL REGISTER document soliciting comments on extending the collection of information, a summary of all public comments responding to the notice, and a description of the agency's actions in response to the comments. Describe efforts to consult with persons outside the agency to obtain their views.

FEDERAL REGISTER NOTICE: A copy of the Federal Register Notice which notified the public of NHTSA's intent to conduct this information collection, and provided a 60-day comment period, was published on December 26, 2013 (Vol. 78, No. 248, Pages 78504-78505). No comments were entered into the NHTSA docket in response to the 60-day Federal Register Notice.

A copy of a second Federal Register Notice (Vol. 79, No. 83 Pages 24493 - 24494), which announced that this information collection request will be forwarded to OMB, was published April 30, 2014.

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

No payment or gift will be provided to respondents for the qualifying interview. Those who qualify for the study and choose to participate will receive a \$100 payment for allowing instruments to record travel patterns to be placed in their cars. Previous experience has shown that this is the minimum amount that will result in recruiting participants.

A.10. Describe any assurance of confidentiality provided to respondents

Older drivers who are qualified and choose to participate in this study will be asked to execute an Informed Consent document that promises that no individual results and no personal information will be published and no personal results will be shared with any licensing regulatory authority. All published results will provide only summary statistics that cannot be used to identify any individual or individual's responses.

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

No questions regarding sexual behavior, orientation, or attitudes; nor questions regarding religion, nor beliefs of any kind, will be asked in the qualifying interview.

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

Information collection to identify respondents who are eligible for the study will be conducted by telephone interviews with an estimated 90 older drivers, 45 of whom are drivers whose medical care providers have determined that they are medically capable of driving, but also indicated that the person needs a driver evaluation with a certified independent driver rehabilitation specialist. Respondents will take an estimated 10 minutes to complete the questions, resulting in 15 burden hours (Table 1a).

Table 1a. Burden Hours: Screening Potential Participants

	Respondents	Hours per respondent	Burden hours
Screening	90	.16	15

Each participant will read and sign a consent form, complete a clinical functional evaluation and a driving evaluation, have a data acquisition system (DAS) installed in their vehicle for one month, and then have the DAS removed, resulting in 180 burden hours (Table 1b).

Table 1b. Burden Hours

	Participants	Hours per participant	Burden hours
Consent	60	.50	30
Functional, Driving Evaluation	60	2.00	120
Install, remove DAS	60	.50	30
TOTAL	60	3.00	180

This results in a total of 195 (15 + 180) burden hours for the entire collection.

A.13. Provide an estimate of the total annual cost to the respondents or record keepers resulting from the collection of information.

We expect that many if not most respondents will be retired from employment. If employed, costs to respondents for the planned collection of qualifying information by NHTSA can be calculated based on mean hourly wages provided by the Bureau of Labor Statistics for All Occupations (http://www.bls.gov/oes/current/oes_va.htm#00-0000). This source indicates mean hourly wage equals \$23.82. If all respondents are employed, the total annual cost to respondents would be a maximum of \$4,644.90 according to the calculation below:

$$\$23.82/\text{hr.} \times (195 \text{ hours}) = \$4,644.90$$

A.14. Provide estimates of the annualized cost to the Federal Government.

The estimated annualized cost to the Federal government is \$55,674.67 (see table 3).

Table 3: Cost to the Government

Contractor activity	Cost
Screening	\$1,874.67
Consent	\$600
Driving evaluations	\$46,300
Install/remove DAS	\$900
Participant payments	\$6,000
TOTAL ESTIMATED COST TO GOVERNMENT	\$55,674.67

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

This is a new information collection. As such, it requires a program change to add the estimated 195 hours for the new information collection to existing burden.

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

Personal information will not be published. AN exact publication date has not been established but would occur no sooner than Quarter 1 of Fiscal Year 2017.

A.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.

NHTSA will display the expiration date for OMB approval.

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

No exceptions to the certification are made.