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## Supporting Statement

Older adults comprise an increasing proportion of the driving population, and previous research indicates that gains in physical fitness improve a number of functional abilities in older adults, including abilities that support safe driving. NHTSA needs to learn more about relationships between fitness/activity and driving performance to support the development of recommendations and educational and outreach materials aimed at improving older drivers' safety. This study aims to assess the effects of physical activity and physical fitness training on the driving performance and driving exposure of adults age 70 and older. Data collected through the study will include: screening questions to determine eligibility for study participation and assign participants to groups based on activity level; clinical measures of cognition and physical functioning; measures of driving performance obtained 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. In addition, participants will wear a pedometer device over a three-week interval to provide an objective measure of activity level. NHTSA will use the information gained in this study to inform recommendations to the public regarding how improved physical fitness can result in better driving performance for the purpose of reducing injuries and loss of life on the highway.

### **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 effects of physical activity and fitness on driving performance. The information from this qualifying interview will be used by NHTSA to determine eligibility for study participation.

**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. Previous research indicates that gains in physical fitness improve a number of functional abilities in older adults, including abilities that support safe driving. NHTSA needs to learn more about these relationships between fitness/activity and driving performance to support the

development of recommendations and educational and outreach materials aimed at improving older drivers' safety.

The objectives of this project are to assess the effects of physical activity and physical fitness training on the driving performance of adults 70 and older. Data analyses will address the following research questions:

1. Do people age 70 and older who participate in regular physical activity perform better in a driving evaluation and/or drive more (in terms of measures such as total miles or unique destinations) than do healthy, sedentary drivers of similar age?
2. Do particular training types relate to improved functioning in specific driving tasks; for example, does neck flexibility training relate to increased shoulder checks?
3. If sedentary older drivers participate in a fitness training program (e.g., aerobic and/or strength and flexibility training), will their driving performance and/or exposure improve?

The first segment of the study will compare driving evaluation scores of participants who take part in regular physical activity with scores for relatively sedentary participants. During the next study segment, a group of sedentary older adults will take part in a six-month exercise program. Driving performance and exposure measures collected before and after the exercise program will provide information on the effects of increased physical activity on driving performance.

The findings will provide information about whether people age 70 and older who participate in regular physical activity perform better in a driving evaluation and/or drive more (in terms of distance or number of unique destinations), than do healthy, sedentary drivers of a similar age; whether particular physical training activities relate to improved functioning in specific driving tasks; and the extent to which driving performance and/or exposure of sedentary older adults will improve following participation in physical activity.

NHTSA proposes a quasi-experimental driving performance and exposure study to document differences in functional abilities, driving performance and driving exposure between participants age 70 and older who participate in regular physical activity, and sedentary drivers of similar age. 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 physical function) as measured using clinically recognized instruments (see Appendix B for descriptions and justifications of these instruments);
3. Physical activity level based on a pedometer-type device; and
4. 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 and development activities, including demonstration projects and the collection and analysis of highway and motor vehicle safety data and related information needed to carry out this section, with respect to all aspects of highway and traffic safety systems and conditions relating to - vehicle, highway, driver, passenger, motorcyclist, bicyclist, and pedestrian characteristics; accident causation and investigations; and human behavioral factors and their effect on highway and traffic safety, including distracted driving. [See 23 U.S.C. 403(b)(1)(A)(i), 23 U.S.C. 403(b)(1)(A)(ii), 23 U.S.C. 403(b)(1)(B)(iii)].

### **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.

Because the purpose of this study is to assess the effects of activity level on driving performance and exposure of licensed adults age 70 and older, we plan to ask questions to ascertain the age, driver license status, and driving exposure of each respondent to a solicitation. Each participant will undergo driving evaluation, agree to wear a pedometer for a three-week interval, and permit researchers to install a data collection system in a vehicle, so we propose asking questions regarding each potential participant's availability to complete testing, and availability of a driver owned or controlled vehicle. Drivers who do not meet these inclusion criteria, who do not have access to a vehicle, or who do not meet minimum driving exposure criteria must not be included in the study.

To ensure prospective participants meet inclusion criteria, we propose to ask the following questions of each respondent to the solicitation:

1. Do you own or have possession and use of a car?
2. Do you have a valid driver's license, and if so, when does it expire?
3. What is your date of Birth?
4. About how many times per typical week do you drive your car?
5. Have you been diagnosed with any medical condition for which your doctor has advised you to limit or adjust your driving habits?
6. Do you use adaptive controls in your car?
7. Will you be spending the next two or three months in the area?

For participants who express interest in participating, activity level will be assessed during participant recruitment using Phone-FITT, a validated self-report instrument to collect information about day-to-day activities and exercise (see NHTSA Form 1227). Responses to Phone-FITT will be used to assign participants to the appropriate activity-level groups.

Following qualification of respondents to participate in the research effort, and after answering all questions each may have regarding the study, we propose to ask each qualified respondent if he or she wishes to join the study. Those who opt to participate in the study will read and sign an informed consent document (see NHTSA Forms 1277 and 1281). Those recruited to study segment 2 (described below) will be assigned to one of three activity types.

Study segment 1 will explore the relationship between participants' activity level, driving performance and driving exposure. Researchers will conduct brief clinical assessments of participants' physical and cognitive functional abilities. Researchers will then document participants' driving exposure and their activity levels for a three-week interval. The study team will install data collection devices in participants' vehicles to document driving exposure, and each participant will receive a pedometer-type device that will provide an objective measure of activity level to wear for that interval. At the end of the three-week interval, a researcher will contact the participant to schedule an appointment for the participant to come to the research site (or another convenient location) to complete a professional driving evaluation. During this visit, data collection systems will be removed from participants' vehicles, and participants will return the pedometers. This will conclude study activities for the segment 1 participants.

Study segment 2 focuses on the effects of increased activity levels on the driving performance and exposure of *sedentary* older drivers. Participants will undergo the same process as those in the first segment (consent, clinical evaluation, collect driving exposure and activity level data, driving evaluation). Participants will then take part in one of two activity types (strength/flexibility or aerobic training), or a control condition for a six-month training interval; drivers will continue to wear the pedometers throughout this period. Following the training interval, data collection systems will again be installed in participants' vehicles, and participants will wear pedometers to document driving exposure and activity levels for three weeks. At the end of the three-week interval, a researcher will contact the participant to schedule an appointment for the participant to come to the research site (or another convenient location) to complete a professional driving evaluation. During this visit, data collection systems will be removed from participants' vehicles, and participants will return the pedometers. This will conclude study activities for the segment 2 group of participants.

The data collected in the proposed interview 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 driving exposure 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 to the interview questions and study participation are 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.**

NHTSA intends to recruit potential participants through public solicitations to residents of one or more planned communities in the vicinity of Chapel Hill, North Carolina. Solicitations will be in the form of flyers posted at a community center, and/or announcements in newsletters and on community listservs, and/or sign-ups at a weekly farmer's market and other local events. Interested residents will contact a designated NHTSA research team member through a toll-free telephone number to enroll. During a brief telephone pre-screening, a project assistant will explain inclusion and exclusion criteria for study participation. Candidate participants who meet these criteria may be enrolled in the study.

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

Some clinical functional data will be collected electronically using computers. 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 engage in specified amounts of physical activity on a regular basis. There is no other 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 physical activity 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 data collection activities will be supported 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 many people become more sedentary, engaging in less physical activity on a regular basis. Loss of (physical) function can significantly increase crash risk; and it is possible that increasing one's level of physical activity and level of physical functioning can improve driving performance and safety. NHTSA has a responsibility to provide guidance to physicians, driver rehabilitation specialists, and other health caregivers who advise older adults, about the potential to extend their safe driving years through improved fitness. 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 is essential to the development of useful and reliable evidence.

**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 November 15, 2013 (Vol. 78, No. 221, Pages 68902-68903 (Attachment 2). No comments were entered into the NHTSA docket in response to the 60-day Federal Register Notice.

A copy of a second, 30-day Federal Register Notice (Vol. 79, No. 84, Pages 24810 - 24811), which announced that this information collection request will be forwarded to OMB, was published May 1, 2014 (Attachment 3). Three comments were received. The comments received were neither substantive nor relevant to this study, and no actions are planned in response to these comments.

**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 older drivers who qualify for the study and choose to participate will receive a \$100 payment for traveling to a study site, completing physical and cognitive assessments, wearing a pedometer and allowing instruments to record travel patterns to be placed in their cars. Experience has



shown that this is the minimum incentive that will result in achieving recruiting goals. Participants will receive feedback regarding their performance on the driving evaluation, a \$350 value. Those who qualify and choose to participate in study segment 2 who are assigned to one of the exercise conditions will receive membership in a fitness training facility/program that has a value of up to \$400.

**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. Those older drivers who qualify for the study and choose to participate will be asked questions concerning their medical conditions and diagnoses as needed to insure their safety if they participate in fitness training activities.

**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, and who meet the activity level criteria for one of the study groups will be conducted by telephone interviews with an estimated 270 older drivers, to identify 180 older drivers who are properly qualified and choose to participate in the study. Respondents will take an estimated 15 minutes to complete the questions, resulting in 67.5 burden hours (Table 1a).

Table 1a. Burden Hours: Screening Potential Participants

	Participants	Hours per participant	Burden hours
Screening	<b>270</b>	<b>.25</b>	<b>67.5</b>

Each participant will take part in only one of the study’s two segments. The first segment, which will involve data for 90 participants, will explore driving performance and exposure of active as compared to sedentary participants and will result in 157.5 burden hours (Table 1b).

Table 1b. Burden Hours: Activity Level Effects

	Participants	Hours per participant	Burden hours
Consent	90	.50	45.0
Functional measures, driving performance evaluation	90	1.00	90.0
Install, remove DAS	90	.25	22.5
<b>TOTAL</b>	<b>90</b>	<b>1.75</b>	<b>157.5</b>

The remaining 90 participants will complete driving evaluation and exposure measures, and then take part in a 6-month exercise program, or in a non-exercise control group (no data are collected during this interval), followed by post-training measures of driving performance and exposure, resulting in 270 burden hours. (Table 1c).

Table 1c. Burden Hours: Physical Fitness Training Effects

	Participants	Hours per participant	Burden hours
Consent	90	.50	45.0
Functional measures, driving performance evaluation 1	90	1.00	90.0
Install, remove DAS 1	90	.25	22.5
Functional measures, Driving Evaluation 2	90	1.00	90.0
Install, remove DAS 2	90	.25	22.5
<b>TOTAL</b>	<b>90</b>	<b>3.0</b>	<b>270</b>

The total estimated burden for screening and both study segments is 495 hours (Table 1d).

Table 1d. Project total burden hours

	Burden hours
Screening	67.5
Activity level effects	157.5
Physical fitness training effects	270.0
<b>TOTAL ESTIMATED BURDEN</b>	<b>495.0</b>

We expect that 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](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 \$11,790.90 based on the calculation below:

Table 2. Cost Burden: Screening Potential Participants

Total estimate burden hours (see Table 1d)	Cost per Hour	Total Cost
495	\$23.82	<b>\$11,790.90</b>

Note, the subjects receiving the physical fitness training would otherwise pay approximately \$400 for this benefit; therefore the hours spent receiving this benefit are not included in the calculations above of burden and cost.

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

There are no record keeping costs to the respondents. Thus there is no preparation of data required or expected of respondents. Participants do not incur: (a) capital and start up costs, or (b) operation, maintenance, and purchase costs as a result of participating in the study.

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

Total estimated cost to the Government for data collection for this study is as follows (note that this does not include costs for project administration, study design, data analyses or report writing):

Table 3: Cost to the Government

	Cost
Contractor	
Screening	\$5,624
Consent	\$900
Driving performance evaluations	\$69,450
Install/remove DAS	\$1,350
Training (\$250 per participant)	\$22,500
Participant payments	<u>\$18,000</u>
<b>Total Contractor Costs</b>	<b>\$117,824</b>
<b>TOTAL ESTIMATED COST TO GOVERNMENT</b>	<b>\$117,824</b>

**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 6,975 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.**

No information from the qualifying interview will be published. When study findings are published, they will not include personal information. 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.