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## Supporting Statement

### **B. Collections of Information Employing Statistical Methods**

NHTSA is seeking approval to conduct a quasi-experimental study to gather objective data regarding the effects of Mild Cognitive Impairment (MCI) on driving performance and exposure.

For this study, 60 participants age 60 and older (30 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 an independent certified driver rehabilitation specialist, and 30 healthy ‘controls’ without any such referral for evaluation) will be recruited to participate in this study and complete a clinical functional evaluation, a driving evaluation, and allow data collection devices to be installed in their personal vehicles to collect driving exposure data for one month. Participants will be recruited from the State of Virginia. Driving Rehabilitation Specialists to whom drivers have been referred by the State for evaluation will provide their clients with flyers describing the study that include a number to call to express interest in participation. Control participants will be recruited from among the general population of drivers 60 and older from the same area.

Researchers will ask each potential participant seven questions regarding their age, driver licensing status, general health, personal vehicle and near-term travel plans to establish their eligibility to participate in the study (see attached questionnaire). A research team member will call back qualified participants and ask them to:

- 1) Travel to the DRS’s office to complete functional testing and a driving evaluation, and to have a data acquisition system (DAS) installed in their vehicle;
- 2) Drive their vehicle as customary for a period of one month; and
- 3) Return to the DRS’s office so that the research team can remove the DAS.

#### Data Analysis Plan

Questionnaire responses will only be used to establish participants’ eligibility; they will not be analyzed. The focus of this study will be to compare driving performance (as measured by a driving rehabilitation specialist (DRS)) and exposure (as measured using a DAS installed in participants’ own vehicles) of older drivers with MCI to that of participants of similar age without cognitive impairment. Additional analysis will explore relationships between specific functional decrements and specific driving errors. Correlational analyses will be used to assess relationships between functional and driving performance measures and between functional and driving exposure measures. Linear regression models will be used to explore group differences; predictors will include cognitive status group and functional measures. Dependent variables will include measures of driving performance and exposure.

**B.1. Describe the potential respondent universe and any sampling or other respondent selection to be used.**

The potential respondent universe is comprised of all drivers age 60 and older licensed to drive in the State of Virginia. From this universe, the new data collection (telephone interview) will qualify 30 drivers known or suspected of having mild cognitive impairment (MCI) and 30 drivers matched as closely as possible on age and sex who are cognitively healthy (no indications of impairment) for participation in this study.

**Potential Respondent Universe**

Group, Licensed Drivers 60+	Universe	N Contacted	Expected Response Rate	Sample
Drivers with MCI	170,000	45	67%	30
Unimpaired drivers	960,000	45	67%	30

**B.2. Describe the procedures for the collection of information.**

NHTSA will coordinate with occupational therapists and driver rehabilitation specialists in Virginia who have expressed willingness to provide their clients with evidence of mild cognitive impairment with contact information they can use to seek information about participating in this study (thus, the research team will only interact with those who choose to obtain more information about the study). When such individuals use a toll-free number to call for information about the study, we will conduct the planned telephone interview to determine whether they qualify for study participation, based on their current driving habits.

Those older adults who qualify and choose to participate in the study will be asked to nominate friends and neighbors who are roughly the same age to contact the NHTSA research team using the same toll-free number. We will conduct the same telephone interview with these prospective control group members to determine if they are qualified to participate in the study.

Following telephone responses to the eligibility questionnaire and acceptance into the study, the procedure for collecting driver evaluation and exposure data is as follows:

- Participants will travel to the study site (the DRS’s office) to
  - a. complete clinically accepted functional assessment instruments,
  - b. complete a driving evaluation conducted by a driving rehabilitation specialist, and
  - c. have a data acquisition system (DAS) installed in their vehicle;
- Each participant will then drive his/her vehicle as customary for a period of one month; and
- Return to the DRS’s office so that the research team can remove the DAS.

**B.3. Describe methods to maximize response rates.**

Participation in this study is voluntary. To maximize response rates we will rely on the active support of cooperating occupational therapists and driver rehabilitation

specialists to inform their clients about the opportunity for study participation, and to encourage them to participate. These professionals will understand that this research will support their mission to help their older clients remain safely mobile in their communities, which is vital to healthy aging. We view these professionals as research partners as much as collaborators. The trust that their patients place in them will lend considerable weight to their encouragement to pursue participation in this study.

We also will attempt to maximize response rates by offering financial incentives to respondents if they qualify for study participation. Participants will receive feedback from the professional driving evaluation by cooperating driver rehabilitation specialists, valued at \$300-\$400. Participants will receive a \$100 gift card to allow instruments to be placed in their own cars for a month to monitor their driving habits and travel patterns. This level of incentive is necessary to successfully recruit participants in a study such as this, given that it is possible for a participant to lose his or her driver's license as a result of study participation.

Additionally, we will provide written assurances of confidentiality, such that no individual will be identified in reports of the study's findings, nor will any driver's data be shared with any licensing regulatory authority.

**B.4. Describe any tests of procedures or methods to be undertaken.**

We do not anticipate substantive changes to the planned telephone interview method that we expect to average 10 minutes in length across respondents. However, we intend to remain sensitive to the nature of responses we receive and will respond with modest changes as needed to meet our participant counts.

**B.5. Provide the name and telephone number of individuals consulted on statistical aspects of the design**

The following individuals have reviewed technical aspects of this research plan:

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