**Information Collection Request Supporting Statement: Section B**

**Visual Scanning Training for Older Drivers**

NHTSA is seeking approval to conduct an experimental study to answer specific research questions about the effects of visual scanning training for older drivers and their attitudes toward the training procedures and perceptions of its benefits. Of primary interest is to determine the effectiveness of the training based using pre-test, immediate post-test and delayed (three month) post-test measures of driving performance as compared to performance of control participants. The effectiveness of the training also will be evaluated using trainees’ attitudes about the training procedures and their perceptions of its benefits.

Ninety older drivers will be recruited for the base study with 60 between the ages of 70 and 79 and 30 ages 80 or older. A roughly equal distribution of males and females will be sought within each age cohort. Within each sex and age group, drivers will be randomly assigned to either the treatment (visual scanning training protocol) or the control (placebo - Internet search strategies for locating safe driving information) group.

Driving performance measures will be collected through three on-road evaluations by the Clinical Driver Rehabilitations Specialist (CDRS): pre-training, immediate (within 1 week) post-training, and three months post-training. Study participants enrolled in the training group will also complete a brief questionnaire following completion of all training sessions to determine their attitudes about the training procedures and their perceptions of its benefits.

 The current plan is for the contractor to produce a draft technical report in 2019 with publication of a final technical report in 2020. The technical report will provide summary statistics and tables as well as the results of statistical analysis of the information, but it will not include any personal information.

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

The researchers plan to focus training and data collection efforts at a Continuous Care Retirement Community (CCRC) in the Greensboro – Winston Salem, North Carolina area where the developer of the training is based. A CCRC located midway between the two cities named above is targeted primarily for participant recruitment, and it may also serve as the venue for training program delivery. The CCRC currently has 420 independent residents aged 63 to 100 years old. The residents are 40% male and 60% female. Many, but not all, of the independent residents drive. Researchers will use Form 1400 to determine eligibility for the study, and potential participants may be excluded due to age, a lack of a valid driver license, or other medical or physical limitations. While the participants will be randomly assigned to treatment versus control groups, participants will be accepted on a first-come, first-serve basis and will not be sampled for study inclusion. There is no reason to believe that the study participants will be substantially different from all eligible participants at the CCRC or from similar older drivers across the Nation.

The total sample size of 90, 45 in each group, should have substantial statistical power to detect meaningful differences in driving performance. In the previous NHTSA’s study “Validation of Rehabilitation Training Programs for Older Drivers” (DOT HS 811 749; April 2013), between 80 and 90% of drivers received the highest score (on a five-point scale) for visual search and scanning tasks during the pre-training (baseline) driving evaluation. The study team has identified the need for more variation in the scores and have asked the CDRS to tailor the on-road evaluation scoring methodology with this goal in mind. If the CDRS decreases the baseline proportion of drivers with the highest score to 65% (about two-thirds), there will be an 80% chance of detecting a statistically significant training improvement of at least 25% at a one-sided 0.05 significance level.

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

The CCRC Administrator will post fliers around the facility and will print recruiting advertisements in the monthly newsletters to residents inviting them to attend a presentation describing the proposed study. These outreach efforts will offer prospective study participants compensation for completing the study.

 During the presentation, attendees will be invited to join the research study. Those interested in participating will be screened for study eligibility (see Form 1400). For those who are eligible for the study, a research team member will make appointments to answer any questions participants may have about the study and to obtain their signatures on an informed consent agreement approved by an Institutional Review Board (see Form 1401). The research team member also will conduct a screen of color vision and binocular vision during the appointment to further determine eligibility.

After signing the informed consent, eligible study participants will be randomly assigned to treatment and control groups within four age and sex categories. The treatment group participants will receive the revised visual scanning training consisting of four one-on-one training sessions of one hour each. Control group participants will receive instruction on Internet search strategies to locate information and resources to improve driving safety that provides an equal amount of ‘training time’ as the treatment group.

Driver performance data will focus upon older drivers’ visual scanning behaviors. Each driving evaluation route will provide multiple instances of driving tasks that require visual scanning including driving on multiple-lane roadways, making lane changes, using entrance and exit ramps, and negotiating intersections of varying complexity. Driver performance will be scored to reflect multiple outcome measures. These include (1) a scoring method commonly used to evaluate the full range of safe driving behaviors and, simultaneously, and (2) a scoring method that specifically focuses on recording glance behaviors and visual search routines. To meet the first scoring objective, the CDRS will ride in the front passenger seat and evaluate the typical aspects of driver performance. The CDRS will have access to a passenger-side brake to ensure the safety of participants and staff. To assist in meeting the second scoring objective, a trained research assistant (RA) will ride in the back seat and, with the aid of special mirror, will monitor and record scanning behavior in relation to the roadway environment and traffic situation. Each participant’s driving performance will be evaluated at three points during the study: pre-training, immediately (within one week) post training, and three-months post training. The CDRS and the RA will both be blind to training group assignment.

After completing vision scanning training, study participants enrolled in the training group will also complete a brief pencil-and-paper questionnaire (see Form 1402) following completion of all training sessions. The purpose of the form is to determine trainees’ attitudes about the training procedures and their perceptions of its benefits.

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

While participation in this study is voluntary, the research team will rely on the active support of the CCRC administrator to inform residents about the opportunity for study participation and to encourage them to participate. These professionals understand that this research will support their mission to help their residents remain safely mobile in their communities, which is vital to healthy aging. Also, the consent form provides 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. Finally, study participants will be offered $200 as compensation for completing the training sessions and on-road evaluations. Each study participant will receive a $100 gift card as compensation for participation after completing the second and the third (final) evaluations. Participants also will receive feedback regarding their performance on the driving evaluation (following the final evaluation). Paying for this type of individual driving evaluation would generally costs $300 to $400 per person.

Our past experience indicates that anything less than the proposed $200 total compensation would likely result in failure to recruit enough participants to provide adequate statistical power. In addition to the time demands related to the training and evaluations, many older adults avoid driving evaluations such as is included in the proposed study because they believe that a poor score will lead to their losing their license, even though this could not happen to participants in the proposed study. Recent studies by NHTSA have confirmed that this level of compensation is necessary to meet recruiting requirements.  These studies, which are still in the field or in final report preparation, include *Older Driver Compliance with Licensing Restrictions* (OMB 2127-0702, expires 8/31/2017), *Older Drivers and Navigation Devices* (OMB 2127-0710, expires 9/30/2018) and *Mild Cognitive Impairment and Driving Performance* (OMB 2127-0712, expires 9/30/2018). These three studies used incentives ranging from $100 to $150 per participant, and yet recruitment remained difficult. More recently, *Older Drivers’ Self-Regulation and Exposure* (OMB2127-0722, expires 1/31/2020) proposed a $200 incentive. In light of our recent field experience, we believe that the compensation of $200 per participant is justified and necessary.

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

Using Certified Driver Rehabilitation Specialist (CDRS) scoring methods that are standard for the profession, driver performance measures will be categorical ordinal values. These results will be described across each of the three evaluations and analyzed using appropriate statistical methods (e.g., sign test) to test for significant differences from each post-training evaluation in relation to the pre-training evaluation for treatment versus control group drivers. Separate analyses are planned for the pre-training versus immediate post-training comparison and for the pre-training versus delayed post-training comparison. In each case, the hypothesis will be a statistically significant *improvement* in safe driving behaviors in the treatment group (and no change in the control group). Testing this hypothesis will require a scoring protocol for each dependent measure that results in few, if any, drivers who perform at the highest possible level in their baseline assessment to avoid ceiling effects. The study team has identified this need to the CDRS, who will tailor the on-road evaluation scoring methodology with this goal in mind. For analyses of scanning activity that rely on categorical variables, non-parametric (chi-squared) tests will be applied. For the other continuous (interval) measures of visual scanning behavior planned in this research, pre-post analyses of performance differences between study groups will be carried out using standard inferential statistical tests (e.g., ANOVA).

### 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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