CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY

Sponsor/Study Title:	**U.S. Department of Transportation/National Highway Traffic Safety Administration, "Visual Scanning Training for Older Drivers"**
Protocol Number:	**TransAnalytics2017VTP**
Study Investigator:	**Loren Staplin, PhD**
Telephone:	**1-215-538-3820, extension 101**
Additional Contact:	**Kathy Lococo**
Address:	**TransAnalytics, LLC** **336 West Broad Street** **Quakertown, PA 18951**

Please read this form carefully. Reading this form may help you decide whether to take part in this study or not. You are encouraged to ask the study staff as many questions about the study as you would like, to help you decide whether to take part in this study, or you may call the number shown above and at the end of this form. If you decide to take part in this study, you must sign your name at the end of this form and date it. You cannot take part in this research study until you sign and date this form.

INTRODUCTION TO THE RESEARCH STUDY

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to participating in some research studies.

The study you are being asked to join is described below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You may contact the Study Investigator named above, or study staff members who may assist him, about any questions you have about this study, at any time.

PURPOSE OF THE RESEARCH STUDY

The purpose of this research study is to learn whether two training programs designed to improve older driver safety are effective. This study will compare the on-road driving performance of two groups of older people age 70 and older: (1) drivers who complete training to improve their visual scanning, and (2) drivers who complete training to improve their ability to find information on the internet about aging and driving safely. All information about your driving will be summarized in tables and graphs along with that of other study participants. In other words, no individuals' identities will be revealed in study reports. The results of your driving evaluation will **not** be shared with the Department of Motor Vehicles and your participation in this study will **not** affect your license status.

This project is sponsored by the National Highway Traffic Safety Administration (NHTSA) of the U.S. Department of Transportation. The study will be carried out by a Pennsylvania firm, TransAnalytics, LLC. TransAnalytics has a long track record in conducting traffic safety research for NHTSA. TransAnalytics is led by the Study Investigator, Dr. Staplin.

INFORMATION ABOUT THE STUDY

If you decide to participate, you will be one of up to 90 people in this research study. You are eligible to participate in this study if you are age 70 or older, you have a valid driver's license, you do not use any adaptive equipment to control your vehicle (for example, hand controls to accelerate and brake, or a device to accelerate with your left foot), you have not been advised by a medical or healthcare professional to alter or restrict your driving, and you do not have a color vision deficiency. You will complete a brief check of your color vision and your binocular vision; this will take less than 5 minutes. You may not participate in the study if you: are younger than age 70, do not have a valid driver's license, fail the color vision test, use adaptive controls in your vehicle, or have been told by a medical or healthcare professional to change when and where you drive.

Your participation in this study will require a total of eight (8) hours as follows. Following this consenting process (which will take approximately 30 minutes, and will include a color and a binocular vision screen) you will be randomly assigned to complete either the visual scanning training program or the internet search training program to learn how to search for driving-safety-related information. Both training programs will require you to attend four (4) sessions, each lasting one (1) hour. The training sessions will be conducted in a room on the campus of your residential community. You will also participate in three (3) driving evaluations that will each last one (1) hour, and will start and end on the campus of your residential community. The first driving evaluation will occur before you start your training program, the second will occur approximately one (1) week following the last training session, and the third driving evaluation will occur three (3) months later. The driving evaluations will be conducted by a Certified Driver Rehabilitation Specialist (CDRS). A Certified Driver Rehabilitation Specialist is a licensed professional who specializes in both training and assessing driving skills. You will drive the CDRS's car while she rides in the passenger seat, and uses a checklist to evaluate your driving skills. A research assistant will ride in the back seat of the car, to record other driving behaviors. You may be asked to answer a few questions about the training program after each session, which will take approximately 5 minutes per session and again at the end of the training program, which will take another 10 minutes.

WHAT WILL HAPPEN DURING THE STUDY

If you agree to take part in the study, we will contact you to schedule an appointment with the CDRS. You will complete an on-road (behind-the-wheel) driving evaluation. You will drive a route with the CDRS using a car equipped with a dual brake on the passenger side. During the driving session, the CDRS, who will be sitting in the passenger seat, will direct you to drive on certain streets and to travel to particular destinations within 15 miles of your residential community. This test drive will include a variety of roadway and traffic conditions including residential neighborhoods, and roadways with several lanes, which may have moderate to heavy traffic. You will drive through intersections, make lane changes, and left turns. The CDRS will use a score sheet to assess your driving performance. The results of your CDRS evaluation will be provided to the TransAnalytics research team.

Approximately one week following the first driving evaluation, a research assistant will contact you to schedule the visual scanning training program or the internet search training program to learn how to search for driving-safety-related information. You will be randomly assigned to the program as noted above. You will meet one-on-one with your trainer, who will be either an occupational therapist (OT) or an OT student. You will meet with the trainer for one (1) hour, once each week, for four (4) weeks at the same location on the campus of your residential community.

Approximately one week following the fourth training session, you will meet with the CDRS for the second driving evaluation starting and ending on the campus of your residential community, similar to the first driving evaluation. Approximately three (3) months later, you will meet with the CDRS for the final driving evaluation, also starting and ending on the campus of your residential community.

Reminder: The results of your driving evaluations will <u>not</u> be reported to the Department of Motor Vehicles.

YOUR ROLE IN THE STUDY

You do not have any special responsibilities as a study participant, beyond participating in the four (4) training sessions and three (3) driving evaluations, and providing feedback about the training program.

RISKS OF THE STUDY

Driving, by nature, is a risky activity. The behind-the-wheel evaluations with the CDRS pose similar risks as are associated with everyday driving. There is a slight increase in risk due to driving a vehicle that you are not used to driving; however, this risk is offset by the dual brake in this vehicle that the CDRS can use to stop a dangerous or negligent action. Talk to the study investigator if you have questions about this. There are no risks associated with your participation in the training sessions.

POTENTIAL BENEFITS OF BEING IN THE STUDY

Research is designed to benefit society by gaining new knowledge. This knowledge may or may not benefit you personally, however. The CDRS will provide feedback on your driving performance following the third evaluation. Assessment of driving skills by a CDRS would normally cost you between $350 - $400. However, the driving evaluation is being provided at no charge to you. The study sponsor (NHTSA) will pay the CDRS for the cost of the evaluation. Thus, you may benefit from learning about your driving performance. You also may benefit from the information provided to you during the visual scanning training sessions or the sessions where you learn how to search the internet for information about aging and driving safely, whichever training program you are assigned to.

COSTS OF BEING IN THE STUDY

There will be no costs for being in the study, other than the time you spend with the CDRS during the three (3) driving evaluations, and the time you spend in training during the four (4) training sessions.

YOUR PAYMENT FOR BEING IN THE STUDY

You will receive a total of $200 in compensation if you decide to participate in and complete this study. This will be paid in two installments: 1) a $100 Visa gift card after completing the initial post-training evaluation (2nd driving evaluation) and, 2) another $100 Visa gift card after completing the final driving evaluation, 3 months after training.

STUDY STAFF PAYMENT

The National Highway Traffic Safety Administration of the U.S. Department of Transportation is paying for all aspects of this study.

HOW WILL YOUR PRIVACY BE PROTECTED?

Individual participants will not be identified in any report or publication about this study. Data will be analyzed and reported only at the group (not individual) level.

The study staff at TransAnalytics who are carrying out this research for NHTSA have completed a course in human research ethics, and have been performing similar research for more than 30 years.

The information collected by the CDRS will be transferred to the researchers at TransAnalytics in Pennsylvania, and will be stored on a computer for analysis along with all the other study participants' information. To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. Only authorized study personnel will have access to study information that personally identifies you or that could be used to personally identify you. A copy of the study data that has been de-identified (all personally identifiable information removed) may be delivered to the USDOT/National Highway Traffic Safety Administration (NHTSA); these data will reference

study participants only as Driver 1, Driver 2, etc. In addition, the NHTSA Project Manager maintains the right to visit a secure facility to view all raw data collected in this study.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, TransAnalytics will take steps allowable by law to protect the privacy of personal information.

It is possible that the Department Health and Human Services and an authorized Institutional Review Board (IRB) may view this study's collected data for auditing purposes. An IRB is responsible for the oversight of the protection of human subjects involved in research.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). ***Contact the study investigator or study staff listed on the first page of this form with any questions, concerns or complaints.***

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser:
Proxxxxxxxx.

BEING A STUDY VOLUNTEER

Entering a research study is voluntary.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- Please be advised that if you drop out of the study before completing the initial post-training evaluation (2nd driving evaluation) you will not receive compensation.

You may be asked to stop the study even if you do not want to stop.

You will be told about any new information found during the study that may affect whether you want to continue to take part.

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____
Driver License Number

_____
Date of Birth

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____
Signature of Person Explaining Consent Date

_____
Printed Name of Person Explaining Consent