

CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY

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Protocol Number: TransAnalytics001

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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 toll-free 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. You cannot take part in this research study until you sign 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 Principal Investigator named above, or 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 about the effects of mild cognitive impairment and early dementia on driving performance. This study will compare the on-road driving performance and driving

habits of two groups of older people: (1) drivers 60 and older with mild cognitive impairment, and (2) drivers of the same age without cognitive impairment. 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 the study results; all data will be anonymous. None of the data will be reported to the Virginia Department of Motor Vehicles, and your participation in this study will have no impact on your driver's license.

This project is sponsored by the National Highway Traffic Safety Administration (NHTSA) of the U.S. Department of Transportation. It is being 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 Dr. Loren Staplin.

INFORMATION ABOUT THE STUDY

If you decide to participate, you will be one of 60 people in this research study. You are eligible to participate in this study if you are age 60 or older and you make at least 3 driving trips per week. Every time you get in your car and start your engine, it is considered a "trip." You may not participate in this study if you use adaptive controls in your vehicle. You also may not participate if you have any medical conditions severe enough to interfere with safe driving.

Your participation will include one appointment with a Certified Driver Rehabilitation Specialist (CDRS) that will last between 1.5-2 hours. A Certified Driver Rehabilitation Specialist is a licensed professional who specializes in both training and assessing driving skills. Your participation will take place at the CDRS's office, or at another mutually agreed upon location convenient to your home. You will complete some preliminary measures of your vision and cognitive abilities, then, you will drive with the CDRS, in the CDRS's car, while the CDRS observes your driving performance.

Within a week after your appointment with the CDRS, a research assistant will contact you. The CDRS will identify this person to you, so you know who to expect a call from. In this call, you will make an appointment for a technician to come to your home, or to another mutually agreed upon location convenient to your home, to install some equipment in your car that will record where and when you drive. The equipment installation will not harm your vehicle in any way. The equipment will remain in your car for 1 month. A technician will contact you at the end of the month to make an appointment to remove the equipment from your car.

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. The CDRS will first check your vision and your ability to use your legs and feet to control the pedals. The CDRS will then lead you through some exercises to check your thinking ability.

Next, you will complete an on-road (behind-the-wheel) driving evaluation. You will drive a route with the CDRS using a car equipped with an emergency brake on the passenger side. You will be given an opportunity to get familiar with the car by driving first in a neighborhood setting. 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 in your local 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.

After you finish your on-road driving evaluation, we will make an appointment with you to install a small camera and a GPS unit (a navigation device) in your car, and a battery to power both devices. These devices are small, roughly the size of a deck of cards. This equipment will keep track of where and when you drive, for a period of 1 month. Depending upon what kind of vehicle you drive, the GPS unit may be installed under your dashboard, under the passenger seat, or on the rear deck under your rear window. It will record the time of day and the starting and ending point for each trip you make; the trip length in miles and duration in minutes. The camera unit will take a snapshot of the interior of your car every few minutes, to confirm that you are the driver. The camera will be installed along the right edge of your windshield, either near the dashboard or the roof, depending upon what is most practical with your make and model of car. The camera does not have audio, so it will not record any conversations, music, or other sounds as you drive. It will take approximately 15-20 minutes to install this equipment. This equipment will not damage your car in any way, or interfere with your ability to operate your car. We can come to your house to install the equipment, or meet you at a public place if that is more convenient. At the end of the 1-month period, we will make an appointment with you to remove the equipment from your car.

Reminder: Your driving data will not be reported to the Department of Motor Vehicles and your driver's license will not be affected by your participation in this study.

YOUR ROLE IN THE STUDY

You do not have any special responsibilities as a study subject. We want you to drive where and when you would normally drive, as if you were not taking part in this study. We do not want you to change your routines or your schedule. There should be no inconvenience to you if you choose to participate in this study.

RISKS OF THE STUDY

Driving, by nature, is a risky activity. The behind-the-wheel evaluation with the CDRS poses the 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 separate brake in this vehicle that the CDRS can use to stop a dangerous or negligent action. For the 1 month where you are driving your own car with our camera and GPS equipment, you will be driving where and when you normally drive, so you will not be exposed to any risks you would not normally be exposed to.

POTENTIAL BENEFITS OF BEING IN THE STUDY

Research is designed to benefit society by gaining new knowledge. This knowledge may not benefit you personally, however. If you have mild cognitive impairment and the Virginia DMV has requested that you have your driving skills evaluated by a Certified Driving Rehabilitation Specialist, it would normally cost you approximately \$400 for this evaluation. However, the driving evaluation is being provided free of charge to you. The study sponsor (NHTSA) will pay the CDRS for the cost of the evaluation. If you choose to participate in this study without any prior contact from the Virginia DMV, the cost of the driving evaluation also will be paid for by NHTSA.

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, and the time it takes for the technician to install and uninstall the equipment in your car.

YOUR PAYMENT FOR BEING IN THE STUDY

You will receive \$100 (either a cash payment or a gift card) if you decide to participate in this study. You will receive this payment when the camera and GPS equipment is removed from your vehicle.

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 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 20 years.

The information recorded by the devices installed in your car 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. Only authorized study personnel will have access to study information that personally identifies you or that could be used to personally identify you. Only the trips where you were the driver will be analyzed. All images collected by this camera will be destroyed at the end of this study. A copy of the study data that has been de-identified (all personally identifiable information removed) will be delivered to the USDOT/National Highway Traffic Safety Administration (NHTSA). The data will reference study participants only as Driver 1, Driver 2, etc.

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.

In some cases, your information in this research study could be reviewed by representatives of Chesapeake Research Review, Inc. (a research Ethics Review Board that reviews this study).

GETTING ANSWERS TO YOUR QUESTIONS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study or at any time during the study). Questions may include:

- Who to contact in the case of a research-related injury or illness.
- Any payment for being in the study.
- Your rights and your responsibilities as a study subject.
- Other questions.

If you have questions, or concerns about the research study, you should contact Dr. Loren Staplin (TransAnalytics) at 1-215-538-3820.

If you have any questions or complaints about your rights as a research subject, contact:

- By mail:

Study Subject Adviser

Chesapeake Research Review, Inc.
7063 Columbia Gateway Drive, Suite 110
Columbia, MD 21046

- or call **collect**: 410-884-2900
- or by **email**: adviser@irbinfo.com

Please reference the following number when contacting the Study Subject Adviser: **CRRJ Number.**

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.
- If you decide to leave the study before the 1-month period of driving is completed, we will make arrangements to remove the equipment from your vehicle at a convenient time and place, and will give you a “progress payment” based on the portion of the month you have completed.

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

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