

CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY

Under the Paperwork Reduction Act, a federal agency may not conduct or sponsor, and a person is not required to respond to collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control number. The OMB Control Number for this information collection is XXXX-XXXX (expiration date: MM/DD/YYYY). The average amount of time to complete the consenting process is 15 minutes. All responses to this collection of information are voluntary. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden send them to Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Washington, DC, 20590.

Sponsor/Study Title: U.S. Department of Transportation/National Highway Traffic Safety Administration, "Older Driver Rearview Video Systems"

Protocol Number: TransAnalytics001

Study Investigator: Kenneth W. Gish, PhD

Telephone: 1-215-538-3820, extension 101

Additional Contact: Loren Staplin, PhD
(Study Staff) Tia Mastromatto, MA

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 about the effects of rearview video systems on backing performance. There are two segments of this study but you will only be participating in one segment. In segment 1, we will compare the backing performance of two groups of older people: (1) drivers 60 and older **without** rearview video system familiarity, and (2) drivers of the same age **with** rearview video system familiarity. In segment 2, we will compare the backing performance of two groups of older drivers: (1) drivers 60 and older **without** rearview video system training, and (2) drivers of same age **with** rearview video system training. 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 Rehabilitation Specialist (DRS) evaluation will not be shared with the Department of Motor Vehicles.

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 Dr. Loren Staplin.

INFORMATION ABOUT THE STUDY

If you decide to participate, you will be one of 200 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 Driver Rehabilitation Specialist (DRS) that will last less than 1 hour. A Driver Rehabilitation Specialist is a trained professional who specializes in both training and assessing driving skills. Your participation will take place at a nearby parking lot. You will drive with the DRS, in the research study car, while the DRS provides instructions for backing maneuvers and observes your driving performance. If you are in segment 2, you may watch a short training video before the drive with the DRS.

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 DRS. Next, you will complete a driving evaluation in a parking lot. You will drive a route with the DRS 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 around the parking lot. During the driving session, the DRS, who will be sitting in the passenger seat, will direct you to perform various backing maneuvers. The results of your DRS evaluation will be provided to the TransAnalytics research team only.

After you finish all of your backing maneuvers, you will be given the opportunity to ask any questions you may have and then paid for your participation.

Reminder: The results of your driving evaluation will not be reported to the Department of Motor

YOUR ROLE IN THE STUDY

You do not have any special responsibilities as a study subject. 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 DRS poses similar risks to 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 DRS can use to stop a dangerous or negligent action, and the fact that this exercise will not take place on the road in live traffic conditions.

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 you will learn about rearview video systems and how they can make backing safer.

COSTS OF BEING IN THE STUDY

There will be no costs for being in the study, other than the time you spend with the DRS.

YOUR PAYMENT FOR BEING IN THE STUDY

You will receive \$100 (a gift card) if you decide to participate in this study. You will receive this payment at the end of your participation in the study.

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 20 years.

The information collected by the DRS and 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. 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: Pro00009898.

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 do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you decide to leave the study before the 1-month period of driving is completed, we 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.

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

____ By checking this space, I confirm my willingness to be contacted about future research opportunities. Please contact me at the following phone number: _____.

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