

East Carolina University



## Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a 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 2127-XXXX. Public reporting for this collection of information is estimated to be approximately 30 minutes per interview, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are voluntary. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, W51-316, 1200 New Jersey Ave, S.E., Washington, DC, 20590

Title of Research Study: Older Drivers, Navigational Devices, and Driving Performance  
Principal Investigator (PI): Dr. Anne Dickerson  
Institution/Department or Division: Occupational Therapy  
Address: 1330 Health Sciences Building  
Telephone #: 252-744-6190

Study Sponsor/Funding Source: Dunlap and Associates, Inc. under Task Order 0008 of Contract DTNH22-09-D-00138 from the U.S. Department of Transportation, National Highway Traffic Safety Administration

Researchers at East Carolina University (ECU) and Dunlap and Associates, Inc. study safety in society and transportation. Our goal is to try to find ways to improve the lives of you and others, such as by assisting older drivers to remain safely on the road as long as they are able. To do this, we need the help of volunteers who are willing to take part in research.

### Why is this research being done?

The purpose of this research is to examine differences in the driving performance of older drivers when using an electronic navigation system (ENS) (e.g., GPS) or paper directions to drive to familiar and unfamiliar destinations. One of the key research questions relates to whether a specially-designed training program can help older drivers use an ENS more effectively. By doing this research, we hope to learn whether the use of technology can extend the length of time older adults can remain driving safely and how to train older drivers to use the technology safely and effectively.

### Why am I being invited to take part in this research?

You are being invited to take part in this research because you are a healthy older adult, ages 60-79 years, who expressed an interest in volunteering. If you volunteer to take part in this research, you will be one of about 50 people to do so. The decision to take part in this research is yours alone to make.

### Are there reasons I should not take part in this research?

You should not volunteer for this study if you are under 60 years of age or over 79 years of age, do not have a vehicle without adaptive hand controls available to drive in the study, do not have a valid drivers license, do not regularly drive at least 3 times per week, or if you have a medical condition that impacts your driving.

Page 1 of 4

**What other choices do I have if I do not take part in this research?**

You can choose not to participate. It is totally your choice.

**Where is the research going to take place and how long will it last?**

Participation in the study consists of several parts. The first part is a brief phone or face-to-face survey to see if you qualify for the study. On another day, the second part (training) of the study will be conducted in Room 1330 at the Health Sciences Building on the medical campus of East Carolina University and will last approximately 60 minutes. For the third part lasting about 60 minutes on the second day, you will be driving in your own vehicle with a researcher sitting in the front passenger seat. The total amount of time you will be asked to volunteer for this study is approximately 2.5 hours over two days that will be scheduled at your convenience.

**What will I be asked to do?**

You are being asked to do the following:

**Part 1.** Answer a few questions about your age, driving habits, access to a vehicle, and how you typically find unfamiliar places.

**Part 2.** Take study-developed training on a personal computer and/or using study-provided printed materials and visuals.

**Part 3.** Take a series of short field drives in Greenville. These field drives will be analyzed to examine the driving performance of the study groups defined in Parts 1 and 2 when they are navigating using a GPS versus with paper directions. You will be asked to allow the PI or another researcher she designates to ride in the right front seat of your vehicle and collect data on the field drives. The PI will also place a device on your dashboard to record time, position, heading and speed. This device does not attach to your car, will not damage the car in any way, and will not affect your driving in any way.

The first drive will be a short trip from the Health Sciences building to the parking lot at the *Physicians East* building. The remaining 4 data collection drives will each be 10-15 minutes long and will be similar in terms of number and type of turns, roadway types, and traffic signals. For each drive, you will get either printed directions or the use of a GPS with the appropriate destination already entered. You will be asked to follow the prescribed printed or GPS route as closely as possible without doing anything you feel would compromise your safety. After completing the drives and returning to the Health Sciences building you will do a data entry task on the GPS.

**What possible harms or discomforts might I experience if I take part in the research?**

The risks associated with this research are no more than what you would experience in everyday life when doing any of the tasks, including driving. Although you may be distracted by using the GPS or paper directions, you are not being asked to use them in a way different from the way you might use them during everyday driving.

**What are the possible benefits I may experience from taking part in this research?**

We do not know if you will get any personal benefit by taking part in this study. This research will help us learn more about how training in the use of technology may help older adults continue driving safely as long as they want to. There may be no personal benefit from your participation but the information gained by doing this research may help others in the future.

**Will I be paid for taking part in this research?**

We will pay you for the time you volunteer while being in this study. For Part 2, you will receive \$50. If you complete the training and go on to Part 3, you will receive an additional \$100 to cover your participation in the driving portion of the study.

**What will it cost me to take part in this research?**

The only out-of-pocket cost you will be expected to pay is for fuel for your vehicle for the research drives in the city of Greenville in Part 3.

**Who will know that I took part in this research and learn personal information about me?**

To do this research, ECU and the people and organizations listed below may know that you took part in this research. They may also see information about you that is normally kept private. With your permission, these people may use but not divulge your private information in order to do this research:

- The research team, including the Principal Investigator and all other research staff (graduate assistants).
- The research site’s staff working on this project.
- Representatives from the sponsors of this study, Dunlap and Associates, Inc.
- The staff at the National Highway Traffic Safety Administration.  
The ECU University & Medical Center Institutional Review Board (UMCIRB) and the staff who have responsibility for overseeing your welfare during this research;
- ECU office staff who oversee this research.

**How will you keep the information you collect about me secure? How long will you keep it?**

All data will be coded with a number and kept in the locked lab of 1330 in the Health Sciences Building. The data will be separated from your name and identified by a code number known only to the PI. Your name will be retained only on this consent form as well as the on a receipt form that indicates you were paid for the study. The consent form and receipt will be retained for 3 years after the completion of the study, and the study data identified only by code number (no identifying information) will be kept by NHTSA and may be analyzed further in the future.

**What if I decide I do not want to continue in this research?**

If you decide you no longer want to be in this research after it has already started, you may stop at any time. You will not be penalized or criticized for stopping. You will be paid for those parts of the study that you have started even if you did not finish them.

**Who should I contact if I have questions?**

The people conducting this study will be available to answer any questions concerning this research now or in the future. You may contact Dr. Anne Dickerson, the PI at 252-744-6190 Monday through Friday between 9:00 am and 6:00 pm.

If you have questions about your rights as someone taking part in research, you may call the Office of Research Integrity & Compliance (ORIC) at 252-744-2914 (weekdays, 8:00 am—5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of the ORIC, at 252-744-1971.

**I have decided I want to take part in this research. What should I do now?**

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form and initial each of its pages:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

