

**University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants**

Consent Form Version Date: December 1, 2014

IRB Study # 13-3557

Title of Study: Physical Fitness and Driving Performance (Phase 2)

Principal Investigator: William Hall

Principal Investigator Department: Highway Safety Research Center

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Funding Source and/or Sponsor: National Highway Traffic Safety Administration (NHTSA)

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What are some general things you should know about research studies?

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 being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researchers or with any staff members at the Duke Center for Living at Fearington and/or Galloway Ridge.

Details about this study are discussed 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 should ask the researcher named above, or staff members who may assist him, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn whether participation in a physical fitness program improves the driving abilities of sedentary older adults. You probably have heard of the health benefits of regular physical activity and exercise. These benefits can include improved strength, flexibility, range of motion, and even improved cognitive function. This study will examine whether the benefits of regular physical activity or exercise also extend to improving your driving abilities and practices.

You are being asked to be in the study because you are an adult, age 70 or older, and because you have a currently valid North Carolina driver's license and access to a car that you can drive.

Are there any reasons you should not be in this study?

You should not be in this study if you have been told by your doctor that you have a medical condition that can make it unsafe for you to drive, or if you require special equipment in your car (such as hand controls or pedal extensions) in order to drive.

How many people will take part in this study?

A total of approximately 90 older adults will take part in this study.

How long will your part in this study last?

Your total time commitment if you choose to participate in this research study will be approximately 80 hours, most of this through your participation in a 6-month long physical fitness class to be held at Galloway Ridge 3 days a week. Members of the research team will also want to meet with you individually on four occasions: twice before the start of your physical fitness class, and twice more after completion of your class. The total length of time for your participation will be 8 months, starting from today.

What will happen if you take part in the study?

If you agree to take part in this study, we will ask you to do a few things for us today before you leave. They include:

- Complete a brief physical activity questionnaire that will ask whether you engage in various types of physical activities, and how often you do so;
- Answer a few questions that will allow us to estimate your "fitness age";
- Complete some simple exercises on a laptop computer to evaluate how quickly you're able to process visual information, how well you perceive spatial relationships among objects, and other skills that have been identified as important to driving;
- Complete two very simple physical assessments, one to check your head and neck flexibility, and the other your leg strength.

Also before you leave today, we will give you a pedometer-type device designed to be worn around your ankle, that we will want you to wear for the next three weeks (except when swimming, bathing or showering). We will also install some equipment in your car that will use GPS (global positioning system) technologies to automatically record information about your driving, such as how many trips you make each week, the number of miles you drive, the speeds you travel, etc. The equipment will also include a small video camera to provide us additional information about your driving, but we will not be capturing any audio. Because we are capturing video data, however, we are required to tell you that if in reviewing the video we observe any instances of possible child abuse, we will need to report this to the proper authorities.

After three weeks have passed, we will contact you to schedule an appointment to meet with a certified driver rehabilitation specialist (CDRS) to have your driving skills evaluated. The individual conducting this evaluation is an occupational therapist with specialized training in driver assessment, training and rehabilitation. Your driving evaluation will take about 45 minutes, and will start and end at the Duke Center for Living at Fearington. After completing the evaluation, the evaluator will remove all equipment from your vehicle, and will also retrieve the physical activity monitor that we will be giving you today.

We will then assign you to one of several physical fitness classes being offered either at the Duke Center for Living at Fearington or at Galloway Ridge, based on the information you've provided us about your usual physical activities, and research about the effects of physical activity on abilities important for driving. You will need to commit to regular participation in your assigned physical fitness class for a period of 6 months.

At the conclusion of the 6 month period, we will schedule a follow up meeting with you during which we will repeat the computer exercises and physical assessments we will be doing today, and will again install some equipment in your vehicle to record your driving activities. And again, after 3-4 weeks, we will ask you to schedule a follow-up driving assessment with Ms. Crompton.

In order to be included in this study, you will need to agree to participate in all of these activities. However, you can choose not to answer specific questions on the physical activity questionnaire, and you always have the right to end your participation in the study at any time.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study will include individualized feedback on your driving strengths and weaknesses from a certified driver rehabilitation specialist (a service typically valued at \$350). You will also benefit from free access to a physical fitness class especially tailored to the objectives of this research study.

What are the possible risks or discomforts involved from being in this study?

You may experience some psychological discomfort in having your driving abilities evaluated. However, the results of the evaluation will be completely confidential and will not be released to the DMV or to anyone else. We do not foresee any psychological or physical discomfort associated with your participation in any of the physical or cognitive tests required for the study.

You may also experience some physical discomfort, and even possible injury, as a result of your participation in the physical fitness classes. However, the staff at DCFL and Galloway Ridge are well qualified to address any questions or concerns you may have, as well as to respond in the event of an injury or other emergency.

There may always be uncommon or previously unknown risks. You should report any problems to the researcher.

How will your personal information be protected?

We will be asking for your name, address, phone number and an electronic mail (email) address if available. This information will only be used for follow-ups in scheduling your driving evaluation and retrieving the physical activity monitoring device and driving exposure equipment installed in your vehicle. No information that could identify you as a participant in this research study will be included in our data analysis files. Instead, your name will be associated with a 3-digit number, and only this number will appear with the data. Your original driving exposure data containing video images of yourself as the driver will be stored in a secured location and destroyed at the conclusion of the project. Paper copies of any forms containing your name will be stored in a locked file at the UNC Highway Safety Research Center, and will only be accessible to designated members of the research team. While each individual participant's data acquired in this research project will be made available to our study sponsor (the National Highway Traffic Safety Administration), no information that could be used to identify you personally will be shared outside of the UNC research team.

Research data may be used by the agency in furtherance of highway safety purposes. In no case, however, will the data be linked to you personally by name or video.

Participants will not be identified by name in any report or publication about this study. No video images of participants will be included in any presentations or publications. 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 contained in the records. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, personal information about you and other participants that are part of this research study could be reviewed by representatives of the University, the research sponsor (NHTSA), or any other government agency for purposes such as quality control or safety.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, there is a possibility that you will be involved in a motor vehicle crash, and be injured, while having your driving evaluated. You might also experience an injury or medical event as a result of your participation in the physical fitness classes. If either of these events should occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. Neither the University of North Carolina at Chapel Hill, Duke Center for Living, nor Galloway Ridge has set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have experienced a medical event that prevents you from going about your normal daily activities (including driving), have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will be given a \$100 gift card for taking part in this study. This gift card will be given to

you immediately upon completion of the final on-road driving evaluation. There will be no pro-rated compensation to participants who do not complete all requirements for the study.

Will it cost you anything to be in this study?

Your only cost to participating in this study will be any costs associated with your travel to the Duke Center for Living at Fearington (or Galloway Ridge) for meetings with members of the research staff and to attend the physical fitness classes. For most of you living in or near Fearington Village, these costs should be minimal.

Who is sponsoring this study?

This research is funded by the National Highway Traffic Safety Administration. This means that the research team is being paid by NHTSA for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researcher listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant

Date

Printed Name of Research Participant

Signature of Research Team Member Obtaining Consent

Date

Printed Name of Research Team Member Obtaining Consent