Research Subject's Bill of Rights

People who volunteer to participate in an experiment (also called a research study or clinical trial) need to understand what is expected of them and why the research is being done. As you think about whether or not to volunteer, it is important that you know that you have rights in place to help protect you. These rights, listed below, will be further explained as you read this informed consent document.

If you are asked to participate in a research study, you have the right to:

1. be told the purpose and details of the research study,
2. have the drugs or devices (tools or pieces of equipment) used in the research study described,
3. have the procedures of the research study and what is expected of you explained,
4. have the risks, dangers, and discomforts of the research study described,
5. have the benefits and advantages of the research study described,
6. be told of other drugs, devices or procedures (and their risks and benefits) that may be helpful to you,
7. be told of medical treatment available to you should you be injured because of the research study,
8. have a chance to ask questions about the research study,
9. quit the research study at any time without it affecting your future treatment,
10. have enough time to decide whether or not to take part in this research study and to make that decision without feeling forced or required to participate, and
11. be given a copy of this signed and dated informed consent form.
You are invited to be in a research study of a new driving simulator to be used for people recovering from a brain injury who have impaired cognition and who are learning how to drive again. People with cognitive impairments typically have difficulty with attention, problem solving or memory. You were selected as a possible participant because you have a mild or moderate cognitive impairment and may have expressed an interest in driving again. Your physician or therapist may have initially identified you as a possible participant, and you were asked some questions over the telephone or in person to determine if you met the inclusion/exclusion criteria for the study.

We ask that you read this form and ask any questions you may have before agreeing to be in the study. This study is being conducted by Professor William Durfee of the Department of Mechanical Engineering, Professor Erica Stern of the Program in Occupational Therapy at the University of Minnesota in collaboration with Elin Schold-Davis of the Sister Kenny Institute, Nancy Huizenga of Courage Center and Dr. Mike Rosen of the University of Vermont and the Driver Rehabilitation Institute. Eighty-five subjects will participate in the study.

**Background Information**

For people with mild or moderate cognitive impairments resulting from brain injury, the decision about returning to driving is a difficult one. Those with impaired cognition have no loss of sensory, nor of motor abilities, but do have difficulties processing information. Driving is a task that requires one to process a tremendous amount of information, for example, determining when it is safe to make a left turn in the presence of on-coming traffic. Impaired cognition can have a profound effect on that decision making process. Often, a patient with cognitive impairment and his or her doctor or rehabilitation therapist disagree on whether and when it is appropriate and safe to drive.

Driving simulators, basically sophisticated and more accurate versions of video driving games, may partially solve this problem. By driving on a simulator, a person gets a chance to improve their driving skills in a safe environment, and also can get a sense of their true driving abilities. Currently, however, there has been very little research on whether driving simulators are an accurate reflection of a person's ability to drive a real car, and very little research on whether driving simulators changes real driving performance.

In this research project, we are studying the effectiveness of using a driving simulator in a rehabilitation program. The purpose of this research is to determine whether driving on a driving simulator, relates to driving a real car and whether driving on a simulator can help a person understand how well they drive.

**How the study works**

If you agree to be in this study, we would ask you to do the following things:

You would come to the clinic at the Sister Kenny Institute for one sessions. At the beginning of the session we will administer a questionnaire as well as a number of other tests designed to determine your cognitive level and your motor skills. Then we will conduct a second series of short tests that measure your reaction time and your visual attention. Following that, we will ask
you a series of questions about how easily you get car sick and about how well you think you drive. This evaluation will take about one hour following which you will drive on the simulator.

When you do a simulator drive, we will show you the driving simulator (which is somewhat like a sit-down arcade video game) and then have you spend about 10 minutes driving on a familiarization run. Next will be the main simulator drive which is in two, 20 minute sections. If you want to stop in the middle of a drive for any reason, just tell the researcher. During the simulator drive, you will be getting lots of feedback from the driving evaluator who may even stop you several times during the run to review what happened. Following the drive, you will be asked another series of questions about car sickness, about what you thought of the simulator, and about how well you thought you drove. The simulator drive session will take about one hour and fifteen minutes.

**Risks and Benefits of Being in the Study**

The study has one risk. When you drive on the simulator, there is the risk of getting car sick. Car sickness is an experience that can produce the feeling of mild to moderate nausea similar to seasickness. The initial familiarization run in the simulator may reduce the chance of car sickness as you become acclimated to the simulator. We will halt the run if either you or the researcher determines you are getting car sick and are unable to continue.

You will be paid $50 if you complete at least one half of the session. If you complete less than one half of the session you will not be paid, although we will reimburse you for parking or bus fare.

A benefit of being in the study is that you will be driving on a simulator that is fairly realistic. This may give you some indication of your driving skills which might be useful when you decide to return to driving.

There is no other direct benefit to you for being in the study.

**Compensation:**

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research-related injury, let the study researchers know right away.

**Confidentiality:**

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify an individual.

**Voluntary Nature of the Study:**

Participation in this study is completely voluntary. You are under no pressure to be in the study. If you decide not to be in the study, it will not in any way harm your relations with your doctors, therapists, or rehabilitation clinic. You are free to have your driving evaluated at any time through normal procedures without having to participate in the study. You are also free to leave the study if you change your mind after entering it. This also would not harm your relations with
your doctors, therapists, or rehabilitation clinic, nor would it harm your ability to have your
driving evaluated.

**Contacts and Questions**

This study is being conducted by researchers at the University of Minnesota, Sister Kenny
Institute, Courage Center and the National Rehabilitation Hospital. The head of the project is
Professor Will Durfee at the University of Minnesota. He can be reached at 612-625-0099, or
wkdurfee@umn.edu. The person in charge of the study at Sister Kenny is Elin Schold-Davis who
can be reached at 612-863-3292 or elin.schold-davis@allina.com.

You may ask any questions you have now.

If you have questions later, you may contact any of the above people at any time. If you have any
questions or concerns regarding the study and would like to talk to someone other than the
researcher(s), you are encouraged to contact the Fairview Research Helpline at telephone number
612-672-7692 or toll free at 866-508-6961. You may contact this office in writing or in person
at University of Minnesota Medical Center, Fairview-- Riverside Campus, #815 Professional
Building, 2450 Riverside Avenue, Minneapolis, MN 55454.

The University of Minnesota Human Subjects’ Code number for this project is 0211M36322.

**Statement of Consent:**

I have read the above information. I have asked any questions I had, and I have gotten answers. I
agree to be in the study.

Signature


Signature of Investigator or Person Obtaining Consent


Date


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