



# SACRED HEART UNIVERSITY

COLLEGE OF HEALTH PROFESSIONS  
PROGRAM IN OCCUPATIONAL THERAPY

## Consent Form for Participation in a Research Study

**Principal Investigator:** Sheelagh Schlegel, DrHSc, MPH, CHES, OTR/L

**Study Title:**

### INVITATION TO PARTICIPATE AND PURPOSE

You are invited to participate in the OT Driving Research program because you are an individual over 18 years of age living with an acquired brain injury. The aim of this project is to prepare adults with acquired brain injuries for on-road driving by using the driving simulator and increase participant's comfort level, confidence, and independence within their occupation of driving. We are occupational therapy faculty who are interested in identifying the impact driving simulation training has on individuals with acquired brain injuries and how it prepares them for on-road driving. This program will be supervised by Dr Sheelagh Schlegel, clinical associate professor, and a licensed occupational therapist. We hope that the information from this project will help us gather information on how driving simulation training improves pre-on-road driving skills related to comfort, confidence, and independence.

### PROCEDURES

You agree to be randomly assigned to the OT group or the Driving Simulator group as part of this OT research study. You will participate in some short assessments with an occupational therapy researchers and research assistants which will take approximately two hours and then an eight-week program of occupational therapy or driving simulation in the OT home suite located in N-308, the occupational therapy home suite of the College of Health Education. After the program, you will complete the same paper tests complete a short survey with a different occupational therapist. If your program starts with traditional occupational therapy for 8 weeks, you will be offered the driving simulator program immediately following for 8 weeks.

### RISKS AND BENEFITS

We do not believe there are any major risks of participating in this study, you may also terminate your participation in the program at any time. There is a mild risk of feeling uncomfortable in the driving simulator due to simulator sickness or motion sickness. We will take all steps to avoid this in the simulator by monitoring your symptoms after every driving scenario and alternating exercises and driving scenarios if needed. We will always take precautions to guard your privacy. There will be no financial benefits from participating in this study.

## **CONFIDENTIALITY AND PRIVACY**

All notes and the consent form will be kept confidential and stored in a locked file or a password protected computer. Your name will not be used in any way. Information on the results will only be presented in summary form. De-identified data from the program may be shared in presentations or articles. You can stop your participation in the program at any time and still continue in the occupational therapy program including the driving simulator at Sacred Heart University.

## **FINANCIAL BENEFITS OR OBLIGATIONS**

It will not cost you anything to participate in this program

## **QUESTIONS?**

We are happy to answer any questions you have about this program. If you have further questions about this project or if you have a research-related problem, you may contact our team by email. You may email Dr Schlegel at [schlegels@sacredheart.edu](mailto:schlegels@sacredheart.edu) or call 203 365 4773

The Institutional Review Board (IRB) is a group of people who review research studies to protect the rights and welfare of research participants. This study has been approved by our IRB at Sacred Heart University.

## **PARTICIPANT WITHDRAWAL**

Your participation is voluntary. Your decision whether or not to participate will not affect you or your relationship with Sacred Heart University. If you decide to participate, you are free to discontinue participation at any time.

**"YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE"**

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Participant's Signature

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Date