

## Project Title: Driving Performance after Concussion

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### WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to examine the differences in driving performance among drivers diagnosed with and without concussion, and to examine the effects of different cognitive workloads on driving performance using a driving simulator. This study also aims to find out whether it is safe for drivers to return to driving after concussion.

### WHO WILL BE A STUDY PARTICIPANT?

Athletes between the ages of 16.5 to 24 with a diagnosed concussion that is confirmed by a physician will be eligible to participate. Additionally, the athletes must have a valid driver license (intermediate or full license). Matched healthy athletes will also be recruited in a 1:1 ratio.

### HOW LONG WILL STUDY PARTICIPANTS BE INVOLVED?

Study participants will be involved in the study for up to 6 weeks from the date of injury.

### WHAT WILL HAPPEN DURING THE STUDY?

If the athlete is eligible for this study, the research team will extend an invitation to participate in the study. The invitation to injured participants will occur within 48 hours of injury and the invitation to matched healthy control will occur after an index injured case completes the assessment 1. The assessment will be done at the Driving Simulation Lab at The Ohio State University.

#### Assessment 1

This assessment will take about 1 hour. All participants will be asked to complete a driving performance test, assessed for functional impairments, and asked about driving behaviors. Injured participants will complete this assessment within 72 hours of injury. Control participants will complete this assessment after the index injured case completes their assessment.



Figure 1. View of roadway from driving simulator

#### Assessment 2

This assessment will take about 1 hour and repeat most items tested in Assessment 1. Only injured participants will be asked to complete this assessment 6 weeks after injury.

### WHAT ARE THE RISKS OF BEING A PARTICIPANT?

We believe that there is very little chance that bad things will happen as a result of being in this study. This study involves a procedure that may result in motion sickness, dizziness, elevated symptoms, or discomfort in the participants. If any of these events occur, participants will be instructed to stop, and their participation in the study will be discontinued. If the participant finds any questions upsetting or don't want to answer a question, they don't have to, and the study coordinator will be available to discuss this further. Participating in this study will not affect any recovery recommendations or treatments given to the athletes following the injury.

# WHAT ARE THE BENEFITS OF BEING A PARTICIPANT?

There are no known direct benefits for participants. However, the findings of study could help others. Our study will help us understand how concussion may influence driving performance and whether it is safe for drivers to return to driving after concussion.

### WHAT ARE THE COSTS AND REIMBURSEMENTS?

All costs related to the research parts of this study will be covered by the research team. However, the parts of the study that would be done for routine clinical care will not be covered by the research team.

All participants will be compensated for their time and inconvenience: Participants will receive \$75 for completing assessment 1 (all participants) and an additional \$100 for completing assessment 2 (participants with concussion only).

## IS BEING A PARTICIPANT VOLUNTARY?

Taking part in this research study is completely voluntary. Athletes may choose not to participate. Anyone who decides to be a participant may stop participating at any time. Routine clinical care will not be changed if an individual chooses not to participate.

### WHAT ABOUT CONFIDENTIALITY?

Any information collected during this study will be securely stored. Only members of the research team will be able to access this information. Information will not be disclosed to outside parties.

## WHAT IF I HAVE QUESTIONS?

If you have questions about anything while on this study or you have been injured by the research, you may contact Dr. Jingzhen (Ginger) Yang at 614-355-5852 or Jinhong Guo at 614-355-5851 Monday – Friday, between 9 AM and 5 PM. They can also be contacted by email at <u>Ginger.Yang@NationwideChildrens.org</u>, or <u>Jinhong.Guo@NationwideChildrens.org</u>, respectively.