

# INFORMED CONSENT FORM

**Principal Investigators:** TBD

**Sponsor:** National Highway Traffic Safety Administration

**Project Title:** Factors That Influence Effectiveness of Hazard Anticipation and Attention Maintenance Training

We are asking you to participate in a research study titled, “Factors That Influence the Effectiveness of Hazard Anticipation and Attention Maintenance Training.” This study is being led by [TBD] and sponsored by the National Highway Traffic Safety Administration. The purpose of the study is to investigate the potential benefits of a training for young people learning to drive.

Joining the study is voluntary, and you may choose not to participate. Below, we will describe this study to you, and we’ll also answer any of your questions. It is important that you understand this information so that you can make an informed choice about being in this research study.

## 1. WHAT IS THIS FORM?

This is an Informed Consent Form. It will give you information about this study so you can make an informed decision about participating. You need to be 18 years of age or older to give informed consent.

## 2. WHO IS ELIGIBLE TO PARTICIPATE?

Young people aged 18 or 19 who do not have a driver’s license or intermediate/provisional license. People who experience motion sickness, either as a driver or passenger in a car or other modes of transport, should not participate.

## 3. WHO IS SPONSORING THIS STUDY?

The National Highway Traffic Safety Administration is sponsoring this study.

## 4. WHO IS REVIEWING THE SAFETY OF PARTICIPANTS FOR THIS STUDY?

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Paperwork Reduction Act Burden Statement: Under the Paperwork Reduction Act, a federal agency may not conduct or sponsor, and a person is not required to respond to, 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-TBD. The average amount of time to complete this portion of the study is 70 minutes, including 60 minutes for a round trip to the research center and 10 minutes to complete the informed consent process. The purpose of this document is to obtain information about the effectiveness of a training for new drivers, and it will be used to inform the development of appropriate traffic safety countermeasures. All responses to this collection of information are voluntary. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, send them to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave. SE, Washington, DC, 20590.

The [TBD] Institutional Review Board is reviewing and overseeing the safety of participants of this study.

**5. WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of this study is to investigate the potential benefits of a training for young people learning to drive. The study will also investigate whether the effects of the training vary among different people.

**6. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?**

This is a single-session study. The study will take place at [TBD]. The study will last approximately 4 hours and includes time using a driving simulator

**7. WHAT WILL I BE ASKED TO DO?**

**During your session:**

- i) The researcher will briefly explain the goals and procedures of the study.
- ii) You will complete a pre-study questionnaire that takes about 5 minute to complete.
- iii) You will complete a brief pre-training evaluation using a tablet that takes about 20 minutes to complete.
- iv) You will then begin a 60-minute training program on a tablet.
- v) Once the training program is complete, you will complete a brief post-training evaluation on a tablet for about 20 minutes.
- vi) When the evaluation is complete, you'll have a 15-minute break.
- vii) Then, the researcher will show you how to drive the research center's driving simulator (referred to as the "RTI simulator") and will give you general instructions for the drives. These instructions will explain that during the simulator drives, you should operate the controls of the simulated car just as you would for any other car to move through the simulated world.
- viii) You will then sit in the RTI simulator and be given a practice drive to become used to the driving simulator. Once you feel comfortable in the RTI simulator, you will begin 6 study drives. These drives will take about 15 minutes each and will involve driving on with roads and traffic conditions similar to those you encounter in the real world. On some of the drives, you may also be asked to complete a simple task while you're driving. You will wear a head mounted eye tracker. **If at any time during the drives you feel discomfort or motion sickness, you should tell the researcher, and they will stop the simulation.**
- ix) During the training program and the 6 study drives, you will be video- and audio-recorded. You will not be recorded at any other point during the study. Following completion of your participation, your recordings will be altered to distort both your face and voice. The distorted video and audio recordings cannot be used to identify you personally. Original copies will be secured in the research center laboratory and will be only accessible by the principal investigators and the other lab researchers for the study, sponsor personnel, and the

[TBD] Institutional Review Board. The original recordings will be deleted after the research team verifies the quality of the distorted versions.

x) Following the study drives, you will complete a post-study questionnaire that will take approximately 25 minutes to complete.

## **8. HOW WILL YOUR DATA BE STORED**

All recorded data will be stored on secure hard drives in a locked file cabinet. We will be recording survey data, training response data, eye tracking data (i.e., video data), and simulator data (e.g., vehicle speed and braking; audio data of any verbal responses you make while driving). At the conclusion of this study, your study data will be anonymized and will not contain anything that can be used to identify you. All non-anonymized data except your signed consent form will be destroyed. The anonymized data will be stored for 5 years at the research center and then destroyed. The anonymized data will also be shared with NHTSA, and NHTSA may make the anonymized data available to the public. Signed consent forms will be stored in a locked file cabinet at the research center and destroyed after 5 years.

## **9. ARE THERE ANY RISKS OR BENEFITS ASSOCIATED WITH PARTICIPATION?**

There may be educational benefits to the participants of this study if the training improves your driving, but these benefits are not guaranteed.

There is a slight risk of simulator sickness when you operate the driving simulator. A small percentage of participants who drive the simulator may experience nausea or feelings of nausea. The researchers work to minimize this risk, but it is still present. Because of this risk, any person who experiences motion sickness while in a real car should not participate in the study. Before the start of the study drives, participants will be asked to complete questions about potential simulator sickness. If during the simulator drives you feel discomfort or nausea, you should inform the researcher immediately so that the simulation can be stopped. Halting the simulation should quickly reduce the discomfort. If you do not feel better soon after the simulation is halted, talk to the researcher.

You may terminate your participation in the study at any time. Your compensation will not be affected by early termination.

## **10. WHO WILL SEE THE RESULTS OF MY PERFORMANCE IN THE STUDY?**

The results of this research may be published and submitted for presentation at academic conferences and/or used by the sponsor for publication of reports about the study or internal purposes. No participant will be identifiable from the reports or presentations, nor will any participant's name, initials, or personal identifiers be used in the reports. The researchers will use codes, rather than names, to identify all data collected during the study. Your face in any video recordings will be blurred, and your voice will be altered. The data will be secured in the research center laboratory and will be only accessible by the principal investigators, the other lab researchers for the study, sponsor personnel, and [TBD] IRB. Upon completion of the study, the anonymized and deidentified data will be published and accessible to the public along with the published report.

*It is possible that your study data, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the National Highway Traffic Safety Administration, or federal or state government agencies, in the course of carrying out their duties. If your data are inspected by the study sponsor (and/or its agents), or by any of these agencies, your confidentiality will be maintained to the extent permissible by law.*

**11. WILL I RECEIVE ANY PAYMENT FOR TAKING PART IN THIS STUDY?**

You will receive payment in the form of a \$165 Amazon gift card for your participation in this study.

**12. WHAT IF I HAVE A QUESTION?**

If you have any questions about the study or any other matter related to your participation in this study, or if you experience a research-related injury as a result of this study, you may call the primary researcher, [TBD]. You may also reach out to [TBD] IRB at [TBD]. A copy of this consent form will be given to you for your records upon request.

**13. WHAT IF I REFUSE TO GIVE OR WITHDRAW MY PERMISSION?**

Your participation is voluntary, and you may refuse to participate or may withdraw consent and discontinue participation in the study at any time without penalty.

**CONSENT SIGNATURES**

**14. SUBJECT STATEMENT OF VOLUNTARY CONSENT**

By signing below, I, the participant, confirm that the researcher has explained to me the purpose of the research, the study procedures that I will undergo and the benefits as well as the possible risks that I may experience. Alternatives to my participation in the study have also been discussed. I have read and I understand this consent form.

\_\_\_\_\_

Printed name of participant

\_\_\_\_\_

Date

\_\_\_\_\_

Participant signature

**RESEARCHER SIGNATURE**

**15. RESEARCHER STATEMENT**

By signing below, I, the researcher, indicate that the participant has read and had explained to them this study and that the participant has signed this Informed Consent Form.

\_\_\_\_\_

Signature of person obtaining informed consent

\_\_\_\_\_

Date