

1 PARTICIPANT INFORMED CONSENT FORM

STUDY TITLE: «Protocol_Title»

STUDY

INVESTIGATOR: «First_Name» «Middle_Name» «Last_Name», «Suffix»

STUDY SITE: «Company_Name»
«Address»
«City_State_ZIP»

TELEPHONE: «Telephone»
«Telephone_2_if_applicable»

SPONSOR: «Sponsor»

You are being asked to participate in a research study. Your participation in this research is voluntary, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the risks and possible benefits of this study are described in this form so that you can make an informed decision. This process is known as informed consent.

This informed consent consists of two parts. The first part describes the purpose, procedures, possible benefits and risks of the study. This form also explains what information will be collected, how your information will be used, how it is maintained, who may use it and secondary research and other uses. If you agree to participate, you will be asked to acknowledge your consent by signing this form prior to the start of the study.

The second part is the consent to disclose information collected during the study, including use of identifiable private information. This consent will be provided to you **after** you complete the study protocol. You may choose to participate, but not to have your information disclosed without any penalty to you.

The study investigator or study staff will answer any questions you may have about this form, the study, the information collected, storage of information, the use of information or the disclosure of information. Please read this document carefully and do not hesitate to ask anything about it or its contents. This form may contain words you do not understand. Please ask the study investigator or study staff to explain any words or information you do not understand. After reading the consent form, if you would like to participate, you will be asked to sign this form. You will be offered a copy of the form to keep for your records.

KEY INFORMATION

Things you should know:

- The purpose of the study is to learn about drivers' use of and behavior in interacting with certain advanced driver assistance technologies and the effects of human-machine interface (HMI) design characteristics.

- If you choose to participate, you will be asked to attend one study session(s) of approximately 3 hours at NHTSA's Vehicle Research and Test Center located on the property of the Transportation Research Center (TRC) proving grounds in East Liberty, Ohio. You will be trained on the use of an advanced driver assistance system in a vehicle and you will be asked to drive a specified route while the system under study is active. Driving will be conducted on a test track, public road, or in a simulated environment. Stationary measurements of your visual angle when glancing at in-vehicle displays (e.g., instrument panel symbols) may also be conducted.
- Risks or discomforts from this research include discomfort associated with driving for 2 hours and any risks normally associated with driving a contemporary motor vehicle while using the original equipment features of that vehicle and the system being studied.
- There is no direct, immediate benefit to you from participating in this study other than the compensation for participation that is provided.
- The results of the study will not be disclosed to you.

PURPOSE

This research study is being conducted by the National Highway Traffic Safety Administration (NHTSA) with support from contractor, Transportation Research Center, Inc. The purpose of this study is to learn about drivers' use of and behavior in interacting with certain advanced driver assistance technologies. Advanced driver assistance systems for crash avoidance present alerts and warnings to drivers via different sensory modalities, such as vibration of the seat or steering wheel and visual or auditory alerts or warnings and may actively intervene via braking or steering input to mitigate or avoid a crash. This research will seek to improve NHTSA's understanding of how crash avoidance warning system HMI characteristics affect system effectiveness and potential safety impacts.

STUDY REQUIREMENTS

You are being asked to participate in this research study because:

- You are between the ages of 25 and 65 (inclusive),
- You are an active driver with a valid, unrestricted U.S. driver's license (except for restrictions concerning corrective eyeglasses and contact lenses),
- You currently have no more than 2 points on your license,
- You have no recent criminal convictions,
- You can read, write, speak, and understand English,
- You have no uncorrected vision or hearing problems,
- You are in good general health, and
- You do not require assistive devices to safely operate a vehicle and drive continuously for a period of 2 hours.

NUMBER OF STUDY SITES AND STUDY PARTICIPANTS

This study will take place at one research site and include up to 200 study participants.

STUDY PROCEDURES

- Participation involves one session of approximately 3 hours that includes up to 2 hours of driving a specified route on either a closed-course test track or on public roads.

The following procedures will take place at your participation session:

- Before participating in this research study, you will be asked to review this Participant Informed Consent Form in its entirety. After all of your questions have been answered, you will be asked to sign the first part of the form to show that you voluntarily consent to participate in this research study.
- After signing this consent form, you will be given an overview of the study protocol and be escorted to the test area to receive instructions.
- The study staff will provide instructions and training regarding how to use the system being studied and will help familiarize you with the system functions. You will be given as much practice as is necessary and reasonable to be comfortable driving the vehicle with the crash avoidance warning system being studied active.
- If driving will take place on a closed course test track, the study staff will explain any rules and procedures for driving on the test track. You will then drive the vehicle for the experimental drive over a specified route.
- At the completion of the study data collection portion of the protocol, you will be escorted to an area where you may be asked to complete a questionnaire, be given a short study debriefing, and asked to review and sign the second part of the consent form. You will receive payment for your participation. Upon receiving payment, your participation will be complete.

NEW INFORMATION

No changes to procedures during this study are anticipated. However, any new information developed during the course of the research that may affect your willingness to participate will be provided to you.

RISKS OF STUDY PARTICIPATION

The possible risks associated with participating in this research study include discomfort associated with sitting in a motor vehicle for the above stated duration. Many people enjoy study participation and do not experience any discomfort.

During your participation in this study, you will be exposed to all risks normally associated with driving a contemporary motor vehicle on a test track, public road, or in a simulated environment. If the study protocol involves driving a motor vehicle on a test track or public roads, you will not be asked to perform any unsafe driving acts. In the event of an unforeseen incident, you should follow emergency procedures which will be communicated to you during training. If your participation involves driving in a simulator, there is a small chance that you could experience

discomfort associated with simulator disorientation. A small percentage of individuals driving in simulators experience symptoms of discomfort, such as slight uneasiness, warmth, or eyestrain. If experienced, these effects typically last for only a short time, usually 10 – 15 minutes, after leaving the simulator.

Your use of any in-vehicle technologies provided is fully discretionary and should be conducted with safety in mind. Any driving that you will do in this study will be of your own volition. Regardless of whether your participation involves driving in a simulator or in a vehicle on a test track or public roads, if you ask to stop driving as a result of discomfort, you will be allowed to stop at once.

There are no known physical or psychological risks associated with participation in this study beyond those normally found in driving while using contemporary in-vehicle technologies.

BENEFITS OF STUDY PARTICIPATION

The study will collect data on drivers' responses to crash avoidance warning system as a function of HMI characteristics. There is no direct, immediate benefit from your participation in this research study other than the compensation for participation that is provided. You may benefit from future vehicle safety improvements that result from this research.

ALTERNATIVES

This study is for research purposes only. Your alternative is to not participate.

CONDITIONS OF PARTICIPATION, WITHDRAWAL, AND TERMINATION

Participation in this research is voluntary. You may withdraw your consent and discontinue participation in the study at any time without penalty.

By agreeing to participate, you agree to operate any research equipment and motor vehicles associated with the study protocol in accordance with all instructions provided by the study staff, and, if the study protocol involves driving on public roads, to operate the motor vehicle in accordance with all applicable traffic safety laws. If you fail to follow instructions, or if you behave in a dangerous manner, you may be removed from the study.

COSTS TO YOU

Other than the time you contribute, there will be no costs to you. While you will incur costs for transportation to the research site, you will be reimbursed for mileage driven to and from and the study site.

COMPENSATION

You will receive \$65 per hour for the time you spend participating in the study. You will receive mileage reimbursement for travel in your personal vehicle to and from the data collection site for participation in the study.

If you voluntarily withdraw or are removed from this study, you will be compensated for the number of hours you participated in the study.

COMPENSATION FOR RESEARCH-RELATED INJURY (for Study Protocols that Involve Driving)

For study protocols that involve driving, TRC will maintain insurance that will provide coverage for you as required under the Federal Acquisition Regulation in the event of a crash occurring while driving a government-owned vehicle. This insurance policy will provide for bodily injury and property damage liability covering the operation of all automobiles used in connection with performing the contract between TRC and NHTSA. Except to the extent covered by such insurance policy, neither the TRC nor NHTSA will be responsible for your actions during this study, nor will they compensate you for any problems arising out of your actions or the normal risks associated with driving. You will not be liable for loss or damage to the vehicle instrumentation, the government-owned research vehicle, or other equipment during your participation unless there is gross negligence on your part. You are responsible for costs and penalties associated with any traffic violations. You do not waive any of your legal rights by signing this form.

INFORMATION COLLECTED

During this study, NHTSA will collect the following data to assess your eligibility for study participation and to document your participation:

1. **Contact information** includes your name, address, e-mail address, phone number(s), and similar information used to contact you regarding your study participation.
2. **Driving background and experience information** includes your driver's license information, number of years of driving experience, the current number of points on your driver's license, and your current personal vehicle's make, model, and model year. This information is used to verify your identity and characterize your level of driving experience.
3. **Health Information** includes your responses to questions regarding certain health conditions you may have and medications you may take that may affect your ability to drive normally. While you have responded to questions asking about specific health information, the individual responses to these questions are not retained by the research team. The only health-related information retained is a yes/no indication of whether you met all health-related participation criteria.
4. **Engineering data** includes driving performance, behavior, and physiological data collected from the vehicle and technologies or systems you interact with during your participation, including sensor data, vehicle operation related data, and subjective questionnaire responses. Sensor and vehicle operation data includes vehicle motion information such as speed and the timing and magnitude of vehicle control inputs made including steering, gas pedal, and brake pedal inputs.
5. **Video/audio data** (the information recorded by video cameras and microphones), if recorded, includes images of your face that will be recorded for later analysis, such as to determine the location and duration of your eye glances while driving and performing other

study-related tasks. Recorded video data containing images of your face could be used to personally identify you. Video of your face and head will include some added space around the head to compensate for any head movements. Video cameras will also capture views of your hands, torso, the forward road scene, or other study task-related images to permit analysis and characterization of your performance of driving and/or other study protocol related tasks. Audio data will include your voice and other sounds recorded while you are driving as part of the study. All video/audio will be captured and stored in digital format (no tape copies will exist).

Any data collected during this study that personally identifies you or that could be used to personally identify you will be treated with confidentiality. Study data (which includes Engineering and Video/Audio data as defined above) is collected without reference to your name or contact information. Study data is kept separate from candidate participant recruitment data (which consists of Contact Information, Driving Background and Experience Information and Health Information as defined above) and is only identified with a unique subject number assigned to each participant. The list correlating subject numbers to participant contact information will be kept in a secure location and only authorized individuals (the research staff) will have access for specific study-related reasons, such as to contact you for an additional participation appointment. Contact information data as well as the list correlating subject numbers to contact information will be stored on password-protected directories and destroyed after the study is complete.

Study data will be securely transferred from the data storage system in the vehicle to secure password-protected directories on a secure file server and verified. Data will be examined to ensure that study staff properly carried out the test procedures and that study equipment properly recorded data. Verified valid data from all study participants will be combined for analysis.

Access to study data will be solely for authorized research purposes or oversight of research activities. Such data will be maintained only on secure computers and/or file directories that are password-protected. Your study data may be reviewed by the study sponsor, federal regulatory agencies (e.g., Office for Human Research Protections within the HHS department), and/or the Institutional Review Board for the purpose of making sure that the data collected are correct and that the study is being performed properly.

At the conclusion of this study, data, without any link to your contact information, will be securely stored for a period of 6 years, consistent with NHTSA's data retention policy.

USES AND RELEASE OF INFORMATION COLLECTED

Information NHTSA may release:

The engineering data collected and recorded in this study will include your driving performance based on the data. This data will be analyzed along with data gathered from other participants. NHTSA may publicly release this data, which will not be linked to your name or contact information, in final reports or other publication or media for scientific, educational, research, traffic safety, or government purposes.

The video/audio data recorded in this study includes images of your face and in-vehicle audio (possibly including your voice). The video/audio data will include information regarding your driving performance and visual and other behavior while driving. Video and in-vehicle audio will be used to examine your driving performance and other driving and non-driving related task performance while driving. NHTSA may publicly release video image data (in continuous video or still formats) and associated audio data, either separately or in association with the appropriate engineering data for scientific, educational, research, or government purposes. NHTSA also may disclose specific clips of video and associated audio to the media, and others involved in efforts to improve traffic safety. When disclosed, the video will not be linked to your name or your contact information and images of your face will be obscured.

NHTSA may show specific clips of video and associated audio internally within the U.S. Department of Transportation. When presented internally or externally, the video images of your face will be obscured, except in cases where showing specific facial behavior, such as where a driver is looking while driving, is essential to support a scientific, educational, research or government purpose. However, the video and audio data will not be linked to your name or contact information.

Information NHTSA will not release:

Any release of engineering data or video/audio data will not include the release of your name, or data that will permit your identification. However, if you sign the Information Disclosure on the final page of this form, NHTSA may release unblurred audio and visual data publicly, which is discussed in more detail above. This information is also described explicitly in the Informed Consent Statement below. However, subject to Federal Law or an order from a court of competent jurisdiction, NHTSA may be required to release your name or other personal identifying information, health information, or driving record.

Secondary research and other use of collected information:

In consenting to this study, you also are consenting to follow-up research involving the data collected, including identifiable private information. This information will be limited to the use of Engineering or Video/Audio data. However, any future use of your identifying data for research purposes will require approval by an Institutional Review Board. In addition, future uses of your identifying data by researchers outside NHTSA will require data sharing agreements that provide an equal or greater level of confidentiality for your data as is provided by this agreement for this study. For any future research or other future uses, you will not be informed of the details or purpose of the research, and you will not have the opportunity to withdraw consent for specific uses. In addition, results of future research will not be disclosed to you.

QUESTIONS

Any questions you have about this informed consent, the study, storage and maintenance of the data and future use of the data can be answered by the person administering this form or the study investigator by calling 937-666-4511.

If you have any questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer

STUDY: TITLE: Crash Avoidance Warning System Human-Machine Interface (HMI) Research

IRB NAME and ID

input, you may contact the Sterling Institutional Review Board (IRB) Regulatory Department at telephone number (888) 636-1062 (toll free) or go to <https://sterlingirb.com/participant-rights/>.

INFORMED CONSENT

By signing the informed consent statement contained in this document, you agree that your participation is voluntary and that the study has been explained to you. You also agree to the collection of information about you and your personnel information during the study. Also, by signing the informed consent statement, you agree to operate the study equipment in accordance with all instructions provided by the study staff. You may withdraw your consent and discontinue participation in the study at any time without penalty.

NHTSA will keep a signed copy of this form. A copy of this signed and dated form will also be offered to you.

INFORMED CONSENT STATEMENT

I certify that:

- I have a valid, U. S. driver's license.
- All personal and vehicle information, as well as information regarding my normal daily driving habits provided by me to NHTSA, and/or Transportation Research Center Inc. employees associated with this study during the pre-participation screening and the introductory briefing was true and accurate to the best of my knowledge.
- I have been informed about the study in which I am about to participate.
- I have been told how much time and compensation are involved.
- I have been told that this study's purpose is to gather data regarding how crash avoidance warning system HMI characteristics affect system effectiveness.
- I agree to operate the research equipment, including operation of any motor vehicles, safely and in accordance with all instructions provided to me by the study staff and applicable laws.
- I have been told that:
 - o The study will involve my operation of or interaction with a motor vehicle and that the risk of associated discomfort is minimal.
 - o For scientific, educational, research, or government purposes, video images of my driving, which may or may not contain obscured views of my face and accompanying audio data, may be used or disclosed by NHTSA, but my name and any health data or driving record information will not be used or disclosed by NHTSA.
 - o For traffic safety and other government purposes, NHTSA may present, internal to the Department of Transportation, video images of my driving or other performance, which may contain obscured or unobscured views of my face and accompanying audio data, but my name and any health information or driving record information will not be used or disclosed by NHTSA.
 - o My participation is voluntary and I may refuse to participate or withdraw my consent and stop taking part at any time without penalty or loss of benefits to which I may be entitled.

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IRB NAME and ID

- o NHTSA nor its authorized contractors or agents shall release your Contact Information, Driving Background and Experience Information or Health Information, unless required by Federal law or an order from a court with competent jurisdiction.
- o I have the right to ask questions at any time and I may contact the study investigator or the study staff at (937) 666-4511 for information about the study and my rights.

I understand the contents of this informed consent form and I have been given adequate time to read it. I hereby consent to take part in this research study.

I, _____, voluntarily consent to participate.
(Printed Name of Participant)

Signature of Participant

Date

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent

Date

INFORMATION DISCLOSURE

By signing the information disclosure statement below, you authorize NHTSA to use, disclose, reproduce to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so the Engineering and Video and Audio data associated with my individual participation.

You understand that unobscured images of your face and accompanying audio data may be shown publicly to highlight specific facial behavior, such as where a driver is looking while driving, when such information is critical to communicating the data in a scientific, educational, research, or government purpose. However, the video and audio data will not be linked to your name, contact, or other personal information.

You understand that you may decline to sign this information disclosure clause and still participate fully in this research.

Your permission to disclose this information will not expire on a specific date.

Information Disclosure Statement

I, _____, grant permission to the National Highway Traffic Safety
(Printed Name of Participant)

Administration (NHTSA) to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so Engineering Data and Video Image and Audio data, as defined in the Participant Informed Consent Form. I have been told that such use may involve widespread distribution to the public and may involve dissemination of views of my obscured or unobscured face in video or still photo formats, but will not result in release of my name or other identifying personal information by NHTSA or its authorized contractors or agents, unless required by Federal law or an order from a court with competent jurisdiction. I have been told that my permission to disclose this information will not expire on a specific date.

Signature of Participant

Date