

## **Attachment 1: Sample Informed Consent Form**

### **PARTICIPANT CONSENT FORM**

#### **IN-VEHICLE DRIVING BEHAVIOR AND CRASH RISK STUDY ("The SHRP2 Driving Behavior Study")**

**SPONSOR:** National Academies, Transportation Research Board, SHRP2 Program

**INVESTIGATORS:** Principal Investigator

#### **WHAT IS THE PURPOSE OF THIS RESEARCH?**

This study will look at how people normally drive. Up to 4,100 primary drivers and a smaller number of secondary drivers (covered by a separate informed consent form) will be participating in this pilot study. The purpose of the study will be to gain an in-depth understanding of driver behavior and driving patterns.

#### **WHAT DO I HAVE TO DO IF I CHOOSE TO PARTICIPATE?**

You are being asked to participate in a naturalistic driving study. The study involves a six-month data collection effort in which a self-contained unit containing sensors and cameras will be installed in your vehicle to record a variety of driving measures. As a participant, you will be expected to participate in the following activities:

1. Bring your vehicle to <contractor> for 2 to 4 hours to have the instrumentation package and cameras installed. The system is about the size of a hardcover book, and will require a single connection to your vehicle network box (the CAN BUS). This connection will provide additional data as well as power for the system; by agreeing to participate, you are providing us permission to access your vehicle network as well as to install new sensors. Before we begin installation, we will show you where we intend to place the system and show you pictures of what the completed installation will look like.
2. While your car is being instrumented, you will complete paperwork and testing at <contractor>, which should take about 2 hours. You will be provided a comfortable area such as a conference room for paperwork and testing. This initial paperwork and testing will include:
  - a. This informed consent form
  - b. Proof of a valid driver's license and insurance
  - c. Permission to examine your [State] and National DMV driving records for the past three years.
  - d. A series of vision tests, using a vision testing machine
  - e. A series of test, questionnaires, and surveys, including the following items:
    - i. Pencil and paper test: Motor Free Visual Perception Test (MVPT) Visual closure Subtest (in DrivingHealth Inventory)
    - ii. Computer based test: Useful Field of View (UFOV®) (in DrivingHealth Inventory)

- iii. Computer based test: Trail Making Test (A & B) (in DrivingHealth Inventory)
  - iv. Computer based test: Conner's Continuous Performance Test II (CPT II)
  - v. Pencil and paper test: Clock Test
  - vi. Rapid Pace Walk
  - vii. Hand strength: HandJamar Hand Dynamometer
  - viii. Pencil and paper questionnaire: Barkley's ADHD Quick Screen
  - ix. Pencil and paper questionnaire: Health Questionnaire
3. When instrumentation is complete, you will be shown the instrumentation system.
    - a. You will be instructed to contact <contractor> if you encounter any difficulties with the vehicle that could be related to the instrumentation system, or if you notice any maintenance issues with the system (for example, a camera that comes loose and dangles).
    - b. Finally, you will then be instructed to drive the vehicle as you normally would.
  4. After you return home, you will be asked to complete a series of online questionnaires. This may take up to an additional two hours, and will cover things such as accident history and medical history. These can be completed over several sessions. When the online questionnaires are completed, you will receive your first payment of \$x via direct deposit. These online tests and questionnaires include:
    - a. CARDS and DeJoy Risk Perception Questionnaires Combined
    - b. Modified Manchester Driver Behavior Questionnaire
    - c. Zuckerman Sensation Seeking Scale
    - d. Sleep Hygiene Questionnaire
    - e. The Epworth Sleepiness Scale
    - f. Morningness/Eveningness (M/E) Scale
    - g. Driving Knowledge Test
    - h. SHRP2 Field Study: Off-Site Detailed Medical History
  5. If you are in an accident while in the study, we ask that you do four things:
    - a. Press the incident button and record a brief audio description of the accident.
    - b. Call us at xxx-xxx-xxxx to notify us of the accident.
    - c. Allow us to retrieve the data from your vehicle's electronic data recorder (EDR or "black box") and from the data collection system we installed.
    - d. Allow us to have access to the police accident report, if any, which results from the accident.
    - e. The data collection system *may* also be able to notify us if you are in a severe accident. There is no guarantee either that we will be notified, or that the notification will be timely. If we do receive a timely notification, you can choose what we should do (check one):
      - Do nothing. I will notify the authorities or let witnesses do so.
      - Do nothing. I have OnStar and will let that system make the proper notifications.
      - Call me on my cell phone and ask me if I am OK and whether I need help. My cell phone number is: \_\_\_\_\_
      - Call the nearest emergency response (911) team and let them know my location.

6. We will download the driving data periodically. This may be done remotely (from outside the vehicle), so that you do not have to be present during the download. However, if we notice a problem with the data we download, we will ask for an appointment to meet with you and correct the problem. This will likely involve access to the interior of your vehicle for up to one hour. As mentioned in #5 above, we will also download data after a crash.
7. After 3 months (about one half of the study time), you will receive your second payment of \$x via direct deposit.
8. After up to 6 months, you will be asked to return to <contractor> while the system is removed from your vehicle. While your vehicle is being worked on, we will ask you to fill out some final questionnaires. This process is expected to take approximately one hour. After this session is complete, you will receive your final payment of \$x via direct deposit.

### **WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?**

The risk to you is no more than you would normally incur while driving. All data collection equipment is mounted such that, to the greatest extent possible, it does not pose a hazard in any foreseeable way. None of the data collection equipment will interfere with any part of your normal field of view. The addition of the data collection systems to the vehicle will in no way affect the operating or handling characteristics of the vehicle. Except for your two visits to <contractor>, you are not being asked to alter your daily driving routines in any way.

### **WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

While there are no direct benefits to you from this research, you may find the experiment interesting. No promise or guarantee of benefits is being made to encourage participation. Participation will help to improve the body of knowledge regarding driving behavior and performance. Participation will also help us design the larger study in a way that is acceptable and comfortable for future participants.

## **HOW WILL MY DATA BE KEPT CONFIDENTIAL AND SECURE AND WHO WILL HAVE ACCESS TO MY DATA?**

The data gathered in this experiment will be treated with confidentiality. Shortly after you begin participation, your name and other identifying information will be separated from the data and replaced with a number. That is, your data will not be attached to your name, but rather to a number (for example, Driver 0011).

While driving the vehicle, a camera will videotape your face with some additional space around the head to accommodate any head-movements. Additionally, video cameras will capture views of the forward view, the rear view, and an external view to the right. All video will be captured and stored in digital format (no tape copies will exist).

If a critical incident or crash occurs, you will be asked to press a button on the dash. This will place a flag in the data set so researchers can more easily locate the event. Also, pressing the button activates a sound-recording microphone for 30 seconds. During this 30 second window, you can describe the critical incident that occurred. No audio will be captured except when you press this incident button.

The video, audio, questionnaire, and sensor data will be stored in a specific password-protected project folder. For the purposes of this project, only authorized project personnel will have access to your data. The data will also be provided to the research sponsor and the other research partners mentioned on the first page of this form under the terms of a data sharing agreement which will provide the same level of protection as this informed consent form. The research team and project sponsor may also show specific clips of video at research conferences and project meetings. Neither your name nor other identifying information will ever be associated with the showing of such video clips. However, your physical facial features may still be apparent and recognizable to those who view them and possibly know you. The data obtained from the DMV records may also be linked anonymously to census records to help us better understand the demographics of participants.

It is expected that the data we capture throughout the course of the entire study, including all 15 drivers, will be a valuable source of data on how drivers respond to certain situations and how the roadway and vehicle might be enhanced to improve driver safety. Researchers who study traffic congestion and traffic patterns may also find the data useful. Therefore, it is expected that there will be follow-on data analyses conducted using all of the data. These follow-on analyses will be conducted by qualified researchers who may or may not be part of the original project team. In every case, the researchers who obtain access to the data will be required to sign a data sharing agreement which specifies the ways in which they may use the data, and which will continue to protect your anonymity and confidentiality. The confidentiality protection provided to you by these data sharing agreements will be as great as or greater than the level provided and described in this document. Any further research efforts will also require additional approval by the Institutional Review Board (IRB). You will not be provided an opportunity, however, to consent to other research uses of the data we gather through this study. In consenting to this study you are consenting to all future research uses of the information and videos we gather from you.

It is possible that the Institutional Review Board (IRB) may view this study's collected data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

To help us further protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality also does not prevent the researchers from disclosing voluntarily matters such as child abuse, or subject's threatened violence to self or others. In terms of a vehicle, this could also include items such as habitually driving under the influence of drugs or alcohol, allowing an unlicensed minor to drive the vehicle, or habitually running red lights at high speed. If this type of behavior is observed, we reserve the right to remove you from the study and inform the appropriate authorities of what we have observed. In all cases, we will notify you first of the behaviors we have observed prior to removing you from the study or informing others of our observations. If you are removed from the study, you will be compensated for any time already spent in the study, but will receive no further payments.

To summarize, your level of confidentiality and anonymity in this study is as follows:

1. There will be video of your face and upper body. There will be audio recorded, but only for 30 seconds after whenever you press the critical incident button. The video, audio, and other data will be held under a high level of security at <contractor>. Your data will be identified with a code rather than your name.
2. For the purposes of this project, only project personnel, project partners, and the project sponsor will have access to the data. The data, including video, may be shown at project meetings and at research conferences reporting on the results of this project.
3. The data may be analyzed in the future for other research purposes by this project team or by other qualified researchers. Such efforts will require the signing of a data sharing agreement which will continue to protect your confidentiality, and will also require additional IRB approval. The confidentiality protection provided to you by these data sharing agreements will be as great as or greater than the level provided and described in this document.

4. A Certificate of Confidentiality has been obtained from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. However, the Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily matters such as child abuse, or a participant's threatened violence to self or others. In terms of a vehicle, this could also include items such as driving under the influence of drugs or alcohol, allowing an unlicensed minor to drive the vehicle, or habitually running red lights at high speed. Such behaviors may result in your removal from the study and reporting of the behavior to the appropriate authorities.

### **WILL I RECEIVE COMPENSATION FOR PARTICIPATING IN THIS STUDY?**

Total payment for participation in this research will be \$x, paid in three installments of \$x each via direct deposit to your bank account. You are required to provide a valid social security number in order to receive your first payment. Payments will be scheduled as follows:

1. After your vehicle is instrumented and you have completed all paperwork, including the online questionnaires, you will receive \$x via direct deposit.
2. When your participation is halfway over (3 months), you will receive a second payment of \$x via direct deposit.
3. After you return to <contractor> to have the system removed from your vehicle and complete a few final questionnaires, you will receive a final payment of \$x via direct deposit. The overall payment for those who complete all requirements will thus be \$x.

If you withdraw from the study or are asked to leave the study, compensation will be issued for a percentage of \$x that matches your time of participation. For example, assuming a 4 week month, if 4 months and of the 6 months is completed (67%), then a payment of \$x will be provided.

### **WHAT ABOUT INSURANCE?**

Please note that since you are driving your own vehicle, Virginia Tech is not liable for the expenses incurred in any accident you may have. In the event of an accident, you are not responsible for damage to the instrumentation in the vehicle.

Participants in a study are considered volunteers, regardless of whether they receive payment for their participation. Under Commonwealth of Virginia law, workers compensation does not apply to volunteers; therefore, the participants are responsible for their own medical insurance for bodily injury. Appropriate health insurance is strongly recommended to cover these types of expenses.

If you should become injured in an accident, whether in or out of an automobile, the medical treatment available to you would be that provided to any person by emergency medical services in the vicinity where the accident occurs.

### **AM I FREE TO WITHDRAW FROM THIS STUDY AT ANY TIME?**

As a participant in this research, you are free to withdraw at any time without penalty. If you choose to withdraw, you will be compensated as described in the compensation section of this document.

**HAS THIS RESEARCH BEEN APPROVED?**

Before this experiment begins, the research must be approved by the Institutional Review Board for research involving human subjects at Virginia Tech. You should know that this approval has been obtained and is valid through the date listed at the bottom of this form.

**HOW DO I PROVIDE MY CONSENT?**

I \_\_\_\_\_ (participant) have read and understand this consent form and conditions of participation. I understand what is being asked of me. My questions have been answered. I freely agree to participate and have not been coerced into participation. I understand that participation is voluntary and that I may withdraw at any time without penalty.

\_\_\_\_\_  
Participant/ (Print Name)                      Signature                      Date

\_\_\_\_\_  
Experimenter (Print Name)                      Signature                      Date

=====  
Should I have any questions about this research or its conduct, I may contact:

- Project Principal Investigator
- Co-Principal Investigator
- Project Manager

**The Participant Must Be Provided With A Copy Of This Consent Form.**