

**PARTICIPANT CONSENT FORM FOR PARENTS OF MINOR PARTICIPANTS
VARIABLE ENROLLMENT PERIOD**

IN-VEHICLE DRIVING BEHAVIOR AND CRASH RISK STUDY
(*"The SHRP 2 Naturalistic Driving Study"*)

SPONSORS: National Academies of Science, Transportation Research Board,
SHRP 2 Program

The United States Department of Transportation

INVESTIGATORS: Christian Richard, John Campbell, Battelle Seattle Research Center
Jon Antin, Virginia Tech Transportation Institute
Ann Brach and Ken Campbell, National Academies, Transportation
Research Board, SHRP 2 Program

WHAT IS THE PURPOSE OF THIS RESEARCH?

The Naturalistic Driving Study is a large research effort directed at improving Highway Safety in the United States where more than 30,000 people are killed and 2 million are injured every year in highway-related crashes. The study will help researchers gain a deeper understanding of the interaction between the driver, vehicle and roadway and lead to safer roadways, vehicles, and driver training programs. The SHRP 2 Naturalistic Driving Study will look at how people normally drive by installing cameras and sensors in people's own vehicles. The study is being conducted at six locations across the United States with up to 3,100 participants. Length of enrollment varies from eight months to thirty months. About 340 participants will be minors.

PARTICIPATION

WHAT SHOULD I KNOW BEFORE DECIDING TO HAVE MY CHILD PARTICIPATE?

1. If you or your child do not own or lease the vehicle to be used in the study, you will have to obtain the owner's written permission to use the vehicle before you enroll in the study.
2. You are providing permission for us to collect data (including video) whenever the study vehicle is used or whenever your child happens to drive another vehicle that is part of the study (for example, a vehicle owned by a friend who also happens to be in the study). If there are drivers of the vehicle who have not signed consent forms, we will delete their data for every trip in which they drove the vehicle.
3. Cameras will record video of your child's face and portions of your child's body and the roadway. Audio will not be recorded unless your child presses a red incident button. We will hold the video, audio, and other data that personally identifies your child, or could be used to

personally identify your child, under a high level of security at one or more data repositories. We will identify your child's data with a code rather than your child's name. Finally, only qualified researchers will be authorized to have access to data that personally identifies your child, or can be used to personally identify your child.

4. We will not collect any identifying information on passengers.
5. You and/or your child will be responsible for insurance coverage. If your child is in a crash, we ask that he/she please contact emergency services as he/she normally would. We will then ask for more information about the crash, as detailed below.
6. Your child may withdraw from the study at any time. If your child does withdraw from the study before the scheduled end date, you and your child must agree to allow us to retrieve the data collection system from the study vehicle as soon as is reasonable.

WHAT WILL MY CHILD HAVE TO DO IF I CHOOSE TO ALLOW HIM/HER TO PARTICIPATE?

The study involves a _____ month data collection effort in which a data collection system containing sensors and cameras is installed in the study vehicle to record a variety of driving measures. As a participant, your child will complete the following activities:

1. Have the vehicle equipped (see the section below: "What will my child have to do to get my vehicle equipped for the study?").
2. Drive as he/she normally would.
3. Give us contact information for all other adult drivers (over the age of 18) who drive the vehicle at least once a week. We would like to contact them to get permission to use data collected any time they are driving the vehicle. We will also ask them to fill out two brief questionnaires.
4. Make an appointment for us to collect the driving data from the vehicle about once every 3 to 6 months. Each appointment could take up to one hour. We will schedule it at a location that is convenient for your child, such as his/her home, work, or school, or a local shopping mall. During this appointment, one of our technicians may ask you or your child questions about the equipment and the operation of his/her vehicle. In addition to talking with our technician, your child will need to give us access to the trunk or interior of the study vehicle. The technician will handle everything else.
5. If your child is enrolled in the study at the time of his/her 18th birthday, we will contact him/her to change from an informed assent form to an informed consent form.
6. We will ask your child to not drive the vehicle into any areas where cameras are not allowed, such as international border crossings, military bases, or similar facilities.

7. Tell other drivers of the vehicle about the video and audio equipment installed in the vehicle and ask them not to drive into areas where cameras are not allowed. Tell these other drivers that data will be collected when they drive the vehicle but will only be kept if they sign a consent form. If they do not sign a consent form, then the data will be deleted for every trip in which they drove the vehicle.

What Will My Child Have To Do To Get The Vehicle Equipped For The Study?

1. If you or your child do not own or lease the study vehicle, you must first obtain the written permission of the vehicle owner. This can be provided on the day you enroll in the study by one of two methods: 1) the owner attends and signs the form in person, or 2) via a telephone call in which a third person at the study site will witness and document the owner's permission form on behalf of the owner. We cannot accept pre-signed owner permission forms in which we have not had personal or telephone contact with the vehicle owner.
2. Bring the study vehicle to the South Seattle instrumentation facility at the scheduled day and time so that we can install the data collection system. Our technicians will try to complete the installation within four (4) hours, but it may take longer for some vehicles. The technicians will need to connect the data collection system to the vehicle's power and network box. These connections will provide additional data as well as power for the system. If you agree to have your child participate, you are giving us permission to install new sensors and to get information from the vehicle network. Before we begin installation, we will show your child where we will place the system, and we will show your child pictures of what the completed installation will look like. We will return the vehicle to its original state when his/her participation ends.
3. While the data collection system is being installed on the vehicle, he/she will have a comfortable place to complete the consent process and tests at the South Seattle instrumentation facility. The consent process and tests should take about 2 - 3 hours. Specifically, your child will be asked to:
 - a. Show us proof that he/she has a valid U.S. driver's license, proof of vehicle insurance, and proof of ownership (vehicle registration showing you, your child, or the person that signed your permission form as an owner, co-owner, or lessee of the study vehicle).
 - b. If you, or your child, lease the vehicle, review the lease agreement to be sure that the installation of the instruments and sensors is allowed under the terms of the lease.
 - c. Review and sign an informed assent form with the same information provided in this consent form.
 - d. Take a 20-minute, non-invasive vision test on a computer monitor, and look into a machine that will not touch or blow air into his/her eyes.

- e. Take several tests on a computer that will assess your child's memory, decision making, and attention skills. These tests will take 30 minutes and they do not require previous computer skill or knowledge.
 - f. Take a 2-minute memory and attention test using pencil and paper.
 - g. Take 2 tests of your child's body movements and strength.
 - i. Your child will be asked to walk as fast as he/she can without falling or tripping to a point 10 feet away, and then to return to the starting point. This test should take about one minute.
 - ii. Your child will be asked to sit down and squeeze a device that measures the strength of his/her grip. This test should take about two minutes.
 - h. Fill out nine (9) questionnaires on a computer. (If your child prefers, he/she may complete some online from home.) The questionnaires vary in length and take between 5 and 15 minutes each to complete. They contain questions about your child's health history and health status; and driving behavior, history, and knowledge.
 - i. Take home and give copies of an Informed Consent form and questionnaires to any other adults who drive the vehicle at least once a week. Give a copy of an Information Sheet to any minor drivers of your vehicle.
4. Allow our technicians to drive the vehicle during the installation and testing process so they can make sure that the data collection system is working.
 5. When the vehicle is ready, we will show him/her the data collection system and give him/her information on who to contact if he/she has any vehicle problems that could be related to the data collection system, or if he/she notices any maintenance problems with the system (for example, a camera comes loose).
 6. We will take some reference pictures of your child in the vehicle so that our software can identify him/her as the driver. To simulate driving at night, we will take some of these pictures with a blanket of material draped over the vehicle while your child is sitting in the driver's seat.

What Does My Child Do After The Study Vehicle Is Equipped For The Study?

1. After your child returns home, he/she will complete any questionnaires he/she did not complete during installation of the data collection system in the vehicle. Once your child has completed all of the online questionnaires, he/she will receive his/her first payment of \$100 in cash or money order at the end of the installation visit. If your child completes the questionnaires at home, we will mail the payment to him/her.
2. Drive as he/she normally would for the duration of his/her enrollment.

3. If your child is in a crash while driving his/her car, we ask that he/she do these five things in order:
 - a. Seek emergency help the way that he/she normally would.
 - b. If possible, press an incident button that is located near the rear view mirror to describe the crash. The system will then record your child's brief description. He/she will know the button is working if the red light comes on when he/she presses it.
 - c. Call us at 206-528-3267 to notify us as soon as it is safe to do so.
 - d. Allow a member of the research team to interview him/her about the crash if we decide to investigate it in more detail. We will interview your child soon after the crash, but only when he/she is ready.
 - e. Allow us to have access to any Police Accident Reports that result from the crash.
4. We will make an appointment with your child to collect the driving data from the vehicle every 3 to 6 months. These appointments will typically take about 15 minutes, but could take up to one hour. We will schedule them at a location that is convenient for your child, such as his/her home, work, or school, or a local shopping mall. Your child will not need to be in the vehicle when we collect the data, but he/she will need to give us access to the trunk or interior. In addition, one of our technicians may ask your child questions about the equipment and the operation of the vehicle. We also will collect data from the vehicle after a crash, either at a place of his/her choice or where the vehicle was towed.
5. You or your child should let us know if he/she notices any unusual warning light activity, for example, warning lights that go on or off or that indicate that the data collection system requires adjustment.
6. If your child is enrolled in the study at the time of his/her 18th birthday, we will contact him/her to change from an informed assent form to an informed consent form.
7. While your child is in the study, he/she should not drive the vehicle into any areas where cameras are not allowed, such as international border crossings.
8. If we notice a new person driving the vehicle, we will contact your child to find out if he/she has already asked the person about participating in the study.

What Happens When The Study Is Over?

1. After _____ months, we will ask your child to return to the South Seattle instrumentation facility so that we can remove the data collection system from the study vehicle. While the vehicle is being worked on, we will ask him/her to fill out some final questionnaires. This process will take about two hours. After your child completes the questionnaires, he/she will

receive his/her final payment, which will be determined by the duration of your child's participation.

2. If your child is 18 years or older when he/she leaves the study, we may ask him/her whether we can keep his/her contact information to contact him/her for participation in possible future studies. This future participation is optional, and if your child does not agree, we will delete his/her contact information one year after data collection is complete at the Seattle study center.
3. Once we have all the data, we will begin data analysis and reporting. You will probably see references to the results of the study in the news. However, these reports will not identify your child or any other participant by name, nor will any video be shown that personally identifies participants.

RISKS AND BENEFITS

WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

The data collection system installed in the study vehicle should not affect its drivability. Thus, driving the vehicle with the system installed should be no more risky than when your child drives the vehicle normally. However, if your child violates state or local driving laws, such as driving under the influence, exceeding posted speed limits, or driving while distracted, the system could record evidence of these violations. This recording has the potential to pose greater than minimal risk of legal harm to your child or anyone driving the vehicle. The research team has set up protections to reduce the potential for legal or economic harms. These protections include automatically encrypting the data obtained by sensors and cameras in your vehicle, using only a code number to identify your child and keeping the code key in a secure location, and obtaining a Certificate of Confidentiality to protect your child's data from court subpoena. Details of these protections are provided below.

All data collection equipment is mounted such that, to the greatest extent possible, it does not pose a hazard or problem for your child when he/she drives. As installed, none of the data collection equipment will get in the way of your child's normal field of view. In most cases, having the data collection system in the vehicle does not affect the operating characteristics of the vehicle. In some cases, the electrical signals from the data collection system may interfere with the vehicle's radio, keyless entry key fob, or other wireless electronic sensors or systems, such as the tire pressure monitoring system. If this happens in the study vehicle, please contact us at (206-854-8357). We will try to eliminate or minimize such interference. If you experience persistent tire pressure monitoring system problems, you will be asked to leave the study, while for other problems, you will be given the option to continue participation with the problem unresolved or to leave the study. If you like, we can give you and your child information about the experience we have had with vehicles of the same make, model, year, and/or equipment package as the study vehicle.

Your child is not being asked to change the way he/she drives or where he/she drives, except for his/her visits to the South Seattle instrumentation facility at the beginning and end of the study.

Your child may opt out of the "blanket" process to record simulated nighttime images if he/she is claustrophobic or if the process otherwise makes him/her uncomfortable.

Several non-driving risks result from participation. We will place five cameras in the study vehicle. If your child drives into an area where cameras are not allowed, such as international border crossings, certain military and intelligence locations, and certain manufacturing plants, he/she may be detained or arrested or the vehicle may be impounded. For this reason, by signing the Informed Assent and agreeing to participate in the study, your child also is agreeing not to drive into any such areas while he/she is in this study. We will give your child a letter to place in the glove box of the vehicle. He/she can use the letter to explain the vehicle's role in this study while still maintaining his/her privacy and keeping confidential his/her role in the study.

Throughout the study, we will protect your child's privacy and keep confidential his/her role in the study and the confidentiality of his/her personally identifying information to the extent allowed by law. To help us protect your child's privacy, we have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services National Institutes of Health. With this Certificate, the researchers and study sponsors cannot be forced to disclose information that may identify your child, 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 or actual harm to self or others. In terms of driver behavior, reportable, threatening, or actual harm to self or others could include driving under the influence of drugs or alcohol, allowing an unlicensed minor to drive the study vehicle, or habitually running red lights at high speed. Such behaviors may result in your child's removal from the study and reporting of his/her behavior to the appropriate authorities. In the event of a crash, the police or an insurance company may obtain the equipment and the data from this study. However, the data are encrypted, and individuals representing these organizations will not be able to access or read them.

You and your child are responsible for taking steps to protect his/her privacy. Do not post or disclose your child's participation on any public forum including websites, Facebook, newspapers, radio and television. Protect your child's role in the study the same way that you protect other personal and private information. If you do not keep confidential your child's role in the study, there is a risk that some of the data collected during the study, including your child's personally identifying information, may be used against him/her in a court case or other legal proceeding.

The risk to your child of completing the pre-collection questionnaires and tests while the data collection equipment is being installed in the study vehicle is no more than when he/she is doing activities in his/her daily life like filling in forms, walking, and working at a computer. The assessment component involves filling in forms, standard vision tests, and standard computer-based tests. These activities involve no more than minimal risk. In addition, your child will be asked to squeeze a grip strength tester and to walk 10 feet back and forth as fast as he/she can without running or falling. The risk of using the grip strength tester is brief hand soreness. The main risk with the Rapid Pace Walk is falling if he/she tries to go too fast. Because the

assessment process may take 2 or 3 hours, your child may get tired, but he/she can take breaks as needed.

If you or your child are not the owner, co-owner, or lessee of the study vehicle, there is a risk that the owner may decide to withdraw the vehicle from the study earlier than the planned term of enrollment. If this occurs, your child will only be compensated for the portion of time he/she was enrolled in the study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no direct benefits to your child from this research, but he/she may find this study interesting. No promise or guarantee of benefits is being made to encourage your child's participation. We believe that your child's participation will help to improve the body of knowledge regarding driving behavior and safety. We also believe that your child's participation may help us design safer vehicles and roadways in future years.

PRIVACY AND DATA CONFIDENTIALITY

HOW WILL MY CHILD'S DATA BE KEPT CONFIDENTIAL AND SECURE AND WHO WILL HAVE ACCESS TO MY CHILD'S DATA?

We will treat all data collected during this study that personally identifies your child or that could be used to personally identify your child as confidential. As soon as your child begins participating in this study, we will separate his/her name and other identifying information from the raw data we collect while he/she drives the study vehicle and replace it with a number. That is, your child's raw data will not be attached to his/her name, but rather to a number (for example, Driver 0011). We will encrypt the raw data collected while your child drives the vehicle, making it unreadable from the moment we collect it until we transfer it to one or more secure central storage locations. We will also separate your child's name from any data either provided by him/her in response to questionnaires or gathered by researchers during the study (including crash investigation data) and we will replace it with his/her driver number (for example, Driver 0011). **YOU WILL NOT HAVE ACCESS TO YOUR CHILD'S DATA RESULTING FROM THIS STUDY.** However, if we have reason to believe that your child is in imminent or ongoing danger to themselves or others, we may notify you of our findings regarding your child.

We will collect the following types of information and data about your child and the study vehicle during the study:

1. **Contact information** includes your child's name, address, email address, phone numbers, and similar information used to contact him/her. We will store the information securely in electronic form during the course of the study and destroy it after the study is complete (unless your child specifically grants permission for us to keep his/her contact information when the study is over). We will not link or mingle this information with your child's study data, and we will not use it in any research or analyses.

2. **Auxiliary study information** includes your child's Social Security Number (only if required for tax purposes), license plate number, and similar information. We will use this information to verify your child's identity and to make payments for his/her participation. We will store this information in an encrypted electronic form, and we will destroy it after the study is complete. We will not link or mingle this information with your child's study data, and we will not use it in any research or analyses.
3. **Driver data** include your child's answers to questionnaires, vision test results, and the results of the brief physical tests described above. These data will not contain your child's name or any identifying information. We will use these data in analyses, both on their own and in combination with driving data, vehicle data, and any crash data. We will store these data securely in electronic form throughout the lifetime of the data (defined below).
4. **Vehicle data** include the vehicle make and model, its condition, how it is equipped, and the part of the VIN number (Vehicle Identification Number) that does not contain identifying information. These data will not contain your child's name or any identifying information. We will use these data in analyses, both on their own and in combination with driver data, driving data, and any crash data. We will store these data securely in electronic form throughout the lifetime of the data (defined below).
5. **Driving data** include the data we collect from the vehicle while he/she is driving, including video data and sensor data. This information will contain video of your child's face and GPS coordinates of your child's trips, both of which could be used to personally identify your child. These data will be encrypted (stored in an unreadable format) from the moment of their creation until they are downloaded from the vehicle, transferred to a secure data storage facility, and verified. From this point on they will be decrypted (made readable) on an as-needed basis for each analysis. We will use these data for analyses, both on their own and in combination with driver data, vehicle data, and any crash data. We will use only the driver number (e.g., Driver 0011) that is not linked to your child's identity to determine which data belong together. These data will be stored securely in electronic form throughout their lifetime (defined below).
6. **Crash data** include items we may collect after a crash, including answers to interview questions with one of our researchers and the Police Accident Report resulting from the crash. These data will not contain your child's name or any identifying information. We will use the data in analyses, both on their own and in combination with driver data, vehicle data, and driving data. We will destroy the Police Accident Reports once non-identifiable information about the crash has been added to the data set. These data will be stored securely in electronic form throughout their lifetime (defined below).

An authorized Institutional Review Board (IRB) or a government regulatory agency that oversees human subjects research may view this study's collected data for auditing purposes. An IRB is responsible for the oversight of the protection of human subjects involved in research. All persons reviewing your child's records will be obligated to protect his/her identifiable information from public disclosure, except as otherwise required by law.

If study sponsors or investigators view the driver and driving data for quality control or administrative purposes, they will be required to maintain the security and confidentiality of any data that personally identifies study participants or that could be used to personally identify study participants.

While your child is driving the study vehicle, a camera will videotape his/her face and some space around his/her head to handle any head movements. An example is shown below. Also, video cameras will capture the forward view, the rear view, an external view to the right of the vehicle, and a dashboard/lap-belt view of the inside of the vehicle. A camera will also periodically take a permanently blurred snapshot of the vehicle interior, which will allow researchers to count the number of passengers and make rough estimates of age, gender, and seatbelt use. We will not be able to identify passengers from these blurred snapshots. All video will be captured and stored in digital format (no tape copies will exist).



We will install in the study vehicle an ambient atmospheric analyzer that can detect the presence of alcohol in the passenger compartment under certain conditions. This instrument is passive and will not impact operation of the vehicle in any way (e.g., it won't lock out the vehicle). The ambient atmospheric analyzer cannot currently tell whether the alcohol was drunk by an occupant of the vehicle or applied (as in hand sanitizer), but future analyses may be able to do so. Also, the atmospheric analyzer will not be able to determine whether the alcohol detected is coming from the driver or a passenger. Future techniques may be able to tell whether alcohol was drunk or applied, but will never be able to determine the amount of alcohol present. However, the instrument will flag the data for possible indications of impaired driving.

If a safety-related incident or crash occurs, we will ask your child to press a button on the equipment mounted near the rearview mirror. He/she will know this button is working if a red light appears when he/she presses it. Pressing the button will allow researchers to find the incident in the database after the data have been collected. Also, pressing the button starts a microphone for 30 seconds. During these 30-seconds, your child can tell us what happened. No audio will be captured except when you press this button. Unlike OnStar™, pressing this button will NOT make a phone call. It simply records your child's voice in an audio file that remains in the study vehicle until the data are collected.

During the data collection phase of this study, we will encrypt (make unreadable) all data collected from the study vehicle from the time of its creation. We will then store it in a password-protected project folder on a secure computer server. We will decrypt (make readable) the driving data only after it has been stored in this folder. At the end of data collection for this study, we will permanently store the driver data, driving data, and additional crash data at one or more secure data storage facilities. One set of data will be permanently stored at Virginia Tech under the supervision of the Virginia Tech Transportation Institute, the organization overseeing the data collection for the entire study. It is possible that, after data collection is complete, one copy of the study data will be transferred to the U.S. Department of Transportation (or other secure facilities as determined by the Transportation Research Board) for permanent storage and oversight.

Only authorized project personnel and authorized employees of the research sponsors will have access to study data that personally identifies your child or that could be used to personally identify your child. As explained below, other qualified research partners have limited access to your child's driver data, vehicle data, driving data, and any crash data, only for authorized research purposes and only with the approval of an IRB. This limited access will be given under a data sharing agreement or contract that, at a minimum, provides your child with the same level of confidentiality and protection provided by this Consent Form. However, without your consent and your child's assent (if your child is younger than 18) or without your child's consent (if your child is 18 years or older), these qualified researchers will not be able to copy raw study data that identifies your child, or that could be used to identify your child, or to remove data from the secure facilities in which they are stored.

Project personnel, the project sponsors, and qualified, authorized research partners may show specific videos at research conferences. The project sponsors also may show specific videos to the media, driver's education teachers and students, and others involved in improving highway and road safety. The face portion of the videos will be blurred, blacked out, or replaced with animation for these purposes. Your child's name and other personally identifying information will not be associated with the showing of these videos. Identifying location information will not be shown in association with these videos.

The data we collect during this study, including data from all the approximately 3,100 primary participants, will be valuable information on how drivers respond to certain situations and how changes to roadways and vehicles could improve driver safety. Researchers who study traffic congestion and traffic patterns may also find the data useful. Therefore, we expect follow-on data analyses using all or part of the data for up to 30 years into the future. These follow-on analyses

will be conducted with IRB approval by qualified researchers with IRB approval, as required by law, who may or may not be part of the original project team. In consenting to this study, you are consenting and your child is assenting to future research uses of the information and videos we gather from him/her, consistent with the protections described above and elsewhere in this document.

If your child is involved in a crash while participating in this study, the data collection equipment in the study vehicle will likely capture the events leading up to the crash. Your child is under NO LEGAL OBLIGATION to voluntarily disclose the data collection equipment or his/her participation in this study at the time of the crash or traffic offense. We will provide a letter that your child should keep in his/her glove box for these cases. The letter describes the vehicle's role in the study without identifying your child as a participant in the study.

CERTIFICATE OF CONFIDENTIALITY

Because the study vehicle camera system is storing continuous video, it may capture some incriminating evidence if an at-fault collision should occur. To help us protect your child's privacy, we have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services National Institutes of Health. With this Certificate, neither the researchers nor study sponsors can be forced to disclose information that may identify your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Identifying information for the purposes of this study includes your child's contact information, your child's auxiliary study information, your child's driving data (including video of your child's face and GPS coordinates which may identify your child's home, work, or school locations), or any information in your child's driver data, vehicle data, or additional crash data that could be used to personally identify him/her. If you or your child are not the vehicle owner, you should know that the vehicle owner will not have access to his/her data. While your child's confidentiality is protected in most cases by the Certificate, you should know that in some rare instances involving alleged improper conduct by your child or others, your child may be prevented by a court from raising certain claims or defenses unless he/she agrees to waive the confidentiality protection. The researchers and study sponsors will use the Certificate to resist any demands for information that would identify your child, 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).

This Certificate of Confidentiality does not mean that the Federal government endorses this study. You and your child should understand that a Certificate of Confidentiality does not prevent your child or a member of your child's family from voluntarily releasing information about your child or his/her involvement in this research. If an insurer, employer, or other person obtains your written consent and your child's written assent 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 a subject's threatened or actual harm to self or others. This could also include behaviors such as habitually driving under the influence of drugs or alcohol, allowing an unlicensed minor to drive the study vehicle, or habitually running red lights at high speed. If this type of behavior is observed, we reserve the right to remove your child from the study and inform the appropriate authorities of what we have observed. In most cases, we will notify your child first of the behaviors we have observed prior to removing your child from the study or informing others of our observations. If your child is removed from the study, his/her compensation will be prorated based on the time he/she has already spent as a participant in the study.

The protections of the Certificate of Confidentiality described in this Informed Consent document may not apply to passengers or drivers of the study vehicle who have not consented to being in this study. For this reason, we will seek Informed Consent from all other adults who drive the study vehicle on a regular basis, and these persons will be protected by the Certificate of Confidentiality to the same extent that your child is.

CONFIDENTIALITY – Summary

To summarize, the level of confidentiality offered in this study is as follows:

1. We will video your child's face and portions of his/her body. If your child presses the red incident button, we will make a 30-second audio recording of his/her voice. We will collect health and driving data about your child. We will keep the video, audio, and other data that personally identifies your child, or could be used to personally identify your child, under a high level of security at one or more data storage facilities. We will identify your child's data with a code rather than his/her name.
2. We will delete all data collected from other drivers who have not signed a consent form. We will not collect any identifying information on passengers.
3. For the purposes of this project, only authorized project personnel, authorized employees of the project sponsors, and qualified research partners will have access to study data containing personally identifying information, or that could be used to personally identify your child. The data, including face video, which has been blurred, blacked out, or replaced by animation, may be shown at research conferences and by the research sponsors for the highway and road safety purposes identified above. Under no circumstances will your child's name and other personally identifying information be associated with the video clips.
4. Our project team and other qualified researchers may use the personally identifying data collected in this study in future research. Researchers who use the data, however, will sign a data sharing agreement, which will continue to protect your child's confidentiality, and will also require additional IRB approval. The confidentiality protection provided to your child by these data sharing agreements will be as great as or greater than the level provided and described in this document. Research partners will not be allowed to copy raw data that identifies your child, or that could be used to identify your child, or to remove it from the

secure facility in which it is stored except with your consent and your child's assent (if your child is younger than 18) or without your child's consent (if your child is 18 years or older).

5. We have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers and study sponsors cannot be forced, even by a court subpoena, to disclose information that may identify your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. However, the Certificate of Confidentiality does not prevent researchers from disclosing voluntarily matters such as child abuse, or a participant's threatened or actual harm to self or others. In terms of driver behavior, reportable, threatening, or actual harm to self or others could include driving under the influence of drugs or alcohol, allowing an unlicensed minor to drive the study vehicle, or habitually running red lights at high speed. Such behaviors may result in your child's removal from the study and reporting of the behavior to the appropriate authorities. While your child's confidentiality is protected in most cases by the Certificate, you should know that in some rare instances involving alleged improper conduct by your child or others, your child may be prevented by a court from raising certain claims or defenses unless he/she agrees to waive the confidentiality protection.

COMPENSATION AND POSSIBLE COSTS

WILL MY CHILD RECEIVE PAYMENT FOR PARTICIPATING IN THIS STUDY?

Total payment for your child's participation in this research will be as follows, depending on the length of enrollment. Your child is scheduled to be enrolled for _____ months. Payments will be scheduled as follows:

1. After your child has been enrolled in the study (the vehicle has been prepared for our study and he/she has completed the enrollment process, including the online questionnaires), he/she will receive \$100 in cash or money order at the end of the installation visit or, if questionnaires are completed at home, payment will be mailed to him/her. This initial payment covers months one through four of your child's participation in the study.
2. Your child will receive a second payment of \$100 cash or money order, during his/her data collection appointment, after the 6th month of participation. This payment covers months five through eight of your child's participation in the study.
3. A third of \$133 via cash or money order at the end of the 8th month (this is an enrollment bonus, prorated from \$200 for every 12 months of enrollment).
4. If your child's enrollment extends beyond 8 months, he/she will receive an additional payment via cash or money order every 4 months. This payment will be \$42 for each month over the minimum 8 month enrollment period (this includes the monthly payment of \$25 plus a \$17 per month prorated bonus).
5. After your child's enrollment is complete, and after he/she returns to the South Seattle instrumentation facility to have the system removed from the vehicle and completes a few final questionnaires, your child will receive any final payment via cash or money order. This final payment will be \$42 for each month or partial month since your child's previous payment (this includes the monthly payment of \$25 plus a \$17 per month prorate bonus).

If your child discontinues his/her participation early, by his/her own choice, because the vehicle owner decides to withdraw their vehicle, or because he/she is asked to leave by someone on the study team, we will pay your child \$25 for every month of his/her participation in the study. For payment purposes, a partial month is considered a full month. Your child will not receive any bonus amounts unless he/she completes the minimum eight months of participation. If your child discontinues enrollment after eight months, for any reason, his/her payment will be described in items 1-5, above.

If you are asked to leave due to persistent tire pressure monitoring system problems, you will be paid \$42 for each month or partial month of participation (this includes the monthly payment of \$25 plus a \$17 per month prorated bonus).

WHAT ABOUT INSURANCE?

Because your child is driving a privately-owned vehicle, neither study personnel nor their respective organizations are responsible for the expenses resulting from any crash he/she may experience. In the event of a crash, your child is **not** responsible for any damage to the data collection system installed in the study vehicle.

If your child is injured as the direct result of taking part in this research study, Battelle will not be able to provide him/her with any medical treatment or financial compensation, except as provided through remedies available at law.

Any expenses for medical treatment in case of injury are the responsibility of you and your child. We strongly recommend that your child has appropriate health insurance coverage.

VOLUNTEER

IS MY CHILD FREE TO WITHDRAW FROM THIS STUDY AT ANY TIME?

As a participant in this research, your child is free to withdraw at any time without penalty. If your child chooses to withdraw, he/she will receive partial payment as described in the Payment for Participation section of this form. Your child **is free to choose not to answer any questions** or respond to any tests that he/she chooses without penalty. If your child withdraws or is dismissed from the study, we will retain data collected before their withdrawal/dismissal, but delete any data collected in the interval between when we become aware of the withdrawal/dismissal and before we are able to remove the data collection equipment.

If your child chooses to end his/her participation in the study earlier than originally planned, we will schedule a time to remove the data collection system from the study vehicle. He/she will not receive his/her final payment until we have removed the instrumentation from the vehicle.

The principal investigator or the sponsor of the research study can end your child's participation in the study at any time without your consent and your child's assent (if your child is younger than 18) or without your child's consent (if your child is 18 years or older). If the principal investigator or sponsor ends your participation, we will schedule a time to remove the data collection system from the study vehicle. Your child will not receive his/her final payment until we have removed the instrumentation from the vehicle.

HAS THIS RESEARCH BEEN APPROVED?

Before this experiment began, the research was approved by the Institutional Review Boards (IRBs) for research involving human subjects at Virginia Tech and Battelle Seattle Research Center. The research has also been approved by the IRB for the National Academies of Science. This approval has been obtained and is valid through the date listed at the top of this form, at which point the IRBs will review the study for renewal.

HOW DO I PROVIDE MY CONSENT?

I _____ (parent of minor participant) have read and understand this consent form and conditions of my child’s participation. I certify that I am the parent or legal guardian of a minor participant in the SHRP 2 Naturalistic Driving Study. As such, I certify that I have legal standing to consent to my child’s participation in this study. I understand what is being asked of my child. My questions have been answered. I freely agree to allow my child to participate and certify that neither he/she nor I have been coerced into participation. I understand that my child’s participation is voluntary and that my child may withdraw at any time without penalty.

I certify that either I or my child is the owner, co-owner, or lessee of the vehicle that will be used in the study, or have permission from the owner, co-owner, or lessee of the vehicle, and that I am permitting the instruments and sensors to be installed in the vehicle. I certify that my child holds a valid United States driver’s license, and that the vehicle that will be used in the study has at least the minimum amount of liability insurance required by the state in which it is registered.

Participant Permission for Video and Audio Recording

_____ By initialing here, I acknowledge that my participation in this study will result in continuous video recording of my face and portions of my body whenever I am driving the study vehicle.

_____ By initialing here, I acknowledge that my participation in this study will result in audio recording of my voice for 30 seconds whenever I press the incident button.

Parent of Minor Participant (Print Name) Signature Date / Time

Experimenter (Print Name) Signature Date / Time

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

- | | | |
|-------------------|--|----------------|
| Christian Richard | Project Principal Investigator | (206) 528-3249 |
| John Campbell | Project Manager | (206) 528-3254 |
| Gary Sapp | Manager, Battelle IRB | (614) 424-7648 |
| Pamela Sutherland | Co-Chair
Battelle Institutional Review Board
BCO Line of Review
505 King Avenue
Columbus, OH 43201 | (614) 424-4493 |

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