

## Primary Driver Informed Consent Language from the SHRP 2 Naturalistic Driving Study:

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

**Any data collected during this study that personally identifies you or that could be used to personally identify you will be treated with confidentiality.** As soon as you begin participating in this study, your name and other identifying information will be separated from the raw data collected while you drive the vehicle and replaced with a number. That is, your raw data will not be attached to your name, but rather to a number (for example, Driver 0011). The raw data collected while you drive the vehicle will be encrypted (made unreadable) from the moment it is collected until it is transferred to one or more secure central storage locations. Your name also will be separated from any data about you, either provided by you in response to questionnaires or gathered by researchers during the study, including crash investigation data, and will be replaced by the same driver number (for example, Driver 0011).

Several types of information and data about you and the study vehicle will be collected during the study:

1. **Contact information** includes your name, address, email address, phone numbers, and similar information used to contact you when needed. It will be stored securely in electronic form during the course of the study and destroyed after the study is complete (unless you grant permission for us to keep your contact information when the study is over). This information will not be linked to or mingled with your study data, and will not be used in any research or analysis.
2. **Auxiliary study information** includes your Social Security Number, license plate number, bank account information (for those using direct deposit) and similar information. This information is used to verify your identity and to make payments for your participation. This information will be stored at the site in electronic form (securely encrypted) destroyed after the study is complete. This information will not be linked to or mingled with your study data, and will not be used in any research or analysis.
3. **Driver data** includes your answers to questionnaires, vision test results, and the results of the brief physical tests described above. This data will not contain your name or any identifying information and will be used in analyses, both on its own and in combination with the driving data, vehicle data, and additional crash data. This data will be stored securely in electronic form throughout the lifetime of the data (defined below).
4. **Vehicle data** includes the vehicle make and model, its condition, and how it is equipped. This data will not contain your name or any identifying information and will be used in analyses, both on its own and in combination with the driver data, driving data, and additional crash data. This data will be stored securely in electronic form throughout the lifetime of the data (defined below).
5. **Driving data** includes the data we collect from the vehicle while you are driving, including

video data and sensor data. This information will contain video of your face and GPS coordinates of your trips, both of which could be used to personally identify you. 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. These data will be used for analysis, both on their own and in combination with the driver data, the vehicle data, and the additional crash data. This data will be stored securely in electronic form throughout the lifetime of the data (defined below).

**6. Additional crash data** includes items we may collect after a crash, including answers to an interview with one of our researchers and the police accident report resulting from the crash. This data will not contain your name or any identifying information and will be used in analyses, both on its own and in combination with the driver data, vehicle data, and driving data. This data will be stored securely in electronic form throughout the lifetime of the data (defined below).

It is possible that an authorized Institutional Review Board (IRB) 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. It is also possible that the study sponsors or investigators may view this study's driver data and driving data for quality control or administrative purposes; in this case, the study sponsors or investigators 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 driving the vehicle, a camera will videotape your face with some added space around the head to handle any head movements. An example is shown below. Also, video cameras will capture views of the forward view, the rear view, an external view to the right, as well as a dashboard/lap-belt view. 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. Passenger identification will not be possible from these blurred snapshots. All video will be captured and stored in digital format (no tape copies will exist).

There will also be an ambient atmospheric analyzer that is capable of detecting the presence of alcohol in the passenger compartment under certain conditions. It may not be able to distinguish whether the alcohol was imbibed or applied (as in hand sanitizer), and it will be unable to determine whether it is emanating from the driver or a passenger. However, this sensor will flag the data for possible indications of impaired driving.

If a safety-related incident or crash occurs, you are asked to press a button on the unit mounted near the rearview mirror. You will know this button is working if a red light appears when you press it. This 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, you can tell us what happened. No audio will be captured except when you press this incident button. Please note that pressing this button does NOT make a phone call, unlike OnStar™. It simply records your voice in an audio file that remains in the vehicle until the data

is collected.

During the data collection phase of this study, all data collected from the vehicle will be encrypted (made unreadable) from the time of its creation and then stored in a specific password protected project folder on a secure server; the driving data will only be decrypted (made readable) once it has been stored in this folder. At the conclusion of the collection phase of this study, the driver data, driving data, and additional crash data will be permanently housed at one or more highly secure data storage facilities. One set of data will be permanently housed 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 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 you or that could be used to personally identify you. As explained below, other qualified research partners may be given limited access to your driver data, vehicle data, driving data, and additional crash data, solely for authorized research purposes and with the consent of an IRB. This limited access will be under the terms of a data sharing agreement or contract that, at a minimum, provides you with the same level of confidentiality and protection provided by this Consent Form. However, even these qualified researchers will not be permitted to copy raw study data that identifies you, or that could be used to identify you, or to remove it from the secure facilities in which it is stored without your consent.

Project personnel, the project sponsors and qualified, authorized research partners may show specific clips of video at research conferences. The project sponsors also may show specific clips of video to the media, driver's education teachers and students, and others involved in efforts to improve highway and road safety. The face portion of the video will be blurred, blacked out, or replaced with an animation for these purposes. Your name and other personally identifying information will never be associated with the showing of these video clips. Identifying location information will not be shown in association with these video clips.

It is expected that the data we capture throughout the course of the entire study, including that from all the approximately 3,100 primary participants, 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 using all or part of the data for up to 30 years into the future. These follow-on analyses will be conducted 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 to future research uses of the information and videos we gather from you, consistent with the protections described above and elsewhere in this document.

If you are involved in a crash while participating in this study, the data collection equipment in the vehicle will likely capture the events leading up to the event. You are under NO LEGAL

OBLIGATION to voluntarily mention the data collection equipment or your participation in this study at the time of a crash or traffic offense. We have provided a letter which you should keep in the glove box for these cases. The letter describes the vehicle's role in the study without identifying you as a participant in the study.

Because the 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 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 you, 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 contact information, your auxiliary study information, your driving data (including video of your face and GPS coordinates which may identify your home, work, or school locations), or any information in your driver data, vehicle data, or additional crash data that could be used to personally identify you. While your confidentiality is protected in most cases by the Certificate, you should know that in some rare instances involving alleged improper conduct by you or others, you may be prevented by a court from raising certain claims or defenses unless you agree to waive the confidentiality protection. The researchers and study sponsors 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).

This Certificate of Confidentiality does not mean that the Federal government endorses this study. 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. If you are not the vehicle owner, you should know that the vehicle owner will not have access to your data.

The Certificate of Confidentiality also does not prevent the researchers from disclosing voluntarily matters such as child abuse, or 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 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 most 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, your compensation will be prorated based on the time you have already spent as a participant in the study. The protections of the Certificate of Confidentiality described herein may not apply to passengers or drivers of the vehicle who have not consented to being in this study. For this reason, Informed Consent will be sought from all other adults who drive the vehicle, and these

individuals will be protected by the Certificate of Confidentiality to the same degree as you are.

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

1. There will be video of your face and portions of your body. There will be audio recorded, but only for 30 seconds if you press the red incident button. The study also will collect health and driving data about you. The video, audio, and other data that personally identifies you, or could be used to personally identify you, will be held under a high level of security at one or more data storage facilities. Your data will be identified with a code rather than your name.

2. All data collected from other drivers who have not signed a consent form will be deleted. No identifying information will be collected 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 you. 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 name and other personally identifying information be associated with the video clips.

4. The personally identifying data collected in this study may be analyzed in the future for other research purposes by this project team or by other qualified researchers in a secure environment. Such efforts will require those researchers to sign 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. Research partners will not be permitted to copy raw data that identifies you, or that could be used to identify you, or to remove it from the secure facility in which it is stored except with your consent.

5. A Certificate of Confidentiality has been obtained from the National Institutes of Health. With this Certificate, the researchers and study sponsors 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 or actual harm 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. While your confidentiality is protected in most cases by the Certificate, you should know that in some rare instances involving alleged improper conduct by you or others, you may be prevented by a court from raising certain claims or defenses unless you agree to waive the confidentiality protection.