Once complete, upload this form as a Word document to the IRB Protocol Management System: https://secure.research.vt.edu/irb

Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

☒ **No**
☐ **Yes,** explain:

1.2 WILL THIS RESEARCH INVOLVE COLLABORATION WITH ANOTHER INSTITUTION?

☐ **No,** go to question 1.3
☒ **Yes,** answer questions within table

IF YES
Provide the name of the institution [for institutions located overseas, please also provide name of country]**:** **National Academy of Science – project sponsor** **Site contractors and locations where data will be collected:** **Battelle - Seattle, WA metro area** **CUBRC - University of Buffalo Research Center (CUBRC), Buffalo metro area** **CUBRC - Tampa Bay, FL metro area** **Westat - Durham, NC metro area** **Pennsylvania State University – several centrally-based counties** **Indiana University – several centrally-based counties**
Indicate the status of this research project with the other institution's IRB: ☐ Pending approval ☐ Approved ☐ Other institution does not have a human subject protections review board ☒ Other, explain: **The exact relationship of each site's IRB to the Virginia Tech IRB is not known at this time. As each site makes its decision (to rely on its own IRB or to use Virginia Tech's IRB via a letter of reliance), that decision will be forwarded to the VT IRB and all proper procedures followed. Each site has been forwarded a copy of Virginia Tech's Policy for Collaborative Research.**
Will the collaborating institution(s) be engaged in the research? (http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html) ☐ No ☒ Yes
Will Virginia Tech's IRB review all human subject research activities involved with this project? ☐ No, provide the name of the primary institution: ☒ Yes *Note: primary institution = primary recipient of the grant or main coordinating center*

1.3 IS THIS RESEARCH FUNDED?

☐ **No,** go to question 1.4

☒ **Yes,** answer questions within table →

IF YES
Provide the name of the sponsor [if NIH, specify department]: Strategic Highway Research Program 2 of the National Academy of Sciences
Is this project receiving federal funds? ☐ No ☒ Yes **If yes,** **Does the grant application, OSP proposal, or "statement of work" related to this project include activities involving human subjects that are <u>not</u> covered within this IRB application?** ☐ No, all human subject activities are covered in this IRB application ☒ Yes, however these activities will be covered in future VT IRB applications, these activities include: **Recruitment which will be conducted for the most part by a national call center located at Virginia Tech (not affiliated with VTTI). This activity will be covered under a separate IRB submission to the Virginia Tech IRB.** ☐ Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows: ☐ Yes, however these activities have been or will be reviewed by another institution's IRB, the name of this institution is as follows: ☐ Other, explain: **Is Virginia Tech the primary awardee or the coordinating center of this grant?** ☐ No, provide the name of the primary institution: ☒ Yes

1.4 DOES THIS STUDY INVOLVE CONFIDENTIAL OR PROPRIETARY INFORMATION (OTHER THAN HUMAN SUBJECT CONFIDENTIAL INFORMATION), OR INFORMATION RESTRICTED FOR NATIONAL SECURITY OR OTHER REASONS BY A U.S. GOVERNMENT AGENCY?

For example – government / industry proprietary or confidential trade secret information

☐ **No**
☒ **Yes,** describe: **Possible proprietary information obtained from vehicle networks (proprietary to automobile manufacturers who are cooperating on this project).**

1.5 DOES THIS STUDY INVOLVE SHIPPING ANY TANGIBLE ITEM, BIOLOGICAL OR SELECT AGENT OUTSIDE THE U.S?

☒ **No**
☐ **Yes**

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

While driving behavior has been widely acknowledged as a primary factor in most collisions, its relationship to factors such as roadway design, environmental conditions, vehicle features, and how they influence the risk of collisions and casualties remains a largely unknown area (TRB, 2007). By using innovative research methods combined with advanced technologies, SHRP 2 sees opportunities to learn more about these factors in a way that is hoped to improve traffic safety for generations to come.

In response to the Transportation Research Board (TRB) SHRP 2 S06/S07 Naturalistic Driving Study (SHRP 2 NDS), the Virginia Tech Transportation Institute (VTTI) has joined together with Battelle, CUBRC, Westat, Pennsylvania State University, and Indiana University to implement the most significant program of highway safety research in the last 50 years. Successful completion of this research will produce a database of pre-crash, near-crash, crash, driving behavior, driving performance, roadway information, and vehicle kinematics data that will allow substantial progress to be made in both the crash-causation and crash-countermeasure domains. Further, it will advance the directives of the 2006 Congress and the SHRP 2 Safety Plan by working to improve highway safety through a more comprehensive understanding of driving behavior.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

Study results will be presented/published at relevant scientific, professional, or technical conferences (e.g., Transportation Research Board, Human Factors & Ergonomics Society) and published in relevant journals (e.g., Transportation Research Record, Accident Analysis and Prevention, Journal of Safety Research, Human Factors). Summary data may also be published online in de-identified form for use by other qualified researchers.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

Participants are being recruited at six different locations throughout the United States (Seattle, WA; Buffalo, NY; central areas of Indiana; Tampa Bay, FL; Durham NC; and Erie County, PA). On the order of 3,100 participants will be recruited, distributed as shown below in Table 1 (some enrolled for one year, and some for two years):

Table 1. Sample Design (with Target Cell Values)

Gender: Age Range	Age Range Description	One Year	Two Years	Primary Participants
M 16-17	Minor Teen	144	28	172
M 18-20	Adult Teen	144	28	172
M 21-25	Young Adult	144	28	172
M 26-35	Adult	144	28	172
M 36-50	Middle Adult	144	28	172
M 51-65	Mature Adult	144	28	172
M 66-75	Younger Older Driver	144	28	172
M 76+	Older Older Driver	144	28	172
F 16-17	Minor Teen	144	28	172
F 18-20	Adult Teen	144	28	172
F 21-25	Young Adult	144	28	172
F 26-35	Adult	144	28	172
F 36-50	Middle Adult	144	28	172
F 51-65	Mature Adult	144	28	172
F 66-75	Younger Older Driver	144	28	172
F 76+	Older Older Driver	144	28	172
Any Advanced Vehicle Technology		0	350	350
Totals:		1,152	798	3,102

There will be two different types of participants: primary drivers and secondary drivers. Primary drivers will be those that are initially recruited and are the primary driver of the instrumented vehicle. Secondary drivers are those that occasionally drive the vehicle of a primary driver enrolled in the study. The eligibility criteria for the two types of participants are explained below:

Primary Drivers
Primary drivers must live in one of the geographic areas of interest. Primary driver participants will be required to hold a valid U.S. driver's license allowing independent, unsupervised driving. Primary drivers must drive at least three days per week on average. Primary drivers must own their own vehicle (or for minors, be able to provide suitable documentation of permission from the vehicle's owner to have the instrumentation installed [via a clause in the parental consent form]). The vehicle to be instrumented must be a vehicle that is one of the models to be included in the study. Primary drivers must plan on driving the vehicle as their main vehicle for the duration of their scheduled participation (i.e., either one or two years, as appropriate), and be able to provide proof of insurance for the vehicle. "Main vehicle" means that the participant expects to drive this vehicle more than 60% of the time during the study. Primary drivers must have no more than three other people who regularly drive their vehicle. Primary drivers must be able to speak, understand, and read English well enough to undergo all study procedures (i.e., all study instructions, forms, and communications will be in English). Primary drivers must be able to read and fill out questionnaires, be able to provide informed consent, follow study instructions, and be sufficiently mobile to conduct assessments, such as vision testing, rapid pace walk, etc. Identical multiples (e.g., twins) who drive the same instrumented vehicle will not be eligible due to potential confusion in properly identifying the driver. Participants must not have a need to drive their vehicles into areas where cameras are not allowed (possibly including locations such as certain military bases, international border crossings, etc.). No participant will be excluded based on gender ethnicity, socio-economic status, or health (except in terms of the physical/perceptual requirements noted above). Primary drivers must be eligible for employment in the U.S. and must be willing to provide their Social Security Number and a voided check (or other means of allowing for payment) when they come in for the study. The telephone screening form to be used by the call center (to be approved under a separate IRB submission) is included as Appendix A. Drivers who drive vehicles with advanced technologies, such as collision avoidance and lane keeping assistance systems, will also be recruited.

It should be noted that as the study progresses, the screening criteria will be tightened up as needed to meet the targeted enrollment (for example, if all sites have enrolled their quota of younger teenage male drivers, then these drivers will be excluded from future recruitment efforts).

Secondary Drivers
Secondary drivers will not be actively recruited by the research team. The primary driver will be provided with a packet (or web address) to give to up to three other individuals who regularly drive his/her vehicle (at least once a month). Therefore the eligibility criteria for secondary drivers are that they must drive the instrumented vehicle of a primary driver and must have a valid U.S. driver's license. All secondary drivers will be 18 or older. Any drivers who are under 18 or who are otherwise unconsented will have their face video data de-identified (blacked out, blurred, or replaced with an animation or avatar).

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

☐ **No,** go to question 3.3
☒ **Yes,** answer questions within table

IF YES
Are these records private or public? ☐ Public ☒ Private, describe the researcher's privilege to the records: **The call center will purchase a list of telephone numbers from Survey Sampling International. This list will be for residences in the cities and counties identified by the site contractors as the areas of interest for recruiting. [Given the specific vehicle types needed for the study, a list of specific vehicle model owners may also be purchased (e.g., from J.D. Polk) to make the recruitment effort more efficient.]**
Will student, faculty, and/or staff records or contact information be requested from the University?

☒ No
☐ Yes, visit the following link for further information: http://www.policies.vt.edu/index.php (policy no. 2010)

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

Primary driver participants will be recruited via cold calls from the Virginia Tech Center for Survey Research. The recruitment protocol has been (or will be) submitted to and approved by both the Virginia Tech IRB (#10-XXX) and the NAS IRB (#XXXX). The current version of the screening instrument they will use is provided as Appendix A.

The second method for recruiting primary drivers (which may or may not be used, depending upon the success of the primary recruitment approach) will be through newspaper advertisements (Appendix C) and flyers (Appendix B). It is possible that web-based or e-mail advertisements or announcements will also be used. It is also possible that presentations will be made at local events or civic/non-profit meetings to identify potential participants. In these cases, the information will be the same as that contained in the flyers and newspaper ads. This recruiting will be conducted by researchers at the various sites, although the potential participants will be directed towards the project website and the call center for screening and scheduling, activities covered under Virginia Tech IRB #10-XXX and NAS IRB #XXXX. Finally, participants may become aware of the study through informational brochures developed by SHRP2 of the National Academies (an example of which is shown in Appendix N). Although not at all intended for potential participants or recruitment, it is possible that viewing such a brochure in another context could induce a potential participant to pursue involvement in the study.

If the first or second recruitment methods listed above do not result in enough participants who are primary drivers of vehicles with advanced vehicle technologies, these drivers may be recruited using additional or separate methods. For example, lists of drivers who have purchased the vehicle types of interest may be obtained from automotive companies, J.D. Polk, or dealerships. [This method of recruiting may also be used for the main body of participants if the call center random dialing approach does not produce the required numbers of vehicles of various models.]

Secondary drivers will be recruited by asking the primary drivers for the names of up to three other people who drive the primary driver's vehicle at least once a month. A packet of information (or web address and password) will be sent home with the primary drivers, who will give it to the secondary drivers. About a week later, research staff from the site will contact the potential secondary driver participant and ask if they have any questions. A second phone call may be made to the potential secondary driver participant if it is noticed that they have experienced numerous events (crashes or near crashes) or if it is noticed that they drive the instrumented vehicle a high proportion of the time (e.g., >30% of the time).

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

The population of interest in this study corresponds to the national statistics. Based on information obtained from the National Highway Traffic and Safety Administration (http://www-nrd.nhtsa.dot.gov/pdf/nrd-30/NCSA/TSFANN/TSF2005.pdf), there are approximately equal numbers of male and female licensed drivers in the United States. No ethnic or socioeconomic groups will either be targeted or excluded from participation. Table 1 in Section 3.1 indicates that all ages from 16 and up and both genders will be recruited, although the very young and very old drivers will be somewhat overrepresented. This is so because these populations are known to be high-risk drivers compared to the middle-aged groups, and their data will be especially useful for answering many of the research questions. The safety impact of vehicles with advanced safety features, such as collision avoidance and lane keeping assistance devices, is also of great interest to the research community and a substantial number of participants with such vehicles will be recruited. Drivers of such vehicles will be recruited primarily based on the presence of the technologies of interest, without regard to age or gender.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link: http://www.irb.vt.edu/pages/consent.htm

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY'S CONSENT PROCESS:

☒ Verbal consent will be obtained from participants
☒ Written/signed consent will be obtained from participants
☐ Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
☐ Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

PRIMARY DRIVERS

Initial contact with potential participants will take place over the phone. The research team will utilize a single, centralized call center to introduce the study to potential participants. Staff from the call center will follow the script in the Telephone Screening (Appendix A) and provide the potential participant with information about the study. Then, if the potential participant expresses interest in the study, the call center researcher will obtain verbal assent/consent prior to asking the eligibility screening questions. If the potential participant is a minor (for each state involved in the study, a minor is defined as being under the age of 18), then the staff at the call center will speak to the parent first and obtain verbal permission to screen the child. These initial research activities (recruiting and determining eligibility) are (or will be) covered under (approved) IRB submission (IRB # 10-XXX).

After they have been screened as part of the Call Center Recruitment process, potential participants will be directed to the project website, where they can learn more about the study, see pictures of what their vehicles will look like with the instrumentation installed, and download and read the appropriate consent and/or assent forms.

An informational video will also be made of the important points of the consent form and instrumentation process (a close-to-final version of the script for this video can be seen in Appendix M). Potential participants will be able to download and watch this video from the website as well. Participants will be strongly urged to carefully review the consent form prior to beginning the intake procedure with the site contractors. Upon arrival at the site contractor facility, the research participant (and parent or guardian in the case of minors) will be greeted by a member of the research team and escorted to a private room. There, the researcher will present information about the vehicle instrumentation, and review the informed consent/assent form(s). The informational video will also be played again at this time (with a caveat that the consent form itself is the true method of consent, while the video presents the same information in somewhat less detail and formality). Those that agree to participate will be asked to sign and date two copies of the informed consent/assent forms. Minors will be required to have parental consent (signed in the presence of the research staff). Minors will be separated from their parents for a few moments at some point before the vehicle is instrumented, during which time research staff will query the minor to make sure there is no parental coercion for the minor to participate. Minors who turn 18 during the course of the study will be scheduled to return to the SHRP 2 NDS site contractor's facility within a month after their 18th birthday to sign an adult Informed Consent Form.

SECONDARY DRIVERS

The research team will ask primary drivers for the names and contact information for up to three other people who regularly drive their vehicle (regularly means at least once a month). The research team

will provide primary drivers with packets (or a web address and password) and will ask the primary driver to distribute the packets to these secondary drivers. The packet will include two copies of the Informed Consent Form for each secondary driver (one for the secondary driver to keep, and one to return to the site contractor). The packet will also include instructions that direct interested participants to sign both copies of the informed consent and mail one copy back to the site contractor's facility. The research team will follow up with potential secondary drivers by telephone within a week to see if they have any questions about participating and to determine whether or not they wish to participate.

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

Verbal consent/assent to conduct the eligibility screening will be obtained by staff from the call center as described in the (approved) IRB protocol (IRB# 10-XXX). Written consent/assent will be obtained by research staff at the different SHRP 2 NDS research facilities. All staff performing these duties must first complete Human Subjects Training.

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

Consent will take place at the offices of one of the site contractors listed in question 1.2.

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

PRIMARY DRIVERS

Verbal consent/assent to conduct the eligibility screening will be obtained over the phone, after describing the study and before asking any of the screening questions. The screening protocol has been (will be) approved by Virginia Tech IRB #10-XXX, Call Center Recruitment. Written consent/assent will be obtained after participants have been provided with detailed information about the study including the benefits and the risks involved. No study tasks (e.g., questionnaires, vehicle instrumentation, etc.) will commence until written informed consent/assent has been obtained.

SECONDARY DRIVERS

It is expected that the primary drivers will provide secondary drivers of their vehicle with the consent form (or access to the consent form via a website and password) prior to the secondary drivers driving the car. It is also expected that there will be some secondary drivers who elect not to participate in the study or who have not been provided with the packet and consent forms (or web address and password) by the primary driver. These drivers will not be considered research participants and after it is determined that the data originates from a driver not enrolled in the study, the face of the driver will be blurred/blacked out/replaced with animation in such a way that they can no longer be identified. It is also possible that during the course of the study, participant's situations will change, and someone not originally qualified as a secondary driver will later be identified as someone who does qualify as a secondary driver. At that point, the primary driver will be contacted and asked to provide contact information for this new driver so that consent can be obtained.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

After being screened as part of the Call Center Recruitment process, potential participants will be directed to the project website, where they can learn more about the study, see pictures of what their vehicles will look like with the instrumentation installed, view a brief informational video about the study and the consent process, and download and read the consent form. Participants will be strongly urged to carefully review the consent form prior to beginning intake procedures at the site contractor's facility.

☐ Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

PRIMARY DRIVERS

Potential participants will either be called on a random basis by the Call Center Recruitment Contractor, or will respond to recruitment advertisements (flyers, newspaper ads, and similar materials) by phone. Advanced vehicle participants may be contacted after their contact information is provided to the call center by car companies, car dealerships, or J.D. Polk. [There is a chance that the main body of participants may also be identified in this manner to ensure that the correct vehicle models are targeted.] The phone calls will be answered by a call center recruiter, and the participants will be read a script (screening script found in Appendix A) that provides them with information about the study. Those that indicate they are interested in participating will be screened for eligibility after they have provided verbal assent/consent. If the potential participant is a minor, verbal consent from his/her parent will be obtained prior to the eligibility screening. The entire telephone call is expected to last approximately 15 minutes. This process is described in more detail in the (approved) recruitment Center IRB protocol (IRB # 10-XXX, which contains the final approved screening materials).

After being screened as part of the Call Center Recruitment process, potential participants will be directed to the project website [www.shrp2nds.us], where they can learn more about the study, see pictures of what their vehicles will look like with the instrumentation installed, view a brief informational video about the study and the consent process, and download and read the consent form. Participants will be strongly urged to carefully review the consent form prior to coming in for the study. [Site option 1: A member of the research team will follow up with the potential participant via email or phone to schedule him/her to attend an information session. This information session will be held at one of the SHRP 2 NDS research facilities and will last approximately 30 minutes. During this session, potential participants will be provided with information about the study including a review of the system that will be installed in the vehicles. Numerous potential participants may be scheduled to attend the same session. Those that indicate interest in participating in the study will be scheduled to return to the site contractor's facility at a later date to be enrolled. Materials presented during this session will be taken from the website and from previously approved IRB materials, followed by a question and answer session.] [Site option 2: Potential participants will be scheduled to come to the SHRP 2 NDS site contractor's facility to undergo consent processes, have their vehicle instrumented, and undergo driver assessments. These activities may be scheduled during a single visit or more, as per individual site practices and participant needs.]

Potential participants will be instructed to drive their primary vehicle to the SHRP 2 NDS site contractor's facility. Upon arriving at the facility, the participant will be greeted by a member of the research team (in the case of minors, a parent will also be present), and be escorted to a private room. The researcher will review the Informed Consent/Assent form (Appendices D1, D2, and D3) and answer any remaining questions the participant (or parent of a minor participant) might have. The brief informational video will also be viewed again at this point. After all questions have been addressed, the researcher will ask the participant to sign and date two copies of the Informed Consent/Assent form. If the participant is a minor, the researcher will also ask the parent to sign and date two copies of the consent form. The researcher will keep one copy and provide the participant/parent with the other copy. Minor participants will be asked out of earshot of their parent/guardian whether they are freely agreeing to participate in the study to avoid any possibility of coercion.

After the consent form has been signed, the participant will be asked to present the researcher with his/her valid U.S. driver's license. The researcher will verify that the license is valid (by checking the date and other state-specific factors, as available) and return it to the participant. The researcher will also ask the participant to provide proof of vehicle liability insurance. Finally, the participant will be asked to show the vehicle registration to make sure that they are the owner or co-owner of the vehicle (or that the signing guardian of a minor participant is the owner or co-owner of the vehicle to be instrumented). Then, the participant will be taken to the garage area and asked to look over their vehicle in conjunction with a vehicle condition checklist prepared by the installation team (Appendix G1). This will ensure that any pre-existing

dents, scratches, tears, or other damage are properly documented and acknowledged by the participant before instrumentation begins. The researcher will then tell the instrumentation staff to begin installing the sensors and data collection equipment in the participant vehicle. The participant will fill out a tax form to ensure proper payment (Appendix G3).

Proposed order of assessment (final order may vary, but will include all components listed here):
The participant will first be asked to fill out Demographic and Vehicle Feature Questionnaires (Appendices E19 and E20). Then a series of vision tests will be performed using an Optec 6500P vision testing machine (Appendix E1). The equipment will include measures of High and Low Light Contrast Sensitivity, Near and Far Static Acuity, color vision, peripheral vision, and Depth Perception/Stereopsis.

Next, a series of tests and questionnaires will be administered. These can be found in Appendices E2 through E6 and E9 through E19 and will include:

- **The Motor Free Visual Perception Test (MVPT)**
- **The Clock Test**
- **The Visual Closure Subtest**
- **Trail Making Test (A & B)**
- **The Useful Field of View (UFOV®) (In DrivingHealth® Inventory)**
- **Conner's Continuous Performance Test II (CPT II) Version 5**
- **Barkley's ADHD Quick Screen**
- **Frequency of Risky Behavior Questionnaire**
- **Perception of Risk Questionnaire**
- **Modified Manchester Driver Behavior Questionnaire**
- **Sensation Seeking Scale**
- **Sleep Quality**
- **Health and Medications**
- **Driving History**
- **Driving Knowledge**

Driver Demographics
Integrated Vehicle Systems

Most of these tests and questionnaires will be self-administered via computer, and some may be completed online at home if time does not allow completion at the site. Two physical tests will be administered: the Rapid Pace Walk test (20 feet total) and a hand strength assessment using the Jamar Hand Dynamometer. Descriptions of these can be found in Appendices E7 and E8.

Finally, participants will be asked to provide contact information for up to three other drivers who regularly drive their vehicle (at least once a month), and will be provided with Informed Consent Forms and questionnaires for those secondary drivers (D4 and Appendices H1 and H2).

The entire intake session (beginning with the review of the Informed Consent/Assent and ending when the participant is provided with Informed Consent Forms or internet address and password for secondary drivers) is expected to last approximately four hours.

When the session has ended, the instrumented vehicle will be returned to the participant and they will be instructed to drive the vehicle as they normally would. Some participants will be enrolled for a one year period and some will be enrolled for a two year period (the expected split is approximately 26% for two-year, and 74% for one year participants). Assignment to the one vs. two year conditions will be random, but based on participants' willingness to continue for two years as well as the expectation they will keep the same vehicle for two years. Participants will be instructed to contact the SHRP 2 NDS research team in the event that they encounter any difficulties with the vehicle that could be related to the data collection system, or if they notice any maintenance issues with the system (for example, a camera that comes loose and dangles).

The participants will also be provided with instructions regarding what they should do in the event of a crash. They will be told that they should perform the following tasks in order:

1. Seek emergency help the way that they normally would.
2. Press a button located near the rearview mirror and describe the event; the system will record their brief description for later download.
3. When it is safe to do so, call the research team to notify them of the crash.

4. Allow one of our crash investigators to interview them about the crash if the research team decides that it should be investigated in more detail (see Post Crash Interview Script in Appendix F).
5. Allow the research team to have access to the police crash report, if any, which results from the crash.

Researchers will be made aware of all apparent crashes on a daily basis, but not in real time. The site contractors will call all those who have been in a crash (who haven't already called them) to determine if/how the participant will remain in the study, if they're hurt, how the HD can be retrieved, to schedule the post-crash interview, etc.

Members of the research team will contact the participant to arrange an appointment to download the data from the vehicle approximately once every three to six months. During this brief (typically 15 minutes) appointment it may be necessary for the researchers to have access to the interior of the vehicle. These meetings will take place with the participant's knowledge and at a time and place convenient for the participant (i.e., at locations where the participant typically parks the vehicle), and will not require the participant to perform any additional driving.

Minors who turn 18 during the course of their participation in the study will be scheduled to return to the SHRP 2 NDS site contractor facility and complete an adult Informed Consent Form within one month of their 18th birthday. A member of the research team will review the form with them prior to asking the participant to sign and date the form. This process is expected to last less than 30 minutes.

After one or two years, depending on length of enrollment, the participant will be asked to return to the SHRP 2 NDS site contractor facility while the system is removed from the vehicle. During the removal process, the participant will be asked to complete an exit survey (example shown in Appendix I; an amendment will be sought for the final version). They will also be asked to repeat the Health and Medications questionnaire (Appendix E15). Finally, they will be asked whether we can keep their contact information in case there are follow-on studies where it would be beneficial to use the same participants. Allowing us to keep their contact information beyond the study completion will be optional and will not affect payment or any other aspect of their study participation. The process is expected to take approximately one hour. At the end of this session, the participant will receive or be scheduled for his/her final payment, and be thanked for his/her time and participation in the study.

SECONDARY DRIVERS
Primary drivers will be provided with information packets that contain Informed Consent Forms and questionnaires (or a web address and password that will enable them to access these materials via computer). Primary drivers will be instructed to give these packets (or web address and password) to up to three other people over the age of 18 who routinely drive their vehicle. The packets will instruct the secondary driver to contact a member of the research team. Research staff will review the Informed Consent Form over the phone with the secondary driver and answer any questions as needed. The research staff will obtain verbal consent from the secondary drivers who wish to participate and instruct them to sign and date both copies of the Informed Consent Form and to return one copy to the site contractor facility. If a potential secondary driver has not contacted the team within a week, the researchers will attempt to contact him/her to review the consent form and ask if he/she is interested in participating.

Secondary drivers will be asked to fill out a brief demographic survey (Appendix H1and driving habits and history questionnaire (Appendix H2) and to mail these to the site contractor facility (or to complete them online after they have provided consent). The research team will also request that secondary drivers provide a digital picture of their face so they can automatically (in the data post-processing phase) be identified as a secondary driver.

Finally, the secondary drivers will also be provided with instructions regarding what they should do in the event of a crash. They will be told that they should perform the following tasks in order:

1. Seek emergency help the way that they normally would.
2. Press a button located near the rearview mirror and describe the event; the system will record their brief description.
3. Call the research team to notify them of the crash.
4. Allow one of the crash investigators to interview them about the crash if the research team decides that the crash should be investigated in more detail (see Post Crash Interview Script in Appendix F).
5. Allow the research team to have access to the police report, if any, which results from the crash.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

The eligibility screening data will be collected verbally over the telephone and entered into an electronic database. Vision screening will be collected using an OPTEC 6500. The results from the vision screening will be entered directly into an electronic database (using standard electronic survey technology). A series of questionnaires will be administered on a computer and the data from these questionnaires will automatically be entered into an electronic database. A pencil and paper Clock Test will be administered, and the results of this test will be scanned to an electronic file format, then that electronic file will be saved to the database. The physical hand strength test will be collected using a Jamar Hand Dynamometer, and the data will be entered directly into an electronic database in the same way. The Fast Pace Walk test will be timed and these data will also be entered directly into an electronic database via the DrivingHealth Inventory software. A series of questionnaires will collect data via a secure online website and will be entered directly into an electronic database.

The data acquisition system (DAS) that will be installed in the vehicle will collect data using a number of sensors and video cameras. The system will collect data whenever the vehicle is turned on (other than the first few seconds that it takes for the system to 'warm up' or begin collecting data. The DAS will compile data from the video cameras, the vehicle network, and sensors, such as accelerometers, added for this particular study. The DAS has the following general design characteristics:

- **Compatible with the vehicle (e.g., power obtained from the vehicle battery, data from in-vehicle network).**
- **Unobtrusive and non-invasive**
- **Not distracting**
- **Does not limit driver visibility**
- **Requires no permanent modifications to the vehicle**
- **Minimal physical space requirements (e.g., the data storage unit is no larger than a collegiate dictionary)**
- **Automatic start-up, shut-down, and continuous operation while driving**
- **No participant tasks required for operation or data downloading**
- **Reliable performance in the often harsh operational environment of driving – minimal data loss and automatic detection of failures**
- **Continuous multi-camera video recording system (15 Hz) to capture driver's face, forward view, rear view, and a view over the driver's shoulder.**
- **A blurred, still snapshot of the passenger cabin to obtain information on the number of passengers, an estimate of their age and gender, and passenger seat belt use. Unconsented passengers will not be identifiable from these blurred snapshots.**
- **Ruggedness and crash survivability**

An engineering analysis was conducted on possible issues resulting from installation of the DAS, resulting in a Frequently Asked Questions document to answer common questions and concerns regarding the DAS (Appendix K). The main unit is quite small and will be mounted in the trunk, under the dash, under a seat or elsewhere, depending on the vehicle make and model, using customized mountings that use existing attachment points to the vehicle. The vehicle network box will be located under the front dashboard and collect information from the vehicle's computer on vehicle speed, throttle position, turn signal use, brake application, and other vehicle information as available.

There are additional sensors that will be installed in the vehicle; they are unobtrusive and non-visible to participants. They include: GPS (to assess location of vehicle at a particular point in time), lane tracker (machine vision software to automatically detect lane deviations), front radar, and accelerometers. There will also be sensors for luminance, yaw, and temperature, and an incident pushbutton. Hard wiring will be run through the normal wire chases on a vehicle to all the various network nodes, as well as to the cameras. Encrypted Bluetooth will be used for wireless data transmission from the front radar unit to the DAS.

There will also be an ambient atmospheric analyzer that is capable of detecting the presence of alcohol in the passenger compartment. It may not be able to directly distinguish whether the alcohol was imbibed or applied (as in hand sanitizer), but we expect to be able to develop signal processing and analysis protocols to reliably distinguish between these two situations. Also, the sensor will be unable to determine whether the alcohol is emanating from the driver or a passenger, but since the majority of trips are single person trips this information is expected to be of value. In general, this sensor will flag the data for the possibility of impaired driving, and will make the data reduction and analysis process go much more quickly for important research questions related to impaired driving.

Digital video cameras will be used to continuously record the driver and the driving environment. Four video cameras and one still camera will be mounted unobtrusively in order to facilitate naturalistic driving behavior. The four video cameras will be multiplexed into a single image (as shown in the consent form). The four camera views will be: (1) forward roadway view, (2) driver face view, (3) an overhead view of the dashboard area and related driver behaviors, and (4) rear and right side view (no license plate or following driver can be seen clearly enough to identify the driver of a following vehicle). The forward camera view will provide coverage of the driving environment. The driver face view will provide coverage of the driver's face and will allow researchers to conduct eyeglance analysis. The over the shoulder view will provide information about what the driver is doing with his or her hands in various driving situations. The rear and right side external view will reveal environmental information (e.g., traffic density). A frame number will be used to time synchronize the video and the vehicle/performance data. A fifth camera will periodically take still snapshots of the cabin to determine passenger information such as passenger count, seating location, seatbelt use, approximate age, and, usually, gender. The still image of the cabin/passengers will be permanently blurred for anonymity.

The digital video files will not contain continuous audio. However, the DAS has been designed such that the driver can press an incident button and record a 30 second verbal comment. The incident box will be mounted near the rearview mirror and will be used by participants who wish to flag a significant driving event (e.g., to point out that someone cut them off) or to describe a crash or near crash. A microphone will be included within the incident box, but will only record the driver's voice when the incident button is activated.

In the event of a crash, a member of the research team will interview the participant at a mutually convenient time. The data collected from this interview will be entered into an electronic database.

There will thus be two categories of information collected and four categories of data. These are presented to participants in the consent form using the following language:

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, driver's license number, license plate number, bank account information and similar information. This information is used to verify your identity and to make payments for your participation. This information will be stored securely in electronic form and 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 your 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 your 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 your vehicle, transferred to a secure data storage facility, and verified. From this point on they will be decrypted (made readable) on as 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).

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the "Policy for Online Research Data Collection Activities Involving Human Subjects" at http://www.irb.vt.edu/documents/onlinepolicy.pdf

☐ **No,** go to question 6.1
☒ **Yes,** answer questions within table

IF YES

Identify the service / program that will be used:

☐ www.survey.vt.edu, go to question 6.1
☐ Blackboard, go to question 6.1
☐ Center for Survey Research, go to question 6.1
☒ Other

IF OTHER:

Name of service / program: **Currently, http://limesurvey.vtti.vt.edu/**

This will become https://limesurvey.vtti.vt.edu/ before the study is operationalized.

URL: **https://limesurvey.vtti.vt.edu/**

This service is…

☐ Included on the list found at: http://www.irb.vt.edu/pages/validated.htm
☐ Approved by VT IT Security
☒ An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages.
☐ None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

The risk to participants is no more than they would normally experience while driving. Except for the primary driver's two visits to a SHRP 2 NDS site contractor facility, they are not being asked to alter daily driving routines in any way. Secondary drivers will not be asked to alter daily driving routines at all.

The vehicle is equipped with cameras. If participants drive into an area where cameras are not allowed, including international border crossings, certain military and intelligence locations, and certain manufacturing facilities, there is a risk that they may be detained or arrested or that the vehicle may be impounded.

The risk to primary drivers of completing the assessment activities while equipment is installed on the vehicle is no more than participants would experience doing activities in daily life like filling in forms, walking, squeezing their hand, and working at a computer. The assessment activities involve filling out forms, standard vision tests, and standard computer-based tests. It is believed that there are no more than minimal risks involved with such activities. The risk with using the grip strength tester is brief hand soreness. Participants will be asked to squeeze a grip strength tester and rapidly walk 10ft back and forth as fast as they can (for a total of 20 ft) without running or falling. The main risk with the Rapid Pace Walk is falling if a participant tries to go too fast. Because the assessment process may take up to four hours, participants may also get tired.

Because the vehicle camera system is storing continuous video, it is likely that it may capture some

incriminating evidence if an at-fault collision should occur.

6.2 EXPLAIN THE STUDY'S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

To minimize risk while driving, all data collection equipment installed in the vehicle 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 the driver's 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.

Researchers will explain to the participants that there are cameras installed in the vehicle and for this reason, participants should not drive the vehicle in any area where cameras are not allowed (e.g., international border crossings, certain military and intelligence locations, and certain manufacturing facilities). The Informed Consent/Assent will ask participants to agree not to drive into any such areas while participating in this study. We will provide a letter for the glove box which can be used to demonstrate the vehicle's role in the study while still maintaining participant privacy and confidentiality (Appendix G2).

Participants may take breaks during the assessment process if they become tired.

To help us further protect the privacy of participants, a Certificate of Confidentiality will be obtained to prevent the continuous video and sensor data from being used against research participants in the event of an at-fault collision. The consent form has the following language which will help the participants maintain the protections of the Certificate of Confidentiality:
"Throughout the study, we will take all possible steps to protect your privacy and keep confidential your role in the study and the confidentiality of your personally identifying information. 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. The protections provided by this certificate will be explained later in this consent form. However, you, too, are responsible for taking steps to protect your privacy and for keeping confidential your role in this study. Do not post this information on public websites or tell people about your participation. Treat this information the same way that you protect other personal, sensitive information such as your bank account numbers or computer passwords. If you do not keep confidential your role in the study, there is a risk that some of the data collected during the study, including your personally identifying information, may be used against you in a court case or other legal proceeding."

Finally, each site will be provided with training in issues which are specific to naturalistic driving studies. The training materials are provided in Appendix L and will help ensure that all sites treat participants in a consistent and respectful manner. Topics to be covered include:
- **Professionalism**
- **Recruitment**
- **Informed Consent**
- **Disqualification Guidelines**
- **Installation**
- **Driver Assessment**
- **Adverse Events**
- **Crash Investigation**
- **Data Retrieval**
- **Payment Issues**
- **Out-processing (de-enrollment)**
- **When to seek help from the Critical Issues Committee**
- **Role Playing**

Note that VTTI is setting aside travel funds for post-approval monitoring for this project (assuming one trip per site per year of data collection; also assuming one person traveling, and one day of monitoring, one night in hotel).

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

There are no direct benefits to participants from this research, other than they might find the experiment interesting. No promise or guarantee of benefits will be made to encourage participation. Participation will

result in a large dataset which will help to improve the body of knowledge regarding driving safety for years to come and, through examination and analyses of this dataset, lead to a better understanding of driving behavior and potential countermeasures to improve driving and traffic safety.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

☒ **No**
☐ **Yes**

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR MENTALLY DISABLED PERSONS?

☒ **No,** go to question 7.3
☐ **Yes,** answer questions within table →

IF YES
This research involves: ☐ Prisoners ☐ Pregnant women ☐ Fetuses ☐ Human in vitro fertilization ☐ Mentally disabled persons

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (http://www.irb.vt.edu/pages/categories.htm), it will not need to go to the Full Board.

☒ **No**
☐ **Yes**

IF YOU ANSWERED "YES" TO ***ANY ONE*** OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT'S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION: http://www.irb.vt.edu/pages/deadlines.htm

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link: http://www.irb.vt.edu/pages/confidentiality.htm

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☐ **No**
☒ **Yes,** to whom will identifying data be released? **During this study, only authorized project personnel and authorized employees of the research sponsors will have access to study data that personally identifies participants or that could be used to personally identify participants. The identifiable video and GPS data will be provided to the research sponsor and the other research partners under the terms of data sharing agreements or contracts**

that, at a minimum, provide participants with the same level of confidentiality and protection provided by the Consent Form. The research team, project sponsor, or research partners may also show specific clips of video at research conferences and project meetings. Participants' names, faces, or other identifying information such as addresses will never be associated with the showing of such video clips at conferences. The face portion of the video will be blurred, blacked out, or replaced with an animation/avatar at research conferences. It is expected that the data we capture throughout the course of the entire study 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, probably for decades to come (see exception noted below). 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 identifiable data (face video and Global Positioning System [GPS] coordinates) 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 participant confidentiality. The confidentiality protection provided to participants by these data sharing agreements will be as great as or greater than the level provided and described in the signed Informed Consent/Assent Form. Any further research efforts using identifiable data will also require additional IRB approval. Current plans are for future analyses of identifiable data to be conducted only in secure data enclaves as recommended by the NIH in their Data Sharing Workbook (see http://grants.nih.gov/grants/policy/data_sharing/data_sharing_workbook.pdf). Future computer technology may enable other methods of securely viewing and analyzing the data; if adopted for this project, every effort will be made to ensure that these new methods are as secure as the secure data enclaves.

If there is video data of a crash involving a serious injury and/or fatality, there will be even more stringent conditions for the data sharing policy described above. In these cases, the video of the crash itself will be kept in quarantine and viewed/reduced by a limited number of qualified researchers who have a legitimate research need to see the crash. Data for sharing using normal procedures will include video up to the instant of crash (so no impact or injury is viewable), vehicle sensor data, driver assessment data, driver injury information where available (for crash-injury biomechanics analysis), and reduced data (questions about the crash answered by the high-level research staff who have viewing privileges for entire video). The current version of the Severe and Fatal Crashes Policy is included as Appendix J.

8.2 WILL ANY STUDY FILES CONTAIN PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select "Yes."

☐ **No,** go to question 8.3
☒ **Yes,** answer questions within table

IF YES
Describe if/how the study will utilize study codes: Participants who provide verbal consent and who express interest in participation at the time of the eligibility screening will be automatically assigned a unique identifier for future processing and tracking. This identifier will be associated with the participant name and contact information in a database separate from any/all other databases that contain any form of participant data gathered in the study (e.g., video data, assessment data, driving data, questionnaire data, crash data, etc.). All participant data will only be associated with the unique identifier.
If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] **be stored and who will have access? Each site will maintain a key for participants located at that site. This key will be used to schedule ongoing activities such as setting up appointments for data download, conducting accident investigations, and scheduling the participant out-processing session at the end of the study. These keys will be kept on a secure computer, and access will only be allowed to those project personnel with a direct need for access (such as to schedule appointments). This key will be destroyed two months after all participants at a site have completed their participation.** **In addition, VTTI will maintain a master key of all participants at all sites. This master key will be destroyed two months after all sites have completed all data collection.**

At participant out-processing, each participant will be asked if they would like to retain their name in a database for possible future follow-up studies, such as longitudinal data about future crashes and citations. Linked code and identifying information will only be kept for those participants who agree to this. Access to this database will be restricted to VTTI and the original SHRP2 team members listed in question 1.2, and only for follow-on projects which attempt to gain deeper insight into the results of the data collected under this IRB approval.

Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.

The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.

8.3 WHERE WILL DATA BE STORED?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

Questionnaire data will be entered directly into the participant database.

The system installed in the vehicle will store the video data until it is downloaded by a study technician (approximately once every 3 to 6 months). The video, audio, and sensor data collected in the vehicle will be encrypted from the onset (at the time of recording) to prevent unauthorized access. The technician will swap out the encrypted portable hard drive and take the filled encrypted portable hard drive to the nearest SHRP 2 NDS data collection site.

A secure data server at each SHRP 2 NDS data collection site will be used exclusively for uploading the encrypted data from the hard drives to the secure servers at VTTI. The data will be automatically uploaded from the site contractor server to the VTTI server where it will be decrypted. After the data are verified at the VTTI server, the hard drives will be erased and placed back into circulation. Decrypted data will be stored at VTTI on a secure server during the course of the study. After the study is complete, data may be stored in one or more data warehouses, likely physically located near secure data enclaves, for future data mining efforts.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

Members of the research team will have initial access to the study data. The oversight contractor (VTTI) will have access to all study data. After the study is complete, the site contractors and other qualified researchers will be granted access to study data on a case-by-case basis for identifiable data, using data sharing agreements which provide at least as much protection to the participant as does the informed consent form under IRB approval. De-identified data will likely be posted online for wider use by qualified researchers and students. It is possible that the access will be under the control of a special committee at the National Academies which will be responsible for ensuring that all uses of the data comply with the original (or amended) IRB approvals and the consent forms signed by participants. This committee will also ensure that consistent standards are applied over time in terms of who may access the data, as well as which data they may access and under what conditions.

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

The data produced as a result of this study are expected to be used by traffic safety researchers and traffic engineers for many years into the future. For example, the data collected during the Indiana Tri-Level study, first published in 1979, is still occasionally re-analyzed and compared to contemporary data. For this reason, the video and other identifying data collected as part of this study will be retained in one or more secure data warehouses for up to 30 years after the last vehicle exits the study. At that point, the identifying data will be destroyed. De-identified continuous sensor data will be kept for 40 years after the last vehicle exits the study, De-identified summary data resulting from various analyses and reductions will be kept indefinitely.

Data distributed to other qualified researchers under the terms of data sharing agreements will have shorter retention times tied to the needs of the specific research project. For example, the data sharing agreement may call for the identifiable data to be destroyed one year after the project ends.

The vehicle condition checklist will be retained for one year after all participants at a site have left the study. The checklist is being retained as evidence of vehicle condition in case questions arise later about possible damage done to the participant's vehicle during installation or de-installation. These checklists will be stored in the same secure manner as other study components.

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

☐ **No,** go to question 9.1
☒ **Yes,** answer questions within table

IF YES
Does the study plan to obtain a Certificate of Confidentiality? ☐ No ☒ Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form) *For more information about Certificates of Confidentiality, visit the following link:* *http://www.irb.vt.edu/pages/coc.htm*

Section 9: Compensation

For more information about compensating subjects, visit the following link: http://www.irb.vt.edu/pages/compensation.htm

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

☒ **No,** go to question 10.1
☒ **Yes,** answer questions within table

IF YES
What is the amount of compensation? Participants who are primary drivers will be compensated as described below. Participants who are secondary drivers will not receive compensation. **Primary Drivers Enrolled for One Year** **Total payment for participation will be $300 per year, paid in 3 installments via direct deposit to participant's bank account or check. Payments will be scheduled as follows:** **1. After all participant intake paperwork is completed, the vehicle is instrumented, and all the driver assessments are completed, including the online questionnaires, participants will receive $100. This will cover months 1-4 of participation in the study.** **2. A second payment of $100 will be received after the 6th month of participation. This will cover months 4-8 of participation in the study.** **3. During the 12th month, after the participant returns to the site contractor's facility to have the system removed from the vehicle and completes a few final questionnaires, he/she will receive a final payment of $100. This will cover months 9-12 of participation in the study. The overall maximum payment for those who complete all requirements will thus be $300.**

Primary Drivers Enrolled for Two Years
Total payment for participation will be $600, paid in 5 installments via check or direct deposit to participant's bank account or check. Payments will be scheduled as follows:
1. After the vehicle is instrumented and all the driver assessment paperwork is completed, including the online questionnaires, participants will receive $100. This will cover months 1-4 of participation in the study.
2. A payment of $100 will be made after the 6th month of participation. This will cover months 4-8 of participation in the study.

3. A payment of $100 will be made after the 12th month of participation. This will cover months 9-12 of participation in the study.

4. A payment of $100 will be made after the 18th month of participation. This will cover months 13-16 of participation in the study.

5. During the 24th month, after the participant returns to the site contractor's facility to have the system removed from the vehicle and completes a few final questionnaires, he/she will receive a final payment of $200. This will cover months 17-24 of participation in the study. The overall maximum payment for those who complete all requirements will thus be $600.

Although not mentioned in the consent form, the project sponsor is willing to pay up to $100 to participants who drop out of the study but are recalcitrant about returning to the data collection site to have the data collection equipment removed from their vehicle. In no case will a participant receive total payment of more than $300 (for a one-year participant) or $600 (for a two-year participant), even with this additional equipment removal payment.

Will compensation be prorated?

☒ Yes, please describe: **If a participant leaves the study early, by their own choice or because they are asked to leave by someone on the study team, they will be paid $25 for every month of participation in the study (for payment purposes, a partial month at the conclusion would be considered a full month).**

☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?

Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link: http://www.irb.vt.edu/pages/recordings.htm

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

☐ **No,** go to question 11.1
☒ **Yes,** answer questions within table

IF YES
This project involves: ☐ Audio recordings only ☐ Video recordings only ☒ Both video and audio recordings

Provide compelling justification for the use of audio/video recording: Video data allows researchers to perform detailed analyses of driving behaviors and driver distraction that are unavailable via any other means. For example, standard variables used in analyzing driver distraction include "eyes off the road time" and "eye glance location." In determining crash or near crash causation, it is also important to classify and understand the external driving environment leading up to the incident. Video data collected from the cameras aimed toward the vehicle exterior accomplish this, providing researchers with information about visibility conditions, positions of other vehicles, potential distractions outside the vehicle, etc.

The audio recordings collected for this study will be created when a participant presses a button located near the rear view mirror. These recording will last 30 seconds and will allow the participant to make a statement about crash or near-crash events to the research team immediately after they happen. The audio recording files will flag the data stream collected from the sensors, and will provide invaluable insight into the event.

How will data within the recordings be retrieved / transcribed? Virginia Tech Transportation Institute has developed a software program that allows trained data reductionists to view the digital video files and code driver behaviors such as eye glance location, failure to signal, etc. The program saves and stores the coded data. Other researchers may use commercial off the shelf software to do the same thing, or may be provided a simple version of the VTTI viewer. The brief audio files triggered by the button press will be synced to the video and can be listened to in conjunction with the video. They may also be transcribed during the reduction process.

How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security? The system installed in the vehicle will store the encrypted video data until the hard drive is swapped out by a study technician (approximately once every 3 to 6 months). The video and audio data (audio only for 30 seconds after the incident button is pressed) will be encrypted from the onset (at the time of recording) to prevent unauthorized access. The technician will swap out the filled encrypted hard drive and take the filled encrypted hard drive to the nearest SHRP 2 NDS data collection site.

A secure data server at each SHRP 2 NDS data collection site will be used exclusively for uploading the encrypted data from the hard drives to the secure servers at VTTI. After the data are received and verified at the VTTI server, the hard drives will be erased and placed back into circulation. At this point the data will also be removed from the data collection site server.

Whenever feasible, the raw video and sensor data files will be held in servers in their encrypted format, only being decrypted as needed to process and analyze the data. These decrypted copies will be deleted upon completion of the processing that requires the decryption. Any access to these data for subsequent analysis will be through role-based access control methods, ensuring the researcher has the appropriate role to access the respective data. Data may also be filtered as needed to ensure they are desensitized as much as possible. Even researchers who may have access to more sensitive data will be encouraged to use the most "desensitized" data possible for subsequent research and analysis.

Who will have access to the recordings? The identifiable video and audio data will be provided to the research sponsor and the other research partners under the terms of data sharing agreements. The research team, project sponsor or research partners may also show specific clips of video at research conferences and project meetings. Participants' names, faces, or other identifying information such as addresses will never be associated with the showing of such video clips at conferences; the face portion of the video will be blurred, blacked out, or replaced with an animation/avatar at conferences.

It is expected that there will be follow-on data analyses conducted using all of the data (see exception noted below). 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 identifiable video and audio 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 participant confidentiality. The confidentiality protection provided to participants by these data sharing agreements will be as great as or greater than the level provided and

described in the signed Informed Consent/Assent Form. Any further research efforts using identifiable data will also require additional IRB approval.

If there is video data of a crash involving a serious injury and/or fatality, there will be even more stringent conditions for the data sharing policy described above. In these cases, the video of the crash itself will be kept in quarantine and viewed/reduced by qualified researchers who have a demonstrated need to view the video for the purposes of their research (such as scientists studying crash biomechanics). In these cases, data for sharing using normal procedures will include video up to the instant of crash (so no impact or injury is viewable except to those who have a need to see it).

Who will transcribe the recordings? At VTTI, trained data reductionists from the VTTI data reduction lab will transcribe these recordings. All VTTI reductionists have received Human Subjects Training.

At other sites, the data will be reduced in a secure environment according to the terms of a data sharing agreement. One of the stipulations of these agreements will be that all persons who are analyzing the identifiable data must have received Human Subjects Training.

When will the recordings be erased / destroyed? The data produced as a result of this study are expected to be used by traffic safety researchers and traffic engineers for many years into the future. For example, the data collected during the Indiana Tri-Level study, first published in 1979, is still occasionally re-analyzed and compared to contemporary data. For this reason, the video and other identifying data collected as part of this study will be retained in one or more secure data warehouses for 30 years after the last vehicle exits the study. At that point, the identifying video and audio data will be destroyed.

Data distributed to other qualified researchers under the terms of data sharing agreements will have shorter retention times tied to the needs of the specific research project. For example, the data sharing agreement may call for the identifiable data to be destroyed one year after the project ends.

Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

☐ **No,** go to question 12.1
☒ **Yes,** answer questions within table

IF YES
Does this study involve conducting research with students of the researcher? ☒ No ☐ Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation: *Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.*
Will the study need to access student records (e.g., SAT, GPA, or GRE scores)? ☒ No ☐ Yes

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

☐ **No,** go to question 11.3
☒ **Yes,** answer questions within table

IF YES
Will study procedures be completed during school hours? ☒ No ☐ Yes **If yes,** **Students not included in the study may view other students' involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:** **Missing out on regular class time or seeing other students participate may influence a student's decision to participate. Address how the study will reduce this outcome:**
Is the school's approval letter(s) attached to this submission? ☐ Yes ☐ No, project involves Montgomery County Public Schools (MCPS) ☒ No, explain why: **Teenage drivers who may be enrolled in high school will not be recruited through the schools, nor will they complete any study activities during school hours.** *You will need to obtain school approval (if involving MCPS, click here: http://www.irb.vt.edu/pages/mcps.htm). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.*

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

☐ **No,** go to question 12.1
☒ **Yes,** answer questions within table

IF YES
Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded: ☒ Included ☐ Actively excluded, describe how the study will ensure that minors will not be included:
Will extra credit be offered to subjects? ☒ No ☐ Yes **If yes,** **What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?** **Include a description of the extra credit (e.g., amount) to be provided within question 9.1 ("IF YES" table)**

Section 12: Research Involving Minors

12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

Note: age constituting a minor may differ in other States.

☐ **No,** go to question 13.1
☒ **Yes,** answer questions within table

IF YES
Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide? ☒ No ☐ Yes, thoroughly explain how the study will react to such reports: *Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.*
Are you requesting a waiver of parental permission (i.e., parent uninformed of child's involvement)? ☐ No, **both** parents/guardians will provide their permission, if possible. ☒ No, **only one** parent/guardian will provide permission. ☐ Yes, describe below how your research meets **all** of the following criteria (A-D): Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The waiver will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the waiver: Criteria D - (Optional) Parents will be provided with additional pertinent information after participation:
Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study? ☐ No ☒ Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors' previously provided assent and parents' permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects' data? If yes, explain how: **When minors are enrolled in the study, researchers will note their birth date. If a minor will be turning 18 years old during the course of his/her participation in the study, he/she will be scheduled to return to the site contractor's facility within one month of his/her 18th birthday to complete an adult Informed Consent Form.** *For more information about minors reaching legal age during enrollment, visit the following link:* *http://www.irb.vt.edu/pages/assent.htm*
The procedure for obtaining assent from minors and permission from the minor's guardian(s) must be described in ***Section 4*** *(Consent Process) of this form.*

Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at http://www.irb.vt.edu/pages/deception.htm

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

☒ **No,** go to question 14.1
☐ **Yes,** answer questions within table

IF YES
Describe the deception:
Why is the use of deception necessary for this project?
Describe the debriefing process:
Provide an explanation of how the study meets <u>all</u> the following criteria (A-D) for an alteration of consent: Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The alteration will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the alteration: Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception): *By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.*
The IRB requests that the researcher use the title "Information Sheet" instead of "Consent Form" on the document used to obtain subjects' signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.

Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

☒ **No,** you are finished with the application
☐ **Yes,** answer questions within table

IF YES
From where does the existing data originate?
Provide a detailed description of the existing data that will be collected or studied/analyzed:
Is the source of the data public? ☐ No, continue with the next question ☐ Yes, you are finished with this application
Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects: ▪ **Directly** (e.g., by name, phone number, address, email address, social security number, student ID number), or ▪ **Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc or ▪ **Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics)

☐ No, collected/analyzed data will be completely de-identified
☐ Yes,

If yes,

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? -select one-

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

----------END----------