INSTRUCTIONS:

- *Use this "TEMPLATE PROTOCOL (HRP-503)" to prepare a study protocol outlining your research plan.*
- *Depending on the nature of your study, some major sections might not be applicable to your research. If so, simply mark as "N/A." For example, a simple survey might have many sections with "N/A." For subsections (e.g., 1.x or 8.x) you can mark as "N/A"if you are certain that the subsection is not applicable.*
- *Once the IRB/HRPP approves your submission, your latest approved version of the protocol will be stored in the IRB Protocol Management online system.*
- *If your research plan changes and you need to modify the protocol, please submit an amendment to Protocol Management with the requested modifications. Download your current protocol from Protocol Management and indicate the changes/revisions using the track changes feature in order to make review of the modifications easier to follow. If you are unable to use track changes, please create a new paragraph wherever you need to make a change, and indicate "Amendment: Date" before making a change to any section. Protocol management will store the older versions of your protocol if the IRB or HRPP staff need to compare them during the review.*

PROTOCOL TITLE:

Include the full protocol title.

Trucking Fleet Concept of Operations (CONOPS) for Managing Mixed Fleets: Road Show Questionnaires

PROTOCOL NUMBER:

Include the number assigned in Protocol Management (verify this has been added before submitting protocol to HRPP).

20-358

PRINCIPAL INVESTIGATOR:

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Email Address: mwalker@vtti.vt.edu

FUNDING:

Sponsor(s): Federal Highway Administration (FHWA) and Federal Motor Carrier Safety Administration (FMCSA)
Funded already or in the proposal phase?: Funded

Is Virginia Tech the primary awardee or the coordinating center of this grant or contract? If not, list the primary institution: Yes

VERSION NUMBER/DATE:

Include the version number and date of this protocol. Versions should start at 1.0.

1.0

REVISION HISTORY:

Use this table to keep track of changes. Add more rows as needed.

Revision #	Version Date	Brief Summary of Changes (i.e., the different sections)	Consent Change?

Table of Contents

1.0 Study Summary

Study Title	Trucking Fleet Concept of Operations (CONOPS) for Managing Mixed Fleets: Road Show Questionnaires
Study Design	Questionnaires will be distributed to investigate attitudes toward truck automation, use cases where automation will provide economic and/or safety benefits, and the ways in which truck drivers and the driving public can expect to interact with truck automation.
Primary Objective	The primary goal of the questionnaires is to inform the CONOPS that will be developed in Phase II of this study, to improve clarity and completeness from the end user's perspective.
Secondary Objective(s)	N/A
Study Population	The participants will be those that attend the VTTI roadshows and conferences. Attendees tend to be those employed in or associated with the trucking industry and 18 years of age and older.
Sample Size	The questionnaires will be distributed at VTTI roadshows and other large gatherings of people. We are expecting approximately 100 participants will fill out the questionnaires at each of the three roadshows (300 total participants).
Research Intervention(s)/ Investigational Agent(s)	questionnaires
Study Duration for Individual Participants	Participants will be asked to take a pre- and post-questionnaire. Each questionnaire will take approximately 10 minutes.
Acronyms and Definitions	CONOPS - Concept of Operations ADS - automated driving system USDOT - United States Department of Transportation FMCSA - Federal Motor Carrier Safety Administration

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives of this study:

Although automated driving system (ADS)-equipped trucks hold the promise of increased safety, productivity, and efficiency, it is not clear how these vehicles should be integrated into fleet operations with conventional trucks. The primary goal of this study is to develop and demonstrate a pragmatic Fleet Concept of Operations or CONOPS. This

CONOPS will provide the trucking industry with clear guidelines on how to safely implement and benefit from ADS-equipped trucks.

To do this, VTTI will host up to three 'roadshows' to be held alongside existing truck shows and conferences. Each roadshow will include multiple hands-on demonstrations provided by various ADS vendors. As part of the roadshow, VTTI will distribute pre- and post-roadshow questionnaires to obtain opinions about the ADS technologies from members of the trucking industry who are attending the roadshow. The data from real-world demonstrations of the CONOPS will provide the U.S. Department of Transportation (USDOT) with critical data to inform rulemaking regarding ADS-equipped trucks.

The IRB protocols associated with this study will be broken down into two phases: I) road show questionnaires; and II) naturalistic data collection. The current protocol is for the road show questionnaires only (Phase I).

2.2 State the hypotheses to be tested:

ADS-equipped trucks hold the promise of increased safety, productivity, and efficiency with the trucking industry. However, most will operate in mixed-fleet operations (a combination of conventional and ADS-equipped trucks) for the foreseeable future. Information is needed from truck industry representatives regarding their opinions and perception of ADSs.

3.0 Background

3.1 Summarize the relevant prior research on this topic and gaps in current knowledge within the field of study:

The goal of this project is to demonstrate a safe, repeatable, commercially viable deployment of L4/L5 ADS technology that moves freight without the aid of the human operator. Current challenges on this topic include maintenance, inspection, driver state monitoring, insurance, identification of safety metrics, roadway infrastructure rating, data security/transfer, and cybersecurity. This study will aim to focus on each of these areas to gain a better understanding of the challenges and ways to improve.

3.2 Describe any relevant preliminary data:

Increasing demand for consumer goods and just-in-time inventory strategies (i.e., receiving goods only as they are needed) place a significant demand on truck drivers and the U.S. highway system as increasing amounts of goods are delivered by trucks. In 2016, the American Trucking Association estimated the truck driver shortage at roughly 63,000 drivers; the driver shortage is now the trucking industry's top concern.

3.3 Based on the existing literature, provide the scientific or scholarly rationale for and significance of your research and how will it add to existing knowledge:

The development of a readily accessible ADS will help mitigate the driver shortage concerns. The Pronto ADS to be used in this study, is a bolt-on aftermarket retrofit, which means that it will be 'backwards compatible' with the current generation of trucks. This means it can be installed on any truck after production and companies do not need to order brand new trucks where the ADS has to be installed during the initial build. ADS equipped trucks have the potential to significantly increase economic output as the delivery of goods via trucks is vital to the health of the U.S. economy.

The questionnaire data collected in this phase of the study will allow us to gather baseline opinions that members of the trucking fleet have regarding ADS technologies. Once they participate in the hands-on demonstrations, we will see if their opinions on the technologies have changed. This will allow us to generalize the acceptability of these technologies into the trucking industry.

4.0 Study Endpoints

*4.1 Describe the primary and secondary **study** endpoints. See links below for discussion of study endpoints and how they may differ from study objectives. These are most common in clinical trials but are sometimes applicable to other types of biomedical research, as well as social, behavioral, or educational research. See link below for a discussion.*

https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing

N/A

*4.2 Describe any primary or secondary **safety** endpoints. These should be included for all studies that are greater than minimal risk. (Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*:

The study involves no more than minimal risk. The minimal risks to the participant include possible minor discomfort from expressing opinions.

5.0 Study Design and Statistical Analysis Plan

5.1 Describe the basic study design/approach (e.g., qualitative study using five focus groups of first year students to describe assimilation into the university community; randomized controlled trial of a behavioral change intervention to increase dietary intake of whole grains; pre- post-test evaluation of new pedagogical techniques to improve adult literacy):

Phase I is a qualitative study where pre- and post-roadshow questionnaires will be distributed to road show attendees to obtain their opinions on the ADS technologies showcased during the demos.

5.2 Describe corresponding data analysis plan/approach (e.g., content analysis of focus group transcripts; descriptive analysis followed by linear regression modeling; nonparametric analysis of pre- and post-test measures):

The questionnaire data will be analyzed with a mix of descriptive statistics, chi-square statistics with frequency count data, and t-tests (e.g., pre-roadshow vs. post-roadshow) where appropriate. Open ended questions will be valuated using a content analysis. *Content analysis* is a research tool used to determine the presence of certain words, themes, or concepts within some given qualitative data (i.e., text). Using *content analysis*, researchers can quantify and analyze the presence, meanings and relationships of such certain words, themes or concepts.

6.0 Setting

6.1 Describe the sites or locations where your research team will conduct the research. Consider each of the items listed below:

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where the team will perform the research procedures.*
- *Describe the composition and involvement of any community advisory board(s).*
- *For research conducted in other locations, describe:*
  - *Site-specific regulations or customs affecting the research at those locations.*
  - *Local scientific and ethical review structure at those locations. Examples include work in other cultures or ethnic groups (within or outside of the U.S.) and work with churches. The HRPP will provide additional guidance for international research.*

VTTI will organize up to three 'roadshows' which will each include multiple hands-on demonstrations, as part of this project. The roadshows will be held at various truck shows and conference across the US such as the Mid-America

Trucking Show, the Great American Trucking Show, Consumer Electronics Show, Automated Vehicle Symposium, SAE COMVEC, or the North American Commercial Vehicles Show, all of which have strong participation from the trucking industry.

During these roadshows, technology vendors will provide hands-on demonstrations of their ADS technology such as in-vehicle demonstrations and closed-course scenarios. Attendees of the truck shows and conferences will be invited to participate in the hands-on demonstrations, during which the questionnaires will be distributed.

7.0 Study Intervention(s)/Investigational Agent(s)

7.1 Describe the study interventions (including behavioral interventions) and/or investigational agents (e.g., drugs or devices) to be used in this study. Consider each of the items listed below:

- *Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer the drugs or devices so that they will be used only on subjects, and only by authorized investigators.*
- *Describe whether any of the following will be used: microwaves, X-rays, DEXA scans, general anesthesia, or sedation*
- *If control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference the SOP in this section.*

The study does not involve any investigational agents (no drugs or devices). However, it does involve comparing questionnaire responses before a demonstration to those collected after the demonstration. In this case, the demonstration of ADS technology by the vendors could be considered the study intervention.

7.2 List the name of all drugs (including any vitamins, supplements, herbs, or nicotine) to be used in the study. Indicate whether they have FDA approval, and list any limitations for their use:

N/A

7.3 List all devices, how they will be used, their purpose in the study, and if they will be used in a manner consistent with their approved uses. If they will be used in ways that are not yet FDA approved, indicate whether they need an IDE or a determination that they are exempt from the IDE Determination. If a determination of significant risk or non-significant risk

is needed for any of the devices, include the researcher's recommendation for each of those devices:

N/A

7.4 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

N/A

8.0 Procedures Involved

8.1 Describe and explain the study design:

Pre- and post- roadshow data will be analyzed using non-parametric analysis techniques to determine whether experiencing hands-on demonstrations with various ADS technologies impacts the opinions of members of the trucking industry.

8.2 Provide a description of:

- *All research procedures being performed*
- *If the study has more than one procedure, session, and/or subject population, describe each procedure, session, and/or study population separately. For complex studies, you are encouraged to include a figure or chart.*

The research team will use the questionnaires listed in 8.3 to collect data for the study. Questionnaires will be loaded onto VTTI owned cell phones (no cellular service or wi-fi capabilities) which will be handed to participants at the start of the roadshow. Prior to the start of the roadshow, participants will be asked to

complete a pre-roadshow questionnaire (Appendix A). After the roadshow is complete, participants will be asked to complete a post-roadshow questionnaire (Appendix A). Questionnaires will be downloaded from the cell phones to VTTI secure servers after the roadshow is complete using a wired connection.

Participants will provide implied consent by completing the questionnaires. They will be asked to create an anonymous ID (e.g., first two letters of first name, first two letters of last name, and day of birth) and enter that ID on each questionnaire so questionnaires may be tied together.

8.3 Describe:

- *Procedures or safeguards intended to reduce the probability and magnitude of risks. (For example: Reducing the risk of injury in a virtual reality study either by having the subjects sit during the study or by providing an obstacle-free space for walking.)*
- *Be sure to describe all drugs and devices used in the research, when they will be administered or used, and their purpose.*
- *Methods used to collect data about subjects. Please upload all data collection forms to Protocol Management. Some common examples are:*
  - *Screening questionnaires*
  - *Survey(s), including online surveys*
  - *Demographic questionnaire(s)*
  - *Interview guide(s), e.g., questions or pool of questions for semi-structured interviews*
  - *Focus group guide(s)*
  - *Other documents used to collect data*

Procedures to reduce probability and magnitude of risk

1) No PII will be collected for this phase of the study. Participants will create an anonymous ID to tie the different questionnaires together. There will be no way to tie questionnaires back to individual participants.

2) The information collected for this effort is not considered sensitive information about the individual. We are simply collecting their opinions about the technology presented during the roadshow.

3) Participants can answer any question with the response 'I prefer not to answer this question' or opt out of submitting the questionnaires if they choose to do so.

Methods used to collect data about participants:

The research team will ask several demographic questions to collect data about the participants. These are included in the pre-roadshow questionnaire (Appendix A):

1) Pre-Roadshow Questionnaire - participant demographics (background and previous exposure to ADS) and pre-roadshow ADS trust/acceptance questionnaire

2) Post-Roadshow Questionnaire - post-roadshow ADS trust/acceptance questionnaire and demonstrations and ADS barriers (which demonstrations did they participate in and barriers in implementing ADS)

8.4 What data will you collect during the study and how you will obtain them? Please include descriptions of electronic data collection, database matching, and app-based data collection:

The research team will use cell phones to collect participant data. The pre- and post-study questionnaire will each be loaded onto a cell phone which will be distributed to participants at the beginning of the roadshow. Each questionnaire will be loaded in an app format. Once the participants submit their answers, the data will be stored on the phone and will not be accessible until researchers download the data to a computer. The phones will not require a password for participants to use, but a password will be required for researchers to access the submitted data. Once downloaded, the questionnaire data will be stored on a secure VTTI server.

8.5 Who will transcribe or code audio and/or video recordings?:

N/A

8.6 Include a description of any deception to be used in the study. Include justification for the use of deception (why the deception is necessary), describe the debriefing process, and describe how the study meets <u>all</u> the following criteria for alteration of consent (deception is considered an alteration of informed consent):

- *The research involves no more than minimal risk to the subjects*
- *The alteration will not adversely affect the rights and welfare of the subjects*
- *The research could not practicably be carried out without the alteration/deception*
- *(Optional but encouraged in most cases) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception)*

N/A

8.7 If the study involves long-term follow-up (once all research related procedures are complete), describe what data will be collected during the follow up period and when it will occur:

N/A

9.0 Data and Specimen Long Term Storage and Use

9.1 If you will store data or specimens for future use, describe where you will store the data or specimens, how long they will be stored, and how and by whom the data or specimens will be accessed:

The questionnaire data will be stored in a project folder on secure VTTI servers. Members of the VTTI study team will have access to this data. The data is de-identified and will be stored indefinitely. Questionnaires will be coded and summarized into a single file for each roadshow. Each file will be hosted on the VTTI Dataverse (https://dataverse.vtti.vt.edu/) for public download. The VTTI Dataverse allows for study data to be hosted publicly. The data will be stored on the VTTI Dataverse for as long as it is deemed relevant. Because the project is funded by federal funds (which includes public money), we are required to make de-identified data available for the public to use.

9.2 For specimens, list the data to be stored or associated with each specimen:

N/A

9.3 Describe the procedures to release data or specimens outside of the research team, including the process to request a release, approvals required for release, who can obtain data or specimens, and what data will be provided with specimens:

As noted in 9.1 above, the de-identified questionnaire data will be shared on the public VTTI Dataverse website.

9.4 Describe the identifiers to be included with stored data or specimens, as well as any key or code that could be used to make them identifiable. Describe where the code will be stored, who will have access to it, and when it will be destroyed:

The questionnaires will be tied together with an anonymous code created by each participate. When the questionnaire data is compiled into a single file, the anonymous code will be replaced with another anonymous code (e.g., 1001) created at VTTI. No identifying data will be collected on the questionnaires. The key tying the participant created anonymous code to the VTTI created anonymous code will be stored in the project folder on a secure VTTI server.

9.5 Please select the identifiers you will obtain (whether directly from participants or from another source), including but not limited to:

☐	*Name*
☐	*Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and equivalent geocodes (note, the initial three digits of a zip code are not considered identifiable)*
☐	*Elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and single year of age over 89 and all elements of dates (including year) indicative of such age (note, such ages and elements may be aggregated into a single category of age 90+)*
☐	*Phone numbers*
☐	*Fax numbers*
☐	*Electronic mail addresses (e-mail)*
☐	*Social Security numbers*
☐	*Medical record numbers*
☐	*Health plan beneficiary numbers*
☐	*Account numbers*
☐	*Certificate/license numbers*
☐	*Vehicle identifiers and serial numbers, including license plate numbers*
☐	*Device identifiers and serial numbers*
☐	*Web Universal Resource Locators (URLs)*
☐	*Internet protocol (IP) address numbers*
☐	*Biometric identifiers, including finger and voice prints (audio recording)*
☐	*Full face photographic images and any comparable images (including video recording)*
☐	*Student record number or identification number*
☐	*User name for online or computer accounts*
☒	*Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)**:*** Participants will create an anonymous ID (e.g., first two letters of name, first two letters of mothers maiden name, day of birth) to be used to tie their questionnaires together.

10.0 Sharing of Results with Subjects

10.1 Describe whether you will share results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject's primary care physician). If so, describe how you will share the results and include this

information as part of the consent document. Upload materials you will use to explain the results to subjects:

The results will not be shared directly with the participants; however, it is possible that the participants may view the results from the public VTTI Dataverse.

11.0 Study Timelines

11.1 Describe:

- *The duration of an individual subject's participation in the study (for example, 1 hour, 2-4 weeks, 3-5 years).*
- *The amount of time expected to enroll all study subjects (weeks, months, years, etc.)*
- *The amount of time expected for the investigators to complete this study including primary data analyses.*

Each questionnaire will take approximately 10 minutes. Participants will be asked to complete two separate questionnaires over the course of the roadshow (one before and one after each roadshow).

It is expected that VTTI will host the roadshows over a period of 3 years.

Analysis of the questionnaires and preparing the data for the public VTTI data repository is expected to take two months.

12.0 Inclusion and Exclusion Criteria

12.1 Describe how you will screen individuals for eligibility. When will screening occur and what procedures will you use? Upload any screening scripts or surveys to Protocol Management:

Anyone attending the roadshow is eligible to participate and complete the questionnaires.

12.2 Describe the eligibility criteria that define who will be included and who will be excluded from enrollment for each procedure of your study. Include any geographic criteria (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France):

Anyone attending the roadshow is eligible to participate in the questionnaires. It is expected that those attending the roadshow will be those employed or interested in the trucking industry. We do not expect any minors to attend the roadshows.

12.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate them in the description of your subject population.)

- *Minors, as defined by state law where the study is performed (infants, children, teenagers)*
- *Pregnant women (can be included in minimal risk studies by mentioning in section 13.1)*
- *Prisoners (including all incarcerated individuals)*
- *Adults not capable to consent on their own behalf*

Minors will be excluded from this study. When distributing the questionnaires, we will indicate that participants must be 18 years or older.

We will not be screening specifically for pregnant women, they may participate in the questionnaires if they are attending the roadshow.

It is assumed that prisoners will not be in attendance of the roadshows.

Adults not capable to consent on their own behalf will be excluded.

13.0 Vulnerable Populations

13.1 If the research involves individuals who are vulnerable to coercion or undue influence, please describe additional safeguards you will include to protect their rights and welfare. Consider the applicable items listed below:

- *If the research involves Virginia Tech students, indicate whether these are students of any of the investigators. If so, describe whether the activities will take place during class time as part of the curriculum and the steps you will take to reduce the possibility that students feel obliged to participate in order to improve their course grade. The HRPP can provide further guidance as needed. Describe whether you will request access to student records (e.g., SAT, GPA, GRE scores).*
- *If the research involves employees of Virginia Tech or the research sponsor, describe steps you will take to ensure that the employees are freely participating and describe how their data will be protected from inspection by their supervisors.*
- *If the research involves Virginia Tech NCAA athletes, you must obtain approval from the athletic department.*

- *For research involving Montgomery County Public Schools, you must obtain county approval (after obtaining contingent Virginia Tech approval). Other locales have different requirements; please check on these and describe here. 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 be uploaded as a supporting document.*
- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (minors), review the "CHECKLIST: Minors (HRP-416)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information in this protocol.*

N/A

14.0 Number of Subjects

14.1 Indicate the total number of subjects to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available subjects in a finite pool, number of tests funding award would allow):

Questionnaire participation will be dependent on roadshow participation. There are no set goals as to how many participants we will include. Anyone willing to participate will be included. We estimate approximately 100 participants will fill out questionnaires at each of the three roadshows.

14.2 If this is a multi-site study, indicate the number of subjects to be enrolled at this site and the total to be enrolled from all sites:

It is expected that the roadshows will take place in various locations across the U.S. The number of participants at each location will depend on the roadshow participation. There are no set goals as to how many participants we will include at each location. Anyone willing to participate will be included.

14.3 If applicable, indicate the number of potential subjects you expect to screen for enrollment, and the number of subjects you will need to complete the research procedures:

Participants will not be screened for enrollment, per se. Anyone attending the roadshow is eligible to participate.

14.4 If the study has more than one procedure, indicate the total number of subjects to undergo each procedure separately:

N/A

15.0 Recruitment Methods

15.1 Describe when, where, and how you will recruit potential subjects:

Participants (i.e., members of the trucking industry) will be attendees of the conferences or truck shows at which the roadshows will be held. As attendees enter the roadshow area, they will be asked to complete the questionnaires (Appendix B).

15.2 Describe the source of subjects (for example, clinic patients with specific conditions, students in the library, community members at a gathering, or members of a local gym):

Participants will be members of the trucking industry that attend a VTTI roadshow.

15.3 Describe the methods that you will use to identify potential subjects:

Any attendee entering the roadshow will be asked to complete the questionnaires.

15.4 Describe materials that you will be use to recruit subjects. Attach copies of these documents with this protocol in Protocol Management and be sure to include the IRB protocol number on each document.

- *For flyers, attach the final copy of printed flyers.*
- *For Virginia Tech News, Facebook postings and ads, newspaper ads, websites, MTurk/SONA/online survey systems, etc., attach the final wording and graphics to be used.*
- *For email recruitments, please include the subject line.*
- *For advertisements meant for audio broadcast, please submit the wording of the advertisement prior to taping (to avoid having to re-record with approved language) and submit the final recorded version for IRB review before use.*
- *Describe any compensation to subjects. Separate compensation into appropriate categories, such as: reimbursement for expenses, time and effort, and additional incentives for study participation. For each category, specify the amount (including any pro-rated amount), schedule, and method of payment.*

Attendees will be read the Questionnaire Distribution Script (Appendix B) as they enter the roadshow, asking if they would like to participate.

Compensation
Participants will not receive compensation for study participation.

16.0 Withdrawal of Subjects

16.1 Describe circumstances under which you anticipate subjects could be withdrawn from the research without their consent:

N/A

16.2 If applicable, describe any procedures for orderly termination (e.g., discontinuation of a study drug or debriefing after a behavioral intervention):

N/A

16.3 Describe procedures that you will follow when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (e.g., participant declines to continue with regular blood draws, but continues with periodic behavioral questionnaires):

If a participant chooses to withdraw from the study before completing all questionnaires, we will keep any data collection prior to their withdrawal.

17.0 Risks to Subjects

17.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include for the IRB's consideration a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, and economic risks. Do not indicate "No risk" or "N/A." Instead, for studies with very low risk (e.g., anonymous online questionnaire on a mundane topic) indicate "The investigators are not aware of any risks from participation in this study." or "No more than risks than are found in everyday life." The example consent form presents a tabular method for risk information, which you can also use here. Common risk types include:

- *Physical (e.g., potential for pain, discomfort, infection)*
- *Psychological (e.g., potential for stress, discomfort, and/or embarrassment)*
- *Social (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*

- *Legal (e.g., potential for disclosure of illegal activity, negligence)*
- *Privacy (e.g., potential for personal information being accessed, used, or disclosed without the subjects' knowledge or consent, breach of confidentiality/security)*
- *Economic (e.g., potential for individuals to lose access to economic services, employment, insurability)*

The risks to participants in this study are minimal.

17.2 Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)

All data is de-identified at the onset of collection.

Participants can skip questions or choose not to submit questionnaires.

The questionnaires are not collecting sensitive data about the participants.

Participating in the study and completing the questionnaires is not required in order to attend the roadshow and participate in demonstrations.

17.3 If applicable, indicate which procedures might have risks to the subjects that are currently unforeseeable. This will be rare, and usually applicable when testing a new drug or device or a new use of an existing drug or device:

N/A

17.4 If applicable, indicate which procedures might have risks to an embryo or fetus should the subject be or become pregnant:

N/A

17.5 If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships):

N/A

18.0 Potential Benefits to Subjects

18.1 Describe the potential benefits that individual subjects might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits, as this will be useful to the IRB's risk:benefit analysis. Do not include benefits to society or others. Do not

list monetary or non-monetary compensation for participation, as this is not a benefit These should be included in section 2 or 3 of this document:

Participants may feel like they contributed to the knowledge of ADS development in this study.

18.2 If applicable, specify that there are no anticipated direct benefits for participants:

There are no anticipated direct benefits for participants.

19.0 Data Management and Confidentiality

19.1 Describe procedures that you will use for quality control to ensure validity of collected data:

Participants will complete each questionnaire on a VTTI owned cell phone. The cell phone will prompt participants to the next question to avoid inadvertently skipping a question. They will be given an option within each question of 'I prefer not to answer this question' in case they choose not to answer.

19.2 Describe any existing data or biospecimens you will obtain as part of this study. Include:

- *Variables or samples to be obtained*
- *Source of the data or specimens*
- *Your authorization to access or receive the data or biospecimens*
- *Whether the data or biospecimens are publicly available*
- *Whether the data or specimens you receive will contain identifiers*

N/A

19.3 Describe the steps that you will take to handle and secure study data during data collection, storage, use, and transmission. Include information about training of study staff, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc.:

Questionnaire data will be collected and stored on VTTI cell phones. Participants will be handed a cell phone when they enter the roadshow and will return it when they are finished. The completed questionnaire data can only be downloaded by a VTTI researcher and download capabilities will be password protected. The data will be stored on VTTI secure servers

with access limited to the research team. While the open-ended questions do not ask for identifying information, these answers will be reviewed, and any potential identifying information will be removed before posting data to the public VTTI Dataverse. The participants' self-assigned ID will also be removed before posting data to the public VTTI Dataverse.

19.4 For multi-site studies, describe how data or specimens will be handled and secured for each site (e.g., central or disseminated data storage, data coordinating center):

While there will be multiple sites, data collection will not take place at multiple sites at the same time. The data collection and security will be handled using the same methods by members of the research team at each of the different sites (roadshows).

19.5 Describe the plan for data disposition following the conclusion of the study (e.g., long term maintenance of data, data destruction methods).

- *What information will be included in the long term storage of data or specimens?*
- *How long will the data or specimens be stored?*
- *Where and how data or specimens will be stored?*
- *Who will have access to the data or specimens during long term storage?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How will data or specimens be shared or transported?*
- *When and how will personal identifiers be destroyed?*

The questionnaire data will be de-identified and therefore kept indefinitely. The data will be posted to the public VTTI Dataverse.

20.0 Provisions to Protect the Privacy Interests of Subjects

20.1 Describe the steps that you will take to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information (e.g., collecting the minimal amount of private information required to complete the study, protecting the data once it is obtained):

Personally identifying information will not be collected during this study. Self- assigned anonymous IDs will be used to tie the questionnaires together. The research team will replace the self-assigned IDs with new anonymous IDs once the data has been downloaded and compiled.

Participants can skip questions or choose not to submit questionnaires.

20.2 Describe steps that you will take to make subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures (e.g., use of a same gender investigator to place sensors on the torso, a private changing area if clothing must be changed, sensitivity when discussing pregnancy testing with subjects, making it clear on surveys that participants can discontinue at any time, not asking questions about private or sensitive issues unless necessary for the research):

Each question will include a response option that says 'I prefer not to answer this question' that the participant may chose if they feel uncomfortable answering.

20.3 Describe how you plan to access existing sources of information about the subjects (e.g., medical records, grades) and how you will protect participant privacy through the data security plan:

N/A

20.4 Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods. Examples for Virginia and Virginia Tech include:

- ***Any*** *suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect*
- *Sexual discrimination and/or sexual violence that involves a student*
- *Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)*
- *Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)*
- *Suspected abuse, neglect or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)*

N/A

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Safety monitoring is required when research involves greater than minimal risk and is sometimes appropriate for other studies.

21.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring*

committee, reporting data monitoring committee findings to the IRB and the sponsor).

- *What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the safety data and with what frequency.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).*

N/A

22.0 Compensation for Research Related Injury

22.1 If the research involves more than minimal risk to subjects, describe the available compensation in the event of research-related injury, if any:

N/A

22.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury. At Virginia Tech, this is most common for sponsored research:

N/A

23.0 Economic Burden to Subjects

23.1 Describe any costs that subjects might be responsible for because of participation in the research, including any uncompensated costs for items such as transportation, missed work, and childcare:

N/A

24.0 Consent Process

24.1 Indicate the process by which you will obtain consent for study participation. Please upload all consent, parental permission, and assent forms, documents, and scripts referenced in this section to Protocol Management.

Describe the following:

- *Where the consent process will take place (e.g., clinic waiting area, classroom, online)*

- *The time interval between sharing the consent information with the prospective subject and obtaining consent. For lab, interview, and focus group studies, the Virginia Tech IRB prefers that subjects have at least 24 hours to review the consent form and study information before the appointment where consent will be obtained. For simple online survey studies, you can typically present the consent information immediately before subjects begin participation.*
- *If applicable, processes to ensure ongoing consent or assent (e.g., for multiple sessions; for research in which a minor will turn 18 during the study; for longitudinal research with minors who will later be asked to provide or affirm their assent).*
- *Please review "SOP: Informed Consent Process for Research (HRP-090)" for recommended procedure. Describe your process, being sure to include:*
  - *The name and role of all study personnel who will be trained and certified by the PI to conduct the consent process*
  - *The time that will be devoted to the consent discussion*
  - *Steps that you will take to minimize the possibility of coercion or undue influence*
  - *Steps that you will take to gauge or ensure the subjects' understanding*

Consent will be implied by the participants willingness to complete and submit the questionnaires. A statement with this information will be included at the top of each questionnaire.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If non-English speakers will be recruited, describe the process you will use to ensure that the oral and/or written consent information provided will be in a language that they understand.*
- *If you translate consent forms and study materials, please provide a certified translation of the form as well as the certification document.*
- *Indicate the spoken language that study personnel obtaining consent will use. Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.*

N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- *Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations (i.e., that it meets the criteria for a waiver or alteration of the consent process).*

  N/A

Subjects who are not yet adults (minors: infants, children, teenagers)

- *Describe the criteria that you will use to determine legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., in Virginia, individuals under the age of 18 years).*
  - *For research conducted in Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "minor."*
  - *For research conducted outside of the state, please describe the legal requirements for the definition of "minor."*
- *Describe the process for obtaining parental permission.*
  - *Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor subject.*
  - *Permission from both parents is required in all other cases (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor).*
- *Describe whether you will obtain permission from individuals other than parents or Legally Authorized Representatives, and if so, who will be allowed to provide permission. Describe the process you will use to determine these individuals' authority to consent to the minor's general medical care.*
- *Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minors will be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent. However, teenagers are likely able to read and sign an assent form).*
- *When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?*
- *Attach parental permission and minor assent forms or scripts in Protocol Management.*

N/A

Adults Unable to Consent

- *Describe the process you will use to determine whether an individual adult is capable of consent.*
- *List the individuals from whom you will obtain permission in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and non-minor child).*
  - *For research conducted in the Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "legally authorized representative."*
  - *For research conducted outside of Virginia, please describe the legal requirements for obtaining permission from a legally authorized representative in the state where the research will occur.*
- *Describe the process for assent of the subjects.*
  - *Indicate whether you will require assent from all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.*
  - *If you will not obtain assent from some or all subjects, please provide justification for not obtaining assent.*
  - *Describe whether and how you will document assent.*

N/A

25.0 Process to Document Consent in Writing

25.1 Consult "SOP: Written Documentation of Consent (HRP-091)" for recommended procedures, and describe whether and how consent of the subject will be documented in writing:

This study will not document consent in writing. Consent will be implied when the participant chooses to submit the questionnaire.

25.2 If the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, you can request that the IRB waive the requirement to obtain written documentation of consent (e.g., consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins):

We are requesting that the IRB waive the requirement to obtain written consent. Consent information will be presented at the top of each questionnaire. Consent to participate will be indicated by submitting the questionnaire.

25.3 If you will document consent in writing, attach a consent document with places for signatures. If you will obtain consent, but not document consent in writing, please attach the consent script or text. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You should use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script:

Detailed consent information will be presented as the front page participants see on the phone (see Appendix A). Each subsequent questionnaire will provide shortened consent information at the onset to remind participants that their participation is optional, that they can skip questions, and that their consent is implied by submitting the questionnaire (see top of questionnaires in Appendix A).

26.0 Resources Available

26.1 Describe the resources available to conduct the research. For example, as appropriate:

- *Describe the PI's availability to supervise the research.*
- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated or unanticipated consequence of participation in the research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions (e.g., training plans, detailed study notebooks).*

The PI and several lead researchers will be present at each roadshow and available to answer questions and help participants as needed. The research team has been conducting heavy vehicle research for almost 25 years and has collected a large number of contacts in the trucking industry who we expect to attend the roadshows. In addition, we have

close connections with the Federal Motor Carrier Safety Administration (FMCSA) who may help provide additional fleet contact information that can be used to invite companies to attend. It is anticipated that we will conduct three separate roadshows, one in 2020, one in 2021, and one in 2022. It is estimated that approximately 125 people will attend each roadshow, and of that 100 participants will fill out the questionnaires at each roadshow (300 total).

VTTI will collect the questionnaire data over a three year period. It is expected that analysis and preparing the data for the public VTTI Dataverse will take two months.

The roadshows will take place at different conventions/facilities over the years. VTTI will obtain presentation/booth space at these facilities. The questionnaire data will be stored on secure VTTI servers in Blacksburg.

All researchers assisting with the project have completed training in the protection of human subjects and will be trained in study protocols before attending a roadshow and collecting data for the study.

27.0 Multi-Site Research

Contact the HRPP for multi-site research (involving multiple institutions) and the details required for this section will be provided. Otherwise, indicate N/A.

N/A