

Connected Vehicle Pilot Deployment Program Phase 1

Human Use Approval Summary –
ICF/Wyoming

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16. Abstract The Wyoming Department of Transportation's (WYDOT) Connected Vehicle (CV) Pilot Deployment Program is intended to develop a suite of applications that utilize vehicle to infrastructure (V2I) and vehicle to vehicle (V2V) communication technology to reduce the impact of adverse weather on truck travel in the I-80 corridor. These applications support a flexible range of services from advisories, roadside alerts, parking notifications and dynamic travel guidance. Information from these applications are made available directly to the equipped fleets or through data connections to fleet management centers (who will then communicate it to their trucks using their own systems). The pilot will be conducted in three Phases. Phase I includes the planning for the CV pilot including the concept of operations development. Phase II is the design, development, and testing phase. Phase III includes a real-world demonstration of the applications developed as part of this pilot. This document presents a summary on the steps taken in regards to human use approval required for the CV Pilot in Phase 1 in preparation for Phase 2 and 3. The document explains the Federal regulations and the Institutional Review Board (IRB) application and approval processes to protect human participants in the pilot. The human use summary documents the IRB application, obtaining participants' consents, review process, and how the pilot team addressed the IRB comments and secured the IRB approval for Phase 2 and 3. The process for amending and renewing the IRB application and approval throughout the project period is also discussed. The interdependency between the human use regulations and policies and the development of the Pilot Deployment Concept of Operations, Privacy and Security Management Operating Concept, Safety Management Plan, Training and Education Plan, Performance Measurement and Evaluation, as well as the Comprehensive Pilot Deployment Plan was full integrated. Various relevant contents produced in these tasks were utilized directly and indirectly as part of the IRB application and approval process.					
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1 Introduction

1.1 System Overview

Wyoming Department of Transportation (WYDOT) is one of the first wave of Connected Vehicle (CV) Pilot sites selected to showcase the value of and spur the adoption of Connected Vehicle Technology in the United States. Connected Vehicle Technology is a broad term to describe the applications and the systems that take advantage of dedicated short-range communications (DSRC) between vehicle to vehicle (V2V), vehicle to infrastructure (V2I) and infrastructure to vehicle (I2V) to improve safety, mobility and productivity of the users of the nation's transportation system.

As one of the three selected pilots, WYDOT is focusing on improving safety and mobility by creating new ways to communicate road and travel information to commercial truck drivers and fleet managers along the 402 miles of Interstate 80 (I-80 henceforth) in the State. For the pilot project, WYDOT will work in a planning phase through September 2016. The deployment process will happen in the second phase (ending in September 2017) followed by an 18-month demonstration period in the third phase (starting in October 2017). At a very high level, the pilot scope includes the following implementation elements:

- **Deployment of about 75 roadside units (RSU)** that can receive and broadcast messages using DSRC along various sections on I-80.
- **Equip around 400 vehicles, a combination of fleet vehicles and commercial trucks, with on-board units (OBU).** Of the 400 vehicles, at least 150 would be heavy trucks. All vehicles are expected to be regular users of I-80. Several types of OBU are being procured as part of the pilot and differ based on their communication capabilities, ability to integrate with the in-vehicle network, and connectivity to ancillary devices and sensors. All OBUs will have the functionality to broadcast Basic Safety Messages (BSM) Part I and will include a human-machine interface (HMI) to share alerts and advisories to drivers of these vehicles.
- **Develop several V2V and V2I (and I2V) applications** that will enable communication with drivers for alerts and advisories regarding various road conditions. These applications include support for in-vehicle dissemination of advisories for collision avoidance, speed management, detours, parking, and presence of work zones and maintenance and emergency vehicles downstream of their current location.
- **Enable overall improvements in WYDOT's traffic management and traveler information practices** by using data collected from connected vehicles. Targeted improvements include better activation of variable speed limits (VSL) and improved road condition dissemination via 511, Dynamic Message Signs (DMS) and other WYDOT sources.

Systems and applications developed in the pilot will enable drivers of connected vehicles to have awareness of hazards and situations they cannot even see. The CV Pilot is considered a System

of Systems, with two system of interest: The Vehicle System and the Wyoming CV System, see Figure 1-1. The *Vehicle System* includes four subsystems that represent the various vehicle and equipment types to be used in the pilot. These subsystems vary in their data collection and sharing capabilities. The *Wyoming CV System* includes the infrastructure used in the pilot and back-office systems in charge of the various processes that lead to the generation and distribution of advisories and alerts. Together, the Vehicle and Wyoming CV Systems support a variety of V2V and V2I applications. Both systems interface with external systems, including WYDOT, USDOT and the National Weather Service (NWS).

The CV Pilot Project will, at its core, provide key information to the drivers through five on-board applications: i) Forward Collision Warning (FCW); ii) I2V Situational Awareness (SA); iii) Distress Notification (DN); iv) Work Zone Warning (WZW); and v) Spot Weather Impact Warning (SWIW). Through them, WYDOT hopes to improve operations on the corridor especially during periods of adverse weather and when work zones are present. By means of the anticipated outcomes of the pilot, fleet managers will be able to make better decisions regarding their freight operations on I-80, truckers will be made aware of downstream conditions and provided guidance on parking options as they travel the corridor, and automobile travelers will receive improved road condition and incident information through various existing, improved and new information outlets.

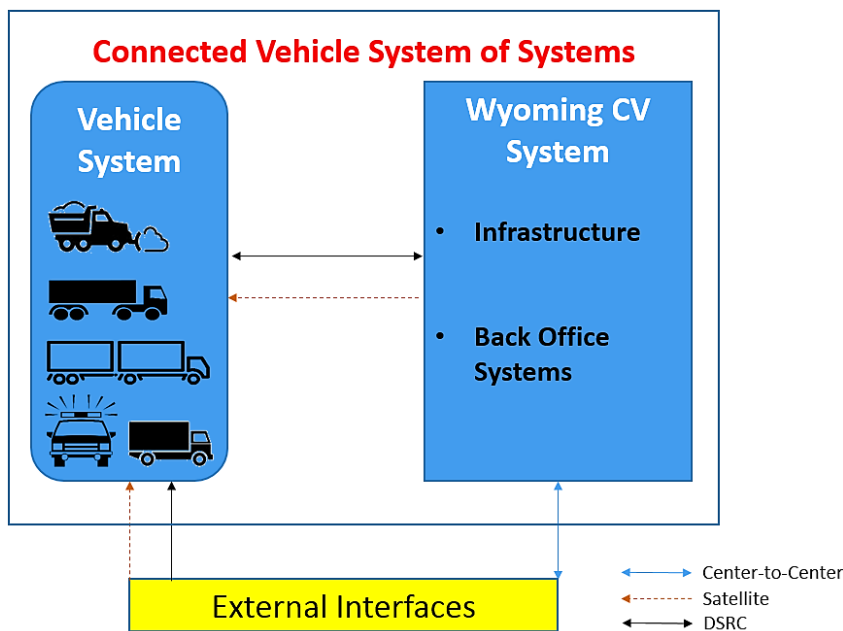


Figure 1-1 Wyoming CV Pilot System of Systems.

A detailed explanation of the Wyoming CV Pilot project can be found in *Connected Vehicle Pilot Deployment Program Phase I, Concept of Operations (ConOps)* (Gopalakrishna, et al., 2015).

1.2 Human Use Approval Summary (HUAS) Objectives

This document is an overview of human use approval required for the CVP deployment. The document explains the Federal regulations and the Institutional Review Board (IRB) application and approval processes to protect human participants in the pilot. The human use summary

documents the IRB application, obtaining participants' consents, review process, how the ICF/ Wyoming team addressed the IRB comments and secured the IRB approval for Phase 2 and 3, and the process for amending and renewing the IRB application and approval throughout the project period, respectively.

1.3 Organization of the Report

This report is divided into eight sections that tackle the different aspects of the Human Use Approval Summary. Particularly:

- Section 2 provides a list of the references used in this document.
- Section 3 provides notes and a glossary of acronyms used in this report.
- Section 4 describes the human use elements.
- Section 5 describes the approval process.
- Section 6 defines the approval management process.
- Section 7 defines the roles and responsibilities of the team and stakeholders.
- Section 8 explains existing dependencies and constraints.
- Section 9 concludes the report.

2 References

The following table lists the documents, sources and tools used to develop the concepts in this document.

Table 2-1. References.

#	Documents, Sources Referenced
1	Deepak Gopalakrishna, et al. (2015). <i>Connected Vehicle Pilot Deployment Program Phase I, Concept of Operations (ConOps)</i> , ICF/Wyoming. U.S Department of Transportation.
2	Deepak Gopalakrishna, et al. (2015b). <i>Connected Vehicle Pilot Demonstration: Phase I, ICF/Wyoming: Privacy and Security Management Operating Concept</i> . U.S Department of Transportation.
3	Deepak Gopalakrishna, et al. (2015c). <i>Connected Vehicle Pilot Demonstration: Phase I, ICF/Wyoming: Safety Management Plan</i> . U.S Department of Transportation.
3	Fred Kitchener, et al. (2015e). <i>Connected Vehicle Pilot Demonstration: Phase I, ICF/Wyoming: Performance Measurement and Evaluation Support Plan</i> . U.S Department of Transportation.
4	Mohamed Ahmed, et al. (2015h). <i>Connected Vehicle Pilot Demonstration: Phase I, ICF/Wyoming: Participant Training and Education Plan</i> . U.S Department of Transportation.
5	Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
6	U.S. Department of Health & Human Services (2009). Code of Federal Regulations Title 45 Public Welfare, Part 46: Protection of Human Subjects. Washington, DC.
7	U.S. Department of Health & Human Services, IRBs and Assurances
8	U.S. Department of Health & Human Services, Office of Human Research Protections
9	Helland A Jenssen G Lervåg L Westin A Moen T et. al., Comparison of driving simulator performance with real driving after alcohol intake: A randomized, single blind, placebo-controlled, cross-over trial, <i>Accident Analysis & Prevention</i> , 2013 vol: 53 pp: 9-16
10	National Highway Traffic Safety Administration Visual-Manual NHTSA Driver Distraction Guidelines for In-Vehicle Electronic Devices, April 26, 2013

3 Notes and Glossary

The following table defines selected project specific terms used throughout this Training and Education Plan document.

Table 3-1. Acronym List.

Acronym/ Abbreviation	Definition
CA	Construction Administration
CDL	Commercial Driving License
ConOps	Concept of Operations
CV	Connected Vehicle
CVOP	Commercial Vehicle Operation Portal
DSRC	Dedicated Short Range Communication
DVI	Driver-Vehicle Interface
FHWA	Federal Highway Administration
FWA	Federal-Wide Assurance
HHS	Health and Human Services
HMI	Human-machine interface
HUA	Human Use Approval
I-80	Interstate 80
I2V	Infrastructure to Vehicle
IE	Independent Evaluator
IRB	Institutional Review Board
ITS	Intelligent Transportation Systems
NWS	National Weather Service
OBU	On-board unit
OHRP	Office for Human Research Protections
RSU	Roadside unit
PII	Personally Identifiable Information
PM & ES	Performance Measurement and Evaluation Support
SCMS	Security Credential Management System
T&E	Training and education

Section 3. Notes and Glossary

TMC	Transportation Management Center
UW	University of Wyoming
V2I	Vehicle to infrastructure
V2V	Vehicle to vehicle
VSL	Variable Speed Limit
WYDOT	Wyoming Department of Transportation
WHP	Wyoming Highway Patrol
WYOSIM	Wyoming Driving Simulator Lab

4 Human Use Elements

This document provides a summary on Human Use Approval (HUA) process required in Phase 1 in preparation for the CV Pilot development, testing, training and education, and deployment involving human subjects (e.g., drivers of equipped vehicles) in Phase 2 and 3.

4.1 Human Use Elements and Issues

The significant abuses in the conduct of research such as the Nazi human experimentation on prisoners sparked the need of regulations controlling the use of human subjects in research. Nuremberg Code was one of the first efforts to establish protections and protocols based on moral, and ethical and legal concepts. The 1979 Belmont Report was a key milestone in the U.S. to identify three crucial principles in conducting ethical research involving human subjects, these principles were considered by the pilot team as follows:

1. **Respect for Persons.** This principle incorporates two main ethical convictions at a minimum: 1) autonomy of subjects, and 2) if autonomy cannot be achieved, additional protections should be provided. Moreover, subjects should voluntarily consent to show that they have full understanding of the research and its benefits and risks they will be involved in to make informed decision. The pilot will obtain and maintain informed consent from all potential research subjects involved in the CV Pilot.
2. **Beneficence.** The design and conduct of all the CV Pilot applications, testing, training, deployment, and performance evaluation will be conducted to “do no harm” to subjects, and maximize research benefits while minimizing risks to subjects. Research risks were systematically identified in the Safety Management Plan, these risks will be assessed to ensure that unacceptable risks are not taken and the risks are reduced to minimum while conducting the research in Phase 2 and 3.
3. **Justice.** Equitable selection, recruitment, and fair treatment of participants will be implemented in the CV Pilot.

The pilot team has considered all the IRB regulations described in the Belmont Report as well as the University of Wyoming policies and procedures manual to protect human subjects in the development of all the interdependent tasks in the CV Pilot Phase I planning activities.

4.2 Human Use Plan

The pilot team’s human use plan is predicated on approval from an accredited Institutional Review Board (IRB). The IRB certification as well as proper training for all the principal investigators and researchers involved in the CV-Pilot must take place prior to any recruitment activity for participants. The IRB at the University of Wyoming (UW) will act as the IRB of record for the pilot. The UW IRB will maintain adequate documentation of the membership files and IRB roster, records required of and related to the study protocol. All records will be made accessible

for inspection and copying by authorized representatives, university officials, and internal auditors at reasonable times and in a reasonable manner.

According to the human use regulations, the human use lead of the project will maintain, in a designated locations, the signed informed consent forms and the written research summary for at least three years after completion of the research. The signed consent forms and the written research summary will be made accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

The team's IRB proposal for Phase 2 and consists of 10 main sections including the following:

- List of responsible project investigators.
- Title and duration of the study.
- Purpose of the CV Pilot project.
- Description of potential participants.
- Descriptions of participants' activities and involvement in the project, location of the study, methods of data collection, equipment used, and termination of participation.
- Confidentiality procedures.
- Benefits to participants.
- Risks to participants.
- Description of procedure to obtain informed consent or other information to be provided to participant.
- Attachments of the Informed Consent forms, CITI IRB Training Certifications, Pre- and Post-Driving Survey Questionnaire, specification of equipment, project technical proposal, concept of operations, safety management plan, and privacy and security management operating concept.

4.3 Description of Potential Participants and Activities

The IRB requires a full description of the human subjects used in research as well as their activities and level of participation in the CV Pilot. This section discusses the participants and their activities in Phase 2 and 3 as provided in the IRB application. The Stakeholder Registry developed under the Program Management task 1 was utilized to identify the various groups of stakeholders that will have human subjects participating in the CV Pilot various activities. The main stakeholder groups identified are:

1. Instructors
2. CV-Pilot Participants
 - a. Drivers of Equipped Vehicles
 - b. WYDOT TMC and Highway Patrol Dispatch Personnel
 - c. WYDOT Operational and Support Personnel
 - d. Fleet Management Center Personnel (CVOP Users)
3. General Public (Third Party Interface Users)

In Phase 2, subjects will participate in CV Pilot in two ways: 1) testing the Human-Machine Interface (HMI) in a Driving Simulator environment, and 2) getting training on the developed suite of CV applications in the Driving Simulator Lab, field demonstrations and/or online training. In both activities, participants will be asked to drive various scenarios on similar roadway classification to the field study location. Participants will be asked to fill out survey questionnaires before and after the simulation.

1. Testing the HMI in a Driving Simulator experiment:

The Driving Simulator Lab (WYOSIM) at the University of Wyoming will be utilized in the development and testing of the Human Machine Interface (HMI) (known also as Driver-Vehicle Interface (DVI)), a user-in-the-loop concept will be followed to design the most effective HMI that achieves the following goals: 1) attracting the driver's attention; 2) communicating the intended safety message timely and spatially so the driver can take the required evasive action; 3) using understandable concise message; and 4) introduce the least distraction possible. The design will take into consideration drivers that have English as second language and that are color blind.

2. Training on the developed suite of CV applications in the Driving Simulator Lab and/or in-person training:

Training and Education plan for all participants identified above will leverage existing training modules by integrating new materials relevant to the CV pilot. The training modules will define all physical equipment (e.g., HMI and respective cables) and their location, as well as all visual elements of the system interfaces (e.g., signal strength, battery percentage, and message buttons). The training will provide insights on the information a driver could receive including each type of Warning, each type of Advisory, Maydays, amongst others.

Reaction to the various messages will also be discussed, as this is equally important as understanding the messages provided through the CV-system. The training team understands that all conditions cannot be simulated nor foreseen; however, the modules will explain, to the extent possible, how a driver should react to each type of received information. For instance, if a warning is received that the Variable Speed Limit changed from 75 mph to 45 mph, the training module will address proper responses, such as how fast the driver should adjust their speeds. Furthermore, the module will also train drivers on how to interact with the system, including potential actions to acknowledge a message, stop a sound, review previous messages, and input information, amongst others. The module will provide training on procedures to report incidents where the connected vehicle might have been involved or not, and what steps to take in the event of an accident. The training will be provided via different approaches such as in the driving simulator lab, desktop simulation, online training and education modules, and field-demonstrations at a WYDOT parking lot. Various modules will be developed to train instructors, operational staff, fleet management center personnel, and third party users. Detailed information about the training and education plan for Phase 2 can be found in the Training and Education Plan.

In Phase 3, subjects will participate in the field pilot deployment and testing of the Connected Vehicle technologies on Interstate 80. Connected Vehicle On-Board Units (OBU) with Human Machine Interface (HMI) devices, and other several pieces of data acquisition systems and equipment will be installed in partnering companies and WYDOT vehicles. Subjects will participate by driving Connected Vehicles in real-life demonstrations and training. Participants will be also required to fill out survey questionnaires and take personal interviews about their experience with the CV Pilot applications. Training will continue throughout Phase 3 for the identified groups including instructors, and the CV Pilot participants.

4.4 Informed Consent

The IRB regulations require that certain information must be provided to participants as part of the consent process. An informed consent document will be used to provide participants with the information they need to make a decision to participate/volunteer in a research study. Although there are different ways to communicate the information to subjects, the CV Pilot will mostly provide the information in the form of a written document (digital and physical). The following are examples of the information that will be provided to participants in Phase 2 and 3.

Phase 2 Example - Driving Simulator Information:

In the real-life CV deployment phase 3, participants will be told:

The Wyoming Department of Transportation (WYDOT) is working on a USDOT sponsored project to deploy Connected Vehicle technology on Wyoming Interstate-80 freeway to improve safety and mobility. In particular, the CV technology will be demonstrated and tested on commercial trucks and later will be expanded to all vehicles in the near future.

Part of the study is based on driving simulation experiments to test and develop the best Human-Machine Interface. To help us achieve this goal, we would like to invite participants to one or more driving simulation scenarios. The truck driving simulator is an open cockpit simulator consisting of three flat screens, driver seat, steering wheel, dashboard, and pedals similar to an actual truck (commercial motor vehicle).

Subjects will be asked to read and sign a consent form. They will then be asked about their age and relevant driving experience for proper data collection. After information is collected, they will be asked to sit down in the seat of the truck simulator open cockpit and drive a simulated scenarios. All collected data while driving the simulator about driving performance and behavior dealing with various traffic situations are anonymous. Data will not be linked to personal information. The only potential risks to subjects during testing could be slight motion sickness, fatigue, dizziness, eye strain, the potential of feeling anxious or stressed, or slight light headedness. The results of the study will help to improve the body of knowledge regarding Connected Vehicle technology. The study will help in testing innovative technologies to reduce number of crashes and crash severity. A \$50 Home Depot gift card will be provided for participants who successfully complete the experiment and take the pre and post survey questionnaires. Participation will help to improve the body of knowledge regarding driving behavior and safety. Participation may also help us to identify more effective countermeasures to make our roadways safer.

Phase 3 Example – Real-life CV Deployment:

In the real-life CV deployment phase 3, participants will be told:

As a participant, you are invited to be part of the testing and deployment of the connected vehicle technology in Wyoming. Length of enrollment is 18 months. There are three options with regard to your participation:

1. Full Participation: by reading and signing this consent form and following the steps below.
2. Decline Participation but Continue to Drive the Truck: If this option is chosen, data will be collected whenever you drive the truck, but the data will be deleted once you were identified as a driver who did not sign a consent form. Truck driving logs will be used to determine drivers with no signed consent forms. There will be an option for you to turn off the driver interface.
3. Decline Participation and Choose Not To Drive the Truck: No data will be collected. No adverse implication on your job will be faced if you chose this option.

The owner, co-owner, or lessee of a commercial truck you sometimes drive has given us permission to install various Connected Vehicle equipment and data acquisition systems in their vehicle as part of this study. As part of this enrollment process, you will be asked to read and complete this informed consent form, a brief questionnaire about you and your driving history, and a questionnaire about your driving behaviors. A training either in a controlled environment, i.e., the Driving Simulator Lab (WYOSIM) at the University of Wyoming, or a real-life demonstration of the CV system will be provided to you via in-person training or a digital video medium.

Driving data will be collected, and safety messages and other advisory messages will be disseminated via visual, audible, haptic interfaces, or a combination of them. You will be asked to perform your normal driving routine and paying attention to the CV warning messages. The CV system and the provided warning messages are designed to improve your safety by providing better situational awareness for road and weather conditions. The messages are only advisory, you will remain in full control. The CV system will not ask you to perform any unsafe driving actions. Let us or your company know if you notice any unusual warning light activity of your truck system or any awkward unjustified activity of the CV HMI system.

If you were involved in a crash while in the study, you should do the following:

1. Seek emergency help the way that you would normally do.
2. If possible, press an incident button that is part of the HMI to audio record your description of the incident. You will know the recording has started if the red light comes on when you press it.
3. If an Automatic Crash Response SOS system (similar to OnStar system) is equipped, you will be contacted by the designated emergency responder. In case of a minor crash or a malfunction that did not trigger the system, you should call the Traffic Management Center (307) XXX-XXXX to notify WYDOT as soon as it is safe to do so.
4. Should the crash be identified for a detailed investigation, we are asking your permission to allow a WYDOT member to interview you about the crash. This should take place right after the crash when you feel comfortable and able to do so.

As part of this study, you will be asked to fill in a questionnaire consisting of general questions about your driving experience and history (how many years have you been driving? how many miles do you usually drive per year? what types of roadways do you drive on most? etc.). In addition, post driving questionnaires will be used to get your feedback about your experience and to check if you recognized/comprehended specific messages disseminated via static or dynamic message signs, in-vehicle devices, etc.

4.5 Recruitment and Participants Qualifications

Participants will be WYDOT employees, drivers from partnering commercial trucking companies and Trihydro, and Wyoming Highway Patrol (WHP). An email will be sent via the WYDOT system for participation. WYDOT will provide a letter of agreement to solicit the participants for this project.

In Phase 2, the target of a sound statistical analysis is arbitrarily estimated to be 30 subjects or more for each simulation experiment. Driving simulator studies usually do not involve a large number of participants because of time and resources constraints (Helland et al., 2013, NHTSA, 2013). In this study, it is anticipated to recruit about 40 participants for the testing and development of the Human-Machine Interface (HMI) in the Driving Simulator Lab during the second phase of this project. To the extent possible, the recruitment process will yield a representative sample of the targeted population (i.e., truck drivers). Participants in the simulator experiments will be mostly from Wyoming, as recruitment of out-of-state drivers could be challenging because of extra time and resources needed.

Based on the scenarios needed and the CV applications, design of the experiment will determine the minimum required number of subjects to control Type I (false-positive) and Type II (false-negative) error risks. A repeated measures design will be adopted to test various CV applications; subjects may participate in multiple simulation experiments (Donmez et. al, 2006). Training will be provided to all participants either in the driving simulator lab or a real-life demonstration of the CV system will be provided via in-person training or a digital video medium. It is anticipated that 400-500 drivers will be recruited for training and education over the course of the project, although this number may change depending on hardware cost and ultimate system design.

In Phase 3, more participants are expected in the real life demonstration and testing of the CV technology in the field. It is expected to recruit a total of 400-500 drivers. Snow plow and highway patrol drivers will be recruited in the pilot by WYDOT. Partnership agreements with cities, commercial fleets will allow for recruitment of other drivers.

For all drivers, only those with a valid U.S. driver's license and, when applicable, a valid Commercial Driving License (CDL) will be allowed to participate in the pilot¹. To the extent possible, all drivers should have at least three years of good driving record while working for partnering companies (or similar), including WYDOT. Similarly, the pilot will attempt to ensure that considered officers from Wyoming Highway Patrol will have at least two years of experience with a focus on operations on I-80. Finally, the pilot will verify that WYDOT drivers have been trained in the appropriate policies and use of state vehicles. For the driving simulator experiment, participants who experience motion sickness or vertigo will be excluded from the study. It is worth mentioning that recruitment of operational and ITS technician staff will require certain qualifications. Detailed information about the recruitment process of participants and their qualifications can be found in the Training and Education Plan.

¹ Section "391.11: General qualifications of drivers" of the Federal Motor Carrier Safety Administration regulation requires that all drivers who have a CDL be able to read and speak English. This project uses this regulation as the standard for minimum proficiency in English.
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4.6 Data Management

A plethora of data will be collected as part of this CV Pilot in Phase 2 and 3. These data will range from driving simulation data, survey questionnaire information, training feedback data, connected vehicle data, crash data, etc. The independent evaluator will have access to all data collected and generated throughout the duration of this pilot. CV-related data is described in the Performance Measurement and Evaluation Support Plan (Kitchener, et al. 2016).

For the driving simulator testing and training in phase 2, data will be collected digitally from the simulation software. These data include simulated driving speed, position of the steering wheel, acceleration and deceleration rates, braking, lateral acceleration, and longitudinal acceleration, amongst others. In addition, an eye-tracking device and face video recording will be used to collect information about drivers' focus on various HMI designs in the simulated environment. The eye-tracking system is a non-intrusive video based system that is integrated with the driving simulator. The system consists of multiple video cameras mounted on the driving simulator to capture and record digital video and real time data from multiple angles. The system uses an image processing software to analyze and track drivers' eyes.

In phase 3, similar driving simulation data may be collected for the training. In the real-life demonstration and testing of the CV technology, several types of information and data about the participants, the instrumented Connected Vehicle and participant driving experience will be collected during the study. Driver data includes participants' answers to questionnaires will be collected as well. These data will not contain subjects' names or any identifying information. The collected data about the participants, their driving experience, and answers to questionnaires may for evaluation of training, etc., both on its own and in combination with the driving data. This data will be stored securely in an electronic form for the duration of the study.

Vehicle and driving data include the information we collect from the truck while subjects are driving are defined in the pilot system requirements and may include speed, braking, heading, GPS coordinates of trips, steering angle, etc. as well as other sensor data if equipped. Connected Vehicle Basic Safety Messages and messages exchanged with other similarly equipped vehicle or the infrastructure will be also collected. These data will be encrypted (stored in an unreadable format) from the moment of their creation until they are downloaded from the truck, transferred to a secure data storage facility/warehouse, 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 other data. These data will be stored securely in an electronic form for the duration of the study. The collected time-series vehicle data as well as other sensor data will not be linked to participants' Personally Identifiable Information (PII).

Crash data include information from before and after crash, post-crash recording, or answers subjects provided to an interview with one of the researchers as well as police crash report will be collected. These data will be stripped off any PII and used in analysis; the data may be used in combination with other driver data, connected vehicle and driving data, and/ or other data.

In Phase 2, the data will be securely stored in computers in UW Simulation Lab. In Phase 3, data collected from the instrumented CV trucks will be maintained at WYDOT and subsequently shared with FHWA data warehouses. The raw data will be encrypted and stored until they are processed. Once processed to not include any identifiable personal information, they will be stored for at least three years after the completion of the project on November 30, 2019. The pilot team will maintain, in a designated location, the signed informed consent forms, and the written

research summary, relating to research which is conducted for at least three years after completion of the research. Furthermore, only the WYDOT Project team, graduate students and Independent Evaluator will have access to the data. The graduate students are not investigators in the study.

4.7 Privacy and Confidentiality

All information in the study records will be kept confidential, to the extent allowed by law. As soon as subjects begin participating in this study, names and other identifying information will be separated from the data collected while they drive the simulator or the instrumented CV trucks and replaced with a number. That is, their simulated or real driving data will not be attached to subjects' names, but rather to a number (for example, Driver 0111). The data collected while a subject drives the simulator or an instrumented CV truck will be encrypted (made unreadable). Names also will be separated from any data about subjects, either provided by subjects in response to questionnaires or gathered by researchers during the study, and will be replaced by the same driver number (for example, Driver 0111).

Driver data includes subject's answers to questionnaires. The questionnaires will consist of general questions about their driving experience and history (e.g., how many years have you been driving? how many miles do you usually drive per year? what types of roadways do you drive on most? etc.). Moreover, a post driving questionnaire will be used to get drivers' feedback about their experience and to check if they recognized/comprehended specific messages disseminated via static or dynamic message signs, Human-Machine Interface (HMI), etc. This data will not contain subjects' names or any identifying information. The collected data will be used in analyses, both on its own and in combination with the driving data. This data will be stored securely in electronic form for the duration of the study.

Driving data includes the data collected from the simulator or the instrumented CV truck while participants are driving, including sensor data and potentially video data. While driving the simulator, a camera will videotape subjects' faces with some added space around their heads to handle any head movements. All video will be captured and stored in digital format (no tape copies will exist). Data will be collected from the instrumented CV trucks while subjects are driving, including speed, braking, headings, headways, GPS coordinates of your trips, steering angle, etc. as well as video and other sensor data if equipped. Connected Vehicle Basic Safety Messages and messages exchanged with other similarly equipped vehicle or the infrastructure (Road Side Unit) will be also collected. These data will be encrypted (stored in an unreadable format) from the moment of their creation until they are downloaded from the truck, transferred to a secure data storage facility/ warehouse, 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 other data. These data will be stored securely in an electronic form for the duration of the study. The captured video-recording will maintain actual images of participants' faces, but these images will not be linked to subjects' names. The collected time-series vehicle data as well as other sensor data will not be linked to participants' PII data.

Crash data include information from before and after crash, post-crash recording, or answers subjects provided to an interview with one of the researchers as well as police crash report will be collected. These data will be stripped from any Personally Identifiable Information (PII) and used

Section 4. Human Use Elements

in analysis, the data may be used in combination with other driver data, connected vehicle and driving data, and/ or other data. In any sort of report we might publish, we will not include any information that will make it possible to identify an individual.

5 Human Use Approval

The pilot team has obtained approval from our IRB of record for the pilot. The IRB application included a brief description of the purpose of the CV Pilot as well as a descriptions of research tasks proposed in Phase 2 and 3. Descriptions of potential participants such as age-range and gender, number of participants, qualifications, recruitment process, benefits and risks to participants, compensations and incentives provided, criteria for exclusion from the study are also included, as well as when participants may terminate participation. A detailed description is provided for the participants' activities and estimated time required in all phases. Method of data collection, procedure that will be used to protect privacy and confidentiality of participants, how and where the data will be stored, how long the data, research summary and signed consent forms will be stored, and who will be giving access to the data are also explained in detail in the application.

The application included 11 attachments required as part of the IRB approval at the University of Wyoming:

- a. Informed Consent Forms for Phase 2, and 3
- b. Pre- and Post-Driving Survey Questionnaire
- c. CITI IRB Training Course Report
- d. Driving Simulator Specifications Sheet
- e. Eye Tracking/Video Recording Specification Sheet
- f. Project Technical Proposal
- g. Concept of Operations
- h. Privacy and Security Management Operating Concept
- i. Safety Management Plan.

5.1 IRB Process and Application

An IRB application has been submitted on April 19th, 2016, and the application was qualified for Full Board Review. The Institutional Review Board at the University of Wyoming met with the human use lead and WYDOT representatives on May 19th, 2016 to discuss and request modifications to the application. All reviews at the University of Wyoming are subject to criteria developed from Belmont Report discussed earlier. The IRB application has been approved by the UW IRB on May 23rd, 2016 for a period of 1-year. The IRB at UW requested more details on the developed CV applications and their potential risks on driver. Particularly, in the real-life deployment Phase 3. It should be noted that while the IRB approval is for 1-year, any changes to the study will be reported to the IRB immediately. The Wyoming/ ICF team is planning to amend the IRB application once more details are available about the CV applications. The potential risks of the CV applications on real-life driving will be determined in Phase 2 in a controlled driving simulator environment. The results from driving simulator experiments will be shared with UW IRB.

5.2 Key Challenges

As mentioned earlier, the IRB process may be a daunting task. The process requires a careful planning and coordination and paying attention to detail and schedule. Ensuring that the diverse partners involved in the CV Pilot understand the IRB process and coordination with information developed in other tasks (e.g., Safety Management Plan, and Training and Education Plan) are critical to the success of the Human Use Approval process. The information developed in other tasks must be consistent with the principles of human use protections as well as the policies and processes for the IRB approval.

5.2.1 Engagement with an Accredited IRB

5.2.1.1 Principal Investigator Understanding of IRB Process

The human use lead, Dr. Mohamed M. Ahmed will serve as the key interface between the project and the IRB. Dr. Ahmed has an extensive experience in developing IRB applications and obtaining approvals. He has been working in coordinating the activities in other tasks to maximizing the probability of IRB approval. Furthermore, Dr. Ahmed satisfies all the training requirements defined by the UW IRB. Other staff involved in human subjects research design or conduct will receive the required training prior the commencement of the research. Dr. Ahmed will determine if additional training may be required for other project staff.

5.2.1.2 Assurance

The UW IRB will act as the IRB of record on this CV-Pilot, the UW IRB is accredited through the US department of Health and Human Services (HHS) – the Office for Human Research Protections (OHRP) - Federal-Wide Assurance (FWA) # 00000186. The IRB at the University of Wyoming will maintain adequate documentation of the research protocol files, the membership files and IRB roster, records required of and related to the PI of the study protocol. All records will be made accessible for inspection and copying by authorized representatives of OHRP, HHS, sponsors, university officials, and internal auditors at reasonable times and in a reasonable manner.

5.2.1.3 Responsibilities beyond single IRB

A formal partnership coordination of Human Use Approval has been initiated via agreements between the UW IRB and all partners on the CV Pilot.

5.2.1.4 Changes and Amendments

While the annual review protocol is required to provide updates on the progress of activities involving human subjects for the CV Pilot, it is anticipated that multiple amendments to the original application will be prepared and submitted for the UW IRB review and approval as the CV-Pilot progresses in Phase 2 and 3. Areas that expected to be amended are provided in the list below:

- More details about the Human Machine Interface (HMI) design and functionality will be submitted to the IRB for their review and approval explaining the actual HMI once it becomes available in Phase 2.
- Updates to other risks than what were originally identified in the Safety and Security Management Plan that may be posted on participants.
- Updates for the survey questionnaires needed for Training and Education.
- Independent Evaluators access to participants' data in Phase 2 and 3.
- Any changes to original plans of data life cycle management.

5.2.2 Ensuring Supporting Information Meets HUA Needs

All the pilot team partners were involved in the development of the research approach and protocols, risks and benefits to participants, and informed consent provisions. The team understands and has successfully incorporated all necessary protections to human participants in all of the CV Pilot tasks.

5.2.2.1 Research Plan

To ensure that planned activities in all tasks are consistent with human use protections, the pilot team took a great consideration of the IRB process. Section 8 provides more information about the interdependency between the HUA and other activities.

5.2.2.2 Recruitment / Informed Consent

While participants on the CV Pilot will be WYDOT employees, drivers from partnering commercial trucking companies, Trihydro, and Wyoming Highway Patrol (WHP), addressing the implications on other non-participants on the road is important. The research approach will be implemented ensuring that no risks are imposed on non-participants and no data will be collected for non-participants. The outreach plan will include stakeholders that may be affected. Informed consents will be collected from all participating subjects.

5.2.2.3 Data collection, storage, usage, disposal

To support Performance Measurement and Evaluation task, various data will be collected. The data collection and handling were planned to satisfy the requirements for the Performance Measurement and Evaluation task while remaining in compliance with human use approval.

5.2.2.4 Benefits / Risks

The pilot team has developed a Safety Management Plan and a Privacy and Security Management Operating Concept addressing all risks associated with the CV Pilot participants and non-participants. Moreover, mitigation plans on how to lessen the risks are discussed in these documents.

6 Human Use Approval Management

The IRB approval for the CV Pilot is for a one-year period. A request to extend the approval accompanied by a report on the status of the project (Annual Review Form) will be submitted to the IRB at least one month prior to the expiration date. Annual review applications will be submitted for approval in April of 2017, 2018, and 2019. Any unanticipated problems will be promptly reported to the Office of Research and Economic Development using the Unanticipated Problem Report Form available at: www.uwyo.edu/research/compliance/human-subjects/index.html. An “unanticipated problem” is defined as an event that 1) was unforeseen, 2) was more likely than not related to the research, and 3) either caused harm to participants or others, or placed them at increased risk of harm.

The IRB will support many tasks in Phase 2 and 3. It is anticipated that multiple amendments to the original application will be prepared and submitted as the CV-Pilot progresses in Phase 2 and 3. For example, the Institutional Review Board at UW requested an amendment of the IRB application to provide a full description of the refined HMI and other CV systems used in Phase III. The pilot team will amend the IRB application to include detailed information about the developed CV applications and the HMI after the completion of Phase II. An addendum will be submitted to the IRB for their review and approval in order to update the protocol before the start of Phase III. In addition, IRB amendments will be submitted for Data Management Planning, Application Development and Testing, Participant and Staff Training, Performance Measurement and Independent Evaluation in Phase 2 as well as various tasks in Phase 3.

7 Roles and Responsibilities

Table 7-1 below defines the roles and responsibilities of each group to obtain and maintain the IRB approval as well as to conform to human use protocols and regulations.

Table 7-1. Roles and Responsibilities of the CV-Pilot Team.

Project Role	Responsibility
Wyoming CV-Pilot system development and execution	<ul style="list-style-type: none"> • Ensure system design, operations, and functionality of the CV-system introduce minimum risk possible to participants. • Ensure compliance with the IRB regulations. • Prepare final Human Use Report.
University of Wyoming	<ul style="list-style-type: none"> • Obtain and maintain human use approval. • Act as the IRB of record for all partners. • Ensure compliance with the IRB regulations.
Wyoming CV-Pilot Training and Education team	<ul style="list-style-type: none"> • Design an adequate training and education plan that suits the needs of equipped drivers, technicians and maintenance staff, operations staff and instructors while maintaining the highest privacy and safety to participants. • Ensure compliance with the IRB regulations.
WYDOT	<ul style="list-style-type: none"> • Support Human Use application and approval. • Recruit participants in testing, training, demonstration, and deployment. • Ensure compliance with the IRB regulations.
Commercial Vehicle Fleet Managers	<ul style="list-style-type: none"> • Participate in CV Pilot activities, as requested.
Connected trucks/drivers	<ul style="list-style-type: none"> • Participate in CV Pilot activities, as requested. • Operate systems as designed/instructed. • Participate in surveys/interviews, as requested.
Connected snow plows/drivers	<ul style="list-style-type: none"> • Participate in CV Pilot activities, as requested. • Operate systems as designed/instructed. • Participate in surveys/interviews, as requested.
Wyoming Highway Patrol	<ul style="list-style-type: none"> • Participate in CV Pilot activities, as requested. • Operate systems as designed/instructed. • Participate in surveys/interviews, as requested.

8 Dependencies and Constraints

As mentioned earlier, the human use approval is an interdependent task that requires inputs from and integration with many other tasks. The pilot team has integrated the human use regulations and policies while developing Phase 1 tasks such as the Pilot Deployment Concept of Operations, Privacy and Security Management Operating Concept, Safety Management Plan, Training and Education Plan, Performance Measurement and Evaluation, as well as the Outreach Plan. Various relevant contents produced in these activities were utilized directly and indirectly as part of the IRB application process.

8.1 Dependencies – Phase 1

8.1.1 Task 2: Pilot Deployment Concept of Operations (ConOps)

While preparing a feasible ConOps for the CV Pilot, the human subjects' interaction with the systems as well as the IRB application requirements were well implemented. Moreover, careful considerations were taken to protect human subjects by minimizing the risks to participants while developing the CV Pilot various applications.

8.1.2 Task 3: Security Management Operating Concept

The Security Management Operating Concept provides guidance material in regards to security and privacy for the deployment. The document is developed based on identifying the impacts of security breaches regarding confidentiality, integrity, and availability along with potential threats. Additional security analyses are included to cover V2V security, the Security Credential Management System (SCMS), and connected vehicle application security needs. Major challenges such as SCMS integration and security for a complex system of systems are considered. The safety operational concept was developed to protect the privacy of users, ensure secure operations, and eliminate the impact of security breaches.

8.1.3 Task 4: Safety Management Plan

Safety management and risks mitigation is one of the most critical components for the IRB approval. The Safety Management Plan identified safety needs and risk scenarios to human participants, the plan also discussed mitigation strategies to minimize potential risks to participants and non-participating drivers. Participants will be informed about the nature of connected vehicle technology, the benefit of the pilot, and the risks that may be imposed on them. Participants will have to give consent to participate in the project according to the IRB regulations.

8.1.4 Task 5: Performance Measurement and Evaluation Support Plan

The Performance Measurement and Evaluation Support Plan defined methods to collect data that are needed for the assessment of the impacts of the pilot deployment. Performance assessments

that involve humans or have potential for impacts to humans were coordinated with human use approval planning. Adverse impacts, protection of data, and fairness treatment to all groups were considered. Moreover, anticipated interactions with the Independent Evaluator such as provision of data were considered in the IRB process.

8.1.5 Task 9: Participant Training and Education Plan

The Participant Training and Education Plan divides its efforts between three objectives. For end-users, like the fleet drivers (be it snow plow operators or truckers), the emphasis will be on developing a level of comfort and understanding of the messaging provided to them in-vehicle. Participants may not be aware of the potential safety scenarios and the actions they are expected to take during emergency situations. Therefore, the safety management plan will be included as part of training plan as a key to prevent personnel injury and eliminate the potential impacts. An end-user training plan were developed to be consistent with the human use approval process that will include training on the truck and car simulators maintained by the University of Wyoming. The simulators will also look at the concerns of distracted driving and help gather feedback on the user-interface design in Phase 2.

For stakeholders that are not direct end-users, like fleet managers, trucking association members, and DOT maintenance and operational staff, the emphasis will be on demonstrating the value and the functionality of these systems. In accordance with the outreach plan in Task 11, training material will be prepared explaining the pilot objectives and how their operations benefit from the successful pilot. Finally, for partners who will be responsible for the demonstration, hands-on field demonstrations, E-training, and online training modules will be developed for different aspects of the system and integrated into existing plans and procedures used by the partners.

All these modules were planned to conform with the Human Use Approval process and IRB regulations. Before any recruitment activity begins for training and education, the pilot team will ensure having a formal IRB approval and participants consent. When data collection is needed for task 5, the team will follow the IRB protocols to protect participants' privacy.

8.1.6 Task 12: Comprehensive Pilot Deployment Plan

The Comprehensive Pilot Deployment (CPD) Plan will build upon previous task reports and add information on the deployment and demonstration plan, data collection and sharing, performance measurement plan, and a detailed schedule and budget for subsequent phases. The plan will be developed to include all the necessary steps to ensure the safety and privacy of participants in conformance with the Human Use Approval process and the IRB protocols. The CPD will include a plan for how future modifications and amendments would be handled in accordance with the IRB protocols.

According the IRB regulation, an annual review will be submitted prior the expiration date of the HUA, any changes to the study will be reported to the IRB immediately. Approval for minor changes, survey questionnaires and interviews that possess minimal risks to participants takes one to two weeks. The ICF/ Wyoming team does not anticipate major changes to the planned CV Pilot applications nor an increase in risks than what have been identified in the Safety and Security Management Plans.

8.2 Dependencies – Phase 2 and 3

As mentioned earlier, Human Use Approval (HUA) will be required for many tasks in Phase 2 and 3. The pilot team will conform to and integrate all IRB regulations and policies in Phase 2 and 3, amendments will be submitted to the IRB for their review and approval in order to update the protocol before involving human subjects in research in Phase 2 and 3. In Phase 2, HUA will be needed for various tasks such as Data Management Planning, Application Development and Testing, Participant and Staff Training, and Performance Measurement and Independent Evaluation. Before recruiting human subjects in real-life deployment and demonstration in Phase 3, the stated procedures in the IRB application of recruitment, acquiring informed consents, protecting confidential personal information, mitigating possible risks to participants will be implemented.

9 Conclusions

This Human Use Summary presents the steps taken by the pilot team to obtain an accredited IRB approval to use human subjects in Phase 2 and 3. The document also explains the Federal regulations and the Institutional Review Board (IRB) application and approval processes to protect human participants in the pilot. The human use summary documents the IRB application process, obtaining participants' consents, review process, how the ICF/ Wyoming team addressed the IRB comments and secured the IRB approval for Phase 2 and 3, and the processes for amending and renewing the IRB application and approval throughout the project period, respectively. Table 9-1 shows the HUAS plan schedule for such activities. The IRB of record on the CV Pilot will provide support to all relevant activities in Phase 2 and 3.

Appendix. IRB Approval Letter

UNIVERSITY OF WYOMING

Vice President for Research & Economic Development
1000 E. University Avenue, Department 3355 • Room 305/308, Old Main • Laramie, WY 82071
(307) 766-5353 • (307) 766-5320 • fax (307) 766-2608 • www.uwyo.edu/research

May 24, 2016

Dr. Mohamed Ahmed, Ph.D., P.E.
Assistant Professor
Civil & Architectural Engineering
University of Wyoming

Protocol #20160524MA01205

Re: *"Ahmed-Wyoming DOT Connected Vehicle Pilot Deployment-Phase 2 and 3"*

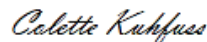
Dear Dr. Ahmed:

The Institutional Review Board for projects involving human subjects reviewed the proposal referenced above at their meeting May 19, 2016. The proposal was approved as one that would not involve more than minimal risk to participants, subject to minor revisions. We have received the requested revisions and the revised protocol is approved.

IRB approval for the project/research is for a one-year period. If this research project extends beyond *May 23, 2017*, a request to extend the approval accompanied by a report on the status of the project (Annual Review Form) must be submitted to the IRB *at least one month prior to the expiration* date. Any significant change(s) in the research/project protocol(s) from what was approved should be submitted to the IRB (Protocol Update Form) for review and approval prior to initiating any change. Per recent policy and compliance requirements, any investigator with an active research protocol may be contacted by the recently convened Data Safety Monitoring Board (DSMB) for periodic review. The DSMB's charge (sections 7.3 and 7.4 of the IRB Policy and Procedures Manual) is to review active human subject(s) projects to assure that the procedures, data management, and protection of human participants follow approved protocols. Further information and the forms referenced above may be accessed at the "Human Subjects" link on the Office of Research and Economic Development website: <http://www.uwyo.edu/research/human-subjects/index.html>.

You may proceed with the project and we wish you luck in the endeavor. Please feel free to call me if you have any questions.

Sincerely,



Colette Kuhfuss
IRB Coordinator
On behalf of the Chairman,
Institutional Review Board

U.S. Department of Transportation
Intelligent Transportation Systems Joint Program Office

U.S. Department of Transportation
ITS Joint Program Office-HOIT
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FHWA-JPO-16-293



U.S. Department of Transportation