

Connected Vehicle Pilot Deployment Program Phase 1, Human Use Approval Summary – Tampa

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16. Abstract This document presents the Human Use Approval (HUA) Summary for the THEA Connected Vehicle (CV) Pilot Deployment. The purpose of this report is to document the process used by THEA in the Tampa CV Pilot Deployment as required in Phase 1, Task 8 in preparation for deployment involving human subjects – auto drivers, pedestrians and bicyclists, and transit drivers - in Phases 2 and 3. Institutional Review Board (IRB) approval of the research protocol is necessary before human subjects can participate in federally-funded CV Pilot research experiments. This HUA Summary document describes the selection of Salus IRB, information used in the IRB application and resolution of comments made by the IRB. Information used in developing the project Research Protocol Document (RPD), Informed Consent Documents (ICDs) and IRB application was derived from tasks already complete or ongoing in Phase 1, including Concept of Operations (Task 2), Security Management Operational Concept (Task3), Safety Management Plan (Task 5), Performance Measurement and Evaluation Support Plan (Task 5), Participant Training and Stakeholder Education Plan (Task 9) and Outreach Plan (Task 11). This information was integrated into a Phase 1, high-level concept Research Protocol and ICDs that safeguard, over the course of the participant's lifecycle, the recruitment, selection, registration, informed consent, training, installation of equipment, safety needs and personal identification security requirements of participants. Salus IRB's determination resulted in approval of the Research Protocol, ICDs for auto drivers, pedestrians and Hillsborough Area Regional Transit and a decision in favor of Expedited Review. The approval is limited to the study's progress to date. Amendments and continuing review are expected for recruitment, training, revisions to ICDs, and wherever changes are made to the approved Research Protocol.					
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Executive Summary

This document presents the Human Use Approval Summary of the THEA Connected Vehicle (CV) Pilot Deployment. The goals of the THEA CV Pilot Deployment are to advance and enable safe, interoperable, networked wireless communications among vehicles, the supporting CV infrastructure, and travelers' personal communications devices in order to make surface transportation safer, smarter, and greener. Since the project is a federally funded research experiment involving human participants, the project also has as a goal the protection of participants. The project, thus, follows the Common Rule, a rule of ethics regarding research with human subjects adopted by the United States Department of Transportation (USDOT) that is codified in U.S. Code of Federal Regulations, 49 CFR Part 11. Among other provisions, the Common Rule warrants an Institutional Review Board (IRB) to have oversight of the treatment of human subjects. The US Department of Health and Human Services (HHS) oversees IRB activities and issued a Federal Wide Assurance (FWA) number (FWA00024177, expiring 5/13/2021) that acknowledges that Salus IRB is the IRB for the THEA CV Pilot Deployment.

The purpose of this document is to present a summary of the Human Use Approval process used by THEA in the Tampa CV Pilot Deployment as required in Phase 1, Task 8. This task identifies the research approach (i.e., the Research Protocol), including the security of Personally Identifiable Information (PII), participant safety, treatment of vulnerable populations, risks and benefits to participants, informed consent provisions, and human use protections in the recruitment and training of participants. This task includes attaining IRB approval of Informed Consent Documents (ICDs) for car owners, pedestrians and the transit agency. Reference is also made to the application forms provided by Salus IRB and their use in the application process.

Much of the information used in the Research Protocol, ICDs and in the IRB application was derived from CV Pilot Tasks already complete or ongoing in Phase 1, including Concept of Operations (Task 2), Security Management Operational Concept (Task3), Safety Management Plan (Task 5), Performance Measurement and Evaluation Support Plan (Task 5), Participant Training and Stakeholder Education Plan (Task 9) and Outreach Plan (Task 11).

The Research Protocol Document (RPD), developed for Salus' review, will be used to ensure that the project team and the IRB fully and comprehensively understand the issues and requirements for participant treatment and have planned for all necessary protections to human participants. Amendments to the Research Protocol will be sent to the IRB as the project concepts are refined and detailed design is undertaken in Phase 2 of the THEA CV Pilot. The schedule of amendments is, therefore, tied to development of other tasks.

THEA selected Salus IRB, an IRB not attached to a university or private entity, as the IRB of the THEA CV Pilot. Salus is fully accredited and its three boards meet multiple times weekly to ensure submissions are reviewed and IRB-approved documents returned as quickly as possible. THEA applied to Salus IRB on May 16, 2016. Salus responded on June 1, 2016 with its determination to allow for Expedited Review, approval of the Draft Research Protocol and approval of the ICDs for auto drivers, pedestrians and Hillsborough Area Regional Transit (HART). Final RPD approval was granted on June 20, 2016 after minor changes to the draft. Final IRB approval is limited to the progress of the study to date. Continuing review is expected for recruitment, training, revisions to ICDs, and wherever revisions are made to the approved Research Protocol.

1.0 Introduction

The Tampa Hillsborough Expressway Authority (THEA) contracted with USDOT on September 14, 2015 to perform a Connected Vehicle (CV) Pilot Study to test the viability of CV technology to improve safety and mobility, reduce environmental impacts, and improve agency efficiency. The project is federally funded through the USDOT FHWA Joint Program office for Intelligent Transportation Systems (ITS). The THEA CV Pilot Deployment develops in three Phases, of which this Task 8, Human Use Approval, is within Phase 1. Phase 1 is scheduled to be complete September 13, 2016.

The THEA CV Pilot involves the use of federal funds and new CV technology that will be tested on city streets with volunteer participants. The project, therefore, requires IRB approval to ensure the rights and safety of participating and non-participating persons. There are no known additional state or local human use research regulations.

The Task 8 USDOT Guidance document states:

The THEA CV Pilot Deployment Task 8, Human Use Approval Deliverables to USDOT are to include a Human Use Approval Summary (Draft and Final) sufficiently delineating what information was given to the IRB to allow USDOT to observe that the IRB had an adequate understanding of all data planned to be recorded, a plan for its use and safe keeping, etc. The summary will include an overview of any findings or changes to the study recommended by the IRB (from section 3.5 USDOT Guidance) (USDOT, 2015).

Thus, this report presents relevant elements of the THEA CV Pilot to explain the approach taken in the study's use of human beings and in obtaining IRB approval. The aim of this report is to present:

- IRB selection
- Application process
- Research Protocol
- ICDs
- IRB comments and response
- IRB HUA and Expedited Review.

Information used in the IRB application was derived from tasks already complete or ongoing in Phase 1, including:

- Concept of Operations (Task 2)
- SMOC (Task3)
- Safety Management Plan (Task 4)
- Performance Measurement and Evaluation Support Plan (Task 5)
- Participant Training and Stakeholder Education Plan (Task 9)
- Outreach Plan (Task 11).

This information was integrated into a Human Use Plan (Task 8) that safeguards the recruitment, selection, registration of PII, informed consent, training and installation of equipment, safety needs of participants and procedures in case of equipment failure to the acceptance of the overseeing IRB.

2.0 References and Acronyms

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2.2 Acronyms

Acronym/Abbreviation	Definition
AAHRPP	Association for the Accreditation of Human Research Protection Programs
AET	All Electronic Toll
BAA	Broad Agency Announcement
BSM	Basic Safety Message
CIP	Certified IRB Professional
ConOps	Concept of Operations
CSM	Client Services Manager
CSW	Curve Speed Warning
CUTR	Center for Urban Transportation Research
CV	Connected Vehicle
CVRIA	Connected Vehicle Reference Implementation Architecture
DMS	Dynamic Message Sign
DSRC	Dedicated Short Range Communications
EEBL	Emergency Electronic Brake Light Warning
FAQ	Frequently Asked Question
FCW	Forward Collision Warning
FIPS	Federal Information Processing Standard
FDOT	Florida Department of Transportation
FWA	Federal Wide Assurance
HART	Hillsborough Area Regional Transit
HHS	Health and Human Services
HUA	Human Use Approval
ICD	Informed Consent Document
IE	Independent Evaluator
IEEE	Institute of Electrical and Electronics Engineers
IMA	Intersection Movement Assist
I-SIG	Intelligent Signal System
IRB	Institutional Review Board
ITS	Intelligent Transportation System
MAFB	MacDill Air Force Base
MOU	Memorandum of Understanding
NIH	National Institutes of Health
OBE	Onboard Equipment
OBU	Onboard Unit
PED-SIG	Pedestrian Mobility
PED-X	Pedestrian in Signalized Crosswalk
PID	Personal Information Device
PII	Personally Identifiable Information
POC	Proof of Concept
RDE	Research Data Exchange
REL	Reversible Express Lane
RPD	Research Protocol Document
RSE	Roadside Equipment
RSU	Roadside Unit
SCMS	Security Credentials Management System

SMOC	Security Management Operational Concept
SOP	Standard Operating Procedure
SPMD	Safety Pilot Model Deployment
STOL	Saxton Transportation Operations Laboratory
THEA	Tampa Hillsborough Expressway Authority
TIP	Toll Incentive Program
TMC	Traffic Management Center
TSP	Transit Signal Priority
UMTRI	University of Michigan Transportation Research Institute
USF	University of South Florida
USDOT	United States Department of Transportation
V2I	Vehicle to Infrastructure
V2V	Vehicle to Vehicle
V2X	Vehicle to Device
VDTO	Vehicle Data for Traffic Operations
VIN	Vehicle Identification Number
VTRFTV	Vehicle Turning Right in Front of Transit Vehicle

3.0 IRB Selection and Application Process

3.1 IRB Selection

THEA explored the field of IRBs for applicability to this project. Though the Center for Urban Transportation Research (CUTR), a key team member, is part of the University of South Florida (USF) and has worked with IRBs in other transportation research, the timeline of this project for completing Human Use Approval with the USF or another university IRB appeared to be problematic. Also, payment mechanisms for IRB oversight are designed for projects within university systems.

In order to put the THEA CV Pilot Deployment project on a firm schedule and to meet the desired completion date of June 20, 2016 for this Task 8, Human Use Approval Summary, THEA sought an IRB with fast turnaround times.

Salus IRB is a public IRB, certified by the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) and meets three times per week with one-week turnarounds, which helps to meet the schedule of the CV Pilot. Salus IRB assigns a Certified IRB Professional (CIP) Client Services Manager (CSM) to each study as the project manager, to enable consistency from planning through final IRB reporting and close-out. The CSM is available for questions via phone, email, or live “chat” support. Salus also offers expedited review services and has the flexibility to work with clients to meet tighter turnaround requirements.

3.1.1 IRB Oversight of Performance Measures PII in Phase 2

CUTR is the task lead for Phase 1, Task 5, Performance Measurement and Evaluation Support. The USF IRB, which has a compulsory role to oversee CUTR’s activities, will review PII elements of CUTR’s Performance Measurement work in Phase 2. USF’s oversight of CUTR’s portion is independent and supplementary to

Salus IRB's oversight of the entire project. Salus IRB is aware of USF IRB oversight of CUTR and has expressed no exception or conflict with USF's additional oversight of CUTR's performance measurement work.

THEA will not be using the USF IRB. CUTR staff is subject to internal IRB requirements as part of their research charter with USF. If there is any PII work done by CUTR, it will be reviewed by USF IRB, but their review has no impact on THEA. The USF IRB may communicate with Salus IRB in the course of monitoring the work performed by CUTR staff.

3.2 Application Process

The application to Salus included several application forms and creating an RPD, ICDs from Salus IRB templates and supporting documents. The application included:

1. Initial Review (Form 100¹)
2. Expedited Review form (Form 100.c)
3. Investigator and Site Information (Form 110.a)
4. Protocol Specific Investigator and Site Resources (Form 110.b).
5. Salus IRB Authorization Agreement signed by THEA
6. FWA document
7. Salus IRB ICDs (Form 650 ICD) for car drivers, pedestrians, and HART
8. Draft Proposed Research Protocol
9. Curriculum Vitae, certifications and licenses for Steven Johnson, Primary Investigator (PI), Victor Blue, Primary Contact, and Andreas Kourtellis from CUTR.
10. Federal Broad Agency Announcement (BAA) No. DTFH6115R00003
11. THEA contract with USDOT
12. Final Reports for Tasks 2-4, Draft Report for Task 5.

Salus requested that THEA (May 25, 2016):

- Provide section in the protocol where compensation for research related injury is available. Particularly for the drivers that are using the CV application, or app, to avoid hazards. It only tells them to call to report an incident (crash, etc) but not what they are offering.

THEA's response (May 31, 2016) was to add language to state in the ICDs and RPD:

- Neither THEA nor USDOT is responsible for damages you [the participant] may incur in the event of a crash and do not offer compensation.
- If the device becomes dislodged or loosens from its installed position, please contact us so the device may be secured.

Salus IRB required certifications equivalent to National Institutes of Health (NIH) web-based training course for "Protecting Human Research Participants" for the Project Manager, Steven Johnson (i.e., Principal Investigator in Salus' terminology). Victor Blue, Task 8 Lead and Primary Contact to Salus IRB also undertook NIH Certification. Achilleas Kourtellis, providing oversight and review for CUTR had prior certification through the Collaborative Institutional Training Initiative (CITI Program). Other THEA staff who make contact with participants will be required to obtain NIH or equivalent certification for properly undertaking interaction with human use participants in the THEA CV Pilot.

¹ For forms see Salus Submission Forms: <https://www.salusirb.com/getting-started/submission-forms/>.

4.0 Project Synopsis, Privacy, Safety and Performance Measurement

The Draft RPD was developed to accompany the Salus Initial Review (Protocol) form². The RPD informs Salus IRB of the nature of the research study being undertaken. The RPD closely follows the structure of the CV Pilot Tasks. The RPD:

- Explains the purpose, scope, schedule, location and boundaries of the THEA CV Pilot Deployment and the CV apps and Use Cases being employed.
- Encapsulates the CV Pilot design concepts complying with requirements of the Belmont Report and HHS rules and regulations regarding PII, Safety and Security, Informed Consent, and Recruitment and Training of participants
- Requests Expedited Review and Provisional Approval to Proceed.

In summary the RPD includes sections on:

- Purpose, scope, schedule, location, boundaries, CV apps and Use Cases derived from the Concept of Operations (ConOps, Task 2)
- Treatment of PII and data security obtained from the SMOC Final Report (Task 3)
- Care for participants' safety from the Safety from the Safety Management Plan Final Report (Task 4).
- PII security issues within Performance Measurement and Evaluation Support (Task 5)
- Plans for participant protections and Participant Human Use (Tasks 8, 9 and 11 in progress)
- Arguments for Expedited Review and Provisional Approval to Proceed.

This section includes the sections of the RPD which covered THEA CV Pilot Tasks 2-5. Participant Human Use is the core of the IRB's interests and so is presented separately in Section 5. The ICDs follow in Section 6. The reader is referred to the above mentioned Task reports for further information. (Section numbers referenced within this Human Use Approval Summary are revised from the RPD to conform to the section numbering in this report.)

4.1. THEA CV Pilot Project Synopsis and ConOps (Task 2)

4.1.1. Background

The THEA CV Pilot Deployment project is funded as part of a USDOT program to test the use and effects of connected vehicles (CVs) in several environments, including I-80 in Wyoming, New York City, and downtown Tampa, Florida. USDOT is testing CV software applications, or apps, in these three environments prior to larger-scale deployment. USDOT undertook an earlier experiment, the CV Safety Pilot Model Deployment (SPMD) in Ann Arbor, Michigan, conducted by the University of Michigan Transportation Research Institute (UMTRI). This Human Use Research Protocol concerns the Tampa project, headed by THEA and its stakeholders.

² Salus Form 100: <https://www.salusirb.com/getting-started/submission-forms/>.

The Common Rule adopted by the USDOT is codified in U.S. Code of Federal Regulations, 49 CFR Part 11. The Common Rule provides guidance on defining when research falls under this rule, and associated requirements for approvals, oversight, and IRB participation. Since the project is federally funded and involves the participation of research subjects, approval of Human Use by an IRB is required (USDOT, 2015).

4.1.2 Overview

To be clear from the outset, this is not an “autonomous-vehicle” (AV) test, where the vehicle drives itself, but a “connected-vehicle” test where the driver is still in full control. Drivers are legally responsible to drive the vehicle. Drivers and pedestrians using CV devices are required to obey traffic laws. Neither THEA nor USDOT is responsible for traveler behavior or for damages in the event of a crash and do not offer compensation.

The THEA CV Pilot project involves the recruitment of approximately 4000 car drivers and a transit agency from which 100-400 employees will use on-board units (OBUs). Approximately 500 pedestrians will use personal information devices (PIDs). This experiment aims to better understand the use and effectiveness of the devices (OBUs and PIDs) in improving safety and mobility in urban environments (for an example of OBUs used in the SPMD see: http://safetypilot.umtri.umich.edu/index.php?content=technology_overview (University of Michigan Transportation Research Institute, 2016 accessed)). Drivers and pedestrians will use these CV devices which can communicate between vehicles (vehicle to vehicle or V2V), between vehicles and traffic infrastructure (vehicle to infrastructure or V2I) and between vehicles and pedestrian smartphones. The entire set of combinations is known as vehicle to device, or V2X. The devices will issue safety alerts covering several driving situations and at least one test crosswalk. The OBU devices will also broadcast from vehicles to traffic signal equipment (i.e., Roadside Units, or RSUs) to give priority to pedestrians and vehicles in order to improve traffic flows, or mobility.

In addition, the Tampa region’s transit agency, HART runs buses and streetcars that have safety and mobility concerns that can potentially benefit from CV apps designed for their use. About 189 buses and 9 streetcars will be outfitted with OBUs. The transit apps will (a) alert motormen to a vehicle turning right in front of a streetcar and (b) give priority to buses at traffic signals under appropriate circumstances. In this Protocol, HART will be treated as the participant and the drivers will be treated as employees with HART’s cooperation in applying Human Use standards of practice. Outside of recruitment, registration and training, in this document (see Section 5.5) HART drivers are grouped with all drivers, since their use of CV apps is not significantly different from car drivers’ use of apps.

4.1.2.1 Project Structure

The THEA CV Pilot Deployment is staged in three Phases following a Systems Engineering model. Systems engineering is a disciplined approach to project development, building, execution and maintenance. The “V-Diagram” in Figure 1 shows the basic steps. Phase 1 is represented in the upper left portion of the diagram, prior to Detailed Design. The three Phases are:

- Phase 1 - Concept Development (up to 12 months) consisting of 13 tasks, of which this report aims to fulfill Task 8, Human Use Approval. The tasks are outlined in detail in the Federal BAA and those of interest to HUA are outlined in the discussion below.
- Phase 2 – Design/Build/Test the system prior to operation (up to 20 months).
- Phase 3 – Operate and Maintain the CV system, assess the impacts and measure performance (minimum of 18 months).

The entire project will span approximately four years (50 months).

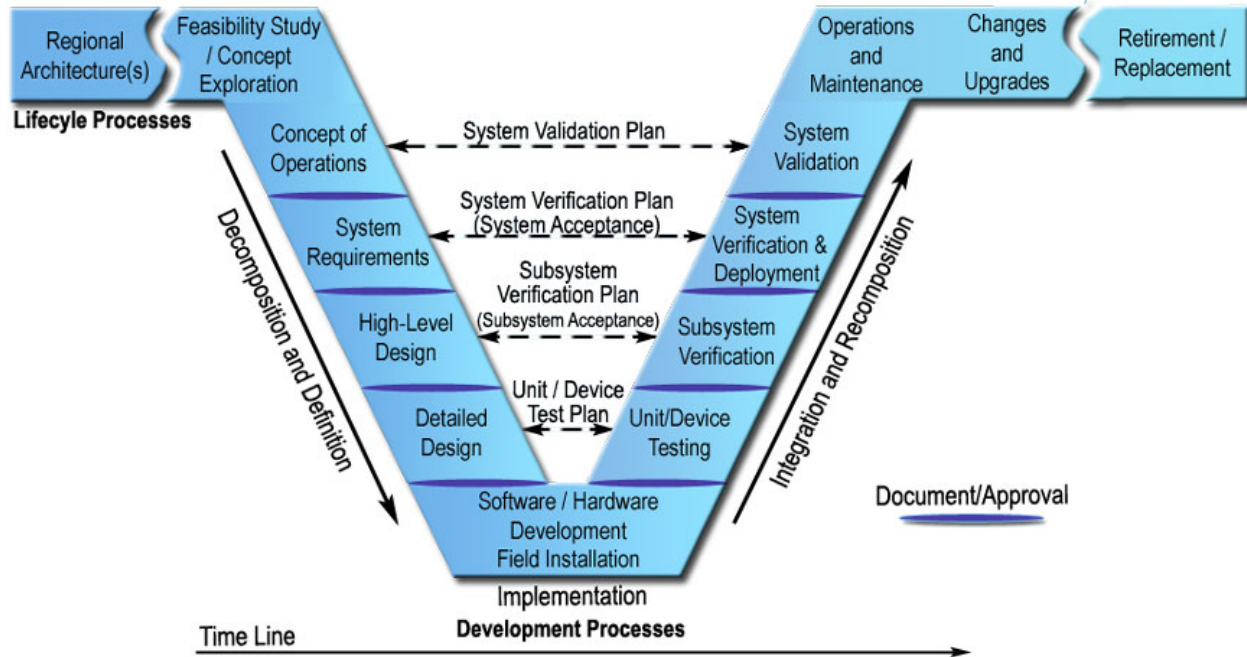


Figure 1: “V-Diagram” of Systems Engineering Development Process.

Source: (THEA, February 2016)

The current phase, Phase 1, is scheduled to take one year beginning September 14, 2015 and is comprised of 13 tasks that include:

- Task 1 Program Management
- Task 2 Pilot Deployment ConOps*
- Task 3 SMOC*
- Task 4 Safety Management Plan*
- Task 5 Performance Measurement and Evaluation Support Plan*
- Task 6 Pilot Deployment System Requirements
- Task 7 Application Deployment Plan
- Task 8 Human Use Approval
- Task 9 Participant Training and Stakeholder Education Plan*
- Task 10 Partnership Coordination and Finalization
- Task 11 Outreach Plan*
- Task 12 Comprehensive Pilot Deployment Plan
- Task 13 Deployment Readiness Summary.

(* marks an input to the HUA application).

The schedule of all tasks is shown at: http://www.its.dot.gov/pilots/cv_pilot_progress.htm.

It should be emphasized that Phase 1 aims to develop conceptual plans and many details of the project are not yet available. Devices, communications and data collection capabilities were tested in the CV SPMD that was done by UMTRI (Bezzina & Sayer, 2015). This project follows on the SPMD as an experiment to further test apps while in use and measure traffic impacts of the devices in an urban setting.

The ConOps, SMOC Plan, Safety Plan, and Performance Measurement and Evaluation Support Plan (Tasks 2-5) support this task, Task 8, Human Use Approval. Task 9, Participant Training and Stakeholder Education Plan and Task 11, Outreach Plan are progressing in a complementary fashion with the HUA Plan. Task 8 brings together all the elements from the aforementioned tasks and the participant perspective, including this Protocol and ICDs, submitted separately. Besides attaining IRB approval, Task 8 will provide USDOT with a HUA Summary Report, intended to document and allow USDOT to assess the process and information used to obtain IRB approval.

4.1.2.2 Project Structure Regarding Human Use Approval

HUA is to be carried out in Task 8 in Phase 1, the Concept Development Phase. While the high-level concepts available at this stage of project development prescribe further development of the hardware, software, recruitment activities and much else of the project in Phase 2, the project developers can only know details to the level the project has conceptually developed. For example, details of the training are not scheduled for this phase. As the Federal BAA states in Phase 1, “The Participant Training Plan [Task 9] shall identify the roles that participants will take during the pilot deployment, including a rough description of their activities and responsibilities, and likely training requirements needed to ensure as-planned execution of the pilot deployment in the operational phase.” (USDOT, 2015). The project timeframe will allow, further along, more detailed design elements to be added to the HUA documentation through amendments to this Research Protocol.

4.1.2.3 Research Protocol Report Structure and THEA CV Pilot Task Deliverables

The following Tasks and documents are summarized in separate sections within this Research Protocol:

- Important elements of the operations of the THEA CV Pilot Deployment are summarized in Section 4.1 from the ConOps Final Report (Task 2) (THEA, February 2016).
- Security for PII and securing the database and communications are summarized in Section 4.2 of this document from the SMOC Final Report (Task 3) (THEA, March 2016).
- Treatment of Safety Management is summarized in Section 4.3 from the THEA CV Pilot Deployment Safety Management Plan Final Report (Task 4) (THEA, March 2016).
- The use of the data must also meet requirements for personal security and not expose anyone, especially vulnerable populations, to identification or discrimination. Data use is summarized in Section 4.4 of this document from the Performance Measurement and Evaluation Support Plan Draft Report (Task 5) (THEA, April 2016).
- Participant Human Use is treated in Section 5 of this document. Recruitment and Training (Task 9) are in development at this stage in Phase 1 and are discussed in Section 5.
- The case for Expedited Review and Provisional Approval to Proceed are developed in Section 7.

4.1.2.4 CV Pilot Stakeholders

The THEA CV Pilot has multiple stakeholders identified with the Pilot. A listing of Stakeholders on the review panel and their roles in the project is shown in Table 1. Core team stakeholders are the members of the project team. Salus IRB is listed as the IRB. Key Agency Partners are those agencies that are directly affected by the Pilot Deployment. Key Stakeholder Agencies and Key Stakeholder Organizations are those agencies/organizations that may interact with the pilot. Key Technology and Vendor Stakeholders are those private companies that may supply hardware or software to be used during the operation of the pilot. Project Originators are the USDOT offices that are overseeing the pilot project. Independent Evaluators (IEs) are those entities that are supporting the USDOT in conducting the review of the pilot project.

Partner/Stakeholder Organization	Stakeholder Category
Tampa Hillsborough Expressway Authority	THEA CV Team (Lead Agency)
HNTB Corporation	Core Team Member
Booz Allen Hamilton (BAH)	Core Team Member
University of South Florida Center for Urban Transportation Research (CUTR)	Core Team Member
Global 5 Communication	Core Team Member
Siemens Industry, Inc. Mobility Division - Intelligent Transportation Systems	Core Team Member
Salus IRB	Institutional Review Board
City of Tampa (COT) Traffic Engineering/Traffic Management Center (TMC)	Key Agency Partner
Hillsborough Area Regional Transit (HART) TECO Streetcar Line (a Division of HART)	Key Agency Partner
Florida Department of Transportation (FDOT) District 7 (D7)	Key Agency Partner
Hillsborough County	Key Stakeholder Agency
Amalie Arena	Key Stakeholder Agency
City of Tampa Police (TPD)	Key Stakeholder Agency
Florida Highway Patrol – Tampa	Key Stakeholder Agency
Hillsborough County Sheriff's Office	Key Stakeholder Agency
MacDill Air Force Base (MAFB) Public Affairs Office	Key Stakeholder Agency
Tampa Bay Port Authority (Cargo and Cruise)	Key Stakeholder Agency
Tampa Convention Center	Key Stakeholder Agency
Tampa Downtown Partnership	Key Stakeholder Agency
Tampa Bay Lightning Hockey Team	Key Stakeholder Organization
Tampa Bay Lightning Hockey Club	Key Stakeholder Organization
BMW/GEWI	Key Technology Stakeholder
General Motors	Key Technology Stakeholder
Honda	Key Technology Stakeholder
Metrotech Net, Inc.	Key Vendor Stakeholder
USDOT ITS JPO	Project Originator
USDOT FHWA	Project Originator
Noblis	USDOT Support Contractor
Tbd	Independent Evaluator

Table 1: THEA CV Pilot Project Stakeholders
Source: (THEA, February 2016)

Several Core Team Members have primary responsibility for the tasks that apply to Task 8, HUA:

- Task 2 – ConOps by HNTB with assistance from Siemens, CUTR and BAH
- Task 3 – SMOC by BAH
- Task 4 – Safety Management by HNTB
- Task 5 – Performance Management and Evaluation Support by CUTR
- Task 8 – HUA by HNTB

- Task 9 – Participant Training and Stakeholder Education by Global 5
- Task 11 – Outreach Plan by Global 5.

These tasks are not “stovepiped” but are interdependent, with mutually shared development. In addition, THEA has oversight of the project and considerable input to all tasks. THEA and the City of Tampa are responsible for the operations on their roadways and so monitor the project development and each task report carefully for consistency with their plans and operations.

4.1.3 Current Situation

Downtown Tampa is bordered by Ybor Channel (Cruise Ship and Commercial Port Channel) to the east, Garrison Channel (local waterway) to the south, Florida Avenue to the west, and Scott Street to the north. A virtually flat topography near sea level helps to simplify the evaluation of traffic flow parameters (see Figures 2 and 3).

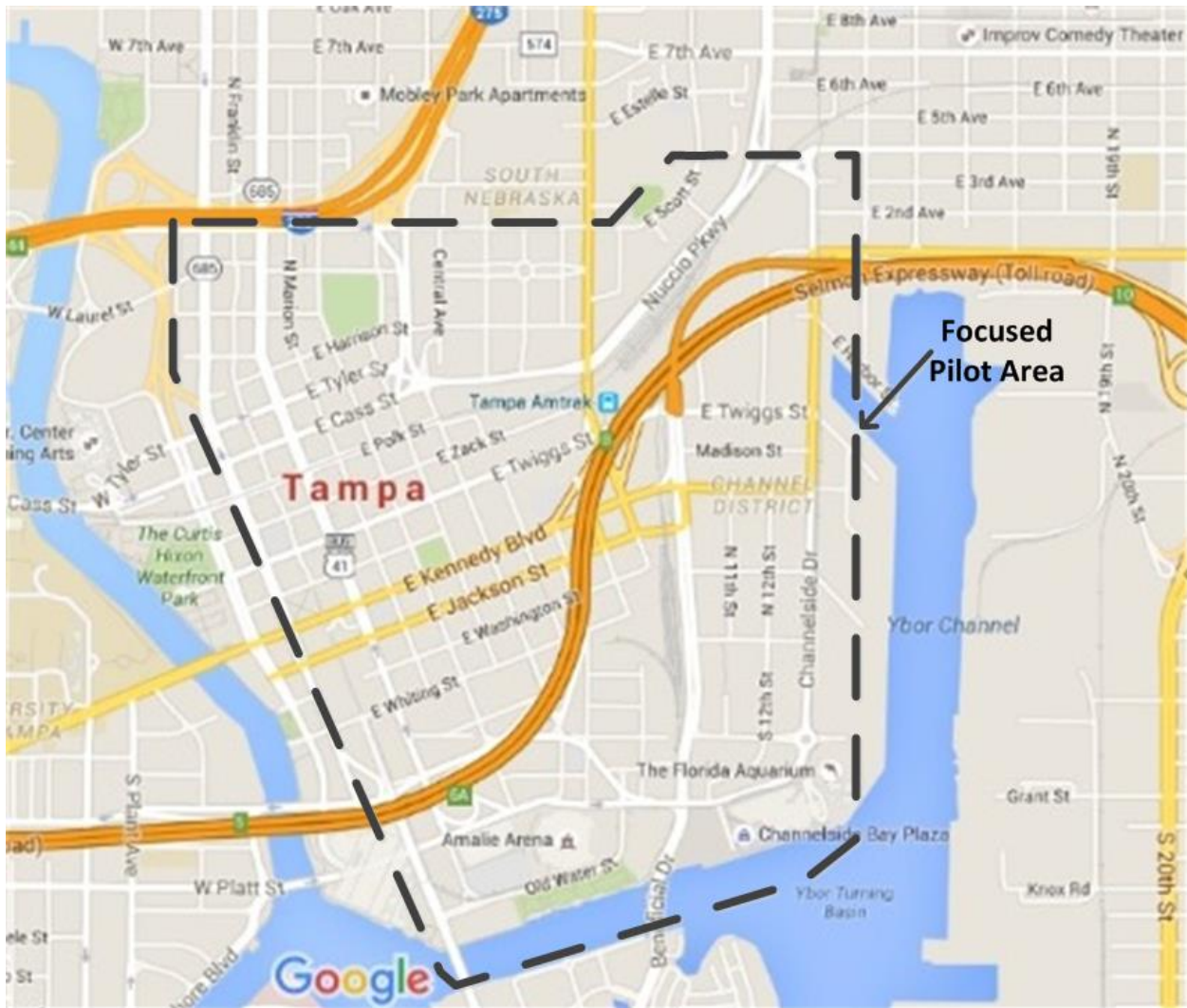


Figure 2: Focused Pilot Area
 Source: (THEA, February 2016)

The main transportation features of the downtown Tampa Central Business District (CBD) are:

1. THEA owns and operates the Selmon Expressway and the Reversible Express Lanes (REL), a reversible elevated express lane, an all-electronic toll (AET) facility that serves as a main commuter route connecting the community of Brandon (a large residential area to the east with a population of 103,000) and Interstate I-75 with downtown Tampa, the Tampa Cruise and Commercial Port, and MAFB southwest of the downtown area 1 (see Figures 2 and 3). REL traffic exits at the intersection of Twiggs Street and Meridian Avenue in downtown. The Selmon Expressway, also AET, runs parallel to the REL and Exits 7 and 8, deposit and collect traffic downtown as well. The final exit is at Dale Mabry Highway, which is the location of MAFB's main gate. Since the spring of 2010, all vehicles on the expressway are tolled electronically as they pass under gantries that hold the tolling equipment. Payment is made through SunPass or license plate-based accounts.
2. THEA's Selmon Expressway was the test bed for connected vehicles on the Audi Autonomous Vehicle Pilot, and THEA is a member of the USDOT Affiliated Test Bed Program for Connected Vehicles.
3. THEA's Selmon Expressway can facilitate real-time traffic tests in a closed-course environment. Taking advantage of this unique functionality, THEA conducted its first automated vehicle test on the REL of the Selmon Expressway that was closed for several days from 10 am–4 pm in late July 2014 while Audi tested its Audi Connect A7 autonomous vehicle.
4. I-275 Exit 44 connects to the study area on the northwest onto N. Orange Avenue and is another significant generator of downtown traffic.
5. Meridian Avenue is a major gateway to downtown Tampa and will be the focal point for several of this pilot's applications. Channelside Drive, on the east and south borders of the test area, connects to Amalie Arena and the Tampa Cruise Ship Terminals.
6. HART bus lines route through this area and an express route utilizes the REL for commuters from the Brandon area. The Marion Transit Center is in the northwest section of the test area on Marion Street at Laurel Street near I-275.
7. The TECO Line Streetcar Line extends through the project area servicing local businesses and the Amalie Arena and Tampa Cruise Ship Terminals that are important special event traffic generators (see Figure 4).
8. Tampa Port Authority operates three International Cruise Ship terminals located in the project area as well as a commercial port area and generates pedestrian tourist traffic with little knowledge of Tampa's street network and transit system.
9. The Tampa CBD has a high volume of pedestrian activity and an active bike share program.
10. There are numerous THEA-leased, City-run and private parking garages/lots in downtown.
11. MAFB is located eight miles south of downtown Tampa adjacent to the western terminus of the Selmon Expressway. A large number of vehicles enter/exit the base daily from the Selmon Expressway and the Tampa street network. Also, the base has a Transportation Incentive Program (TIP) in which about 1,450 base personnel use express bus or van pools. The TIP provides monthly express HART line bus passes to commuters who live in suburban areas east of Tampa. The van pool program provides commuters, in groups of five or more, funding to secure a passenger van for their daily commute.

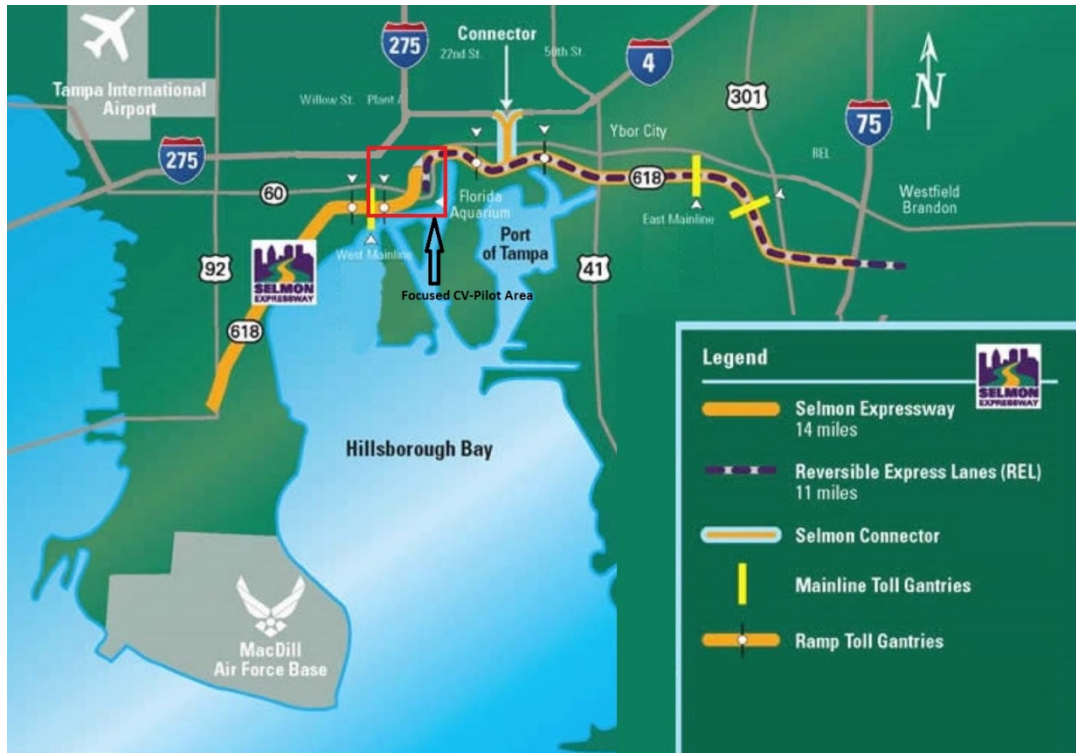


Figure 3: Selmon Expressway and Environs
 Source: (THEA, February 2016)

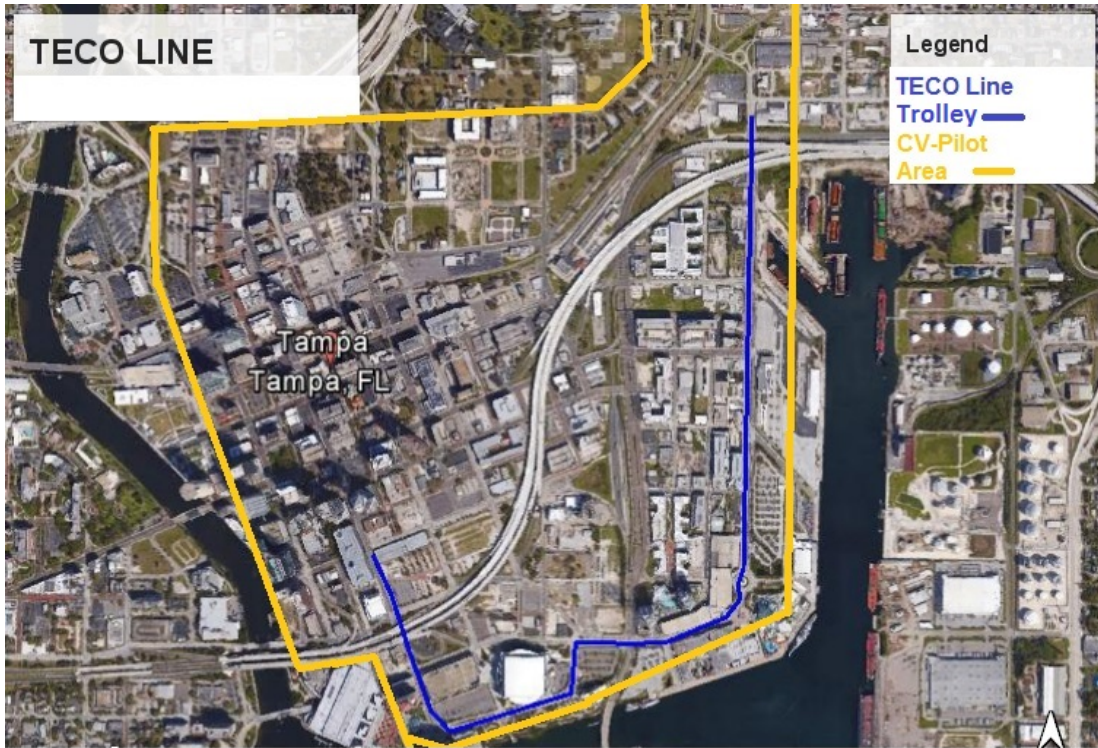


Figure 4: TECO Line Trolley
Source: (THEA, February 2016)

These transportation features have the following identified issues:

1. The Selmon Expressway's REL morning commute endpoint is at the intersection of Twiggs Street and Meridian Avenue. Twiggs Street and Meridian Avenue are also major routes for HART buses into and out of the downtown Tampa CBD. Drivers experience significant delay during the morning peak hour resulting in, and often caused by, a correspondingly large number of rear-end crashes.
2. At the entry to the Selmon Expressway REL during inbound operations (6:00 AM – 1:30 PM weekdays) there are occasionally wrong-way entries.
3. Bus Rapid Transit (BRT) routes offer efficiency gains in moving more people; however, during peak periods, the BRT service suffers from poor signal progression, heavy volumes and passenger vehicles blocking access to bus stops.
4. Meridian Avenue and West Kennedy Blvd experience transit signal delay, pedestrian conflicts and signal coordination issues.
5. At the Hillsborough County Courthouse on Twiggs Street, there is significant competing vehicular and pedestrian traffic during the morning peak hour (7:00 AM – 10:00 AM). There are a significant number of pedestrian-vehicle mishaps.
6. Vehicles and pedestrians conflict with the TECO Line Streetcar Trolley at crossing locations throughout the project area, particularly along Channelside Drive.
7. On the east portion of the project area along the Channelside Drive corridor, visitors experience delays associated with arrivals and departures at the International Cruise Ship terminals and the Amalie Arena.
8. MAFB experiences long queue times at controlled access points during the peak morning arrival time. THEA is working with MAFB to add Dynamic Message Signs (DMS) at decision points and real-time

cellphone-based routing to facilitate the dissemination of queue time and alternative entry point information. A study is currently underway to determine the best approach to this issue and it is likely that the project will benefit from this Pilot by adding a CV component. MAFB presents an opportunity to create a fleet of vehicle probes for data collection. This is possible through its commuter vehicle population and through its Toll Incentive Program (TIP) that has van pool vehicles in addition to HART buses. MAFB employees have proved to be willing participants in transportation enhancement projects.

4.1.3.1 Traffic Operations

The THEA Transportation Management Center (TMC) is at the site of the THEA offices at the entry/exit point of the Selmon REL on Twiggs Street. The TMC is used to oversee the traffic operations in the City of Tampa and the Selmon Expressway by a computer controlled traffic signal system, CCTV coverage of key locations for verification of incidents and dispatch and coordination of aid in the City of Tampa and with the Regional TMC operated by Florida Department of Transportation (FDOT).

Traffic Operations Characteristics:

- THEA owns and maintains the TMC while the City of Tampa staffs the TMC.
- The City of Tampa operates and maintains signing and flashers at the mid-block crossing at the Hillsborough County courthouse. The City of Tampa also operates the parking garage across from the courthouse.
- THEA owns the Meridian Avenue roadway and the City of Tampa operates the Meridian Avenue signals.
- The City of Tampa owns the city streets with the exception of Meridian Avenue and operates the traffic signal system citywide.
- THEA owns and operates the Selmon Expressway, a primary route into downtown and to MAFB.
- HART owns, maintains, and operates its transit operations center. HART operates an REL-based express route that goes through the downtown city streets to the Marion Street Transit Station. HART operates many other routes of which about 9 use the Marion Street Transitway. HART operates the TECO Streetcar line. HART has 189 buses and 9 operating streetcars that are run by approximately 400 bus drivers and 25-30 motormen.

4.1.4 Apps, Use Cases and Locations

The THEA CV Pilot Deployment is an experiment that uses a subset of the applications, or apps, that are delineated in the Connected Vehicle Reference Implementation Architecture (CVRIA) (Iteris, Accessed June 2015). The project uses ten apps³ from CVRIA that are listed in Table 2 with a brief description. (More complete descriptions are available on the CVRIA website.) Several of the applications to be examined in this traffic-effects study were tested in the UMTRI CV Safety Pilot (EEBL, FCW and IMA) (Harding, et al., August 2014).

³ The current number is eleven. Red Light Violation Warning (RLVW) is part of Use Case 2.

Application	Description
Curve Speed Warning (CSW)	Alerts driver approaching curve with speed safety warning
Emergency Electronic Brake Light (EEBL)	Enables broadcast to surrounding vehicles of severe braking
Forward Collision Warning (FCW)	Warns driver of impending collision ahead in same lane
Intersection Movement Assist (IMA)	Indicates unsafe (i.e., wrong way) entry into an intersection
Pedestrian in a Signalized Crosswalk (PED-X)	Alerts vehicle to the presence of pedestrian in a crosswalk
Pedestrian Mobility (PED-SIG)	Gives pedestrians priority with signal phase and timing
Intelligent Traffic Signal System (I-SIG)	Adjusts signal timing for optimal flow along with PED-SIG and TSP
Vehicle Data for Traffic Operations (VDTO)	Uses vehicles as probes to detect potential incidents, (also called Probe-enabled Data Monitoring or PeDM)
Transit Signal Priority (TSP)	Allows transit vehicle to request and receive priority at a traffic signal
Vehicle Turning Right in Front of Transit Vehicle (VTRFTV)	Alerts transit vehicle driver that a car is attempting to turn right in front of the transit vehicle

Table 2: Connected Vehicle Apps in the THEA CV Pilot.

Source: (THEA, February 2016)

The THEA CV Pilot has developed six Use Cases that combine the ten CV apps. They are summarized in Table 3 and mapped in Figure 5. The Use Cases, apps and locations are summarized in the “Spider Diagram” in Figure 6.

Use Case	Condition	Location
UC1	Morning Backups	Selmon Expressway REL at E. Twiggs Street
UC2	Wrong Way Entry	REL at E. Twiggs Street and Meridian Street
UC3	Pedestrian/ Vehicle Conflicts	E. Twiggs Street at George E. Edgecomb Courthouse
UC4	Traffic Progression	Meridian Street to MAFB
UC5	Transit Trip Time, Transit Safety	REL to Marion Street Transit Mall
UC6	Trolley/Auto/Pedestrian/Bike Conflicts	Channelside Drive

Table 3: THEA CV Pilot Deployment Use Case Summary

Source: (THEA, February 2016)

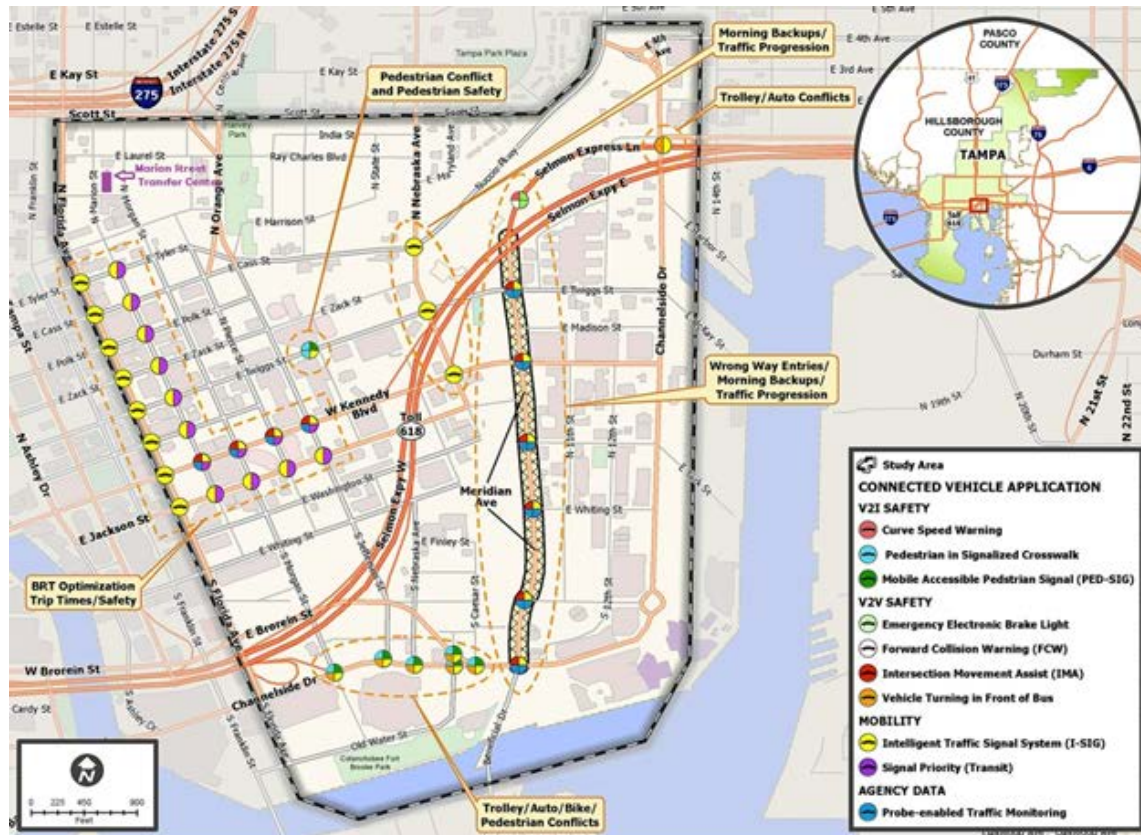


Figure 5: THEA CV Pilot Deployment Locations
 Source: (THEA, February 2016)

4.1.4.1 Use Case 1: Morning Peak Hour Queues

As vehicles exit the inbound Selmon Expressway REL onto Meridian Street and make right turns onto East Twiggs Street, the right-turn lane backs up due to local congestion. An additional issue is that many of these vehicles then want to make a right turn onto Nebraska Street which is almost an immediate right turn after turning onto East Twiggs Street. The combination of these issues causes the queue to backup up onto the REL. This backup causes exiting vehicles wanting to turn right to use the shoulder as part of the right turn lane. As vehicles approach the REL exit, they may not be able to anticipate where the end of the queue is for the right turn lane, potentially causing them to hard brake or attempt a rapid lane change. Applications to be deployed at this location are:

- V2I – CSW
- V2V – EEBL
- V2V – FCW
- V2I – I-SIG.

4.1.4.2 Use Case 2: Wrong Way Entries

At the exit of the REL onto East Twiggs Street and Meridian Avenue, there is a relatively easy opportunity for a driver to become confused and attempt to enter the REL going the wrong way, especially when traffic flow from the REL is low near the end of the AM peak operation. Drivers traveling cross-directionally on East Twiggs Street can mistakenly enter the REL by inadvertently making a left turn or right turn onto the REL exit. Though

there are barriers that can be seen on the straightaway entry from Meridian Avenue, drivers approaching the intersection on Meridian can misunderstand the purpose of the barriers straight ahead and veer slightly to the left into the REL exit. Each of these possibilities is a safety concern. The CV applications to be used in this Use Case are:

- V2I- IMA
- V2I- I-SIG
- V2I – PeDM (VDTO in CVRIA)⁴.

4.1.3.3 Use Case 3: Pedestrian-Vehicle Conflicts

At the George E. Edgecomb Hillsborough County Courthouse, there is one primary mid-block crosswalk for pedestrian access to/from the main parking garage. The crosswalk is marked and has a yellow flashing beacon light to warn drivers that they are approaching a crosswalk. This crosswalk is the primary route for jurors, lawyers and others to get to/from the courthouse. During morning rush hour, there is significant pedestrian traffic as potential jurors unfamiliar with the area attempt to arrive on time. This is compounded on Mondays and Tuesdays when new juror pools of up to 400 persons are required to report during rush hour. Lack of attention by drivers causes a safety concern for pedestrians trying to reach the courthouse. Some pedestrians elect to take a shortcut by crossing East Twiggs Street mid-block and outside the crosswalk.

Pedestrian-vehicle conflicts also occur at other intersections in the study area including the Port Cruise Line area and Amalie Arena. Inclusion of intersections along Channelside Drive and Meridian Avenue in the vicinity of the port and arena are under consideration.

Planned CV deployments in this Use Case include:

V2I – PED-X

V2I – PED-SIG.

4.1.4.4 Use Case 4: Traffic Progression Enhancement

There is significant congestion and delay along Meridian Avenue during morning peak travel periods. A large proportion of drivers are MAFB commuters traveling through downtown from the REL, from other exits on the Selmon Expressway or from additional arterial routes, trying to reach one of four MAFB entrance gates. These drivers lack information on the travel times for their route versus other routes or the length of the queue at each gate. As some of these commuters are using surface roads through downtown, they interact with other traffic and pedestrians. The interaction of traffic modes increases the potential for pedestrian incidents, creating a safety concern. The CV technologies that will be used to improve mobility and safety through the downtown area for this Use Case are:

- V2I - I-SIG
- V2I – PeDM (VDTO in CVRIA).

4.1.4.5 Use Case 5: Bus Rapid TSP Optimization, Trip Times and Safety

Marion Street is a two-lane urban arterial in the heart of the Tampa CBD that serves as the primary bus route and Transitway and terminates on the north end at the Marion Transit Center. HART operates several routes that converge onto Marion Street at the Marion Street Transit Station. Along these routes, many of the bus stops are on the near-side approach to an intersection. When there is congestion, buses are unable to reach their stops causing them to potentially fall behind schedule, thus, causing a mobility concern. CV technology will be used to address delay. Buses and traffic signals will communicate, and if a bus is behind schedule, the

⁴ Red Light Violation Warning (RLVW) is now part of this Use Case.

traffic signal system will either give the bus priority or flush the vehicle queue allowing the bus to reach its stop, when there are no higher priorities. Performance will be measured in reduced trip times and increased travel time reliability. CV applications planned for deployment of this Use Case include:

- V2I - I-SIG
- V2I - TSP.

4.1.4.6 Use Case 6: Trolley/Auto/Pedestrian/ Bike Conflicts

The TECO Streetcar Line, operated by HART, runs along Channelside Drive from the Amalie Arena area up Channelside Drive and past the Selmon Expressway. The streetcar is a steel wheel on steel rail fixed-guideway system in a dedicated right-of-way. It is powered by an overhead catenary and crosses intersections at grade. As the pedestrians disembark from the streetcar and the streetcar prepares to depart, it is possible for a vehicle to attempt a right turn in front of the streetcar. Pedestrians may be crossing the intersection where the vehicle is turning right as well. The potential of a streetcar-vehicle crash and a pedestrian incident are safety concerns. CV Technology will be used to provide information to streetcar operators, bus drivers, auto drivers, and pedestrians to improve safety at these locations. Performance will be measured by the number of alerts when pedestrian warnings are heeded, or not, and instances of observed and reported conflicts and crashes. Total number of incidents for a similar period before and after the CV-Pilot will also be compared. The CV applications to be used in this Use Case are:

- V2I - I-SIG
- V2I - VTRFTV.

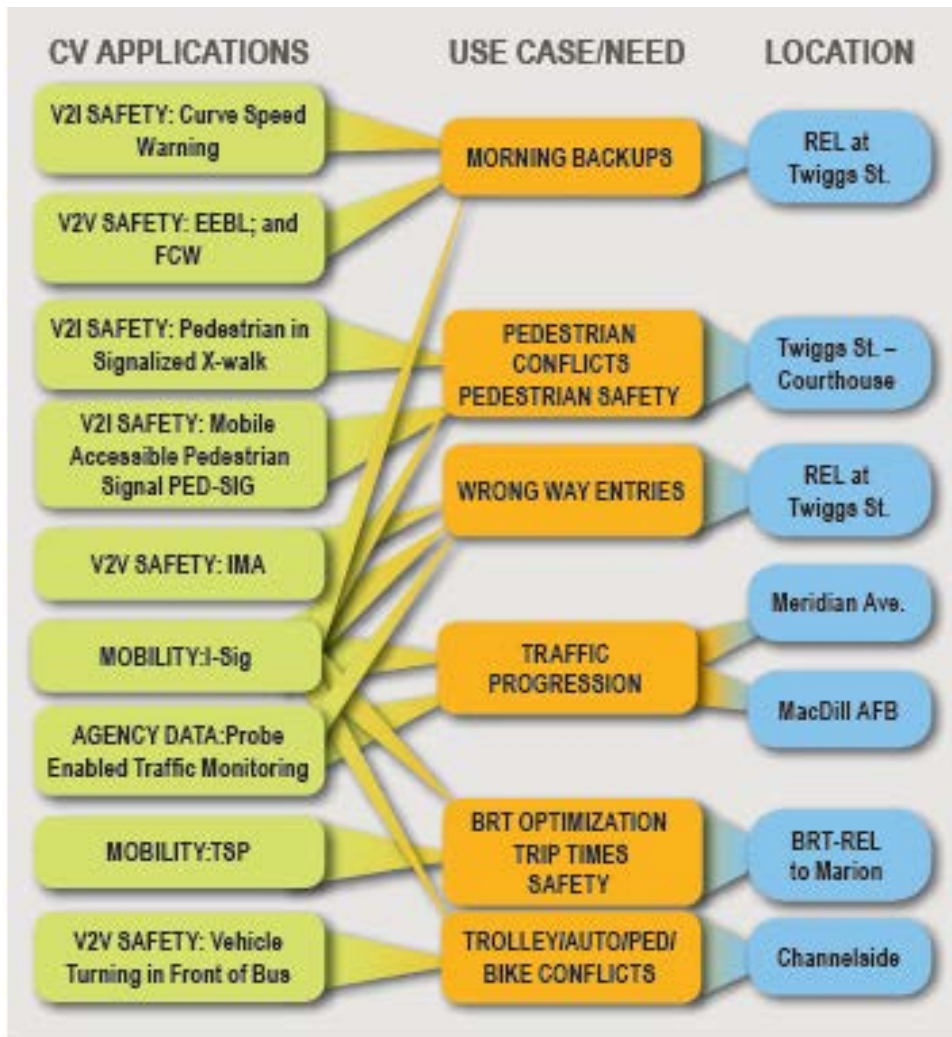


Figure 6: THEA CV Pilot Deployment “Spider Diagram” of CV Applications, Use Cases and Locations
Source: (THEA, February 2016)

4.1.5 Operational Scenarios

Besides defining the scope and background of the project and the Use Cases, the ConOps also supports the systems engineering approach to developing the project. As part of this effort, the ConOps presents user-oriented operational scenarios for each Use Case in terms of:

- Normal Operations - a “no problem” or “no issue” perspective, without any initiation of the proposed CV technologies, which is as the system operates today. This establishes a baseline understanding.
- CV Activation Conditions - conditions that activate or trigger the CV application
- CV Failure/Anomaly/Exception Conditions - situations that require temporarily “turning off” the CV technology/system/device, such as “false” warnings and any “fail-safe” mode that the system would revert to
- CV Maintenance Conditions - the condition of the system where repair is done for a breakdown of equipment functionality or preventative maintenance.

These scenarios establish the What, Where, When, Why, Who and How of the operational condition and together comprise the many operational states that users may experience in the six Use Cases.

With respect to protecting human research participants, the operational scenarios identify conditions where activation, false warnings, fail safe mode, and systems maintenance may arise or be needed. Readers are referred to the Final User ConOps Report (THEA, February 2016) for details.

4.2 Privacy and SMOC – Task3

4.2.1 Preliminary Information about CV Technology for Security Issues

CV technology relies on communications between vehicles (V2V) and between vehicles and traffic infrastructure (V2I). The entire set of combinations which includes Personal Information Devices (PIDs, e.g., smartphones) is known as vehicle to everything or V2X. The infrastructure in V2I is usually referred to as RSUs or Roadside Equipment (RSE).

Vehicle OBUs send out a “Here I am” message, or Basic Safety Message (BSM), every tenth of a second over Dedicated Short-Range Communications (DSRC) which are one-way or two-way short-range to medium-range (about 1 kilometer) wireless communication channels specifically designed for automotive use and with its own protocols and standards. Briefly, the BSM safety V2V core data elements consist of: time, position, speed, heading, acceleration, braking system status and vehicle size. The data within the BSM does not include information on the vehicle owner/operator, make/model, license plate, or VIN. Additional data elements can be added and sent less frequently, depending on vehicle model and purpose, such as heavy braking events and windshield wiper status. (See: http://www.its.dot.gov/itspac/october2012/PDF/data_availability.pdf for an overview) (Cronin, Accessed 2016).

Within Task 3, SMOC, the team developed requirements to maintain privacy and security of users and equipment (THEA, March 2016). These requirements address communications security (to maintain privacy and security V2X device communication), access security (in regard to accessing data and devices), hardware security, and software and operating system security.

4.2.2 Personal Information and Privacy

In general, there will be three types of data collected for the pilot: administrative participant data, CV application data and performance measurement data. Participant data is necessary to track involvement, conduct training, and maintain communications. CV data is the data generated by connected vehicles and/or the communications systems. Performance measurement data is generated from CV data as well as from additional sources, such as video cameras installed on REL infrastructure. Performance measurement data is also discussed in Section 4.4, Performance Measurement and Evaluation Support Plan.

To ensure that data is appropriately protected, these data types should only be accessed and used for their intended purpose. Pilot applications and communications are formulated to protect the privacy of the users to the highest degree possible. Some applications will reveal more data than others. Therefore, it is important that applications only reveal necessary information for applications to function correctly, as revealing the information within application A may allow it to be correlated with information from application B.

To address these concerns for broadcast and transactional unicast (from one point to one other point) communications, the THEA CV Pilot team will implement the following recommendations to maintain privacy:

- Authorization
 - The definition of “authorized to use the service” will be application specific.
- Privacy
 - Not require either party to reveal sensitive information unencrypted.
 - Not contain the User’s location information unless this is necessary as part of service.
 - Not use identifiers that can be straightforwardly linked to the User’s real-world identity (VIN, license number, etc.).
 - Use temporary and one-time identifiers. Separate instances of the exchange shall not use identifiers (USER MAC address, UE-ID (IMEI), IP address, certificate, temporary ID, session ID, etc.) that have been used in a previous instance of the exchange.

For all data that is collected and shared for further research, permissions must be obtained from the personnel that generated the data. Of course, these privacy concerns differ between state/local-owned vehicles and privately owned vehicles. The privacy process for determining how to manage data for processing and sharing is listed below. These processes and rules reside within the Performance Management Plan in development which provides more detail on the process.

- 1) **Establish data ownership.** As a general rule, whoever owns the vehicle generally, but not always, owns the data generated by that vehicle.
- 2) **Secure consent from the data owner.** The owner of data must consent to providing the data in an agreement (drafted by the CV Pilot THEA team) that spells out how the data is used and by whom. This should include the redistribution of data to third parties.
- 3) **Protect the privacy of the data owner.** Any information that reveals the identity of the data owner must be eliminated.
- 4) **Identify data aggregation issues.** In some cases, aggregating CV data over time can reveal patterns that are sensitive from the point of view of commercial, military or other propriety information about the internal operations of firms or agencies.
- 5) **Obtain data sharing agreements prior to uploading data to any repository.** These data sharing agreements must be approved by all entities, and/or their representatives, whose data will be included in the data sets that the CV Pilot team will be providing to the USDOT Research Data Exchange (RDE) or the Saxton Transportation Operations Laboratory (STOL) repositories. The RDE will provide publicly available data services that support CV research activities (USDOT FHWA, Accessed 2016).

If a stakeholder would like to receive vehicle data for their vehicle or vehicle fleet (e.g., HART), such data could be available to them at intervals if specified within the consent agreement. In the event that any data is actually collected by the device and periodically downloaded by the THEA CV Pilot team (e.g., buses and streetcars), the owner will have the opportunity to receive a copy of that data. The vehicle situation/probe data collected by RSEs will not be available to users, because the privacy of vehicle situation/probe data is protected by the “privacy by design” features of the Security Credentials Management System (SCMS) Proof of Concept (POC) and IEEE 1609.2 IEEE Standard for Wireless Access in Vehicular Environments — Security Services for Applications and Management Messages, which will be discussed further in the following sections, and the owner will not be known.

4.2.2.1 Participant Data

Currently, the team anticipates that Participant Training and Stakeholder Education will require collection of the following PII in order to administer training and education leading up to and continuing throughout the pilot deployment.

- Name
- Date of Birth
- Contact information
 - Home and work mailing addresses
 - Email
 - Phone number
- Copies of
 - Driver license identification number
 - Insurance card
 - Vehicle registration
 - Vehicle type data, VIN data
- Demographic data (as defined by Task 5: Performance Measurement)
 - Age
 - Sex
 - Race
 - Language preference (English/Spanish)
 - Recruitment method that attracted participation

Data on age, gender and race/ethnicity for will be used to show how all groups are represented in the conduct of the study.

The THEA team is currently planning for Participant Outreach to include the following methods and avenues of communication.

- Public-facing website
- Secure participant portal on the website for communications with participants
- Electronic newsletter to participants
- Email and/or SMS alert system for critical communication with participants.

These communications methods will require collection of information on participant contact information such as email address and phone number to send newsletters, emails, and/or SMS alerts. Participants will also have to register for access to the secure participant portal on the website with a username and password. If there is a security breach related to personal information of participants, the THEA pilot team will notify the participants of the breach, the nature of the breach, and how the team will resolve it.

The participant data collected for registration, ICD signing, incident reporting, questionnaires, leaving the project and so forth must be in an encrypted, standalone, password-protected database and kept separate from CV data used by the TMC and Performance Measurement team. There should be an established list of team personnel that have access to the data and should be physically separated from CV data. The THEA CV Pilot team will limit access to those personnel who require access to the data in order to perform their duties within the pilot deployment.

4.2.2.2 CV App Data

Personal information collected in the THEA CV pilot will be kept to the minimum necessary for the V2X system to function effectively. CV app data collected by the V2X communication system as described in the THEA CV Pilot ConOps will not contain specific PII or PII-related data. The application assessment does not directly reveal any PII or PII-related information being collected. However, concerns have been raised on the overall privacy implications of a system in which vehicles broadcast location and motion information 10 times every second. Much of these privacy concerns are addressed in the SCMS POC and associated security standards that will be implemented during the CV Pilot.

The SCMS POC being built by the USDOT and Crash Avoidance Metrics Partnership (CAMP) has “privacy by design” as a major tenet of the system development. The CAMP partnership is a consortium of auto makers working in cooperation with the National Highway Traffic Safety Administration (NHTSA) to advance the safety research objectives of USDOT’s Intelligent Vehicle Initiative. All V2X system communications will utilize the SCMS POC design along with the IEEE 1609.2 standard to provide communications security and protect user privacy. In order for vehicle Onboard Equipment (OBE), PIDs, and RSUs to communicate, they must be enrolled with the SCMS which will provide certificates to prove authenticity of their BSMs and other messages. Note that the BSM does not contain personal information. It only contains the location and motion characteristics of the vehicle (e.g., speed, heading, acceleration) and certificate information. To protect privacy and prove authenticity, OBEs and PIDs will use pseudonym certificates to sign all messages. Based on information provided by USDOT on the current SCMS POC design, the device will have a pool of 20 certificates that are valid simultaneously for only one week. Certificates for consecutive time periods (i.e., each week) are valid simultaneously for one hour. The device will rotate through certificates every five minutes to limit trackability, which is a commonly voiced concern, and preserve privacy. Also, any communication to the SCMS through the RSE, for example to replenish certificates, is encrypted and also passes through the Location Obscure Proxy which strips the request of any device identifying information. All devices will be compliant with the SCMS POC Implementation End Entity Requirements and Specifications Supporting SCMS Software Release documentation to support execution of SCMS POC interaction.

4.2.3 V2X System and Device Security

As stated in the previous section on PII, communications security for the THEA CV Pilot is largely ensured through compliance with the SCMS POC design and existing standards and protocols, such as IEEE 1609.2. However, these designs and standards do not cover the security for every aspect of the full V2X communications system. The team developed further requirements and guidance on access security, hardware security, and software and operating system security to limit vulnerabilities and protect users and equipment. Even if the devices malfunction or are compromised, the SCMS POC will specify misbehavior detection strategies to determine if devices are misbehaving (e.g., sending BSMs with blatantly incorrect data, such as a speed of 200 mph) and identify to remaining devices within the V2X system that the specific device is misbehaving. Devices that receive messages from a known misbehaving device will simply ignore the messages. The team will also implement external reporting mechanisms where the participant, technician, TMC operator, etc. can report suspected device misbehavior. In these cases, the misbehaving device will be replaced and evaluated to determine the cause of misbehavior.

4.2.3.1 Access Security

The Privacy and SMOC addresses access security, such as the various role-based users that can access V2X devices, user name and password policies, and whether remote access to devices is permitted in the THEA CV Pilot. The team will leverage existing THEA access security related policies, such as the THEA Network Security Policy, THEA/City of Tampa Joint TMC Memorandum of Understanding (MOU), and Standard Operating Procedures (SOP) to reuse as appropriate and modify as necessary for use in the Pilot. New organizational roles will be created to oversee the execution of the security concept and continued operation of the V2X security and privacy system. These new roles include an Information Security Director, Information Security Manager, Provisioning and Maintenance Engineers, and Network Administration. These new roles may be filled by existing personnel as additional duties. The THEA CV Pilot team will provide training to personnel filling new roles, as well as the TMC and the rest of the THEA CV Pilot team in general, on new privacy and security processes and procedures. Physical device access will require role-based authentication

and remote access (which will only be supported by RSUs and other fixed infrastructure) will require identity-based authentication.

At least one server with adequate disk space will be dedicated to archive pilot data. Data collected by the pilot will eventually become part of the USDOT RDE, and be available to Test Bed Affiliates and other IEs. CV data collected from vehicles and RSUs will not contain any PII or PII-related information. There will also be controls in place to limit the ability to string vehicle trips together, such as the strategy of having mandatory gaps in the vehicle situation/probe data. Even with these controls, the THEA CV Pilot team will scrub vehicle situation data to determine the effectiveness of strategies in providing privacy, not necessarily just anonymity, to participants. If not effective, these strategies will be supplemented by existing sanitization algorithms used by SE Michigan Testbed to remove pieces of trip data before submission to the RDE.

CV app data used to produce traffic data (e.g., volume, occupancy, travel times, location, heading, speed) collected from vehicles, RSUs, and other devices will not be housed with PII and PII-related data on the participants, which is maintained for administrative and performance management reasons. These databases will be maintained separately and one person or role will not have access to both databases. Only TMC personnel and/or roles will have access to the CV data stored and analyzed by the TMC. Only select human use, registration and participant training personnel, or other group as specified in later concepts and plans, and/or roles will have access to participant data. Participant data will only be used for administrative purposes in tracking devices (and reconfiguring malfunctioning devices) and for performance management purposes. The THEA CV Pilot team will look into the potential to have these databases on separate networks and/or physical locations to increase privacy and security.

4.2.3.2 Physical Security

Security requirements for each device classification that will be used in the pilot specify hardware security control requirements to prevent physical key extraction and similar attacks. The team used a widely accepted standard used to specify hardware security requirements, Federal Information Processing Standard (FIPS) 140-2: Security Requirements for Cryptographic Modules. FIPS 140-2 covers security requirements for cryptographic modules, including protections to prevent device tampering such as tamper evident protections and tamper resistant protections.

4.2.3.3 Software and Operating System Security

While FIPS 140-2 addresses the majority of hardware security requirements, it does not cover all software and operating system requirements, which also need to be addressed. These requirements ensure BSMs cannot be modified and that additional software cannot be installed that would allow an attacker to generate false BSMs using valid BSM keying material, among other threats. Software and operating system security requirements were developed to cover various types of device architecture, manufacturing and operational states, secure device boot, and operating system.

4.3 Safety Management Plan – Task 4

4.3.1 ICDs and Safety

The Safety Management Plan is applied in the ICDs. As the Safety Management Plan Final Report (THEA, March 2016) states and the ICDs confirm, the driver must be in control of the vehicle, and pedestrians, as well, must assess the situation and react appropriately, and obey traffic signs and Florida law. The ICDs for drivers clearly state this Pilot experiment is not an autonomous vehicle test. The ICDs for all participant groups - car

drivers, pedestrians and transit drivers - include instruction details for contacting the THEA representative so the participant can get instructions for reporting any issues and getting the device repaired or replaced. The following twelve situations were identified in the Safety Management Plan and addressed in the ICDs as possible failures that would require such help:

- Any device failure where the device is not operating as user was instructed that it should.
 - The device installed inside the cabin of the vehicle may detach and cause damage or harm in the case of a crash.
 - Problematic location of device installation.
 - The device installed inside the cabin of the vehicle detaches while the vehicle is in normal operation.
 - There is a short circuit in the equipment installed that causes overheating.
 - Improper installation causes device to drain the battery of the test vehicle.
- The detection at the pedestrian crossings malfunctions failing to issue a warning to either a participating pedestrian or a participating driver.
- Communication failure causes device to issue incorrect warnings or not to issue a warning when a hazard is present.
- A misconception by the participant results in the participant believing the system takes control of the vehicle in case of a hazard.
- The driver is distracted by the device information and warnings.
- The participant becomes dependent upon the application to warn them of safety risks.
- The driver reacts to the warning messages in an undesirable way, such as hard breaking, swerving, becoming distracted or startled and causing a crash.

4.3.2 Safety Functions

There are several safety functions that will be addressed in the Safety Operational Concept. Further details are to be found in Section 6 of the Safety Management Plan Final Report:

- Equipment Procurement
- Device Installation
- Fail-Safe System Mode
- Quality Training.

Equipment Procurement will utilize quality equipment by requiring all of the suppliers to provide and follow an approved quality management process in designing, constructing and producing their devices.

Device Installation will be comprised of manufacturer approved vendors or THEA CV Pilot partner personnel who have been sufficiently trained by manufacturer approved vendors and will include lessons learned and best practices in the installation procedures.

Fail-Safe System Mode guarantees that in the event of a system failure, the system and devices will respond in a way that will cause no harm to the system, devices, participants, or other road users

Quality Training means that all participants, system operators, system maintainers, installer/maintainers and owners of a response plan referenced herein will receive adequate, approved training based on their point of interface with the system. This training will be documented as it occurs as part of the THEA CV Pilot Deployment. This training will include a training course in protecting human research participants as prescribed and delineated in Section 5 of this Research Protocol.

4.3.3 Safety Management

Safety Management requires oversight by a Safety Manager, with responsibility for all the key safety areas:

- Leadership and direction in safety procedures
- Ensuring compliance with applicable regulations and the Safety Management Plan
- Incorporating safety into design, deployment, and operational phases
- Guidance for equipment procurement and acceptance
- Oversight for device certification, testing and installation
- Safety leadership for maintenance and updates
- Operational safety and monitoring
- Safety documentation and training
- Incident reporting, documentation, and investigation
- Maintaining and updating safety processes and the Safety Management Plan
- Safety coordination with other entities and task leads.

The Safety Incident Process is designed to standardize the management of any roadway incidents involving the CV Pilot's participants. As Figure 7 shows, in Step 1, when an incident occurs involving a participant, the appropriate law enforcement and emergency services are notified immediately and in Step 2 agencies respond. Steps 1 and 2 are standard for anyone involved in a traffic incident. In Step 3 the Safety Manager fills out an Incident Report (see Appendix A of Task 4 Report (THEA, March 2016)). Step 4 includes the incident as part of the Safety Review (see Appendix B of Task 4 Report (THEA, March 2016)). Steps 5 and 6 indicate the action to be taken and the communication to the THEA team and incorporated into the Safety Management Plan. Sections 4.3.4 and 4.3.5 give more detail on Steps 3 and 4 for Incident Reporting and Safety Reviews (THEA, March 2016).

4.3.4 Safety Incident Reporting

Incidents will be reviewed following the procedures in Section 6.2.3 of the Safety Management Plan and documented utilizing the Incident Report Form in Appendix A. The intent of a safety incident reporting process is to identify improvements that can be made to prevent a recurrence of that incident. The following safety incident reporting policy will be followed.

- Safety incidents will be reported and recorded by the participants and team members using the draft Incident Report Form in the Appendix.
- Participants will receive guidance on safety reporting during their training.
- Safety incidents will be investigated and the underlying causes identified.
- Serious harm incidents will prompt a review of the Safety Management Plan.
- A regular review of all safety incidents occurs to identify any trends.

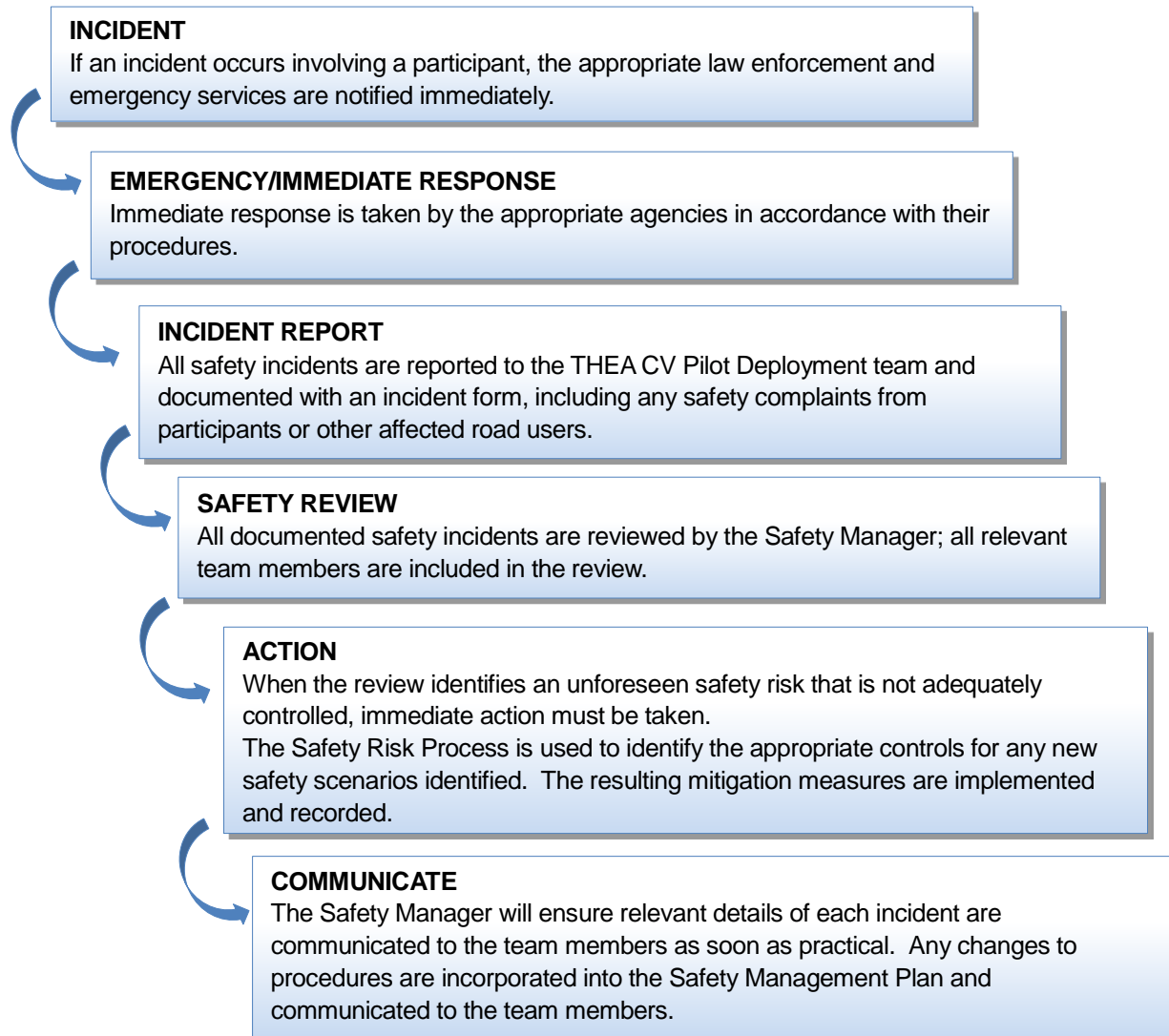


Figure 7: Safety Incident Process

Source: (THEA, March 2016)

4.3.5 Safety Reviews

Regular assessments help to identify any new safety risks and develop the appropriate control measures. When THEA conducts safety reviews (Safety Review Template, Appendix B) THEA will ensure that:

- Reviews are conducted by the appropriate technical experts and team members
- Opportunities for improvement are identified
- Outcomes are communicated to the team members
- Actions arising from reviews are implemented
- Ongoing monitoring is maintained to ensure that our operations comply with the Safety Management Plan.

Reviews will be conducted at the following key points:

- Safety review for each project deliverable in Phase 1 to determine if there are any impacts to safety risk assessment and to ensure mitigation of risks
- Safety review of the design
- Design review before installation
- Safety review before deployment
- System security review before deployment
- Equipment, software and process check before deployment
- Periodic equipment, software, and process checks during operation
- Regular safety communications and updates
- Safety investigation after an incident
- Following a critical event or significant change that may impact safety
- After a complaint of a safety nature is received from participants, team members, or others
- Following a change in the applicable standards and codes of practices.

4.4 Performance Measurement and Evaluation Support – Task 5

This summary offers a human-use-oriented overview of the Performance Measurement and Evaluation Support Plan (THEA, April 2016) which outlines the goals and objectives for the Pilot as well as the proposed performance metrics. The document addresses:

- Problems and operational needs by Use Case of the Pilot goals - improving Mobility, Safety, Environment and Agency Efficiency
- The improvements desired for the six Use Cases
- The goal-related performance measures for each of the Use Cases
- Confounding factors
- System deployment impact evaluation
- Methods and procedures for data collection
- Methods for estimating and reporting each identified performance measure
- The interface between THEA and the Independent Evaluation effort.

Because this deployment will utilize several CV technologies in different locations to deal with a collection of safety and mobility field conditions, an experimental design, participant selection and set of performance measures are described for each of six Use Cases. The experiment design identifies three approaches to control and minimize the impact of study-area specific and deployment-specific confounding factors: random design, quasi-experimental design, and before and after comparison (time series analysis). These experiment designs are applied, as appropriate, to each Use Case. While each Use Case may not be appropriate for evaluation in each of the four evaluation pillars - Safety, Mobility, Environment, and Agency Efficiency, the assessment of the full set of CV application deployments will address all of them.

Section 4.2 of this report, Personal Information and Privacy treats PII and the permissions that must be obtained from the personnel that generated the data. In general, there will be three types of data collected for the pilot: administrative participant data, CV application data and performance measurement data. Participant data is necessary to track involvement, conduct training, and maintain communications. CV data is the data generated by connected vehicles and/or the communications systems. Performance measurement data is generated from CV data as well as from additional sources, such as video cameras installed on REL infrastructure.

The Performance Measurement approach safeguards human research participants:

- All data will be securely transmitted, scrubbed of PII, stored, and released for analysis as delineated in the SMOC Plan (Section 4.2.2).
- Permissions must be granted from the personnel that generated the data for all data shared for further research. Consent must be secured from the data owner (Section 4.2.2).
- CV data will be analyzed in aggregate for standard traffic engineering measures such as average travel time, percent arrivals on green, etc. as shown in Table 4 without identifying individuals. Aggregate data may reveal operational security issues at sensitive facilities (e.g., MAFB) or identify groups and must be cleared for use, though scrubbing of PII may make such stratifications impossible.
- Statistical measures will be applied to crash, incident and alert warnings from a secure database. Individual drivers will not be identifiable nor of interest to the research.
- Video data will be used to observe and verify traffic situations, not individual vehicles or pedestrians. Pilot participants will not be visually distinguishable from non-participants by equipment design. It may be necessary to mask license plates before release or limit authorization.
- An IE will use scrubbed CV data and perform simulation and other analysis of the traffic network to reach its own conclusions on CV performance. Other researchers and USDOT contractors may gain access to the scrubbed data only through permissions with mutual agreement of THEA and USDOT.
- Survey data will be requested from participants to better understand participant experience with the apps and will be stored securely and accessed as in the SMOC Plan
- Participants will not be unduly inconvenienced to fill out surveys or requested to go to a location to download data from OBUs and PIDs. Their survey information will be scrubbed of PII.

The procedures and processes detailed in this plan will be edited and clarified in the Final Phase 1 submission on May 16, 2016 and scheduled for USDOT approval by May 23, 2016. The final plan will be modified as the Pilot deployment for Tampa moves into Phase II. Amendments with respect to performance measures and evaluation support for protecting human research participants will be submitted as details come to light and revisions are suggested.

4.4.1 Oversight of Performance Measures PII in Phase 2

CUTR is the task lead for Phase 1, Task 5, Performance Measurement and Evaluation Support. The USF IRB, which has oversight of CUTR's activities, will review PII elements of CUTR's Performance Measurement work in Phase 2.

Performance Pillars	Performance Measures	UC1 Morning Peak Hour Queues	UC2 Wrong Way Entries	UC3 Pedestrian Conflicts at Courthouse	UC4 Bus Rapid Transit Signal Priority Optimization , Trip Times and Safety	UC5 TECO Line Streetcar Trolley Conflicts	UC6 Enhanced Signal Coordination and Traffic Progression
Mobility	Travel time	✓	✓	✓			✓
	Travel time reliability	✓		✓			✓
	Queue length	✓		✓			✓
	Vehicle delay	✓	✓	✓			✓
	Pedestrian delay			✓			
	Percent (%) arrival on green	✓			✓		✓
	Percent (%) red light violation/running	✓			✓		✓
	Bus travel time				✓		
	Bus route travel time reliability				✓		
	Percent (%) arrival on schedule				✓		
Safety	Crash reduction	✓	✓	✓		✓	✓
	Crash rate	✓	✓	✓		✓	✓
	Type of conflicts / near misses	✓	✓	✓		✓	✓
	Severity of conflicts / near misses	✓		✓		✓	✓
	Approaching vehicle speed	✓	✓	✓			✓
Environmental	Emissions reductions in idle	✓	✓	✓	✓		✓
	Emissions reductions in running	✓	✓	✓	✓		✓
	Excess time spent in idle		✓				
Agency Efficiency	Mobility improvements through the mobility pillar analysis	✓	✓	✓	✓		✓
	Safety improvements through the safety pillar analysis	✓	✓	✓		✓	✓
	Customer satisfaction through opinion survey and/or CV app feedback	✓	✓	✓	✓	✓	✓

Table 4: Summary of Performance Measures

(Note: UC 4, 5 and 6 are referred to as UC 5, 6, and 3 elsewhere in this report.)

Source: (THEA, April 2016)

5.0 Participant Human Use

Participant Human Use is the primary subject of interest to the IRB addressed in the RPD. The discussion is broken out by user group: auto drivers, pedestrians and transit agency. For each traveler type a common set of issues was identified that addressed the lifecycle of participant involvement, including:

- recruitment
- selection
- registration/ICD signoff
- training
- installation
- device use
- reporting
- retiring
- retrieval.

These issues are discussed in the RPD in Section 5. The treatment of vulnerable populations is unique to this Human Use Approval task and developed in conjunction with recruitment issues in the Participant Training and Stakeholder Evaluation Plan (Task 9) and the Outreach Plan (Task 11). Salus IRB approved the inclusion of these vulnerable populations in the THEA CV Pilot and added that employees and family members of the study team and sponsor could participate as well without conflict of interest or repercussions over participation.

Changes to activities in this section will determine the need for and timing of amendments to the RPD and ICDs. The timeline of amendments to participant human use, and other tasks as well in Section 4, is, therefore, tied to their development schedules.

The remainder of Section 5 is taken from the RPD that presents Plans for Participant Protections and Participant Human Use. This important topic is presented as it was approved by the IRB in the THEA CV Pilot, Phase 1, Task 8, Human Use Approval. (Section numbers used in this Human Use Approval Summary coincidentally conform to the section numbering in the RPD.)

5.1 Safeguards for Protecting Vulnerable Populations

Among the vulnerable populations who may participate in this research are: pregnant women, non-English speaking persons (eight percent Spanish and one percent Haitian-Creole), educationally disadvantaged and economically disadvantaged persons. Vulnerable persons are not targeted for this study, nor are they to be systemically left out. Participation by anyone meeting minimal requirements is welcome. Because of the expense involved, efforts may not be made to attract non-English speakers by offering Spanish versions of the recruitment advertisements, though it is anticipated that ICDs and training materials will be made available in Spanish.

5.1.1 Drivers

The automobile portion of the project is targeted to licensed auto drivers of any age, which may include vulnerable groups. If a person is qualified to drive a car, he or she is considered qualified to participate in the

car-driver portion of the study. Only drivers who travel through the study area are needed for the study. If a registered vehicle does not appear on an RSU in a given period, the owner will be contacted to see if they are participating. Drivers are expected to agree to participate for the 18 months of the study, though they can leave at any time by making arrangements to have the equipment removed upon withdrawing.

5.1.2 Pedestrians

The project does not expect or require pedestrian participants to have a driver's licenses. Pedestrian requirements are a suitable cellphone or other PID, contact information and meeting the age of majority in Florida which is 18. No maximum age is set.

5.1.3 HART

It is proposed that, as a stakeholder and the owner and operator of the transit system and vehicles, HART will be the CV Pilot participant. HART will be given an ICD to sign which will include provisions for drivers' participation. The Amalgamated Transit Union Local 1593, AFL-CIO-CLC represents the HART workers under a contract that expired September 15, 2015 and is still in use under continuance. According to the contract HART has the authority to modify job assignments (Article 4) and HART "shall make reasonable provisions for the safety and health of its employees during the hours of their employment in accordance with all applicable Federal, State, and local laws" (Article 33) (Hillsborough Area Regional Transit and Amalgamated Transit Union Local 1593, October 1, 2012).

Only vehicle information will be needed. Project managers will not need to contact a driver (e.g., for an OBU repair appointment), and so drivers' personal information will not be needed or collected. HART rotates its buses among different routes such that the drivers of an equipped bus may change frequently. Identification of a driver with a vehicle will not be possible with the CV Pilot database. HART does keep its own independent records of driver and vehicle assignments. Training, possibly by video, which offers consistency, will be provided to HART drivers for familiarization with the equipment and safety reporting procedures. A person with certification in protecting human research participants will introduce the research study and answer questions.

5.1.4 MAFB

A proportion of persons who use the Selmon Expressway REL, Meridian Avenue and Twiggs Street are MAFB employees. MAFB is a Stakeholder in the project and their employees could conceivably be considered vulnerable populations. While MAFB will help to advertise the study, MAFB employees will be registered through the standard process used for everyone off the base. Special incentives beyond those offered to everyone else or special treatment will not be offered to MAFB study participants.

5.1.5 Traffic Management Center (TMC) Operators

Traffic operations personnel in The THEA TMC have a variety of duties which include documenting incidents. The Performance Measurement Plan includes collecting data on alerts that come through the TMC from passenger car OBUs, pedestrian apps, and HART streetcars and buses. Digital data will be collected automatically, but the THEA CV Pilot will add reporting of alerts that involve incidents into the THEA CV Pilot database. The TMC Operators are not human research participants in the study and have no direct contact with the participants. It is not expected that THEA TMC Operators will need to sign ICDs, but that the reporting procedure will be incorporated as part of their regular duties as TMC personnel. To make TMC Operators aware of the human use issues of the reporting they will be doing, THEA TMC Operators will be trained in the reporting procedure for alerts by THEA engineering staff that are working for the THEA CV Pilot and who have taken training in protecting human research participants.

5.2 Participant Lifecycle

When the project viewpoint moves from systems engineering and device functionality to human use, the project takes on a substantially different look and feel. Participants have an entirely different set of concerns from systems engineers and their needs and treatment is a subject unto itself. Through the lifecycle of participant involvement, the tasks include: recruitment, selection, registration/ICD signoff, training, installation, device use, reporting, retiring and retrieval. The THEA staff persons who work in the selection, registration training and installation process will complete a course in *Protecting Human Research Participants* from the NIH web-based training course or obtain equivalent certification.

5.3 Human Use Treatment of Drivers

5.3.1 Recruitment

Participating car drivers are expected to come from the Tampa commuter shed in the outlying Brandon suburbs, where the Selmon Expressway REL originates, and from the commuter population in the greater Tampa area whose morning commutes terminate in or travel through downtown Tampa. Recruitment will target commuters headed to downtown Tampa, other destinations near downtown and MAFB, who use the REL, Meridian Avenue, Twiggs Street, Channelside Drive, and other roads in the study area.

The study design is intended to provide a balanced sample of drivers by age and gender. However, obtaining the desired number of participants in the specified age groups in a timely way may prove to be difficult. Of most concern is attracting both younger (ages 18 to 20) and older (ages 70 and above) drivers and pedestrians. Special efforts may be necessary to meet sample requirements. The study also expects to attract a number of non-English-speaking participants, especially native Spanish speakers, who make up approximately eight percent of the Hillsborough County population, according to the U.S. Census Bureau. However, there will not be a specific effort to recruit non-English speakers.

THEA will take a staged approach to recruiting. Most recruiting efforts will point potential participants to the THEA CV Pilot website which will feature a recruiting page that includes:

- A video introducing potential participants to CVs, THEA and the basics of participation
- A Frequently Asked Questions (FAQ) section, with the ability to ask additional questions (via online form and email)
- A questionnaire that will screen potential participants based on pre-established criteria
 - Adult (18+)
 - Valid driver license
 - Valid automobile insurance
 - Vehicle ownership (not lease vehicle) and Vehicle Identification Number (VIN)
 - 1997 model year or newer vehicle (OBD II port availability)
 - Commute point of origin and destination
 - Basic demographic information
 - Age
 - Gender
 - Race
 - Language preference (English/Spanish)
 - recruitment method that attracted participation
- An online scheduling function to allow pre-screened participants to set up an appointment for Registration/ICD signoff, Training and OBU installation.

The staged approach will allow THEA to grow its recruiting efforts based on success, making use of more cost-effective methods first. Task 5, Performance Measurement will establish the recruiting goals and timelines for each stage. The preliminary recruitment plan activities include:

- Stage 1
 - News media
 - Recruitment kickoff media event
 - At THEA TMC and/or
 - At installation location to demo technology and OBUs
 - News coverage provides legitimacy for other recruitment efforts
 - THEA DMS (overhead digital signs) messaging
 - Selmon Expressway
 - Meridian Avenue
 - Partner fleets (invite their commuters to participate in their personal vehicles)
 - HART
 - TECO Streetcar Line
 - City of Tampa
 - Craigslist ads
 - Printed material distributed to stakeholders (downtown businesses and organizations)
 - Flyers
 - Posters
 - Email
 - Existing THEA customers
 - Stakeholders (from the Stakeholder Registry)
 - MacDill probe study participants
 - THEA newsletter articles
 - Social media
 - THEA (Twitter and Facebook)
 - Partners
 - Stakeholders
 - Out-of-home messaging
 - Traveling display, sandwich boards
 - Downtown buildings
 - Downtown events
 - WaWa, CVS, Publix locations (partnership possibilities)
 - Building banners on THEA building, other buildings in/around downtown
- Stage 2 (continue above efforts and add ...)
 - News media
 - Additional stories, events
 - Presentations at stakeholders
 - Employer outreach
 - Rotary and civic groups
 - Paid messaging
 - Online (targeted to age, gender as necessary)
 - Google
 - Social media (e.g., Facebook)
 - Targeting
 - Physical home/work locations
 - Age and/or gender
 - Interests

- Pandora (reaches in-car)
 - Out-of-home messaging
 - Traveling display, sandwich boards
 - Downtown buildings
 - Downtown events
 - Brandon Town Center Mall
 - Regency Park (in Brandon)
 - Movie theater (AMC at Regency Park)
 - Retail stores (focus on tech?)
 - Apartment complexes
 - WaWa, CVS, Publix locations (partnership possibilities)
 - Building banners on THEA building, other buildings in/around downtown
- Stage 3 (continue above efforts and add ...)
 - Out-of-home messaging
 - Billboards along the Selmon Expressway/REL
 - HART bus exterior advertisements
 - Portable Dynamic Message Signs along Use Case roads
 - Paid messaging
 - Radio
 - TV
 - In Brandon (and other) movie theaters

It has not been determined as to which of these media methods will be employed in the study. Amendments to the Protocol will clarify what methods will be employed. Presentation details will be forwarded with the amendments, as needed, for IRB review.

5.3.2 Driver Registration, Training and Installation Location Requirements

Several of these tasks — selection, registration/ICD signoff, training and installation, and retiring and retrieval — must have a location and, ideally, one where all these tasks may be done in one relatively brief visit. While a site has not been chosen at this time and is scheduled for Phase 2, there appear to be several attractive options in the vicinity of the test area (i.e., the Selmon Expressway and Meridian Avenue) that would be accessible to potential participants.

5.3.3 Driver Registration Facility Requirements

The registration facility requirements are for a safe and secure room where the registrar(s) and recruit(s) can talk without distraction or interruption. The potential participant will not be trained or the vehicle modified until selection and registration/ICD signoff are complete. Training and installation will occur concurrently. During the UMTRI CV Safety Pilot, OBU installation took from one-half hour to one hour with few exceptions. This is anticipated to be sufficient time for the training of the driver and installation of the device.

5.3.4 Driver Participant Selection

Selmon Expressway REL and City of Tampa drivers will account for 4,000 vehicles equipped with devices. Subjects willing to have a device installed in their personal vehicle will be screened based on their ability to meet the following criteria:

1. Current, valid driver's license

2. Adult (18+)
3. Valid automobile insurance
4. Owns (or is financing for ownership) a vehicle (not lease vehicle)
5. The vehicle is 1997 model year or newer vehicle (OBD II port availability)
6. Their daily commute intersects downtown Tampa, or they routinely drive on Meridian Avenue, Twiggs Street or use the Selmon REL
7. Willing, at least initially, to participate for the 18-month duration of the model deployment,
8. Allow THEA periodic access to retrieve data or check device health,
9. No existing crash warning systems on the vehicle.

Scheduling of device installations, data downloads, and any other necessary interactions will be conducted via an on-line scheduling system where participants can select times and dates that accommodate their schedules. For persons without online access alternative measures (e.g., phone, email) will be used.

Persons agreeing to have a device installed in their personal vehicle may receive small gifts of appreciation, such as free SiriusXM service for the life of the CV Pilot or a FitBit, for example, but no direct monetary compensation from the project budget. A Selmon Expressway toll reduction is also under consideration. THEA is currently exploring these and other options.

5.3.5 Driver Registration Process

If, after watching an introductory video and reading the FAQs, a person wishes to participate, he or she must complete and pass an online selection questionnaire and set an appointment for registration, ICD signing, training and OBU installation. THEA will communicate electronically with the candidate to remind him/her of the appointment.

At the registration location, the potential participant will watch a brief video explaining the Informed Consent process. A THEA staff person will present the person with an electronic ICD document (on a tablet or PC) and ask him/her to read it. (The ICD will be available in English and Spanish.) The staff person will offer to answer questions. Some staff will be bilingual (English/Spanish) to accommodate Spanish-preference participants. The participant will then sign or not sign the ICD. If the participant signs, they go on to the training and their vehicle is taken for installation of the device.

THEA will use secure software for taking of PII data when participants register (see Section 4.2.2.1). THEA will supply software for the taking of data by the registrar(s), which the participant will verify with ID – driver's license, vehicle registration and proof of insurance for drivers. The data will be uploaded to a secure database (per Section 4.2). With respect to the ICD signature there are two possibilities:

- Store paper copies of the signed ICD in a secure, locked file cabinet at the THEA registration facility.
- Store digital copies of the electronically signed ICD in the secure facility with the other registration information.

Participants will be given a paper copy or emailed a copy of their signed ICD which will also act as a registration certificate with instructions for contacting the CV Pilot administrators if the participant has questions, sells the car, is involved in a crash, relocates, wishes to quit the study, and so forth.

5.3.6 Driver ICD

The completed Salus ICD template for auto drivers is attached. The ICD follows the Salus ICD template that treats:

- Purpose of the study
- What will happen during the study

- What the participant needs to know
- Potential risks to participants
- Benefits of the study
- Payment and incentives for participation
- Injury and Legal Rights
- Voluntary nature of participation
- Whom to contact with questions, concerns, complaints or traffic incidents.

At this stage the ICD cannot define all requirements precisely, such as the location or time period for returning the vehicle for data collection. Revisions and additional details will be clarified by ICD amendment as needed.

5.3.7 Driver Trainers and Participant Training

THEA will provide training to a corps of trainer/registrars who will provide training in use of the OBU at the installation site. The trainer/registrars will receive training and certification in protecting human research participants. Some trainer/registrars will be bilingual (English and Spanish) so they can provide services in Spanish to participants who are more comfortable speaking and signing legal documents in Spanish.

Upon signing the ICD, a trainer will instruct the participant in the use of the OBU while the OBU is installed in the vehicle. During the UMTRI CV Safety Pilot, OBU installation took from one-half hour to one hour with few exceptions. This is presently anticipated to be sufficient time for the training of the driver and installation of the device.

The participant training will be done primarily by video for consistency followed by trainer Q&A during the installation process. The conceptual plan for the training aims to cover the following points:

- CV 101 – CV User-Oriented Fundamentals
- USDOT CV program background
- THEA Pilot Deployment background
 - FHWA contract
 - Traffic problems
 - CV treatments
 - Working to get experiment results – measuring CV app outcomes for safety, mobility and the environment
- Functions of the OBU and apps
 - OBU normal use and care
 - User-accessible functionality
 - Post-vehicle-service check (e.g., did the Jiffy Lube guy disconnect the OBU?)
 - Reporting issues to the CV Pilot participant software system
 - Requesting service, replacement
 - In case you move or wish to leave the CV Pilot
 - If your OBU doesn't appear in the system THEA will contact you
 - Driver-Vehicle Interfaces (DVI) and BSMS
 - Alerts that will elicit response, and expected response
 - Driver responsibility to control the vehicle (CV is not AV)
 - USDOT/THEA not responsible for traveler behavior or damages and do not offer compensation
- Participant communication
 - Electronic newsletters from THEA
 - Reporting alerts, incidents and crashes
 - Feedback
- Safety – Once again - Driver responsibility to control the vehicle at all times
- Questions.

Training documents at this Phase 1 stage of the project are in preliminary development. A draft high-level Training plan will be submitted for sponsor review (USDOT) by May 27, 2016 and for final acceptance by August 8, 2016. Also, since the apps are in development, detailed training for use of the app is not available at this stage. The intention is to have the training elements follow best practices for training of participants. Training details will be made available in IRB amendment documents as they become available.

5.3.8 Vehicle Installation

Training and installation will occur concurrently. During the UMTRI CV Safety Pilot, OBU installation took from one-half hour to one hour with few exceptions. This is anticipated to be sufficient time for the training of the driver and installation of the device.

Installations will require a clean, well-lit, light-duty garage with equipment for installing the OBU. During the UMTRI CV Safety Pilot OBUs were installed without the use of a lift to elevate the vehicle. Skilled installers can work through the non-invasive installation with light tools. Drilling holes in the vehicle body should not be necessary. The most invasive part of the installation will usually be running a small magnetically attached antenna out the window onto the roof. If any holes, etc. need to be made, the driver will be informed beforehand for consent. The driver's wishes will be respected (per ICD).

Supervisors of installers will obtain certification in protecting human research participants. This will hold for any OBU automotive supplier that wishes to install its OBUs. The supervisors will get certification in protecting human research participants.

5.3.9 OBU Device Use

If the driver has a problem with the device, the driver is still responsible for the operation of the vehicle and should take every measure to report the problem to a THEA representative. This will also be covered in the training session. This is discussed at length in the Safety Management Plan.

5.3.10 Driver Reporting Procedures

Drivers will stop by the installation site for data retrieval occasionally (e.g., once every six months) as defined in the ICD. Participants will be informed by email of the time period over which they can have the data collected and how to make an appointment.

Incident reporting, documentation, and investigation will be carried out according to the SMOC (Section 4.2) and the Safety Management Plan (Section 4.3). The Safety Manager will fill out the Incident Report Form and enter the data into the secure participant database software. In the same manner the Safety Manager will also conduct a Safety Review by filling out a Safety Review Template when there is an injury.

Legal issues may arise with crashes. The ICD for passenger car drivers states: *There may be times when the study investigator will not be able to guarantee privacy, such as when the study records are requested by a court of law.* If required by legal procedure, THEA will make selected raw BSM data available over the time period and location in question without analysis or interpretation.

5.3.11 OBU Retiring and Retrieval

A driver may leave the CV Pilot for a number of reasons, including dissatisfaction with the device or the program, selling the car, crashing the car (inoperable), relocation, changing jobs or travel route, illness, injury, death, termination of the project and so forth. If the driver leaves the study prior to the 18 month agreement, the manufacturer/supplier would require that the device be properly removed by the THEA installers for reuse in the study, so the driver will be responsible to notify a THEA representative in a timely way as delineated in the ICD. In some situations, with the driver's permission, THEA staff may be authorized to travel to the site of the vehicle to remove it.

If the vehicle is in a crash and inoperable, the driver should notify a THEA representative to have the OBU removed. The driver will not be responsible for any damage to the OBU in the event of a crash (per ICD).

If the vehicle does not appear on any RSU for some time (e.g., six weeks), a THEA representative may contact the driver to find out the status of the OBU and the driver's relationship to the project (e.g., still in the area?) as stated in the ICD.

When a participant leaves the study or at the study's completion, THEA staff will offer participants a questionnaire to voluntarily complete, as stated in the ICD. The study may allow participants to keep and use the OBUs after the completion of the study if they wish. Details of this survey are not yet available, but it will inquire only into how participant use of the equipment enhanced or detracted from driving, program evaluation, human factors or quality assurance.

5.4 Human Use Treatment of Pedestrians

Pedestrians called for jury duty at the Hillsborough County Courthouse often elect to cross East Twiggs Street at a mid-block crosswalk and sometimes cross outside the crosswalk. Planned CV deployment at this location includes:

- V2I – PED-X, an in-vehicle app
- V2I – PED-SIG, a smartphone app to aid pedestrians of vehicles approaching the crosswalk.

In addition, pedestrians use the intersections on Channelside Drive and have conflicts with vehicles turning right in front of streetcars and with traffic at Amalie Arena. The same apps may be applied with these pedestrians.

5.4.1 Pedestrian Recruitment

Recruitment is the first step in the process. One plan is to recruit through jury duty notification, by offering online information, FAQs, and appointments. Selection and preliminary registration may be done online, as with auto drivers or, perhaps, only in person at a booth at the courthouse, which would reduce false registrations. Registrations will need to be verified in person.

Another plan is to do only in-person recruitment with a booth at the courthouse Tuesday through Friday for those selected for jury duty and who will use the mid-block crossing for several days. Recruitment would include employees of the courthouse and nearby businesses who use the Twiggs Street mid-block crossing.

For locations outside the courthouse (e.g. Amalie Arena, Channelside Drive), recruitment of pedestrians could come, in part, from HART's TECO Streetcar Line and study area bus route customers. Postcards handed out onboard would be one way of targeting potential participants.

Amendment to the IRB Approval will be requested when the app and pedestrian recruitment are further developed.

5.4.2 Pedestrian Registration, Training and Installation Location Requirements

Use Case 3 will be tested at the mid-block Twiggs Street crossing at the Hillsborough County Courthouse and in the Channelside District at streetcar stops. The courthouse would be a natural site for the registration process for that site.

Arrangements will be made with the cruise lines, Amalie Arena or another entity in the Channelside District or downtown to induct new participants. A covered booth at a TECO Streetcar Line stop might be used for this purpose if a more substantial, well located farecard sales outlet cannot be identified.

5.4.3 Pedestrian Processing

Similar to the process for auto drivers, pedestrians would go through a process of Selection, Registration/ICD signoff, Training and app Installation when they go to a facility located at the courthouse or Channelside Drive. A registrar certified in protecting human research participants would examine the participant's ID, verify that they meet the smartphone requirements (e.g., iOS 3.0 or later), enter the applicant's information into the secure participant software and offer the Pedestrian ICD to the potential participant to read and sign. The registrar would be available for questions.

The registrant's data will be uploaded to a secure database (per Section 4.2). With respect to the ICD signature, since the pedestrians are using smartphones, paper copies would not seem to be necessary. The participant software will store digital copies of the electronically signed ICD in the secure facility with the other registration information and email the participants a copy of their electronically signed ICD that will also act as a registration certificate with instructions for contacting the CV Pilot administrators if the participant has questions, difficulties with the app, is involved in a crash, completes their jury duty, wishes to quit the study, and so forth.

5.4.4 Pedestrian ICD

The completed Salus ICD template for pedestrians is attached. The ICD follows the Salus ICD template that treats:

- Purpose of the study
- What will happen during the study
- What the participant needs to know
- Potential risks to participants
- Benefits of the study
- Payment and incentives for participation
- Injury and Legal Rights
- Voluntary nature of participation
- Whom to contact with questions, concerns, complaints or injuries.

At this stage the ICD cannot define all requirements precisely. Revisions and additional details will be clarified by ICD amendment as needed.

5.4.5 Pedestrian App Training and Installation

Upon signing the ICD, the participant will receive a brief training and will install the app over a secure WiFi connection. The registrar will have equipment to test that the app is working.

Training of trainer/installers will also be part of the pedestrian training plan and will include certification in protecting human research participants.

Training documents at this Phase 1 stage of the project are in preliminary development. A draft high-level plan will be submitted for sponsor review (USDOT) by May 27, 2016 and for final acceptance by August 8, 2016. Also, since the apps are in development, detailed training for use of the app is not available at this stage. The intention is to have the training elements follow best practices for training of participants. Training details will be made available in IRB Approval amendment documents as they become available.

5.4.6 Pedestrian Reporting Procedure

Incident reporting, documentation, and investigation will be carried out according to the Privacy and SMOC Plan (Section 4.2) and the Safety Management Plan (Section 4.3). The Safety Manager will fill out the Incident Report Form and enter the data into the secure participant database software. In the same manner the Safety Manager will also conduct a Safety Review by filling in the Safety Review Template when there is an injury.

Legal issues may arise with crashes. The ICD for pedestrians states: *There may be times when the study investigator will not be able to guarantee privacy, such as when the study records are requested by a court of law.* If required by legal procedure, THEA will make selected raw Pedestrian App and BSM data available over the time period and location in question without analysis or interpretation.

5.4.7 Pedestrian App Retirement and Removal

To leave the project, presumably when the participant is finished with jury duty, visiting the Tampa area, or at the end of the study, retiring and retrieval of the app would be at the discretion of the participant. The app will not function outside the study area. There will be an option in the app to notify THEA that the participant is done with participation. Participants will be sent a query to fill out a questionnaire about their experience with the apps upon their termination with the study. Details of this survey are not yet available, but it will inquire only into how participant use of the equipment enhanced or detracted from safely crossing the street, program evaluation, human factors or quality assurance.

5.5 Human Use Treatment of HART Drivers

5.5.1 HART Recruitment, Registration and Training

Recruitment, registration and training of HART drivers will be done at the HART worksite. Training of trainers will also be part of the HART driver training plan and will include certification in protecting human research participants. Drivers will be informed during their training that they are part of a study to evaluate the effectiveness of the devices that will be installed in the vehicles.

At this stage it is not known what proportion of HART buses or bus drivers will take part in the study. Buses must be rotated approximately every three months as to the routes they cover according to Title VI of the Civil Rights Act (Hillsborough Area Regional Transit, November 5, 2015) so the same buses will not be used throughout the study. One plan is to equip all the buses for signal priority, even those that would not pass

through equipped intersections. The logistics of driver assignment means that at present it can only be determined that the minimum number of bus drivers who would need training would be about 80, but it might turn out to be more efficient to train all the drivers (about 400), whether they end up using the equipment or not, so that scheduling can be done on an ad hoc basis when needed. There are only nine streetcars and so all the 25-30 streetcar motormen will receive training.

Training documents at this Phase 1 stage of the project are in preliminary development. A draft high-level plan will be submitted for sponsor review (USDOT) by May 27, 2016 and for final acceptance by August 8, 2016. Also, since the apps are in development, detailed training for use of the apps are not available at this stage. The intention is to have the training elements follow best practices for training of participants. Training details will be made available in amendment documents for IRB approval as they become available.

5.5.2 HART ICD

It is proposed to treat HART as the participant and the attached ICD (see Section 6.3) is written for a HART representative's signature. HART employees will be covered by their contract with the agency. No driver PII will be collected for the CV Pilot. Only vehicle data will be collected. Project managers will go through HART to repair OBU installations, when needed.

The completed Salus ICD template for HART and its drivers is attached. The ICD follows the Salus ICD template that treats:

- Purpose of the study
- What will happen during the study
- What the participant needs to know
- Potential risks to participants
- Benefits of the study
- Payment and incentives for participation
- Injury and Legal Rights
- Voluntary nature of participation
- Whom to contact with questions, concerns, complaints or injuries.

Revisions and additional details will be clarified by ICD amendment as needed.

5.5.3 HART Reporting Procedure

Drivers will report incidents as they normally would, according to HART policies and procedures, and HART will contact the CV Pilot Safety Manager. CV incident reporting, documentation, and investigation will be carried out according to the Safety Management Plan (Section 4.3). The Safety Manager will fill out the Incident Report Form and enter the data into the secure database software. In the same manner the Safety Manager will also conduct a Safety Review by filling out the Safety Review Template when there is an injury.

Legal issues may arise with crashes. The ICD for HART states: *There may be times when the study investigator will not be able to guarantee privacy, such as when the study records are requested by a court of law.* If required by the legal system, THEA will make raw BSM data available over the time period in question without analysis or interpretation.

5.5.4 HART OBU Installation, Repair and Removal

The supplier/manufacture will install the OBUs with the help of the HART maintenance staff. Installation of equipment is part of the HART staff's regular duties and they are not human research participants.

5.5.5 HART User Survey

THEA will offer drivers a questionnaire about their experience with the apps upon completion of the study period. Details of this survey are not yet available, but it will inquire only into how participant use of the equipment enhanced or detracted from driving, program evaluation, human factors or quality assurance.

6.0 Informed Consent

One important duty of the IRB is to oversee that participants in research trials are given sufficient information to form a reasoned decision. This is based on the Belmont principle of Respect for Persons that is primarily applied by requiring that all human subject research participants provide voluntary informed consent to participate in research. The Belmont Report (U.S. Department of Health, Education and Welfare, 1979), created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, summarizes ethical principles and guidelines for research involving human subjects.

The three fundamental aspects of informed consent are:

- **Voluntariness** - Individuals' decisions about participation in research should not be influenced by anyone involved in conducting the research: "...consent must be freely given or truly voluntary."
- **Comprehension** - Individuals must have the mental or decisional capacity to understand the information presented to them in order to make an informed decision about participation in research.
- **Disclosure** - HHS regulations ([45 CFR 46.116\(a\)](#)) require that researchers disclose:
 - The purpose of the study
 - Any reasonably foreseeable risks to the individual
 - Potential benefits to the individual or others
 - The extent of confidentiality protections for the individual
 - Compensation in case of injury due to the protocol
 - Contact information for questions regarding the study, participants' rights, and in case of injury
 - Conditions of participation, including right to refuse or withdraw without penalty.

This disclosure must be made in such a way that it provides a "reasonable person" the information she or he would need in order to make an informed decision (https://phrp.nihtraining.com/respect/03_respect.php).

Salus IRB supplied a template for ICD development that THEA followed⁵. The ICDs developed for auto drivers, pedestrians and transit are, thus, designed to meet the requirements of the Belmont Report and HHS regulations. Each ICD that follows treats:

- Context and Introduction
- Purpose of the study
- What will happen during the study
- Before deciding to participate what you (the participant) should know
- Potential risks of participation
- Benefits of the study
- Payment for participation

⁵ See Salus IRB webpage: <https://www.salusirb.com/getting-started/template-study-documents/>.

- In case of an injury related to this research study
- Legal Rights
- Confidentiality
- Employees or Family Members
- Voluntary participation
- Whom to contact.

At this stage the ICDs cannot define all requirements precisely, such as location and phone number of whom to call with a problem. However, the expected necessary information is present. Revisions and additional details will be clarified by ICD amendment as needed. The final ICDs were approved by Salus IRB on June 1, 2016.

6.1. Auto Owner ICD

6.1.1 Context and Introduction

The context of the ICD is first laid out for the potential participant or “recruit.” The ICD prominently presents the IRB, sponsor, investigator and contact information, clearly invites the recruit to take part in this “actual use” research study, tells the recruit to read this ICD and invites the recruit to ask questions.

6.1.2 Purpose of the Study

The ICD explains the purpose of the study to examine the use and effects of the CV devices to alert users to specific developing hazards and to improve traffic safety, mobility and environmental effects. The following sections are included verbatim from the Auto Owner ICD as it was approved in Phase 1 of the THEA CV Pilot. “You” in the sections below refers to the recruit considering participation and “We” is THEA.

6.1.3. What Will Happen During the Study

After we confirm that you are eligible to participate in this study and you agree to be in this study, we ask that you sign this form before any study training or device installation in your vehicle begins. Otherwise, we will not continue with your session.

Once you have signed this document we will proceed with the session, in which we will ask you to:

- Provide us with proof of a valid U.S. driver’s license, proof of vehicle insurance, and proof of ownership (vehicle registration showing you as an owner or co-owner of the vehicle).
- Assure us that you drive in the test area and have no existing crash warning systems on the vehicle
- Assure us that, at least initially, you are willing to participate in the 18-month duration of the test
- Watch a training video and ask questions about points to clarify
- Verbalize understanding of device instructions for use
- Wait while the device installation is completed
- Report to staff problems that arise with the device
- Bring your vehicle in for data downloading from the device when you are offered an appointment, which you may arrange to your schedule
- Assent or decline to receive newsletters, email, etc. as part of the study
- Notify us if you sell the vehicle, are involved in a crash, or change your travel to outside the test area
- Answer questions about your continued participation in the project if your vehicle does not register on our recording devices for some time
- Return your vehicle for removal of the device at the end of your participation
- Complete a questionnaire about your experience with the device at the end of your participation.

We will be collecting data on your use of the device in order to better evaluate the use of this product.

Approximately 4000 drivers, 500 pedestrians, ages 18 to 80, and up to 200 transit vehicles will participate in this study. Participation will involve installation of the device in your vehicle and driving while using the device over a period of one and a half years (18 months).

6.1.4 Before You Decide to Participate What You Should Know

1. During the study, we are gathering information on the performance of the connected vehicle technology, and not evaluating you as a driver. You are providing permission for us to collect data whenever your vehicle is used or whenever you happen to drive another vehicle that is part of the study (for example, a vehicle owned by a friend who also happens to be in the study). If there are drivers of your vehicle who have not signed consent forms, we will not be able to delete data from trips in which they drove your vehicle.
2. Any data that personally identifies you or could be used to personally identify you will be held under a high level of security at one or more data repositories. Your data will be identified with a code rather than your name. Only qualified researchers will be authorized to have access to data that personally identifies you, or can be used to personally identify you, and the level to which they have access will be based on their level of authorization.
3. No identifying information will be collected on passengers or other drivers of your vehicle.
4. For the duration of your participation, you will be responsible for your insurance coverage and for control of the vehicle. Neither THEA nor USDOT is responsible for damages you may incur in the event of a crash and do not offer compensation. If you are in a crash, please contact emergency services as you normally would. We will then ask for more information, as detailed below. In the event of a crash, you are not responsible for any damage to the device that is installed into your vehicle. If the device becomes dislodged or loosens from its installed position, please contact us so the device may be secured.
5. You may withdraw from the study at any time. If you do withdraw from the study before your scheduled end date, you must agree to allow us to retrieve the device from your vehicle as soon as is feasible.
6. The equipment you will be issued will be capable of issuing the following safety alerts that are further explained in the training video to follow:
 - a. Curve Speed Warning
 - b. Emergency Electronic Brake Light
 - c. Forward Collision Warning
 - d. Wrong-Way Entry
 - e. Pedestrian in a Signalized Crosswalk.⁶
7. The equipment will also be capable of issuing the following mobility enhancements:
 - Intelligent Traffic Signal System
 - Probe-enabled Data Monitoring.⁷

⁶ The ICD gives definitions of the apps which are derived from the CVRIA and are not included here (Iteris, Accessed June 2015).

⁷ The ICD gives definitions of the apps which are derived from the CVRIA and are not included here (Iteris, Accessed June 2015).

8. This is not an autonomous-vehicle test, where the vehicle drives itself, but a connected-vehicle test where the driver is still in full control. This equipment will be under test, so that its capabilities can be evaluated. You are legally responsible to drive the vehicle. Neither THEA nor USDOT is responsible for damages you may incur in the event of a crash and do not offer compensation.
9. If the equipment fails to respond as expected (e.g., without giving an alert), you will be expected to notify the installers, so that the equipment may be examined or replaced as needed. If the device becomes dislodged or loosens from its installed position, please contact us so the device may be secured.
10. If any installation difficulties arise, we will notify you for your approval before we perform any intrusive solutions (e.g., drilling of holes).

6.1.5 Potential Risks of Participation in This Study

Please tell the study staff if you feel uncomfortable with the equipment or as a result of the study session. You will not be penalized for your honesty.

As mentioned, this is an “actual use” study where you will participate in real-life scenarios of typical device use. As a result, you will be exposed to normal driving risk as a result of participating in this study and you will still be responsible for operating the vehicle responsibly. It is unlikely, due to the informative nature of the device, that you will be exposed to additional risk as a result of participating in this study. The device is designed to add a margin of safety to your driving experience. However, we have identified the following potential risks, which include:

1. Failure of the device to not operate as user was instructed that it should
2. Failure of the device to fulfill its designed safety function to alert the driver
3. Failure of a device to fulfill its designed mobility function to prioritize the vehicle at signals
4. Distraction from false alerts or unnecessary alerts
5. Inability of the driver to identify the driving problem associated with an alert(s) Driving to the limits of the device’s abilities or driving too fast while expecting the device to inform when to slow down
6. Expecting the device to yield benefits without your cooperation or proper use
7. Breach of device data protections by “hackers” or hostile actors
8. Breach of personal data protections by “hackers” or hostile actors
9. Breach of confidentiality by inadvertent mistake of a researcher.

6.1.6 Benefits of the Study

The device is designed to provide safety and mobility benefits to you. The device may reduce the travel cost of your trip. It is not known how much the device will enhance your driving experience or safety. The researchers are interested in how the device improves or diminishes your driving experience and how all the devices taken together impact traffic flows, crashes, delay and the environment.

6.1.7 Payment for Being in the Study

You will not receive monetary payment.⁸

6.1.8 In Case of an Injury Related to This Research Study

⁸ THEA has been in the process of creating incentives to participate including use of Sirius XM or toll reductions on the Selmon Expressway REL, use of which is integral to the study.

It is important that you tell your study staff, either in person, by email or by phoning the number provided on this form, if you have been in a crash or experienced difficulty in using the device or a malfunctioning of the device. If you are in a crash, please contact emergency services as you normally would. After emergency services have completed their work, please contact the Study Investigator, at the phone number listed on page one of this document, who will complete an Incident Report concerning the location, type of incident and the use of the device in the incident. For the duration of your participation, you will be responsible for your insurance coverage and for control of the vehicle. Neither THEA nor USDOT is responsible for damages you may incur in the event of a crash and do not offer compensation.

6.1.9 Legal Rights

You do not lose any legal rights by signing this consent document. The above statement, "In Case of an Injury Related to This Research Study," does not stop you from seeking legal help in case of negligence.

6.1.10 Confidentiality

Records of you being in this study will be kept private. There may be times when the study investigator will not be able to guarantee privacy, such as when the study records are requested by a court of law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The following people will have access to study records:

- Study Investigator and staff
- Sponsor Agency or its designees
- The USDOT and its consultants
- Salus IRB.

In the event of a breach in security related to your personal information, we will notify you of its nature and what we are doing about it.

Salus IRB and accrediting agencies may inspect and copy study findings, including this document, which may have your name on them. Therefore, your total privacy cannot be guaranteed.

6.1.11 Employees or Family Members of the Study Staff or Sponsor

If you are an employee or family member of the study staff or sponsor, the following statements apply:

- Your decision to participate or not, will not affect your or your family member's performance evaluations
- Your decision to participate or not, will not affect your or your family member's opportunity for promotion
- Your decision to participate or not, will not affect your or your family member's pay

6.1.12 Voluntary Participation

Your participation in this study is voluntary. You are free to withdraw at any time. You may be withdrawn from the study at any time, by the study investigator, sponsor, USDOT or Salus IRB, without your consent, for any of the following reasons:

- to protect your safety/health
- if you do not follow the instructions of the study staff
- if there are not enough volunteers enrolled/participating in the study
- if the sponsor chooses to halt the study.

If you are discontinued or withdraw from this study, no new data about you will be collected, however, all data that has been collected, could be shared with the study sponsor.

6.1.13 New Findings

During the study, you will be told of any important new findings about the study. You can then decide if you still want to be in the study.

6.1.14 Whom to Contact

You may contact the study investigator or study staff at the phone number listed on the first page of this document for answers to questions, concerns, or complaints about this study, to report a research related injury, or for information about study procedures.

You may contact Salus IRB if you would like to speak with someone unrelated to the study, have questions, concerns, or complaints regarding the study, or have questions about your rights as a research participant.

The ICD then gives the address, phone and email of Salus IRB.

6.1.15 Agreement to Be in the Study

The ICD then presents a format for signing the ICD by the recruit and by the person explaining the ICD. It also states that the participant will be given a copy of the ICD to keep.

6.2 Pedestrian ICD

6.2.1 Introductory Material

With minor, obviously needed revisions, the Pedestrian ICD is derived from the Auto Driver ICD. The Pedestrian ICD follows the same initial introductory narrative through the Context and Introduction. The Purpose of the Study is the same except to say that a Pedestrian App is being studied on a mobile phone. Since pedestrians do not need a driver's license and the mobile device is with the recruit, the ICD drops some requirements from What Will Happen During the Study. While the ICD states to bring the phone in for downloading, it has been determined since the approval of the ICD that data will be collected during use instead. The following sections are included verbatim from the Pedestrian ICD as it was approved by the IRB in Phase 1 of the THEA CV Pilot. "You" in the sections below refers to the recruit considering participation and "We" is THEA.

6.2.2 Before You Decide to Participate What You Should Know

1. You are providing permission for us to collect data whenever your Pedestrian App is used.
2. Any data that personally identifies you or could be used to personally identify you will be held under a high level of security at one or more data repositories. Your data will be identified with a code rather than your name. Only qualified researchers will be authorized to have access to data that personally identifies you, or can be used to personally identify you, and the level to which they have access will be based on their level of authorization.
3. For the duration of your participation, you will be responsible for your pedestrian activities. If you are in a crash, please contact emergency services as you normally would. We will then ask for more information, as detailed below.

4. You may withdraw from the study at any time by deactivating the App or by de-installing it yourself. You may also bring it in for de-installation.
5. The App you will be issued will be capable of issuing the following safety alert that is further explained in the training video to follow or that you may view online:
 - Pedestrian in a Signalized Crosswalk⁹.
6. The equipment will also be capable of issuing the following mobility enhancements:
 - Mobile Accessible Pedestrian Signal¹⁰.
7. This is not a connected-vehicle test, where participating drivers and pedestrians are still in full control. This equipment will be under test, so that its capabilities can be evaluated. You are legally responsible to drive the vehicle. Neither THEA nor USDOT is responsible for damages you may incur in the event of a crash and do not offer compensation.
8. If the equipment fails to respond as expected (e.g., without giving an alert), you will be expected to notify the installers, so that the app may be examined or replaced as needed.

6.2.3 Potential Risks of Participation in This Study

Please tell the study staff if you feel uncomfortable with the equipment or as a result of the study session. You will not be penalized for your honesty.

As mentioned, this is an “actual use” study where you will participate in real-life scenarios of typical App use. You will be exposed to normal walking risk while participating in this study and you will still be responsible for crossing the street responsibly. It is unlikely, due to the informative nature of the App, that you will be exposed to additional risk as a result of participating in this study. The App is designed to add a margin of safety to your street crossing experience. However, we have identified the following potential risks, which include:

1. Failure of the App to fulfill its designed safety function to alert the user
2. Failure of the App to fulfill its designed mobility function to prioritize cross walking at signals
3. Distraction from false alerts or unnecessary alerts
4. Inability of the user to identify the problem associated with an alert
5. Crossing to the limits of the App’s warning abilities
6. Expecting the app to yield benefits without your cooperation or proper use
7. Expecting the App to work at crosswalks that are not in the test area
8. Leaving the smartphone off, sound off, or App off while relying on it to cross the street
9. Leaving the sound alert on too low a setting to not be heard in a noisy street environment
10. Leaving the smartphone in a pocket where the sound or vibration alert will not be noticed or felt in a distracting street environment
11. Answering the phone instead of responding appropriately to an alert
12. Breach of App data protections by “hackers” or hostile actors
13. Breach of personal data protections by “hackers” or hostile actors
14. Breach of confidentiality by inadvertent mistake of a researcher.

6.2.4 Benefits of the Study

⁹ The ICD gives definitions of the apps which are derived from the CVRIA and are not included here (Iteris, Accessed June 2015).

¹⁰ The ICD gives definitions of the apps which are derived from the CVRIA and are not included here (Iteris, Accessed June 2015).

The App is designed to provide safety and mobility benefits to you. It is not known how much the App will enhance your street-crossing experience or safety. The researchers are interested in how the App improves or diminishes your street-crossing experience and how all the devices taken together impact traffic flows, crashes, delay and the environment.

6.2.5 Payment for Being in the Study

You will receive a FitBit device for your participation¹¹. You will not receive monetary payment.

6.2.6 In Case of an Injury Related to This Research Study

It is important that you tell your study staff, either in person, by email or by phoning the number provided on this form, if you have been in a crash or experienced difficulty in using the App or a malfunctioning of the App. If you are in a crash, please contact emergency services as you normally would. We will then ask for more information. After emergency services have completed their work, please contact the Study Investigator listed on page one of this document, who will complete an Incident Report concerning the location, type of incident and the use of the app in the incident.

6.2.7 Legal Rights

You do not lose any legal rights by signing this consent document. The above statement, “In Case of an Injury Related to This Research Study,” does not stop you from seeking legal help in case of negligence.

6.2.8 Remaining Sections

The remaining sections of the Pedestrian ICD are unchanged from Section 6.1.10 to Section 6.1.15 regarding auto drivers.

6.3 HART ICD

6.3.1 Introductory Material

With minor, obviously needed revisions, the HART ICD is derived from the Auto ICD. The HART ICD follows the same initial introductory narrative through the Context, Introduction and Purpose of the Study. The following sections are included verbatim from the HART ICD as it was approved by the IRB in Phase 1 of the THEA CV Pilot. “You” in the sections below addresses the HART transit agency and “We” is THEA.

6.3.2 What Will Happen During the Study

After you agree to be in this study, we ask that you sign this form before any study training begins.

Once you have signed this document we will ask you to:

- Provide us with assurance that each participating HART employee has a valid driver’s license for the vehicle class and is insured to drive HART vehicles.
- Assure us that HART is, at least initially, willing to participate in the 18-month duration of the test (HART has the right to withdraw at any time.)

¹¹ The FitBit is an incentive that is under consideration and negotiation and is part of this draft ICD as an example of a possible incentive. THEA will amend the final ICD as necessary.

- Allow THEA to present to HART employees a training demonstration or video and ask for questions about points to clarify
- Verify that drivers will send an electronic message that signifies that a pedestrian who was sent an alert by a streetcar heeded the warning or not
- Report to THEA staff problems that arise with the device
- Allow for periodic downloading of data every few months
- Notify us when a driver is involved in a crash or other incident.
- Allow employees time to complete a questionnaire(s) about their experience with the device at the end of their participation.

We will be collecting data on your use of the device in order to better evaluate the use of this product.

Approximately 4000 drivers, 500 pedestrians, ages 18 to 80, and up to 50 transit vehicles at a time will participate in this study. Participation will involve installation of the device in HART's selected vehicles and driving while using the device over a period of one and a half years (18 months).

6.3.3 Before You Decide to Participate What You Should Know

1. You are providing permission for us to collect data whenever the equipped HART vehicle is used in the study area.
2. No data will be collected by THEA that personally identifies a driver or could be used to personally identify a driver.
3. No identifying information will be collected on passengers of HART's vehicles.
4. HART will be responsible for drivers' insurance coverage. If a driver is in a crash, please contact emergency services as you normally would. We will then ask for more information, as detailed below. In the event of a crash, HART is not responsible for any damage to the device that is installed in your vehicle.
5. HART may withdraw from the study at any time.
6. The equipment HART will be issued will be capable of issuing the following safety alerts that are further explained in the training video to follow:
 - a. Vehicle Turning Right in Front of a Transit Vehicle (for streetcars)
 - b. Vehicle in crosswalk alert (PED-SIG) for streetcars
 - c. TSP (for buses)¹².
7. The equipment will also be capable of issuing the following mobility enhancements:
 - a. TSP (buses only)¹³.
8. This is not an autonomous-vehicle test, where the vehicle drives itself, but a connected-vehicle test where the driver is still fully in control. This equipment will be under test, so that its capabilities can be evaluated. HART and the driver are legally responsible to drive the vehicle.
9. If the equipment fails to respond as expected (e.g., without giving an alert), the driver will be expected to notify the installers, so that the equipment may be examined or replaced as needed.

6.3.4 Potential Risks of Participation in This Study

¹² The ICD gives definitions of the apps which are derived from the CVRIA and are not included here (Iteris, Accessed June 2015).

¹³ The ICD gives definitions of the apps which are derived from the CVRIA and are not included here (Iteris, Accessed June 2015).

Please allow drivers to tell the study staff if they feel uncomfortable with the equipment or as a result of the study session and that they will not be penalized for their honesty.

As mentioned, this is an “actual use” study where drivers will participate in real-life scenarios of typical device use. As a result, drivers will be exposed to normal driving risk as a result of participating in this study and you will still be responsible for operating the vehicle responsibly. It is unlikely, due to the informative nature of the device, that drivers will be exposed to additional risk as a result of participating in this study. The device is designed to add a margin of safety to the driver’s driving experience. However, we have identified the following potential risks, which include:

1. Failure of the device to not operate as user was instructed that it should
2. Failure of the device to fulfill its designed safety function to alert the driver (streetcar only)
3. Failure of a device to fulfill its designed mobility function to prioritize the vehicle at signals (bus only)
4. Distraction from false alerts or unnecessary alerts (streetcar only)
5. Driving to the limits of the device’s abilities or driving too fast
6. Expecting the device to yield benefits without user cooperation or proper use
7. Breach of device data protections by “hackers” or hostile actors
8. Breach of personal data protections by “hackers” or hostile actors
9. Breach of confidentiality by inadvertent mistake of a researcher.

6.3.5 Benefits of the Study

The device is designed to provide safety or mobility benefits to drivers as they do their job. It is not known if the device will enhance their driving experience or safety. The researchers are interested in how the device improves or diminishes driver’s driving experience and how all the devices taken together impact traffic flows, crashes, delay and the environment.

6.3.6 Payment for Being in the Study

You will not receive monetary payment for your participation.

6.3.7 In Case of an Injury Related to This Research Study

It is important that you tell the THEA CV Pilot study staff, either in person or by phoning the number provided on this form, if a driver has been in a crash or experienced difficulty in using the device or a malfunctioning of the device. In the event of a crash or other incident the driver will seek aid according to standard HART policies and procedures. Also, HART will contact the THEA CV Pilot Study Investigator who will fill an Incident Report form and conduct a Safety Review as needed.

6.3.8 Legal Rights

HART does not lose any legal rights by signing this consent document.

6.3.9 Remaining Sections

The remaining sections of the HART ICD is unchanged from Sections 6.1.10 to Section 6.1.15 regarding auto drivers.

7.0 IRB HUA and Expedited Review

This section reports on the outcome of the application to Salus IRB. Some of these outcomes are being repeated from previous sections for completeness and continuity of the presentation.

7.1 HUA

Salus IRB approved the application for USDOT DTFH6115R00003, THEA CV Pilot Deployment on June 1, 2016. The approval must be validated annually and expires on May 31, 2017. A Continuing Review Report is required prior to the expiration date. Approval included:

- Principal Investigator
- Investigative site(s)
- Draft Protocol Version 1 dated 5/16/16
- ICD, Drivers, English version dated 1 June 2016, with modifications made by Salus IRB
- ICD, HART, English version dated 1 June 2016, with modifications made by Salus IRB
- ICD, Pedestrians, English version dated 1 June 2016, with modifications made by Salus IRB
- Enrollment of Pregnant Women
- Enrollment of Non-English speakers
- Enrollment of Educationally Disadvantaged
- Enrollment of Economically Disadvantaged
- Enrollment of Employees and Family Members of the Study Staff or Sponsor.

THEA requested in the RPD that certain vulnerable populations such as pregnant women, non-English speakers and educationally and economically disadvantaged persons be allowed to participate, since they were part of the driving and pedestrian population, though they would not be systemically targeted for or excluded from participation. Salus IRB will allow these populations as participants. Salus inserted a change to each ICD "because participants who are employees or family members of THEA or sponsor (USDOT) may be enrolled:

- Your decision to participate or not, will not affect your or your family member's performance evaluation
- Your decision to participate or not, will not affect your or your family member's opportunity for promotion
- Your decision to participate or not, will not affect your or your family member's salary."

THEA accepted this change. It allows HART drivers, as well as THEA and USDOT employees, equally, to participate freely, without repercussions to their jobs.

The approval is limited in scope:

"The IRB-approved consent document may be used for recruitment/screening, but research participants may not begin additional study procedures until a final protocol has been approved by Salus IRB."

Final documentation will detail: recruitment materials (e.g., newspaper advertisements, websites, etc.), registration site(s), registration process and PII security, training materials (e.g., video) and environment and procedures for on-board unit (OBU) or personal information device (PID) installation. Adequate documents showing how the rights of human research participants are protected will be submitted and approved before induction of participants begins.

The approval document further states:

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The Salus IRB requires that you [THEA] submit the following for review and/or approval:

- Changes in research that were initiated without IRB review and approval to eliminate apparent immediate hazards to the research participants to ensure the continued safety and welfare of participants;
- Non-compliance issues which affect participant rights, safety or welfare or the conduct of the study (report within 10 business days of discovery);
- Request for modification(s) to the Salus IRB approved ICD(s);
- Request for new and/or modifications to Salus IRB approved recruiting materials;
- Continuing review report prior to expiration of the study;
- Final/Close-out Report upon completion or termination of the study;
- Amendments/Revisions to the protocol/study plan, or any other information provided to study participants (notify Salus IRB prior to the initiation of such changes unless the changes are implemented to eliminate an apparent immediate hazard to participants);
- Change of the Principal Investigator;
- Change of site address or addition of a study site(s);
- Any incident, experience, or outcome that is (1) unexpected, (2) related or possibly related to the research, AND (3) suggests that the research places participants or others at a greater risk of harm than was previously known or recognized¹⁴.; and
- Findings detected in the monitoring process when those findings could affect the safety of the participants or their willingness to continue participation, influence the conduct of the study or alter Salus IRB's approval to continue the study (report within 10 business days of discovery).

7.2 Expedited Review

According to USDOT Guidelines (USDOT, 2015),

“Depending on the nature of the project and an individual institution’s protocols, either a full review by the entire IRB committee, or an expedited review by a single qualified member of the committee is required. For multiyear projects like the THEA CV Pilot, an annual continuing review may also be conducted. If there are any revisions or enhancements to this Research Protocol during the course of the study, a formal modification, or amendment, describing the change must be submitted and reviewed by the IRB.”

As requested in the THEA application and in the RFD, Salus IRB found that:

“The research was determined to involve no more than minimal risk and qualified for expedited review in accordance with 21 CFR 56.110 and 45 CFR 46.110, under the following research category(ies): Category 7.”

Category 7 entails: “research on individual or group characteristics or behavior ... or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.”¹⁵

¹⁴ Examples of events that may meet the criteria may be found in Salus Form 300 for Unanticipated Problems: <https://www.salusirb.com/getting-started/submission-forms/>.

¹⁵ From Salus IRB form 100.c for Expedited Review: <https://www.salusirb.com/getting-started/submission-forms/>

7.3 Revisions and Final Acceptance

7.3.1 ICD Revisions

Salus offered a revision to the Original ICD to include:

EMPLOYEES OR FAMILY MEMBERS OF THE STUDY STAFF OR SPONSOR

If you are an employee or family member of the study staff or sponsor, the following statements apply:

- Your decision to participate or not, will not affect your or your family member's performance evaluations
- Your decision to participate or not, will not affect your or your family member's opportunity for promotion
- Your decision to participate or not, will not affect your or your family member's pay

THEA did not take exception to this revision and accepted the Final ICDs as delineated in Section 6 of this report.

7.3.2 Final Research Protocol

The Draft Research Protocol was accepted by Salus IRB on June 1, 2016. However, the draft did not mention what is in Section 3.1.1, that the USF IRB, which has oversight of CUTR's activities, will review PII elements of CUTR's Performance Measurement work in Phase 2. A change was made to the Draft RPD (June 16, 2016) to include this and to make the Draft RPD into the Final RPD. Salus IRB accepted the Final RPD on June 20, 2016.

U.S. Department of Transportation
ITS Joint Program Office-HOIT
1200 New Jersey Avenue, SE
Washington, DC 20590

Toll-Free "Help Line" 866-367-7487

www.its.dot.gov

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