

## AGREEMENT TO BE IN A RESEARCH STUDY

### INFORMED CONSENT DOCUMENT FOR DRIVERS OF PERSONAL VEHICLES

**Sponsor / Study Title:** City of Columbus / “Connected Vehicle Environment (CVE) Research Protocol for Protecting Human Research Participants”

**Principal Investigator:** Alyssa Chenault

**Telephone:** 614 493 7253  
989 284 0495 (24-Hour)

**Address:**  
2 Brothers Automotive  
1248 E Dublin Granville Rd  
Columbus, OH 43229

#### KEY INFORMATION

- This research study is studying the use of Connected Vehicle Devices ((henceforth referred to as the ‘Study Device’) to determine if they improve vehicle safety, specifically to improve driver awareness and reduce the occurrence and severity of crashes.
- What are the main reasons you will want to join this study?
  - *To receive at no cost the after-market vehicle safety device (the Study Device) which will provide you with warnings and alerts to improve your awareness of developing roadway hazards and assist in avoiding crashes along the study corridor of Morse Road, High Street, Cleveland Avenue, and Alum Creek.*
- What are the main reasons you will not want to join this study?
  - *The study requires you to have after-market equipment (the Study Device) installed on your vehicle, receive training on the operation of the equipment and the alerts it provides, and commit to completing two surveys providing your feedback on the equipment.*
- What is the research question the study is trying to answer? Why is it relevant to you?
  - *The research objectives for the study are below. Items in bold are relevant to you as a private sector participant:*
    - *Reduce emergency response times in the study corridor*
    - **Improve driver awareness of [traffic] signal status**
    - **Increase driver awareness of speed limits within school zones**

- *Demonstrate dedicated short-range communication for use in a transit signal priority application*
  - *Reduce truck wait (delay) time at signalized intersections*
- What aspects of research participation in this study are likely to be unfamiliar to you, differ from your expectations, or require special attention?
  - *The Study Device will provide you with a heads-up display, which will be used to provide the warnings and alerts. These alerts will be new and unfamiliar, but you will receive training on the device and the alerts as well as take-home materials containing literature and a website where additional training and information will be available.*
- What information about you is being collected as part of this research?
  - *To register you as a participant in the study, study staff will collect basic information from you to enable follow-up surveys:*
    - *First name*
    - *Last name*
    - *Email address*
    - *Home address*
    - *Cell phone number*
    - *Work Zip code*
    - *Driver's License*
    - *Insurance Card*
- What are the types of activities that you will do in the research?
  - *No special activities are expected of you as a study participant, beyond driving along the study corridor as normal. To qualify for participation, you must traverse the study corridor at least three times per week. A map of the study corridor is found at the end of this consent document and at the installation facility.*
  - *Complete two online surveys during the course of the study.*
- What impact will participating in this research have on you outside of the research?
  - *The Study Device will not interfere with your normal driving or existing safety technologies within your vehicle. The Study Device is intended to supplement and provide additional warnings and alerts regarding roadway hazards.*
- How will your experience in this study differ from treatment outside of the study?
  - *As a study participant, you will receive the Study Device, which will include a heads-up display to provide the alerts. Only participants who sign and date the informed consent and complete the installation and training will receive the Study Device and the alerts it provides.*
- In what ways is this research novel?
  - *This research is intended to demonstrate the benefits of enhanced communication between vehicles and other vehicles and traffic signals. The enhanced communication enables the development of warnings and alerts that can be used to enhance safety and improve mobility. Please note the main objective of the Columbus study is to enhance safety, but mobility is a future benefit that can be achieved using this technology.*

## **INTRODUCTION**

- You are invited to take part in a research study. The City of Columbus, with funding from the United States Department of Transportation, is sponsoring this research study.
- Before you decide to take part in this study, you should read this document. This Informed Consent Document explains the study and ensures that you are given complete information about the study, including potential benefits and risks. Please read this form carefully. Take your time to ask the study investigator as many questions about the study as you would like. The study investigator can explain words or information that you do not understand. Reading this form and talking to the study investigator or study staff may help you decide whether to take part or not.
- If you decide to take part in this study, you must sign your name at the end of this form and date it.

## **PURPOSE OF THE STUDY**

You are being asked to take part in a research study examining the use of a Connected Vehicle Device (henceforth referred to as the 'Study Device'). The Study Device has been developed for use by drivers to improve awareness and reduce the occurrence and severity of crashes. The Study Device is 'Investigational' which means that the Study Device is being tested for its ability to improve safety by the United States Department of Transportation.

Approximately 250-500 private automobile drivers 18 years of age and older will participate in this study as operators of vehicles equipped with a Study Device. There are also over 350 Central Ohio Transit Authority (COTA) buses and supervisor vehicles, over 250 City of Columbus fleet, police, fire, and emergency vehicles, along with 10 private freight heavy duty vehicles (HDV) participating in this study. Participation will involve installation of the Study Device in your vehicle and driving with the Study Device in your vehicle from July 2020 to March 2021 in the study area. A map of the study area is available in this registration facility and included at the end of this Informed Consent Document.

This Study Device will be used to alert you to some specific developing roadway hazards described later in this document.

Study Staff will be passively collecting data from the Study Device and conduct surveys in order to better evaluate the use of the Study Device in the study area.

## WHAT WILL HAPPEN DURING THE STUDY

After confirming that you are eligible to participate in this study and you agree to be in this study, the Sponsor asks that you sign and date this form before any study training or Study Device installation in your vehicle begins. Otherwise, you will be withdrawn from consideration for participating in the study.

Once you have signed and dated this document the session will begin, during which you will be asked to:

- Provide a valid U.S. driver's license
- Provide proof of vehicle insurance
- Provide proof of ownership or lease (vehicle registration showing you as an owner, co-owner or leaseholder of the vehicle).
- Verbally affirm that you drive in the Study Area on a recurring basis
- Provide notification of crash warning systems on your vehicle
- Verbally affirm that you are currently willing to participate for the duration of the Study Period
- Watch a training video and ask questions about points to clarify
- Verbally affirm understanding of Study Device instructions for use
- Wait while Study Device installation is completed
- Consent to receive newsletters, email, etc. as part of the study

Failure to comply with any of the above steps or answers that indicate that you are not qualified to participate will result in you being withdrawn from consideration to participate in the study. Once the Study Device is installed on your vehicle, it is your responsibility to:

- Report any problems that arise with the Study Device to Smart Columbus via an online support desk. The link to this site will be at: [www.columbusconnectedcars.com](http://www.columbusconnectedcars.com).
- Notify Smart Columbus if you sell the vehicle, are involved in a crash, or change your travel to outside the study area
- Return your vehicle for removal of the Study Device if you end your participation prior to completion of the study
- Familiarize yourself with the Study Device at the start of the demonstration, and up to three times during the Study Period

You will receive a notification of the end of the Study Period. Thereafter, you may keep the Study Device installed on your vehicle or have it removed. You will have a period of 2 months after the end of the Study Period (from March 31 to May 31, 2021) to schedule professional removal of the Study Device if you decide to have the Study Device removed. After May 31, 2021, removal of the study device will cost the participant approximately \$90.

## Before You Decide to Participate What You Should Know

1. During the study, the Study Staff is gathering information that will be used to evaluate the performance of the connected vehicle technology. You are providing permission for the Study Staff to collect data from the Study Device when driving within wireless communications range of roadside devices located along the Study Area. This data, by itself, is not associated with you. You will be expected to inform other drivers of your vehicle about the Study Device in your

vehicle and how to use the Study Device, and that data is collected from the Study Device when driving within wireless communications range of roadside devices located along the Study Area.

2. Any data that personally identifies you or could be used to personally identify you will be held under a high level of security.
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 maintaining insurance coverage. The City of Columbus is not responsible for damages you or your vehicle may incur in the event of a crash and does not offer compensation. You are not responsible for any damage to the Study Device that is installed into your vehicle. You are not responsible for replacement of the Study Device if it is stolen. If the Study Device becomes damaged or stolen, please contact Study Staff.
5. You may withdraw from the study at any time. If you withdraw from the study before your scheduled end date, you must allow the Study Device to be removed from your vehicle as soon as is feasible.
6. During the demonstration period for this study (September 2020 to March 2021), Smart Columbus will offer free removals of the study device to private drivers who withdraw from the study early. Participants who complete the study can also schedule free removal of the study device after the study concludes, from March 31, 2021 until May 31, 2021. After May 31, 2021, removal of the study device is not covered by the study team and will cost the participant approximately \$90.
7. The Study Device includes the following applications that determine when safety warnings are provided. These are further explained in a training video and in the text that follows.
  - a. Forward Collision Warning
  - b. Emergency Electronic Brake Light
  - c. Intersection Movement Assist
  - d. Lane Change Warning / Blind Spot Warning
  - e. Red Light Violation Warning
  - f. Reduced Speed School Zone

### **Warning Definitions**

- A *Forward Collision Warning* is provided when the Study Device determines that you may be following another Study Device-equipped vehicle too closely. It intends to provide you with increased awareness of a potential rear-end crash with another Study Device-equipped vehicle. This warning may be provided outside of the Study Area
- An *Emergency Electronic Brake Light* warning is provided when the Study Device determines that another Study Device-equipped vehicle is braking in an emergency fashion in front of you. It intends to provide you with additional time to look for, and assess situations developing ahead. This warning may be provided outside of the Study Area
- An *Intersection Movement Assist* warning is provided when the Study Device determines that you may be turning across the path of travel of another Study Device-equipped vehicle, or that another Study Device-equipped vehicle may be moving across your path of travel. This warning may be provided outside of the Study Area

- A *Lane Change Warning* is provided when the Study Device determines that another Study Device-equipped vehicle is approaching from the rear left or rear right of your vehicle and You are indicating a lane change using the turn-signal indicator. It intends to provide you with increased awareness of vehicles behind you on your left and right. These warnings may be provided outside of the Study Area. A *Blind Spot Warning* is provided when the Study Device determines that another Study Device-equipped vehicle is in the rear left or rear right of your vehicle, and you are indicating a lane change using the turn-signal indicator.
- A *Red Light Violation Warning* is provided when the Study Device determines you are approaching a signalized intersection and you will enter the intersection in violation of a traffic signal indication (for example, red). It intends to provide you with improved awareness of a signal that will turn red before arriving at the intersection. Under normal conditions, Red Light Violation Warnings will be available at every intersection throughout the study area (please see the map in Attachment 1).
- A *Reduced Speed School Zone* warning is provided when the Study Device determines you enter or are inside of an active school zone above the posted speed limit. It intends to increase awareness of active school zones and the school zone speed limit to reduce speed when in school zones. Under normal conditions, the Reduced Speed School Zone Warnings will be issued near the following schools/locations in the study area:

School Name	Intersection Name
Linden STEM Academy	Aberdeen Ave. at Cleveland Ave.
	Cleveland Ave. at Weber Rd.
Clinton Elementary	High St. at North Broadway
	High St. at Oakland Park Ave.
Our Lady of Peace School	Dominion Blvd. at High St.
	High St. at Weisheimer Rd.

8. You will receive a Driver Manual in English and tip card with contact information for the Study Website and online support form after your training. These resources will list the connected vehicle applications, warnings, answers to frequently asked questions, and inquiries that should be directed to the Online Support Desk (appointment-related, incentive-related, repair/troubleshooting, or other).
9. The online support desk can be utilized to ask general questions related to Study Device use, to set up an appointment for Study Device repair, to report a crash, or to withdraw from the study.
10. Data from the Study Device can be collected immediately, and the Study Device will be capable of issuing Forward Collision Warnings, Emergency Electronic Brake Light warnings, Intersection Movement Assist warnings, and Lane Change Warning/Blind Spot Warning immediately. The Study Device will not be able to issue Red Light Violation Warnings or Reduced Speed School Zone Warnings until July 2020. Study Staff will notify you of this change several days beforehand by electronic message.

11. 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. The City of Columbus is not responsible for damages you may incur in the event of a crash and does not offer compensation. The Study Device is designed to provide warnings without adjustments or modifications. Do not tamper with the Study Device.
12. If the Study Device persistently displays an error message you will be expected to notify the Study Staff so that the Study Device may be examined or replaced as needed. If the Study Device becomes dislodged or loosens from its installed position, please contact the Study Staff so the Study Device may be secured.
13. If any installation difficulties arise, the Study Staff will obtain your approval before performing any intrusive solutions (for example, drilling of holes).
14. An application may be disabled for system maintenance, if needed. The Study Device will notify you if an application is disabled at start-up / power-on. Do not expect warnings from the application when system maintenance is underway.

### **POTENTIAL RISKS OF PARTICIPATION IN THIS STUDY**

Please notify the Study Staff if you feel uncomfortable with the Study Device or as a result of the study. You will not be penalized for your honesty.

This is an “actual use” study where you will participate in real-life scenarios of typical Study Device use. As a result, you will be exposed to normal driving risk as a result of participating in this study and you will be responsible for operating your vehicle in accordance with State and local laws governing the operation of motor vehicles. It is unlikely, due to the informative nature of the Study Device, that you will be exposed to additional risk as a result of participating in this study. The Study Device is designed to add a margin of safety to your driving experience. However, there are potential risks to you, which could include but are not limited to:

1. Failure of the Study Device to operate as you were instructed that it should
2. Failure of the Study Device to fulfill its designed safety function to provide a warning
3. Distraction from false warnings or unnecessary warnings
4. Inability to identify the driving problem associated with a warning(s)
5. Driving too fast while expecting the Study Device to inform when to slow down
6. Expecting the Study Device to yield benefits without your cooperation or proper use
7. Breach of Study Device data protections by “hackers” or hostile actors
8. Breach of personal data protections by “hackers” or hostile actors
9. Risks which are currently unknown.

### **BENEFITS OF THE STUDY**

The Study Device is designed to provide safety benefits to you. It is not known how much (or if) the Study Device will enhance your driving experience or safety. The researchers are interested in how the Study Device improves or diminishes your driving experience and how all the Study Devices taken together impact potential crashes and potential unsafe situations.

## **PARTICIPATION INCENTIVES**

You will receive incentives for your participation in the study in the form of gift cards. The total amount of the incentive depends on the extent of your involvement in the study but will not exceed \$315. The distribution of the incentives is as follows:

- You will receive \$15 upon completing the pre-qualification questionnaire and qualifying to participate.
- You will receive \$200 once you have signed and dated the consent form and have the Study Device installed.
- You will receive an incentive for each survey completed for a total of two surveys over the Study Period:
  - \$40 for the first survey
  - \$60 for the second survey

CVE participants will be surveyed quarterly, from the time the OBU is installed. Recruiting will take place from August to November 2020; therefore, participants will take two surveys since no participants will have an OBU installed after November 2020 and the demonstration concludes in March 2021. Participants that take two surveys will earn \$30 and \$50 respectively.

All gift cards will be distributed digitally via email except the pre-qualification incentive which will be distributed in-person at the installation site. If you prefer to have a physical gift card mailed to you, you should call or email Alyssa Chenault, Study Investigator and Communications Project Manager at 614-493-7253 or [anchenault@columbus.gov](mailto:anchenault@columbus.gov). Digital gift cards can only be used for online purchases. Physical gift cards can be used anywhere gift cards are accepted. The value of the gift card expires one year after distribution.

Upon completion of the study, the Study Device will continue to be operational within the study intersections and between Study Device-equipped vehicles. If you complete the study, you may keep the Study Device for your continued use.

## **WILL IT COST ANYTHING FOR ME TO BE IN THE STUDY?**

There will be no cost for my participation in the study. There may be a cost to have the study device removed from your vehicle if it is requested after May 31, 2021. After May 31, 2021, removal of the study device is not covered by the study team and will cost the participant approximately \$90.

## **IN CASE OF AN INJURY RELATED TO THIS RESEARCH STUDY**

You are responsible for notifying Study Staff, either in person or using the online support desk if you have been in a crash, experienced difficulty in using the Study Device, or a malfunctioning of the Study Device. If you are in a crash, call 911. After emergency services have completed their work, please submit a request via the contact form on the ColumbusConnectedCars.com website. The Smart Columbus Safety Manager will use this information to complete an Incident Report concerning the location, type of incident and the use of the Study Device in the incident.

## LEGAL RIGHTS

You do not waive any legal rights by signing and dating 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.

## 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 persons will have access to study records:

- Study Investigator and Study Staff
- Sponsor, the City of Columbus
- Advarra Institutional Review Board (IRB).

In the event personal information is breached, the Study Investigator will notify you of the nature of the breach and what is being done to address it.

Advarra 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.

## FUTURE RESEARCH STUDIES

De-identified information collected during this study and **may be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

## EMPLOYEES OR FAMILY MEMBERS OF THE STUDY INVESTIGATOR, STUDY STAFF OR SPONSOR

If you are an employee or family member of the Study Investigator, Study Staff, or Sponsor, the following statements apply:

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

## VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. You are free to choose not to participate, or to withdraw at any time without any penalty or loss of benefits to which you are entitled. You may be withdrawn from the study at any time, by the Study Investigator, Sponsor, or Advarra IRB, without your consent, for any of the following reasons:

- To protect your safety/health;
- If you do not fulfill your responsibility as a participant, as indicated in other sections of this document;

- If there are not enough participants enrolled/participating in the study;
- If the Sponsor chooses to halt the study.

If you are withdrawn or decide to withdraw from this study, no additional data about you will be collected, however, all data that has been collected, could be shared with the Sponsor.

### **NEW FINDINGS**

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

### **WHOM TO CONTACT ABOUT THIS STUDY**

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:  
Study Subject Adviser  
Advarra IRB  
6940 Columbia Gateway Drive, Suite 110  
Columbia, MD 21046
- or call **toll free:** 877-992-4724
- or by **email:** [adviser@advarra.com](mailto:adviser@advarra.com)

Please reference the following number when contacting the Study Subject Adviser: Pro00040123.

**CONSENT TO BE IN THE STUDY**

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Explaining Informed Consent Document

\_\_\_\_\_  
Signature of Person Explaining Informed Consent Document

\_\_\_\_\_  
Date

You will be given a signed and dated copy of this informed consent document to keep.

### **Attachment 1: Connected Vehicle Environment Installation Map**

The applications that will reside on the individual RSUs will vary depending on the issue identified for the specific location. **Figure 1** presents a complete overview of the CVE with respect to the individual intersections, the applications that will be available at each intersection, and the presence of contributing elements (such as schools, police and fire stations, and freight corridors) that led to the selection of the intersection/application combination proposed.

### CONNECTED VEHICLE APPLICATION BY INTERSECTION

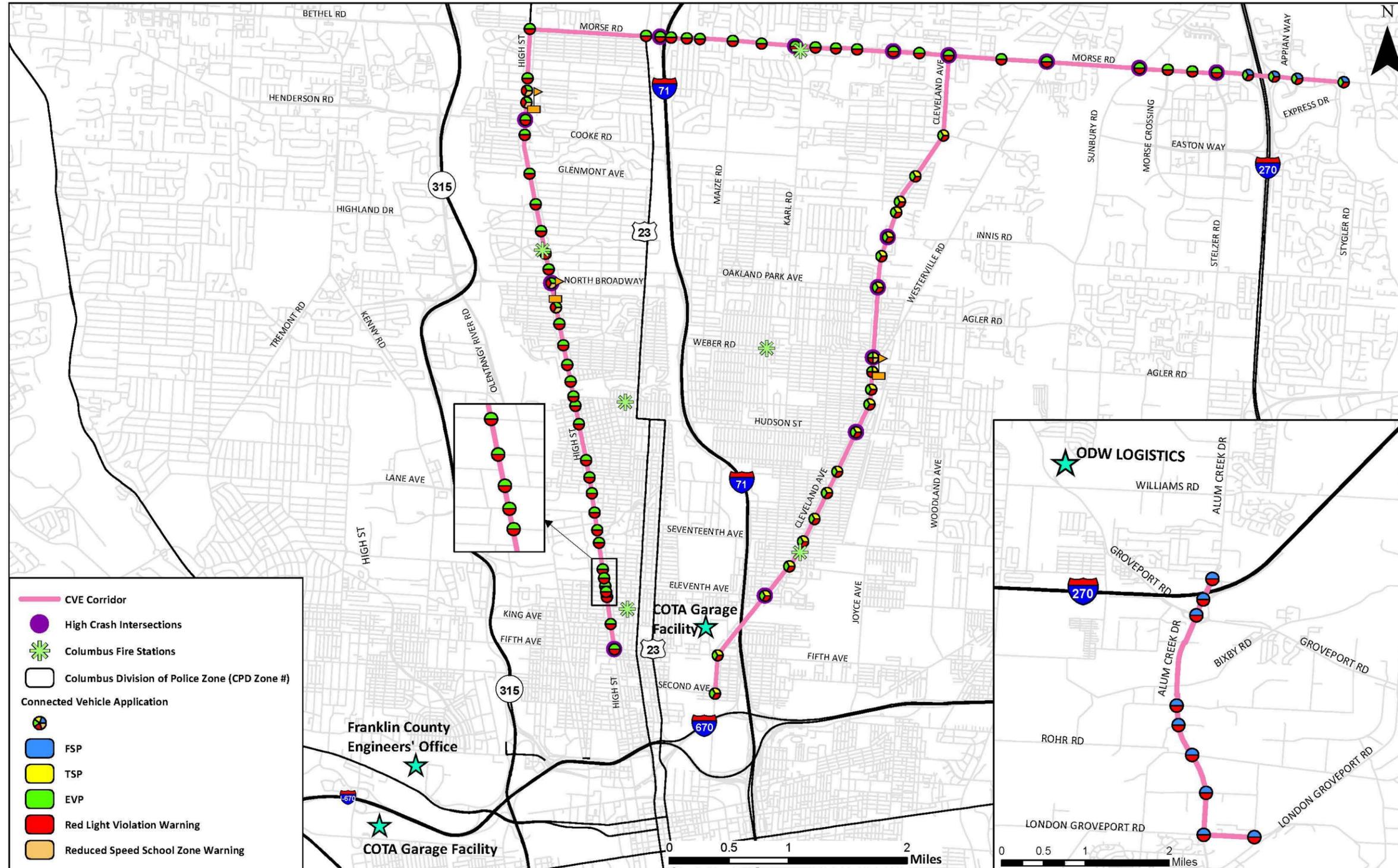


Figure 1: Connected Vehicle Environment Applications by Intersection

Alyssa Chenault

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