Connected Vehicle Pilot Deployment Program Phase 1

Human Use Approval Summary New York City

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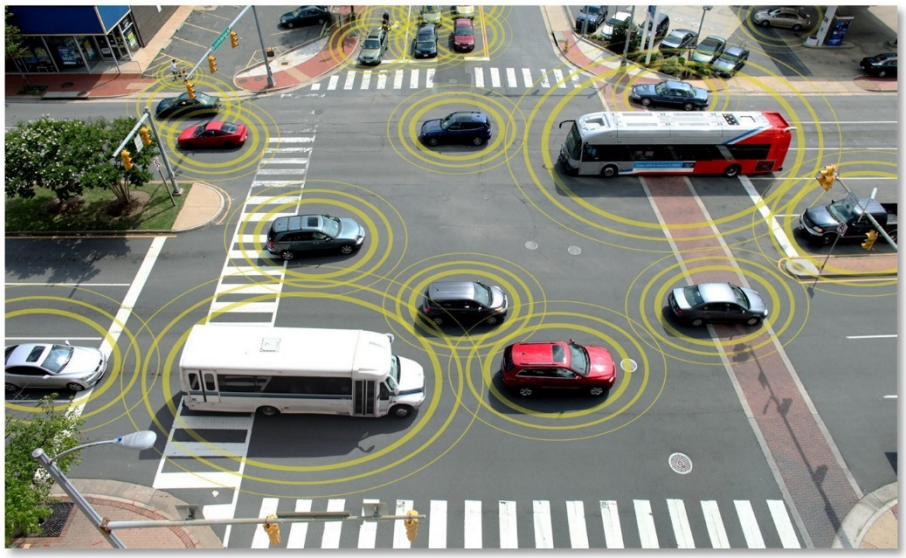

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16. Abstract

The New York City (NYC) Connected Vehicle (CV) Pilot Deployment will be the largest deployment of connected vehicle technology to date. The purpose of the human use approval activity is to apply the Institutional Review Board (IRB) process to the NYC CV Pilot Deployment effort to assure that research involving human participants is designed and conducted in an ethical manner and in accordance with applicable laws and regulations. This report, documents the Battelle IRB's authority to conduct an IRB review, summarizes the content of the initial IRB application and the Battelle IRB's feedback from their review, describes the coordination between this Task 8 activity and other project tasks, and reviews next steps with respect to the IRB review and approval process. Because the deployment is in its concept phase, this report should be considered a preliminary IRB summary. Continued diligence in revising the IRB application and seeking continued IRB reviews will be necessary as the program evolves through the design and deployment phases.

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- *Task 2: Pilot Deployment Concept of Operations (ConOps*)
  - Steve Galgano, Mohamad Talas; NYCDOT
  - David Benevelli, Robert Rausch, Samuel Sim; TransCore
  - Keir Opie, Mark Jensen; Cambridge Systematics
  - Chris Stanley, Battelle
- *Task 3: Security Management Operating Concept*
  - William Whyte, Jonathan Petit; Security Innovation
- *Task 4: Safety Management Plan*
  - Douglas Pape, Hunter McCracken; Battelle
- *Task 5: Performance Measurement and Evaluation Support Plan*
  - Keir Opie; Cambridge Systematics
- *Task 9: Participant Training and Stakeholder Education Plan*
  - Steve Galgano, Mohamad Talas; NYCDOT
  - Peg Bradley, TransCore

Finally, the team wants to thank the USDOT for sponsoring this project and laying the foundation for future connected vehicle deployments.

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1 Introduction

The New York City (NYC) Connected Vehicle (CV) Pilot Deployment will be the largest deployment of connected vehicle technology to date. This project brings New York City another step toward reaching the Vision Zero goal of eliminating the injuries and fatalities due to traffic crashes.

This report:

- documents the Battelle IRB's authority to conduct an IRB review,
- summarizes the content of the initial IRB application and the Battelle IRB's feedback from their review,
- provides the IRB's Notice of Approval for the pilot deployment,
- describes the coordination between this Task 8 activity and other project tasks, and
- reviews next steps with respect to the IRB review and approval process.

The submitted IRB application, as well as the response and feedback provided by Battelle's IRB, is provided in Appendices B, C, D, and E of this report.

This report reflects a focus and commitment on the part of the NYC team to conducting this project and interacting with all participants in an ethical and responsible fashion. Team discussions regarding IRB topics and issues began last fall and have included both regularly-scheduled meetings amongst all relevant team members, as well as ad hoc meetings to address specific or urgent topics. These discussions have included open and honest dialogue regarding participants' rights, the team's responsibilities towards participants, the contractual and legal obligations to the human use process, as well as practical constraints and trade-offs. Importantly, the Battelle IRB has been included in this process from the beginning of the project. The project team has regularly consulted with the Battelle IRB staff on both general procedures and specific IRB questions and topics; these interactions have helped guide the approach to the human use approval process.

As discussed in Chapter 5, this report also reflects careful coordination across project tasks to ensure: compliance with the IRB review and approval process, consistency between planned activities and human use protections, and uniformity in the representation of IRB-related topics and plans across task reports to the United States Department of Transportation (DOT).

Because the deployment is in its concept phase, this report should be considered a preliminary IRB summary. Continued diligence in revising the IRB application and seeking continued IRB reviews will be necessary as the program evolves through the design and deployment phases.

As discussed below, since Battelle will not interact or intervene with human subjects, or have access to information collected about a human subject, Battelle will not be engaged in research and the Battelle IRB cannot – by Battelle policy - serve as the IRB of record. Thus, the IRB activities on this project will be shifted to the New York University (NYU) researchers and the NYU IRB as soon as possible. The fact that the Battelle IRB will not be the IRB of record was an unexpected problem for the entire project team. However, once it became clear to the team that the Battelle IRB could not be

the IRB of record in Phases 2 & 3, the team took immediate action to find a replacement. Since there was not time to get the NYU IRB engaged and involved in Phase 1, the team utilized the Battelle IRB to obtain preliminary approval and obtain recommendations for future IRB issues and activities. Although IRB's are individual, they have the same and common goal of protecting participants. The IRB-related work that has been done to date has been extremely valuable to the project team and to the project as a whole in terms of understanding the IRB process, thinking through future needs, and identifying potential issues to enable work with the NYU IRB to proceed efficiently. Though the Battelle IRB is not directly familiar with any relevant NY State and City regulations, NYU staff were asked about any such regulations and informed the team that they were unaware of any (based on their previous research work).

All the material used for the Battelle IRB application was provided to the NYU team and saved significant time in the application development process.

2 Documentation (U.S. Dept. of HHS) of IRB for Project

In its commitments to the projection of human research subjects, Battelle subscribes to the ethical principles and the application of those principles as described in the Belmont Report. Battelle has formally committed to the federal government that it will comply with federal laws and regulations for the design, conduct and oversight of human subject's research.

These commitments are described in Battelle's Federal-Wide Assurance (FWA) with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP):

- Federal-Wide Assurance Number - FWA00004696
- Battelle Institutional Organization Number - IORG00000172
- Battelle Institutional Review Board Number - IRB00000284

The Battelle IRB is an internal review committee made up of Battelle employees and community representatives. The IRB's review process is intended to assure that research involving human participants is designed and conducted in an ethical manner and in accordance with applicable laws and regulations. The IRB will confirm that any risks to participants are minimized, that the selection of participants is equitable, and participants are informed fully of what their participation will entail and of the potential risks and benefits.

The Battelle IRB is the sole authority at Battelle to approve, require modifications in or disapprove all human subjects' research that falls within its jurisdiction. The Battelle IRB will also determine if it or another qualified IRB will act as the "IRB of Record" to review a proposed Battelle study.

As discussed above, future IRB activities on this project will be shifted to the NYU researchers and the NYU IRB as soon as possible. The team utilized the Battelle IRB to obtain preliminary approval and obtain recommendations for future IRB issues and activities. The IRB-related work that has been done to date has been extremely valuable to the project team and to the project as a whole in terms of identifying relevant issues and future topics.

3 IRB Application Summary

3.1 Summary of Application Content

The IRB application for the New York City Connected Vehicle Pilot Deployment was submitted to the Battelle IRB Review Board on June 9, 2016. The full and final application is provided in Appendix B. The application included the program (Section 1), and study personnel (Section 2), and provided the details of the IRB request (Section 6). Some notable highlights from the application are provided below.

3.1.1 Study Description

New York City is implementing CV technology as a tool in its quest for Vision Zero, the goal of eliminating injuries and fatalities due to traffic crashes. The project will introduce CV technology and communications into the NYC travel environment by equipping several large vehicle fleets with the technology and equipping three distinct areas in the boroughs of Manhattan and Brooklyn with the corresponding CV infrastructure.

3.1.2 Study Design

The CV Pilot Deployment consists of three phases, 1) Concept Development (up to 12 months); 2) Design/Build/Test (up to 20 months); and 3) Operate and Maintain (18 months). There are three pilot deployment sites in Manhattan and Brooklyn; Manhattan (1), which has 204 intersections; Manhattan FDR (2), which is a limited access highway that excludes trucks and buses and consists of short radius curves; and Flatbush Avenue in Brooklyn, which has 28 intersections and over-height restrictions. Approximately 250 intersections will be equipped with roadside equipment (RSE) to communicate with vehicles equipped with aftermarket safety devices (ASDs).

The following applications will be deployed via the in-vehicle ASDs: those to manage speed – Speed Compliance, Curve Speed Compliance, and Speed Compliance in Work Zones; those to reduce vehicle-to-vehicle crashes – Forward Crash Warning, Emergency Electronics Brake Lights, Blind Spot Warning, Lane Change Warning, Intersection Movement Assist, Red Light Violation Warning, and Vehicle Turning Right in Front of Bus Warning; those to reduce vehicle-to-pedestrian crashes – Pedestrian in Signalized Crosswalk Warning and Mobile Accessible Pedestrian Signal System (PED-SIG; as described below); those to reduce vehicle-to-infrastructure crashes – Oversized Vehicle Compliance; and those to inform drivers of serious incidents – Emergency Communications and Evacuation Information.

Of the two pedestrian-oriented applications, 1) the Pedestrian in Signalized Crosswalk application will use commercial pedestrian detection hardware at a limited number of specific intersections to detect pedestrians and inform motorists of pedestrians in the roadway and 2) PED-SIG will provide support for visually impaired (blind) pedestrians at specific signalized intersections.

In addition to “before” and “after” periods, a control and treatment group will be used for taxi fleet vehicles that are generally stored and operated out of a centralized location or “barn” (e.g., home

base, depot, garage, etc.) that the driver will return to at the end of their shift. Each "barn" will be designated as either a control "barn" or treatment "barn." As the daily assignments of drivers to vehicles occur within each barn, the driver can be assured of driving either a control vehicle or treatment vehicle. The use of control and treatment groups will be limited to taxi vehicles as all other planned CV-equipped vehicle fleets generally operate from a single "barns" making it impossible to isolate control and treatment "barns" so that drivers encounter only control or treatment vehicles.

3.1.3 Intended Subject Population

Approximately 10,000 vehicles (7,500 taxis and limousines; 1,500 MTA/NYCTA buses; 500 UPS vehicles; 500 sanitation and NYCDOT vehicles) will be equipped with ASDs. Study subjects will fit into one of three categories:

1) City-owned vehicle operators: These are operators of sanitation vehicles, city vehicles, and Metro Transit Agency bus operators.

2) Privately-owned vehicle operators: These are operators of taxi's and UPS vehicles.

3) Pedestrians: Approximately 100 visually impaired individuals will be recruited to participate using the PED-SIG application.

3.1.4 Plans to Identify and Recruit Subjects

Any fleet driver who is an employee of a participating organization and drives a vehicle with a device installed may be a pilot project participant. No formal recruitment or consent of fleet drivers will be conducted. Fleet owners/managers will require any driver of the installed vehicle to utilize the information provided regarding safety warnings and alerts. Pedestrians will be recruited from groups that NYCDOT has worked with in the past in order to recruit a diverse group of individuals with disabilities.

3.1.5 Data Collection Procedures

CV Pilot Deployment participants will drive in their respective vehicles as they normally would. The only difference is that during the pilot deployment, they will receive warnings and alerts via aftermarket safety devices providing information pertaining to managing speed, reducing vehicle-to-vehicle crashes, reducing vehicle-to-pedestrian crashes, reducing vehicle-to-infrastructure crashes, and informing drivers of serious incidents.

In-Vehicle ASDs will log relevant information surrounding a triggered event. The trigger will be configurable and will include the CV application warnings, acceleration criteria, brake system status, etc. The time periods for collected data before and after the trigger event will be configurable for each event trigger. The relevant information (data) will be limited to what the ASD provides and it may include vehicle data when the ASD is connected to the vehicle's data bus. Each event log entry will include locations (i.e., latitude, longitude, elevation, 3-axis acceleration), indicated warnings, and the action (i.e., lights, wipers, turn signals, steering angles, brakes) of the vehicle. This event log will be encrypted and stored on the vehicle for later retrieval when the vehicle returns to its fleet terminal where the data will be offloaded. The definition of an event will be configurable so it can be used to collect short-term driver behavioral data for aggregation and performance measures.

Also, an anonymous driver survey instrument will be developed. The exact modalities of the survey instrument have not been developed, but it is anticipated that it would be a combination of web forms (over the internet) and mobile apps on tablet devices positioned at select locations where CV vehicles are serviced/stored and where the vehicle operators will start or stop shifts (taxi barn, MTA Depot, etc.).

3.1.6 Privacy and Data Confidentiality Procedures

The project will manage participant's personal contact information as follows. No personal information for drivers will be collected or stored. Any pedestrian participant contact information will be stored in a secure file at the NYCDOT Traffic Management Center. Only authorized project team staff will have access to the list of participant contact information during the study. This list will not be linked to any participant or vehicle data – it will be used purely for scheduling the installation and removal of the equipment and for tracking its reliability and operational integrity. Event data will be collected in encrypted files and processed within 7 days to remove all personal information or time and location information that could be matched with other data to identify specific pedestrians, drivers or vehicles.

Safeguards to protect identifiable research information include:

- Event log data will be cleansed of any traceable personal data (exact location and time) to prevent from being correlated to other records, such as police reports.
- Vehicle IDs will be anonymized based on the ASD device. The anonymization will be updated regularly to prohibit tracking a single vehicle throughout the study, even with an anonymized ID number. No driver ID will ever be recorded in the ASD unit or recorded data.
- Time and date information will be obfuscated and recorded to have exact date and time scrubbed from records and instead will be registered in different categories or bins of date and time. For example, an action log data set recorded on Tuesday, January 5, 2015 starting at 8:35 am may instead be recorded as January Tuesday 8-9am or January Weekday 8-9am.
- Detailed latitude and longitude data recorded by the ASD will be scrubbed and converted to an undefined Cartesian Coordinate system for storage and later evaluation. Each event data set will be recorded with full precision for all trajectory points relative to each other in the same event data set, but will not be tied to an exact real-world coordinate. The obfuscation of location will be done independently for each event action log data set recorded.
- The exact level of scrubbing or obfuscation to time, date, and location data has not yet been finalized and cannot be fully be finalized until the deployment is underway.
- Pedestrian Aftermarket Safety Devices / Smartphone Applications will follow the same data privacy and data obfuscation that exist with the in-vehicle ASDs and similar solutions to ensure the safety and privacy of the pedestrians will be utilized.
- Collaborators and those outside of the project team will only have access to disaggregated obfuscated data and aggregated processed performance metrics. All raw data will be destroyed following the obfuscation process.
- No identifiers from subjects will be recorded.

The use and sharing of the data will be governed by the agreements (MOUs) between NYCDOT and the stakeholders. The guiding principles of these agreements are that the data will be obfuscated to remove any personally identifiable information (PII) and that the data is being collected to evaluate the system performance related to safety, consistent with NYCDOT's Vision Zero initiatives. The use of the data by the USDOT and the research community via the USDOT Research Data Exchange (RDE) should also respect the principles of privacy contained within those signed agreements.

3.1.7 Informed Consent Procedures

Any fleet driver who is an employee of a participating organization and drives a vehicle with a device installed may be a pilot project participant. No formal recruitment or consent procedure will be conducted for these participants.

The only participants that will be consented will be the pedestrians using the Mobile Accessible Pedestrian Signal System. These participants will have access to a copy of the consent form prior to scheduling an appointment to complete the consent process. During the informed consent appointment, participants will be provided with ample time to read through the consent form. Once the participant has read the consent form, a trained member of the project team will discuss the Informed Consent form with each prospective participant and ask them questions about the content of the consent form to gauge their understanding of the study and its requirements. Each prospective participant will have an opportunity to ask questions about the study and will be provided with ample time to make the decision about whether or not to participate.

3.1.8 Potential Risks and Benefits to Subjects

There is minimal physical, psychological, social, and legal risk associated with the study. The first potential risks are the risks that come with driving. However, the risks involved in the study are no different than what participants would encounter in their day-to-day driving without the benefit of the warnings and alerts.

Second, a potential risk is that the ASD equipment that will be mounted in the cab of the vehicle might cause distraction. The system should be designed in a way that it does not cause the driver any distraction. This is planned to provide audio alerts and warnings only using threat conditions; there are no plans for a visual display to cause further distraction.

Third, since the driver vehicle data and pedestrian data are being collected in three distinct areas in the boroughs of Manhattan and Brooklyn and obfuscated as soon as it is created, there is potential risk of breach of the data even though it is encrypted when collected and uploaded to the NYCDOT Traffic Management Center. However, confidentiality would not be compromised in this event since the data being collected does not contain any personal identifying information.

Finally, the risk of incorrect information being provided to the driver or a false alarm is possible. The appropriate measures will be taken to make the likelihood of this occurring as small as possible.

All study participants will receive training on the applications and information that they will be provided via the ASD and pedestrian application as well as instruction on how to report issues and feedback on the applications to the project team. By providing training, participants will have a better chance of knowing when the ASD is providing incorrect information and will be able to report this to the project team.

The primary benefit to participants is evidence that will hopefully contribute to the CV technologies body of knowledge by showing that the use of these technologies can help with speed management, reducing vehicle-to-vehicle crashes, reducing vehicle-to-pedestrian crashes, reducing vehicle-to-infrastructure crashes, and informing drivers of serious incidents. Each of these efforts can help contribute to the Vision Zero goal of eliminating injuries and fatalities due to traffic crashes. This is the first large scale implementation of this technology in an enclosed area (Manhattan) that will provide the opportunity to measure the benefits and serve as a baseline for other urban markets as they could consider the deployment of connected vehicle technology.

3.2 Summary of IRB Feedback/Revisions

Appendices C, D, and E provide the details of the Battelle IRB's response to the application provided in Appendix B. The bullets below provide a summary of the feedback, recommendations, and questions provided by the IRB.

- Since Battelle will not interact or intervene with human subjects, or have access to information collected about a human subject, Battelle will not be engaged in research. The Notice of Approval provided in Appendix E is preliminary only and is intended to describe the decision logic for a future ruling by an IRB of Record.
- The Battelle IRB strongly recommends that:
  - Any future IRB of Record should re-evaluate if it is possible that one or more tasks may not require categorization as human subjects research (failing DHHS OHRP (DOT under the Common Rule – 45 CFR 46, Subpart A; definition of "human subject")), or could reasonably be ruled human subjects research, but exempt. This could be the case for the Fleet Drivers-related tasks.
  - For Phase 2, JHK/Transcore and collaborating institution(s) engage the designated IRB of record to assess entire scope of work to determine if it is appropriate ONLY to rule on those tasks that clearly can be defined as "human subjects research."
- All data collection activities described are considered to present minimal risk to human subjects regardless of the status of voluntariness.
- The Principal Investigator/Project Manager(s) must assure that all study investigators have completed initial training in human subject's ethics, regulations, and applicable policies and that all investigators complete human subjects re-training at required intervals.
- Given that there may be a considerable number of participants from a foreign culture who are not native English speakers, the project should anticipate resources to include these individuals or include inclusion/exclusion criteria for a fluent English speaker.
- The IRB provided a number of questions and suggestions related to data handling, data privacy, data access, dealing with adverse events, and if/how participants will return in-vehicle equipment (see also Appendix C). The IRB suggested that these questions and suggestions could be addressed in a future Application.
- The IRB indicated that the future IRB of record could issue a waiver of informed consent for certain participants if the project meets specific regulatory criteria. This issue should be revaluated by the future IRB.
- The IRB also provided a separate set of recommendations for activities that the project team should consider and information that could be added to training materials and consent documents (see also Appendix D).

Based on the IRBs feedback and suggested revisions, future IRB-related plans for the NYC Connected Vehicle Pilot Deployment Program include:

- Identifying an IRB that can serve as the IRB of record for Phases 2 and 3. As discussed in section 6.1.1 below, we expect that the New York University (NYU) IRB will be taking over as the IRB of record for this project starting in Phase 2. All original documents related to IRB matters – including this report – have been provided to NYU staff to facilitate their IRB activities and reviews in Phases 2 and 3.
- Considering and addressing the IRB's recommendations regarding the:
  - categorization of certain elements of this project as human subjects research,
  - requirements for all study investigators to have completed initial training in human subject's ethics,
  - handling, access, and privacy aspects of study data,
  - requirements to more fully describe plans for recruiting, screening, training, consenting, data collection, and the general management of study participants,
  - necessity, in general, to develop and submit future IRB applications and amendments that address these and other issues as they arise during the conduct of Phases 2 and 3.

3.3 Documentation of Approval

Appendix E provides the preliminary Notice of Approval from the Battelle IRB; it describes the decision logic for a future ruling by an IRB of Record.

3.4 Approved Timeline

The preliminary Notice of Approval identifies June 10, 2017 as the final day of approval. The IRB has provided a set of specific recommendations for the research team to address with the future IRB of Record during Phase 2.

3.5 Recruitment/Informed Consent Documentation

All recruitment and informed consent documentation will be developed in Phase 2 of this program.

4 State/Local Human Use Compliance

The team has not identified any relevant regulations or requirements from New York State or New York City that are distinct from the existing IRB requirements, and warrant discussion in this report. However, such regulations or requirements may emerge during the conduct of Phase 2 or 3. Battelle recommends that the investigation of this issue continues and that the USDOT is made aware of and that any such issues that might impact this project are addressed.

5 Coordination with other Tasks (Summary of Human Use Approval-related Information)

5.1 Overview

This report also reflects careful coordination across project tasks to ensure: compliance with the IRB review and approval process, consistency between planned activities and human use protections, and uniformity in the representation of IRB-related topics and plans across task reports to the USDOT.

In particular, much of the material included in the IRB application was produced in other tasks and incorporated (either directly or in some summary form) into the IRB application. Below is a summary of the information related to human use approval gleaned from other tasks within this project.

- Key information obtained from *Task 2: Pilot Deployment Concept of Operations (ConOps*):
  - General description of the planned research and the scientific objectives of the research
  - Intended subject population(s) of the study
  - In general, how human subjects will interact with the pilot deployment
- Key information obtained from *Task 3: Privacy and Security Management Operating Concept:*
  - Procedures for gathering, handling, and protecting data and personal information
- Key information obtained from *Task 4: Safety Management Plan*:
  - Descriptions of potential risks to participants while participating, including any safety risks that are associated with using the CV technology, & any risks to non-participants, such as other drivers or pedestrians
- Key information obtained from *Task 5: Performance Measurement and Evaluation Support Plan:*
  - Details of the anonymous driver survey that will be used to collected driver feedback
  - General design of the study and data collection procedures
  - Details regarding data sharing and data transmission
- Key information obtained from *Task 9: Participant Training and Stakeholder Education Plan:*
  - Plans for recruiting, training, and consenting participants
  - Participant qualifications

5.2 Changes to other Tasks due to IRB Review

At this time, no changes to other project tasks (in Phase 1) due to the IRB review are required or have been identified.

6 Significant Areas of Uncertainty & Potential Future Amendments

6.1 Significant Areas of Uncertainty

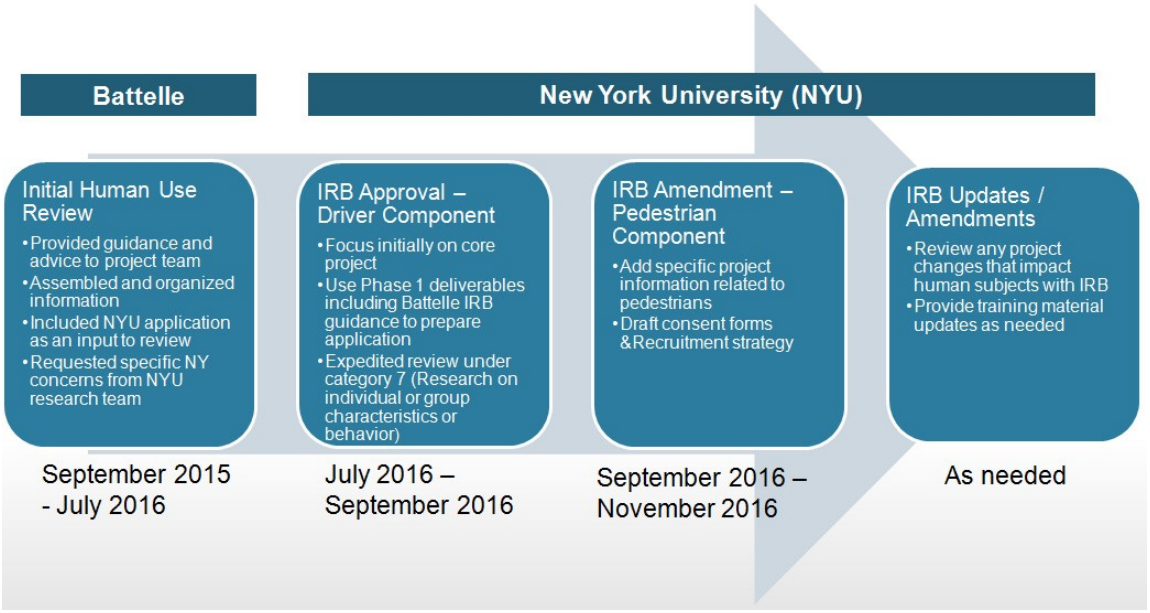
6.1.1 Expected Change of IRB of Record in Phases 2 and 3

The Battelle IRB exists to review and approve human subjects research conducted by Battelle staff. Because Battelle staff are not participating in the research activities associated with Phases 2 and 3, the NYC team has been required to identify another IRB that can serve as the IRB of record in Phases 2 and 3. At this time, we expect that the New York University (NYU) IRB will be taking over as the IRB of record for this project starting in Phase 2. Importantly, the Battelle IRB was provided with a copy of the NYU IRB's application form and consulted this form while reviewing the Task 8 IRB application. Thus, the Battelle IRB's feedback to the project team regarding plans and procedures, and study documents takes into account application elements and requirements in the NYU IRB's application. Also, all original documents related to IRB matters – including this report – have been provided to NYU staff to facilitate their IRB activities and reviews in Phases 2 and 3.

This transition to the NYU IRB has already started. As a risk mitigation strategy, the application will be submitted initially with only the vehicle component of the project. The Pedestrian component will be added as an amendment when NYU's IRB has completed their initial review. The project team chose this route as the vehicle component of the project is the largest by far (8000 vehicles vs. 100 pedestrians) and the human use impacts of the two components are quite different.

No personal data will be collected for any drivers and the project team will have no direct interaction with any drivers. The fleet owners are responsible for determining which vehicles are equipped and for training any drivers of an equipped vehicle. This approach has been discussed with the NYU IRB. Based on these discussions and the human use work conducted as part of Phase 1, the NYU IRB has indicated that they will be completing an expedited review under category 7 (Research on individual or group characteristics or behavior) of the application and as depicted in the schedule, it is anticipated that this will be complete on or before September 15, 2016.

Pedestrian participants will be recruited and will provide informed consent. The IRB application will be amended after the initial application is approved. It is anticipated that this will be approved by the end of November 2016. Pedestrian training is not slated to begin until 2018 so this leaves adequate time to recruit and consent the 100 pedestrian participants.



Source: CV Pilot Deployment Program Phase 1, Comprehensive Deployment Plan – New York City, 2016

Figure 6-1. IRB Transition

The transition of IRB responsibility from Battelle to NYU introduced two new project risks:

- Delay in IRB approval Impacts overall project schedule/delivery
- IRB recommendation requires project changes (such as need to consent all drivers or changes to applications to reduce safety concerns)

The primary mitigation strategy is to gain IRB approval as soon as possible so that the schedule impact can be minimized and so that there is time to address any project changes required for IRB approval without impacting the overall project schedule or budget. The plan laid out in Figure 6-1 addresses the strategy to achieve this approval as quickly as possible. The NYC team put a mitigation plan in place as soon as the issue was identified. Below is a high level view of the mitigation plan. Note that many of the items are already complete.

- Identify alternate IRB to replace Battelle (complete)
- Move forward with Battelle IRB as an interim solution (complete)
- Share NY and NYU specific information with Battelle IRB (complete)
- Share Battelle IRB guidance with NYU (complete)
- Expedite NYU IRB Application (in process) – Initial application was submitted to NYU on 7/29/2016.
- Prioritize Vehicle Component of IRB Application (in process) - Initial application was submitted to NYU on 7/29/2016.
- Assess feedback from NYU IRB immediately and prepare a response plan.

6.1.2 Potential Risks to Participants from the PED-SIG Application

The Safety Management Plan indicated the possibility of significant risks to pedestrians using the PED-SIG application in this project. At this time, these risks are best viewed as potential risks that will need to be managed and addressed as part of the broader system design and data collection activities. That is, this safety application will need to have very high levels of reliability in terms of the timing and nature of information provided to the pedestrians, appropriate training must be developed and provided to users, and the consent process must make any remaining risks very clear to potential participants. Future IRB applications and amendments should address the nature of this potential risk and describe any actions required to eliminate or mitigate the risk.

6.2 Potential Future Amendments

As noted in Section 3.2, the feedback from the Battelle IRB included a number of specific recommendations for the future. Appendices C, D, and E provide more details on these recommendations. In general, though, future IRB submittals will need to include specific recruiting, screening, consent, data collection instruments, and other relevant study documents prior to conducting human subjects research in this program.

7 Summary and Conclusions

This report has documented the Battelle IRB's standing to conduct an IRB review, summarized the content of the initial IRB application and the Battelle IRB's feedback from their review, described the coordination between this Task 8 activity and other project tasks, and reviewed next steps with respect to the IRB review and approval process.

As noted above, the NYC team's preparations for deployment involving human subjects highlights the focus and commitment on the part of the team to conducting this project and interacting with all participants in an ethical and responsible fashion. This report represents the current status of an IRB approval process that has been underway and includes the various individuals and organizations that are a part of the NYC team, as well as the Battelle IRB. It also reflects careful coordination across project tasks to ensure: compliance with the IRB review and approval process, consistency between planned activities and human use protections, and uniformity in the representation of IRB-related topics and plans across task reports to the USDOT.

This report has documented the current plans and procedures associated with:

- Study Design
- Intended Subject Population
- Plans to Identify and Recruit Subjects
- Data Collection Procedures
- Privacy and Data Confidentiality Procedures
- Informed Consent Procedures
- Potential Risks and Benefits to Subjects

It has also provided a summary of the Battelle IRB's feedback and suggested revisions in response to the IRB application that was submitted, described the approved timeline, and described the future plans for developing the more detailed recruitment and informed consent procedures and documentation.

Although this report describes the current status of the human subjects plans and procedures, considerable work related to human use approvals is expected to be accomplished in Phases 2 and 3 of this project. Specifically, because the deployment is in its concept phase, this report should be considered a preliminary IRB summary. Continued diligence in revising the IRB application and seeking continued IRB reviews will be necessary as the program evolves through the design and deployment phases.

Appendix A: Abbreviations

Acronym/Abbreviation	Definition
ASD	Aftermarket Safety Device
ConOps	Concept of Operations
CV	Connected Vehicle
DHHS	Department of Health and Human Services
DOT	Department of Transportation
DSNY	New York City Department of Sanitation
FWA	Federal-Wide Assurance
IRB	Institutional Review Board
ITS	Intelligent Transportation System
JPO	Joint Program Office
MOU	Memorandum of Understanding
MTA	Metropolitan Transportation Authority
NYC	New York City
NYCDOT	New York City Department of Transportation
NYCTA	New York City Transit Authority
NYU	New York University
OHRP	Office for Human Research Protections
PII	Personally Identifiable Information
RDE	Research Data Exchange
RSE	Roadside Equipment
UPS	United Parcel Service
USDOT	United States Department of Transportation

Appendix B: Original IRB Application

BUSINESS SENSITIVE IRB APPLICATION – Section 1

BATTELLE INSTITUTIONAL REVIEW BOARD (IRB)
DHHS Federal-wide Assurance: FWA00004696
DoD Addendum to FWA: DoD-NA3093
IRB Registration Number: IRB00000284

APPLICATION for IRB REVIEW and APPROVAL of HUMAN SUBJECTS RESEARCH

SECTION 1: STUDY SUMMARY SHEET

Name of Battelle Principal Investigator/Project Manager/Project Director: **Chris Stanley**
Battelle Site Name: **Crystal City** Phone Number: **(703) 413-7267**

Full Study Title (and common or short title): **New York City Connected Vehicle (NYC CV) Pilot Deployment Program**
IRB Number (if already assigned):

Project & Activity ID Number (or B&P number): **100072168, Task 8**
Proposal Number (OPP Number):

Type of Award

- ☐ Contract/cooperative agreement
- ☐ PHS grant
- ☐ Other grant
- ☐ Battelle Internal Research & Development (IR&D) /Science & Technology (S&T) Funding
- ☒ Subcontract to Battelle from: **JHK Engineering/TransCore**

Client / Funding Agency: **FHWA/JPO** List any additional funding sources
Agency Principal Investigator: **Sarah Khan (Phase I)**
Sarah Tarpgarrd (Phase II)

Address:
Phone: ( ) -
e-mail Address

Agency Contract Officer:
Phone: ( ) -
e-mail Address

Will another IRB review this study?
Yes ___X_____ / No_____
If yes, identify the IRB(s):
Unknown at this time

Period of Award

Contract/grant start date **9/4/2015**
Contract/grant end date **9/19/2016 (Phase I)**
Date human subject contact begins (or began) **10/1/2018 (During Phase II)**

Does the contract/grant include Terms & Conditions for the ethical conduct of human subjects research? ☐ No ☒ Yes

If Yes, briefly describe any special requirements.
Approval of a certified IRB must be obtained prior to initiating the research.

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BUSINESS SENSITIVE IRB APPLICATION –Section 2

SECTION 2: STUDY PERSONNEL

1. Identify the Battelle Principal Investigator:
   Chris Stanley
2. Identify the Battelle Project Manager:
   Chris Stanley
3. Identify Battelle "Key Personnel[1]":
   John Campbell and Paige Bacon-Abdelmoteleb (Phase I only- no interaction with human subjects during the Phase II data collection)
4. Have "Key Personnel" completed human subjects training[2]? ☐ No ☒ Yes
5. Identify all "Key Personnel" who will administer and obtain human subjects' informed consent.
   None
6. Will Battelle subcontract any part of this work? ☒ No ☐ Yes
   a. If yes, identify ALL subcontractors (organizations, institutions, or Individual Investigators) and briefly describe their role in the study
   b. Will a Battelle subcontractor conduct or support Human Subjects Research? ☒ No ☐ Yes
      i. If Yes, identify all subcontractor personnel (by name and title/education level) who will act as "Key Personnel, including any subcontractor Principal Investigator or Project Manager"?
      ii. If Yes, will a Battelle subcontractor be dependent upon the rulings of Battelle's IRB? ☐ No ☐ Yes
      iii. If Yes, have subcontractor "Key Personnel" completed human subjects training[3]? ☐ No ☐ Yes

   Depending upon the specific role of the subcontractor, the Battelle IRB may require subcontractors to enter into an Individual Investigator Agreement.
7. Will any other institution be dependent upon the rulings of Battelle's IRB? ☒ No ☐ Yes
   a. If yes, describe the other institution's scope of work
8. Identify ANY OTHER teaming partners or collaborators in the study and briefly describe their role in the study.
   New York City Department of Transportation (NYCDOT) is the prime contractor – under contract to USDOT; TransCore is the principle subcontractor to NYCDOT providing design services, project management, systems

[1] *"Key Personnel" are those staff members who will interact or intervene with human subjects or who will have access to private, identifiable information about human subjects.*

[2] *Battelle Principal Investigators and Project Managers must assure that all Key Personnel have been trained in human subjects ethics, regulations and Battelle policies.*

[3] *Battelle Principal Investigators and Project Managers must assure that all subcontractor Key Personnel have been trained in human subjects ethics and regulations.*

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engineering, and project planning; Battelle is a subcontractor to TransCore providing engineering and design services for the connected vehicle project for a number of applications; Cambridge Systematics is providing support services and performance evaluation and benefit analysis services.

BUSINESS SENSITIVE IRB APPLICATION – Section 6

SECTION 6: REQUEST FOR INSTITUTIONAL REVIEW BOARD REVIEW

A. STUDY DESCRIPTION AND RECRUITING

1. Provide a general description of the planned research and the scientific objectives of the research.

New York City (NYC) is implementing Connected Vehicle (CV) technology as a tool in its quest for Vision Zero, the goal of eliminating injuries and fatalities due to traffic crashes. The project will introduce Connected Vehicle technology and communications into the New York City travel environment by equipping several large vehicle fleets with the technology and equipping three distinct areas in the boroughs of Manhattan and Brooklyn with the corresponding CV infrastructure.

2. Describe the general design of the study. For example, does the research involve a single phase or multiple phases? Are there control or experimental groups? Will the study require deception of human subjects? Describe sampling procedures (sampling plan and sampling sizes; power calculations; stratifications, etc.

The whole CV Pilot Deployment consists of three phases, 1) Concept Development (up to 12 months); 2) Design/Build/Test (up to 20 months); and 3) Operate and Maintain (18 months). There are three pilot deployment sites in Manhattan and Brooklyn; Manhattan (1), which has 204 intersections; Manhattan FDR (2), which is a limited access highway that excludes trucks and buses and consists of short radius curves; and Flatbush Avenue in Brooklyn, which has 28 intersections and over-height restrictions.

Approximately 250 intersections will be equipped with roadside equipment (RSE) to communicate with vehicles equipped with aftermarket safety devices (ASDs).
The following applications will be deployed via the in-vehicle ASDs: those to manage speed – Speed Compliance, Curve Speed Compliance, and Speed Compliance in Work Zones; those to reduce vehicle-to-vehicle crashes – Forward Crash Warning, Emergency Electronics Brake Lights, Blind Spot Warning, Lane Change Warning, Intersection Movement Assist, Red Light Violation Warning, and Vehicle Turning Right in Front of Bus Warning; those to reduce vehicle-to-pedestrian crashes – Pedestrian in Signalized Crosswalk Warning, and Mobile Accessible Pedestrian Signal System (as described below); those to reduce vehicle-to-infrastructure crashes – Oversized Vehicle Compliance; and those to inform drivers of serious incidents – Emergency Communications and Evacuation Information.

Two pedestrian-oriented applications will be deployed, 1) a generalized warning to vehicles of pedestrians in the roadway and 2) support for visually impaired (blind) pedestrians. The first application (Pedestrian in Signalized Intersection Warning) will use the pedestrian detection information to indicate the presence of pedestrians in a crosswalk at a signalized intersection. As a vehicle approaches a signalized intersection, the pedestrians will be detected by the traffic control system. At the same time, the pedestrian will carry a personal information device (PID) in the form of a smartphone which will communicate with the NYC CV infrastructure. The pedestrian detection information will be sent to and processed by the Road Side Equipment (RSE), which will then broadcast it into the Aftermarket Safety Devices (ASDs) in the approaching vehicles. The second application (Mobile Accessible Pedestrian Signal System) will provide support for the visually impaired and it is assumed that the application will be implemented using a portable personal information device (e.g., a smartphone). The application is intended to use the Map Data Message (MAP) and Signal Phase and Timing (SPaT) messages to provide the intersection geometrics and the current status of the intersection displays (PED signals and vehicle signals) along with other confirmation information to assist the pedestrian in safely crossing the street. The application will assist the pedestrian in confirming their location (street and cross street), and orientation and provide verbal information regarding the signal state, thus, improving their ability to safely cross the street.

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Data collection and benefit analysis is a critical part of this program. Data will be collected for a time period (typically 10-20 seconds) before a safety warning/alert to the driver and the system will continue to collect data for a period of time after the alert/warning (typically 10-30 seconds). This data will include such information as heading, speed, acceleration, braking, steering wheel angle, and location to allow a complete analysis of the situation leading up to the alarm/warning and actions taken by the driver after the alert/warning is "delivered" to the driver.
The system will be deployed incrementally; as the on-board units are initially installed, they will detect situations requiring warnings and alerts, but will not provide them to the driver so that the system can collect baseline data. This situation is referred to as the "silent" period.
Once all of the vehicles have been equipped and tested, the system will be activated and start issuing warnings and alerts to the drivers when the on-board unit detects a possible condition that could cause a crash or injury. The drivers will receive instructions in the operation of the warning system prior to its activation. The above will be used for all fleet vehicles except the taxis.
In addition to "before" and "after" periods, a control and treatment group will be used for taxi fleet vehicles that are generally stored an operated out of a centralized location or "barn" (e.g., home base, depot, garage, etc.) that the driver will return to at the end of their shift. Each "barn" will be designated as either a control "barn" or treatment "barn." As the daily assignments of drivers to vehicles occur within each barn, the driver can be assured of driving either a control vehicle or treatment vehicle. The use of control and treatment groups will be limited taxi vehicles as all other planned CV-equipped vehicle fleets generally operate from a single "barns" making it impossible to isolate control and treatment "barns" so that drivers encounter only control or treatment vehicles. By restricting the control group to all of the vehicles within one or more "barn," drivers will be subjected to the same situation (silent or active) throughout the testing period.

3. Describe the intended subject population(s) of the study. For example, what is the anticipated number of subjects, ages, gender, ethnic background, health status.

Approximately 10,000 vehicles (7,500 taxis and limousines; 1,500 MTA / NYCTA buses; 500 UPS vehicles; 500 sanitation and NYC DOT vehicles) will be equipped with aftermarket safety devices (ASD).
Study subjects will fit into one of three categories:
1) City-owned vehicle operators: These are operators of sanitation vehicles, city vehicles, and Metro Transit Agency bus operators.
2) Privately-owned vehicle operators: These are operators of taxi's and UPS vehicles.
3) Pedestrians: Approximately 100 visually impaired individuals will be recruited to participate using the PedApp.
All subjects will be 18 years or older.

Many of the vehicle fleet's drivers/operators are governed by collective bargaining agreements with the fleet owners. These agreements establish work rules and cover the operation of fleets. The exception to this relationship involves taxis. While the Taxi and Limousine Commission regulates taxi companies, the relationship between the taxi companies and drivers is not covered by a collective bargaining agreement. The project expects to be dealing with a potentially much larger pool of drivers/operator due to the nature of fleets and that multiple drivers are used to keep vehicles such as taxis operating for extended periods of time. Many of the fleet vehicles will be kept in service more than five days a week and for periods well beyond an eight-hour shift.

4. Indicate subject population category(ies) that may warrant additional protections, including vulnerable populations (* as defined by 45 CFR 46)? Use "OTHER to describe any other population that may warrant additional protections.

BUSINESS SENSITIVE IRB APPLICATION – Section 6

☐ Minors / Children*	☐ Terminally ill individuals
☐ Pregnant women*	☐ Comatose individuals
☐ Fetuses or Neontates*	☐ HIV-infected patients
☐ Prisoners or parolees*	☐ Individuals with alcohol, drug or mental health dependencies or who have committed illegal acts
☐ Battelle staff or families	☐ Non-English speaking individuals
☐ Institutionalized individuals	☐ Impaired capacity to give or continue informed consent
☐ Genetically susceptible/impaired individuals	☐ Military personnel and/or immediate family
☒ Cognitively/psychologically/physically impaired individuals	☐ Tribal, Hispanic, Asian, or other targeted ethnicities
☐ Socially or economically disadvantaged individuals	☐ Workers/Employees
☐ Emergency patients	☐ Secondary Subjects (genetic/medical relationship)
☐ Students	☒ OTHER: Healthy Adults

5. Explain briefly the criteria for inclusion of any populations identified in Question #4 (above).

Fleet Drivers: Fleet drivers must be an employee of the participating organization who drives a vehicle with a device installed. The driver selection process is left to the fleet owners normal Human Resources processes.
Pedestrians: Must be a visually impaired resident who regularly crosses the streets in the equipped study areas. Participants will be selected by the City of New York's support services.

6. Explain briefly the criteria for exclusion of any population from the study.

No criterion has been established for exclusion.

7. Describe plans to identify and recruit subjects, including how the population(s) will be identified, and how initial contact will be made with prospective subjects by those having legitimate access to the subjects' identity and the subjects' information.

Any fleet driver who is an employee of a participating organization and drives a vehicle with a device installed will be a pilot project participant. No formal recruitment or consent will be conducted. Fleet owners/managers will require any driver of the installed vehicle to utilize the information provided regarding safety warnings and alerts.

Pedestrians will be recruited from groups that NYCDOT has worked with in the past in order to recruit a diverse group of individuals with disabilities.

8. Will participants receive incentives, including monetary or other compensation? ☒ No ☐ Yes

If Yes, describe:
a) the type and amount of incentive as well as any schedule for pay-out
b) the conditions that must be fulfilled to receive full or partial payments
c) why the incentive(s) is reasonable.

9. Will participation in the study impose any costs that are the subjects' responsibility? ☒ No ☐ Yes

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If yes, describe the costs.

10. Are there non-English speaking subjects or subjects from a foreign culture? ☒ No ☐ Yes

If yes, describe how information about the study will be communicated to potential subjects appropriate for their culture and, if necessary, how new information about the research may be relayed to subjects during the study?

NOTE: Any Informed Consent Form written in a non-English language will require a translation certificate. See Section D.

BUSINESS SENSITIVE IRB APPLICATION – Section 6

B. DATA COLLECTION PROCEDURES

1. Provide a brief, sequential description of the data collection procedures, including any procedures that are experimental. Include the anticipated length of time that it will take for subjects to complete each procedure.

CV Pilot Deployment participants will drive in their respective vehicles as they normally would. The only difference is that during the pilot deployment, they will receive warnings and alerts via an aftermarket safety devices providing information pertaining to managing speed, reducing vehicle-to-vehicle crashes, reducing vehicle-to-pedestrian crashes, reducing vehicle-to-infrastructure crashes, and informing drivers of serious incidents.

In-Vehicle Aftermarket Safety Devices (ASDs) will log relevant information surrounding a triggered event. The trigger will be configurable and will include the CV application warnings, acceleration criteria, brake system status, etc. The time periods for collected data before and after the trigger event will be configurable for each event trigger. The relevant information (data) will be limited to what the ASD provides and it may include vehicle data when the ASD is connected to the vehicle's data bus. Each event log entry will include locations (i.e., latitude, longitude, elevation, 3-axis acceleration), indicated warnings, and the action (i.e., lights, wipers, turn signals, steering angles, brakes) of the vehicle. This event log will be encrypted and stored on the vehicle for later retrieval when the vehicle returns to its fleet terminal where the data will be offloaded. The definition of an event will be configurable so it can be used to collect short-term driver behavioral data for aggregation and performance measures.

An anonymous driver survey instrument will be developed. The exact modalities of the survey instrument have not been developed, but it is anticipated that it would be a combination of web forms (over the internet) and mobile apps on tablet devices positioned at select locations where CV vehicles are serviced/stored and where the vehicle operators will start or stop shifts (taxi barn, MTA Depot, etc.).

2. Will all data collection be conducted in the United States? ☐ No ☒ Yes
If No, identify other country(ies)/location(s)

3. Identify all types of Data Collection(s) that may apply:

Survey or Interview / Focus Group	☐ No ☒ Yes	☐ Mail return ☒ Self-administered at site ☐ Telephone/CATI questionnaire ☐ In-person interview/CAPI ☒ Other, specify: Online at home
Existing Data Records Review or Abstraction	☐ No ☒ Yes	☒ Electronic data ☐ Print / Hard copy data ☐ Other, specify:
Biological Specimen Collection	☒ No ☐ Yes	Describe Type of Specimen(s): -Will specimens be obtained directly from subjects? ☐ No ☐ Yes -Will specimens be provided by clients or collaborators? ☐ No ☐ Yes -Will specimens be linked to original human donor(s)? ☐ No ☐ Yes -Will specimens be utilized for follow-on research? ☐ No ☐ Yes -Will specimens be destroyed after study is completed? ☐ No ☐ Yes

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Collection of data through non-invasive clinical procedures	☒ No ☐ Yes	Describe the procedures, if not described above: -Do procedures require general anesthesia or sedation? ☐ No ☐ Yes
Observation	☒ No ☐ Yes	-Will participants be aware of observation? ☐ No ☐ Yes -Is observation in a public location? ☐ No ☐ Yes
Environmental Specimen Collection/ Measurements	☒ No ☐ Yes	Type of Specimen(s): ☐ Air; ☐ Soil; ☐ Water; ☐ Food; ☐ Other; specify: -Are specimens collected from subjects' homes or possessions? ☐ No ☐ Yes
Taste, Food Quality-Consumer acceptance	☒ No ☐ Yes	
Audio, Video or Image Recording	☒ No ☐ Yes	
Electronic interaction or monitoring, e.g. FACEBOOK, GPS, or website activity tracking/responses?	☒ No ☐ Yes	-Will informed consent be obtained from subjects ☐ No ☐ Yes Describe the procedures, if not described above:
Collection of data through non-commercially available software?	☐ No ☒ Yes	-Will informed consent be obtained from subjects ☐ No ☒ Yes Describe the procedures, if not described above: Red light cameras may take a photos, but this system is external to the current system and reflects established protocols. Data will also be likely collected through questionnaires online.
OTHER	☐ No ☒ Yes	OTHER, specify: Aftermarket Safety Device Data from in-vehicle devices and pedestrian devices.

C. PRIVACY AND DATA CONFIDENTIALITY PROCEDURES

1. Specify where data/specimens will be stored and how the investigator will protect both the data and the specimens with respect to privacy and confidentiality. Describe the:

   a. Physical Security (e.g., secured locations; file cabinets; restricted access; workstation use and security)

The participant contact information will be stored in a secure file at the NYCDOT Traffic Management Center.

   b. E-Data Security (e.g., unique passwords or user identifications; data encryption; firewall)

Data collected and all personal information will be collected in encrypted files and processed within 7 days to remove all personal information or time and location information that could be matched with other data to identify specific drivers or vehicles.

   c. Administrative Security (e.g. institutional security and clearance procedures in place; staff members trained; only authorized study personnel have access to subject data):

Only authorized research team staff will have access to the list of participant contact information during the study. This list will not be linked to any participant or vehicle data – it will be used purely for scheduling the installation and removal of the equipment and for tracking its reliability and operational integrity.

BUSINESS SENSITIVE IRB APPLICATION – Section 6

d. Safeguards to protect identifiable research information (e.g., coding, links, Subject I.D.s, NIH Certificate of Confidentiality, de-identification, separation and storage of study documents containing subject identifiers away from study data associated with Subject I.Ds.).

Event log data will be cleansed of any traceable personal data (exact location and time) to prevent from being correlated to other records, such as police reports.

Vehicle IDs will be anonymized based on the ASD device. The anonymization will be updated regularly to prohibit tracking a single vehicle throughout the study, even with an anonymized ID number. No driver ID will ever be recorded in the ASD unit or recorded data.

Time and date information will be obfuscated and recorded to have exact date and time scrubbed from records and instead will be registered in different categories or bins of date and time. For example, an action log data set recorded on Tuesday, January 5, 2015 starting at 8:35 am may instead be recorded as January Tuesday 8-9am or January Weekday 8-9am.

Detailed latitude and longitude data recorded by the ASD will be scrubbed and converted to an undefined Cartesian Coordinate system for storage and later evaluation. Each event data set will be recorded with full precision for all trajectory points relative to each other in the same event data set, but will not be tied to an exact real-world coordinate. The obfuscation of location will be done independently for each event action log data set recorded.

The exact level of scrubbing or obfuscation to time, date, and location data has not yet been finalized and cannot be fully be finalized until the deployment is underway.

Pedestrian Aftermarket Safety Devices / Smartphone Applications will follow the same data privacy and data obfuscation that exist with the in-vehicle ASDs and similar solutions to ensure the safety and privacy of the pedestrians will be utilized.

e. Procedures the project will use if subject data will be shared with contractors, collaborators, or others outside the research team during or after the research (e.g. "honest broker, if applicable", written agreement with recipient not to re-identify).

Collaborators and those outside of the research team will only have access to disaggregated obfuscated data and aggregated processed performance metrics. All raw data will be destroyed following the obfuscation process.

f. Procedures the project will use to procure, store or share bio-specimens or data expressly for use in in current or future research.

N/A

2. Will identifiers from living human subjects be recorded for the research? ☒ No ☐ Yes

If yes, list the identifiers that will be recorded and explain why this information is needed to conduct the study.

3. Will the study generate electronic data (E-data)? ☐ No ☒ Yes

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If yes, where will actual study e-data be stored (e.g., locally on mobile devices, local PCs, networked PCs, e-media like thumb drives or CDs, local Battelle servers, client-owned and administered servers, cloud-based servers)?

The obfuscated data will be hosted on servers in the NYC DOT Traffic Management Center. Portions of the obfuscated data will be shared with USDOT and its contractors and with the larger transportation research community via the USDOT's Research Data Exchange website.

4. Will mobile devices (laptops, wireless phones, thumb drives, etc.) be used to collect or store study data?

☐ No ☒ Yes

If yes, describe safeguards to assure that mobile devices remain secure (e.g. encryption, user password, always in the user's possession except when secured in a locked location.)

During configuration, the OBEs will be provided with a public encryption key for the Data Collection functionality entity. This will not change thoughout the lifetime of the project. OBEs are not expected to provide an interface to change this key. The purpose of encryption is to protect staff at intermediate points in the connection between the Data Collection functional entity and the OBE from being required to collect the log files. The OBE uploads encrypted log files to the TMC; the TMC passes them to the Data Collection functional entity. Hence, the server running the Data Collection functional entity is the only node within the system that has access to the log file contents. If the the public encryption key is compromised, it cannot be replaced. We consider this risk to be acceptable. Consider two scenairos:

- The decryption private key is obtained by a bad actor who does not have ongoing access to the Data Collection functional entity or to network connections to it. In this case, the bad actor can only read log files off OBEs that they have physical access to.
- The decryption key is obtained by a bad actor who does not have ongoing access to the TMC but has access to the network connections to it. In this case, the bad actor can read log files off the network. We consider this risk remote and not important to mitigate.
- The Data Collection functional entity itself is compromised, either by a hacker, by an insider or by some kind of law enforcement access. In this case, changing the keys is no help. However, the amount of time that the data is "held" in the analysis server is expected to be relatively short (days) before it is normalized aggregated, and truncated thus eliminating the possibility that any of the data collected will contain anything that can be merged with other databases to reconstruct PII.

All log files will be signed with the Basic Safety Message signing key that is currently in use. Log file entries will be encapsulated in a leee1609Dot2Data as defined in IEEE 1609.2, of type signed, using the PSID (0x28) for misbehavior detection. The PSID is included in the BSM signing certificates in the current Security Credential Management System.

5. Will Web-based Surveys or similar methods be used to collect data? ☐ No ☒ Yes

If yes, is the survey hosted by a third-party vendor? ☐ No ☒ Yes

If yes, identify the vendor: TBD

Does the third-party vendor has adequate privacy and security provisions, including a commitment to NOT capture and save subjects' IP addresses? ☐ No ☒ Yes

6. Are data being collected that would identify someone who is not the target study participant ("third parties"), e.g., family members, friends? ☒ No ☐ Yes

If yes, identify:

7. Is there a data analysis plan? ☐ No ☒ Yes

If yes, describe.
The primary method of evaluating the ASD action log data for the impacts of the CV technology will be to assess the changes in the vehicle trajectory and CAN bus metrics in response to the CV issued warning. The aggregate change in driver behavior will not only be assessed, but the different ranges of response will be tracked to arrive at a distribution of the driver responses in reaction to the deployed CV technology.

8. Is there a data sharing plan? ☐ No ☒ Yes

If yes, describe what is being done with the data and who will have access to the data during and after the study.

The data being collected by the NYC CV Pilot is owned by the individual stakeholders. The use and sharing of the data will be governed by the agreements (MOUs) between NYCDOT and the stakeholders. The guiding principles of these agreements are that the data will be obfuscated to remove any personally identifiable information (PII) and that the data is being collected to evaluate the system performance related to safety, consistent with NYCDOT's Vision Zero initiatives. The use of the data by the USDOT and the research community via the USDOT Research Data Exchange (RDE) should also respect the principles of privacy contained within those signed agreements.

9. If data leave Battelle, are all identifiers removed? ☐ No ☒ Yes

10. Is there a data retention plan? ☐ No ☒ Yes

If YES, describe where samples are being stored, when the data are destroyed, what data are being returned to the client, etc.

Obfuscated data will be hosted on servers in the NYCDOT Traffic Management Center. The data or selected subsets of the data will then be transferred to either the USDOT and their contractors and/or to the USDOT Research Data Exchange.

If NO, provide a time table for destroying the study data/specimens and identify how they will be destroyed OR provide rationale for perpetual maintenance.

11. If not described above, describe the procedures for protecting against or minimizing any risks for **breach of confidentiality** or **invasion of privacy**, e.g., medical or professional interventions, data monitoring.

D. INFORMED CONSENT PROCEDURES

1. Describe how participants will be informed and how their questions will be answered.

The only participants that will be consented will be the pedestrians using the Mobile Accessible Pedestrian Signal System. Participants will have access to a copy of the consent form prior to scheduling an appointment to have complete the consent process. During the informed consent appointment, participants will be provided with ample time to read through the consent form. Once the participant has read the consent

form, a trained member of the research team will discuss the Informed Consent form with each prospective participant and ask them questions about the content of the consent form to gauge their understanding of the study and its requirements. Each prospective participant will have an opportunity to ask questions about the study and will be provided with ample time to make the decision about whether or not to participate.

2. Is there any waiting period between informing the prospective subject and obtaining consent? ☒ No ☐ Yes

3. How and by whom will it be determined if the subjects or their legally authorized representatives understand the information provided during the consent briefing?

Participant consent will be obtained in-person. Qualified research team staff members will be authorized to obtain informed consent. Participants must be functional enough to hold a valid driver's license. If we are uncertain about their ability to understand the informed consent form, we will ask them questions about the content of the consent form to gauge their understanding.

4. Will any information about the research study be withheld from human subjects? ☒ No ☐ Yes

If Yes, describe the deception. Explain why it is necessary to accomplish the research aims and describe the plans for a post-study debriefing of the subjects?

5. If third parties may be identified during the research study, will consent be obtained from the third party(ies)? ☒ No ☐ Yes

If Yes, describe how consent will be obtained.

6. Is a copy of the Informed Consent form(s) given to the human subject? ☐ No ☒ Yes

7. Is translation of the informed consent/assent/parental permission documents required? ☒ No ☐ Yes
If Yes, a translation certificate must be provided to the IRB.

8. Does the project request a Waiver of Documented Informed Consent? ☒ No ☐ Yes

If Yes, do one of the following conditions apply?

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.	☐ No ☐ Yes
That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.	☐ No ☐ Yes

BUSINESS SENSITIVE IRB APPLICATION – Section 6

D. POTENTIAL RISKS

1. Describe any potential risks that subjects may encounter as a result of their participation in the study, including physical, psychological, social, legal, or other risks, e.g., breach of confidentiality. Assess the risks' likelihood and seriousness.

There is minimal physical, psychological, social, and legal risk associated with the study. The first potential risks are the risks that come with driving. However, the risks involved in the study are no different than what participants would encounter in their day-to-day driving without the benefit of the warnings and alerts.

Second, a potential risk is that the ASD equipment that will be mounted in the cab of the vehicle might cause distraction. The system should be designed in a way that it does not cause the driver any distraction. This is planned to provide audio alerts and warnings only using threat conditions; there are no plnas for a visual display to cause further distraction.

Third, since the driver vehicle data and pedestrian data are being collected in three distinct areas in the boroughs of Manhattan and Brooklyn and obfuscated as soon as it is created, there is potential risk of breach of the data even though it is encrypted when collected and uploaded to the NYCDOT Traffic Management Center. However, confidentiality would not be compromised in this event since the data being collected does not contain any personal identifying information.

Finally, the risk of incorrect information being provided to the driver or a false alarm is possible. The appropriate measures will be taken to make the likelihood of this occurring as small as possible.

2. If not described in other sections of this application, what specific steps will be taken to prevent/minimize potential risks or discomfort?

All study participants will receive training on the applications and information that they will be provided via the ASD and pedestrian application as well as instruction on how to report issues and feedback on the applications to the research team. By providing training, participants will have a better chance of knowing when the ASD is providing incorrect information and will be able to report this to the research team.

3. What, if any, is the relationship between the client/sponsor/investigator team and the subject population?

For some subject populations, like privately-owned fleets (e.g., taxis and UPS vehicles), there is not a relationship with the client/sponsor/investigator team. However, for city-owned fleets, like sanitation vehicles, city vehicles, and Metro Transit Agency bus operators, the subject population are employees of the client/sponsor/investigator team.

4. Is there any potential for perceived coercion or undue influence of the subject population? ☒ No ☐ Yes
If Yes, describe.

5. Will the study require use of recombinant DNA, use of toxic, hazardous, regulated or otherwise controlled materials, use of pressurized vessels, use of radioactive materials or radiation producing devices, or use of animals in research?

☒ No ☐ Yes

If Yes, describe.

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BUSINESS SENSITIVE IRB APPLICATION – Section 6

If Yes, has the Battelle internal review committee[4] approved the proposed use? ☐ No ☐ Yes

6. How will UNFORESEEN EVENTS[5] be handled and by whom?

Adverse events would consist of crashes. Participants will be instructed to contact local emergency or law enforcement personnel in this scenario

Another adverse event could be a vehicle break-in due to the addition of the ASD. While it is expected that this will be infrequent, participants again will be instructed to contact law enforcement personnel.

The system includes security measures that will minimize or eliminate the possibility that theft of any in-vehicle or roadside equipment could be used to provide false information to the subject vehicles. The system is operable 24x7x365 and responds immediately to any loss of infrastructure signal; security credentials time-out within a week.

[4] *Battelle Internal Review Committees could include: Institutional Biosafety Committee (IBC), Biosafety Committee (BC), Pressure Vessel Committee (PVC), Radiation Safety Committee (RSC), or Institutional Animal Care and Use Committee (IACUC). Contact Battelle Environment, Safety & Health (ESH) for assistance.*

[5] *UNFORESEEN EVENTS include Adverse Events, Serious Adverse Events, Unanticipated Problems Involving Subjects and Others, and Nonconformances.*

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BUSINESS SENSITIVE IRB APPLICATION – Section 6

E. POTENTIAL BENEFITS

1. Describe any benefit from the information provided to study participants.

☒ No direct benefit
☐ Medical or physical data
☐ Sociological data
☐ Psychological data
☐ Environmental data
☐ Other, specify:

2. Describe any benefit from the services provided to study participants.

☒ No direct services provided
☐ Medical or rehabilitation treatment
☐ Social/economic service
☐ Psychological counseling
☐ Environmental cleanup or correction
☐ Other, specify:

3. What are the benefits, if any, to society that may be expected from this research study?

The primary benefit is evidence that will hopefully contribute to the CV technologies body of knowledge by showing that the use of these technologies can help with speed management, reducing vehicle-to-vehicle crashes, reducing vehicle-to-pedestrian crashes, reducing vehicle-to-infrastructure crashes, and informing drivers of serious incidents. Each of these efforts can help contribute to the Vision Zero goal of eliminating injuries and fatalities due to traffic crashes. This is the first large scale implementation of this technology in an enclosed area (Manhattan) that will provide the opportunity to measure the benefits and serve as a baseline for other urban markets as they could consider the deployment of connected vehicle technology.

F. PROTECTION OF SUBJECTS

1. Summarize the protections assured to human subjects from all study documents, including the Informed Consent or Minor Assent form.

☒ Anonymity (no link between individual and data)
☐ Confidentiality (links between individual and data may exist, but are adequately safeguarded)
☐ Data and Safety Monitoring Board / Plan
☐ Medical treatment or Counseling
☐ Environmental remediation
☐ Certificate of Confidentiality (CoC)
☐ Other, specify:

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G. RISK/BENEFIT RATIO

1. Describe why the risks to subjects are reasonable in relation to the anticipated benefits to subjects/society and in relation to the importance of the knowledge that may reasonably be expected to result.

The risks to subjects are reasonable in relation to the anticipated benefits to subjects/society because the technology augments information about the complex traffic environment and does not attempt to eliminate the risks normally associated with driving as subjects drive as part of their regular duties. Also, as the proposed benefits are expected to help drivers in managing speed, reducing vehicle-to-vehicle crashes, reducing vehicle-to-pedestrian crashes, reducing vehicle-to-infrastructure crashes, and informing drivers of serious incidents, the risks seems reasonable, as a successful pilot deployment will provide evidence showing that CV technology can directly benefit society.

2. If the study requires participation of vulnerable populations, justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them.

By including visually impaired pedestrians, this pilot deployment can potentially show that CV technology can help visually impaired pedestrians navigate traffic intersection more safely than they are currently able. As such, the pedestrian application should receive the greatest attention during design and the greatest rigor in testing, which will help reduce the risks to the participants.

3. Describe any available alternative treatment(s) for the human subjects, if they choose not to participate in the study. NOTE: Alternative may be to NOT participate in the study.

Alternatives are up to the fleet owner since drivers are not fleet owners.

4. Assess the level of risk / benefit to human subjects.

- ☐ Minimal risk, minimal benefit
- ☒ Minimal risk, substantial benefit
- ☐ Substantial risk, substantial individual benefit
- ☐ Substantial risk, substantial research/society benefit
- ☐ Other, describe:

H. HIPAA-REGULATED STUDY NOTE: See MyProcess "Using PHI" Procedure Area.

1. Will the study require collection or access to a medical patient's Protected Health Information[6]? ☒ No ☐ Yes

   If Yes, has/will Battelle enter into a Business Associate Agreement ☐ No ☐ Yes

[6] ***Protected Health Information*** *or* ***PHI*** *is individually identifiable health information that is transmitted or maintained in any form or medium by a Covered Entity or Business Associate.* ***Individually Identifiable Health Information*** *or* ***IIHI*** *is information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual*

If Yes, will Battelle disclose patients' PHI to any subcontractors or collaborators? ☐ No ☐ Yes

If Yes, will the study develop a Patient's Authorization for Release of PHI or request an IRB Waiver of HIPAA Authorization? ☐ No ☐ Yes

If Yes, will electronic PHI (ePHI) be managed in the Battelle HIPAA Compliant Environment (BHCE or BISC), in an external HIPAA-compliance cloud-based server controlled by Battelle, or in a HIPAA-compliant environment managed by another entity? Describe how ePHI will be managed:

I. FDA-REGULATED or NIH CLINICAL RESEARCH STUDY

a. Will the study be subject to FDA regulations or be categorized as NIH-sponsored Clinical Research or as a FDA-sponsored Clinical Investigation? ☒ No ☐ Yes

If NO, DO NOT complete this section.

i. Does the study involve the use of a DRUG in a human other than the use of an approved drug in the course of medical practice? ☐ **No** ☐ **Yes**

If Yes, the IRB may follow up with additional questions.

ii. Does the study involve the use of a BIOLOGIC in a human other than the use of an approved biologic in the course of medical practice? ☐ **No** ☐ **Yes**

If Yes, the IRB may follow up with additional questions.

iii. Does the study evaluate the safety or effectiveness of a DEVICE in research subjects, a control group, or their biological specimens? ☐ **No** ☐ **Yes**

If Yes, the IRB may follow up with additional questions.

iv. Will results of the study be submitted to or held for inspection by FDA as part of an application for a future permit for research or marketing? (See 21 CFR 50.3(c)) ☐ **No** ☐ **Yes**

If Yes, the IRB may follow up with additional questions.

b. Will results of this study be posted to www.ClinicalTrials.gov? ☐ **No** ☐ **Yes**

If Yes, why?

If Yes, will Battelle be identified as the "Responsible Party" for reporting? ☐ **No** ☐ **Yes**

NOTE: Typically, the SPONSOR is the Responsible Party, but may defer to the PI.

Appendix C: IRB Application with Battelle IRB Comments

INSTRUCTIONS AND SUBMISSION for
BATTELLE INSTITUTIONAL REVIEW BOARD (IRB)
APPLICATION for IRB REVIEW and APPROVAL of HUMAN SUBJECTS RESEARCH

STEP 1. Complete and Submit ONLY the sections of this ***Application*** that apply to the proposed study. Check Below:

- ☐ Request for Exemption from Regulation (Cover Page, Sections 1, 2 & 3)
- ☐ Continuing Review and Approval (Cover Page, Sections 1, 2 & 4)
- ☐ Modification/Amendment to IRB approved protocol (Cover Page, Sections 1, 2, & 5)
- ☐ Pre-award Review for Proposal (Cover Page, Sections 1, 2; Battelle Statement of Work and/or Proposal)
- ☒ Pre-test/Pilot/Full Study Review only (Cover Page, Sections 1, 2, & 6)

STEP 2. ATTACH a COPY of all study documents required for the IRB's review and approval. Check Below:

- ☐ Research Protocol/Study or Test Plan
- ☐ Proposed Informed Consent, Minor Assent, and Parental Permission forms
- ☐ Translation Certificate, if documents given to human subjects are in a non-English language.
- ☐ Participant Contact letters
- ☐ Interview scripts, Screener scripts, etc.
- ☐ Data Collection instruments
- ☐ Focus Group Discussion Guides, draft questions or description of questions
- ☐ Recruitment materials (e.g., advertisement scripts, posters, brochures, flyers, e-mailers, social media)
- ☐ PI human subjects protection training documentation (e.g., CITI or NIH certificate)
- ☐ IRB approvals from other institutions
- ☐ Any other relevant documents requested by IRB or that will be helpful to the IRB for this review

When necessary, the IRB can request other study-related documents, e.g., recent/updated literature on risks; information about sub-contractor(s), including CV or resume; Statements of Work; Investigator Brochure; Notice of Approval from other internal review committees, e.g. Radiation Safety Committee.

STEP 3. REVIEW and SIGN the PRINCIPAL INVESTIGATOR / PROJECT MANAGER ACKNOWLEDGEMENT

Commented [SGM1]: The federal sponsor has mandated that this project shall undergo IRB review, approval and oversight.

While Battelle will not be engaged in research for out phases of this project, Battelle's IRB has agreed to assist Battelle's project to meet its deliverables by considering an example "IRB Application", proposing and defining an IRB review pathway(s), and issuing an "Example" Notice of Approval.

This review is intended to consider the entire CV pilot project as a whole and to establish controls appropriate for human subjects (study participants) at all levels of the project.

However, there are many different discrete data collection activities involving different CV systems, different vehicles, including motorized or non-motorized, and different participant populations, including fleet drivers and pedestrians. For some activities there may be no element of voluntariness, e.g., fleet driver.

Although task-level study documents were not available for the IRB's review, it's reasonable to assume that one or more tasks may not require categorization as human subjects research (failing DHHS OHRP (DOT under the Common Rule – 45 CFR 46, Subpart A; definition of "human subject", or could reasonably be ruled human subjects research, but exempt. This could be the case for the Fleet Drivers-related tasks.

For Phase 2, recommend that JHK/Transcore and collaborating institution(s) engage the designated IRB of record to assess entire scope of work to determine if it is appropriate ONLY to rule on those tasks that clearly can be defined as "human subjects research"

Commented [MRK2]: I've moved Gary's comment to the Notice of Full Approval so it is visible if this document is PDF'd as a deliverable.

E-Signature is acceptable.

Principal Investigator / Project Manager ACKNOWLEDGEMENT:

To the best of my knowledge, the sections of this application that will be submitted for the Battelle Institutional Review Board (IRB)'s review, approval and oversight are accurate and complete. As the Principal Investigator / Project Manager for this study, I agree to conduct this Human Subjects Research in accordance with ethical standards, regulatory and contractual requirements, Battelle policy, and the rulings of the IRB of record.

Submitted by: Chris Stanley Date: 06/03/2016 Project-Activity Number: **100072168-8**

STEP 4. Submit the IRB Application and Study Documents.

Documents should be submitted electronically in any easily reproducible or editable format (MS Word preferred); however, if desired, Documents may also be submitted as a complete printed copy (Acrobat .pdf).

Electronic document packages can be delivered to the IRB via

- E-mail (sappg@battelle.org) (≤ 3MG)
- FX (File Transfer) or BOX (>3MG) to sappg@battelle.org

Contact Gary Sapp at 614-424-7648 or sappg@battelle.org for assistance with this application or IRB review scheduling

Commented [SGM3]: ALL questions asked in this application are rhetorical and intended to suggest other information that could be added to the Application or the application package.

BATTELLE INSTITUTIONAL REVIEW BOARD (IRB)
DHHS Federal-wideAssurance: FWA00004696
DoD Addendum to FWA: DoD-NA3093
IRB Registration Number: IRB00000284

APPLICATION for IRB REVIEW and APPROVAL of HUMAN SUBJECTS RESEARCH

Name of Battelle Principal Investigator/Project Manager/Project Director: **Chris Stanley**
Battelle Site Name: **Crystal City** Phone Number: **(703) 413-7267**

Full Study Title (and common or short title): **New York City Connected Vehicle (NYC CV) Pilot Deployment Program**
IRB Number (if already assigned):

Project & Activity ID Number (or B&P number): **100072168, Task 8**
Proposal Number (OPP Number):

Type of Award

☐ Contract/cooperative agreement
☐ PHS grant
☐ Other grant
☐ Battelle Internal Research & Development (IR&D) /Science & Technology (S&T) Funding
☒ Subcontract to Battelle from: **JHK Engineering/TransCore**

Client / Funding Agency: **FHWA/JPO** List any additional funding sources
Agency Principal Investigator: **Sarah Khan (Phase I)** **Sarah Tarpgarrd (Phase II)**
Address:
Phone: ( ) -
e-mail Address

Agency Contract Officer:
Phone: ( ) -
e-mail Address

Will another IRB review this study?
Yes X_____/ No_____
If yes, identify the IRB(s):
Unknown at this time

Period of Award
Contract/grant start date **9/4/2015**
Contract/grant end date **9/19/2016 (Phase I)**
Date human subject contact begins (or began) **10/1/2018 (During Phase II)**
Does the contract/grant include Terms & Conditions for the ethical conduct of human subjects research? ☐ No ☒ Yes
If Yes, briefly describe any special requirements.
Approval of a certified IRB must be obtained prior to initiating the research.

SECTION 2: STUDY PERSONNEL

1. Identify the Battelle Principal Investigator:

Chris Stanley

2. Identify the Battelle Project Manager:

Chris Stanley

3. Identify Battelle "Key Personnel[1]":

John Campbell and Paige Bacon-Abdelmoteleb (Phase I only- no interaction with human subjects during the Phase II data collection)

4. Have "Key Personnel" completed human subjects training[2]? ☐ No ☒ Yes

5. Identify all "Key Personnel" who will administer and obtain human subjects' informed consent.

None

6. Will Battelle subcontract any part of this work? ☒ No ☐ Yes

   a. If yes, identify ALL subcontractors (organizations, institutions, or Individual Investigators) and briefly describe their role in the study

   b. Will a Battelle subcontractor conduct or support Human Subjects Research? ☒ No ☐ Yes
      i. If Yes, identify all subcontractor personnel (by name and title/education level) who will act as "Key Personnel, including any subcontractor Principal Investigator or Project Manager"?
      ii. If Yes, will a Battelle subcontractor be dependent upon the rulings of Battelle's IRB? ☐ No ☐ Yes
      iii. If Yes, have subcontractor "Key Personnel" completed human subjects training[3]? ☐ No ☐ Yes

[1] *"Key Personnel" are those staff members who will interact or intervene with human subjects or who will have access to private, identifiable information about human subjects.*

[2] *Battelle Principal Investigators and Project Managers must assure that all Key Personnel have been trained in human subjects ethics, regulations and Battelle policies.*

[3] *Battelle Principal Investigators and Project Managers must assure that all subcontractor Key Personnel have been trained in human subjects ethics and regulations.*

Depending upon the specific role of the subcontractor, the Battelle IRB may require subcontractors to enter into an Individual Investigator Agreement.

7. Will any other institution be dependent upon the rulings of Battelle's IRB? ☒No ☐ Yes
   a. If yes, describe the other institution's scope of work

8. Identify ANY OTHER teaming partners or collaborators in the study and briefly describe their role in the study.

New York City Department of Transportation (NYCDOT) is the prime contractor – under contract to USDOT; TransCore is the principle subcontractor to NYCDOT providing design services, project management, systems engineering, and project planning; Battelle is a subcontractor to TransCore providing engineering and design services for the connected vehicle project for a number of applications; Cambridge Systematics is providing support services and performance evaluation and benefit analysis services.

SECTION 6: REQUEST FOR INSTITUTIONAL REVIEW BOARD REVIEW

A. STUDY DESCRIPTION AND RECRUITING

1. Provide a general description of the planned research and the scientific objectives of the research.

New York City (NYC) is implementing Connected Vehicle (CV) technology as a tool in its quest for Vision Zero, the goal of eliminating injuries and fatalities due to traffic crashes. The project will introduce Connected Vehicle technology and communications into the New York City travel environment by equipping several large vehicle fleets with the technology and equipping three distinct areas in the boroughs of Manhattan and Brooklyn with the corresponding CV infrastructure.

2. Describe the general design of the study. For example, does the research involve a single phase or multiple phases? Are there control or experimental groups? Will the study require deception of human subjects? Describe sampling procedures (sampling plan and sampling sizes; power calculations; stratifications, etc.

The whole CV Pilot Deployment consists of three phases, 1) Concept Development (up to 12 months); 2) Design/Build/Test (up to 20 months); and 3) Operate and Maintain (18 months). There are three pilot deployment sites in Manhattan and Brooklyn; Manhattan (1), which has 204 intersections; Manhattan FDR (2), which is a limited access highway that excludes trucks and buses and consists of short radius curves; and Flatbush Avenue in Brooklyn, which has 28 intersections and over-height restrictions.

Approximately 250 intersections will be equipped with roadside equipment (RSE) to communicate with vehicles equipped with aftermarket safety devices (ASDs). The following applications will be deployed via the in-vehicle ASDs: those to manage speed – Speed Compliance, Curve Speed Compliance, and Speed Compliance in Work Zones; those to reduce vehicle-to-vehicle crashes – Forward Crash Warning, Emergency Electronics Brake Lights, Blind Spot Warning, Lane Change Warning, Intersection Movement Assist, Red Light Violation Warning, and Vehicle Turning Right in Front of Bus Warning; those to reduce vehicle-to-pedestrian crashes – Pedestrian in Signalized Crosswalk Warning, and Mobile Accessible Pedestrian Signal System (as described below); those to reduce vehicle-to-infrastructure crashes – Oversized Vehicle Compliance; and those to inform drivers of serious incidents – Emergency Communications and Evacuation Information.

Two pedestrian-oriented applications will be deployed, 1) a generalized warning to vehicles of pedestrians in the roadway and 2) support for visually impaired (blind) pedestrians. The first application (Pedestrian in Signalized Intersection Warning) will use the pedestrian detection information to indicate the presence of pedestrians in a crosswalk at a signalized intersection. As a vehicle approaches a signalized intersection, the pedestrians will be detected by the traffic control system. At the same time, the pedestrian will carry a personal information device (PID) in the form of a smartphone which will communicate with the NYC CV infrastructure. The pedestrian detection information will be sent to and processed by the Road Side Equipment (RSE), which will

then broadcast it into the Aftermarket Safety Devices (ASDs) in the approaching vehicles. The second application (Mobile Accessible Pedestrian Signal System) will provide support for the visually impaired and it is assumed that the application will be implemented using a portable personal information device (e.g., a smartphone). The application is intended to use the Map Data Message (MAP) and Signal Phase and Timing (SPaT) messages to provide the intersection geometrics and the current status of the intersection displays (PED signals and vehicle signals) along with other confirmation information to assist the pedestrian in safely crossing the street. The application will assist the pedestrian in confirming their location (street and cross street), and orientation and provide verbal information regarding the signal state, thus, improving their ability to safely cross the street.

Data collection and benefit analysis is a critical part of this program. Data will be collected for a time period (typically 10-20 seconds) before a safety warning/alert to the driver and the system will continue to collect data for a period of time after the alert/warning (typically 10-30 seconds). This data will include such information as heading, speed, acceleration, braking, steering wheel angle, and location to allow a complete analysis of the situation leading up to the alarm/warning and actions taken by the driver after the alert/warning is "delivered" to the driver.
The system will be deployed incrementally; as the on-board units are initially installed, they will detect situations requiring warnings and alerts, but will not provide them to the driver so that the system can collect baseline data. This situation is referred to as the "silent" period.
Once all of the vehicles have been equipped and tested, the system will be activated and start issuing warnings and alerts to the drivers when the on-board unit detects a possible condition that could cause a crash or injury. The drivers will receive instructions in the operation of the warning system prior to its activation. The above will be used for all fleet vehicles except the taxis.
In addition to "before" and "after" periods, a control and treatment group will be used for taxi fleet vehicles that are generally stored an operated out of a centralized location or "barn" (e.g., home base, depot, garage, etc.) that the driver will return to at the end of their shift. Each "barn" will be designated as either a control "barn" or treatment "barn." As the daily assignments of drivers to vehicles occur within each barn, the driver can be assured of driving either a control vehicle or treatment vehicle. The use of control and treatment groups will be limited taxi vehicles as all other planned CV-equipped vehicle fleets generally operate from a single "barns" making it impossible to isolate control and treatment "barns" so that drivers encounter only control or treatment vehicles. By restricting the control group to all of the vehicles within one or more "barn," drivers will be subjected to the same situation (silent or active) throughout the testing period.

3. Describe the intended subject population(s) of the study. For example, what is the anticipated number of subjects, ages, gender, ethnic background, health status.

Approximately 10,000 vehicles (7,500 taxis and limousines; 1,500 MTA / NYCTA buses; 500 UPS vehicles; 500 sanitation and NYC DOT vehicles) will be equipped with aftermarket safety devices (ASD).
Study subjects will fit into one of three categories:
1) City-owned vehicle operators: These are operators of sanitation vehicles, city vehicles, and Metro Transit Agency bus operators.

2) Privately-owned vehicle operators: These are operators of taxi's and UPS vehicles.
3) Pedestrians: Approximately 100 visually impaired individuals will be recruited to participate using the PedApp.
All subjects will be 18 years or older.

Many of the vehicle fleet's drivers/operators are governed by collective bargaining agreements with the fleet owners. These agreements establish work rules and cover the operation of fleets. The exception to this relationship involves taxis. While the Taxi and Limousine Commission regulates taxi companies, the relationship between the taxi companies and drivers is not covered by a collective bargaining agreement. The project expects to be dealing with a potentially much larger pool of drivers/operator due to the nature of fleets and that multiple drivers are used to keep vehicles such as taxis operating for extended periods of time. Many of the fleet vehicles will be kept in service more than five days a week and for periods well beyond an eight-hour shift.

4. Indicate subject population category(ies) that may warrant additional protections, including vulnerable populations (***** as defined by 45 CFR 46)? Use "OTHER to describe any other population that may warrant additional protections.

☐ Minors / Children*	☐ Terminally ill individuals
☐ Pregnant women*	☐ Comatose individuals
☐ Fetuses or Neontates*	☐ HIV-infected patients
☐ Prisoners or parolees*	☐ Individuals with alcohol, drug or mental health dependencies or who have committed illegal acts
☐ Battelle staff or families	☐ Non-English speaking individuals
☐ Institutionalized individuals	☐ Impaired capacity to give or continue informed consent
☐ Genetically susceptible/impaired individuals	☐ Military personnel and/or immediate family
☒ Cognitively/psychologically/physically impaired individuals	☐ Tribal, Hispanic, Asian, or other targeted ethnicities
☐ Socially or economically disadvantaged individuals	☐ Workers/Employees
☐ Emergency patients	☐ Secondary Subjects (genetic/medical relationship)
☐ Students	☒ OTHER: Healthy Adults

5. Explain briefly the criteria for inclusion of any populations identified in Question #4 (above).

Fleet Drivers: Fleet drivers must be an employee of the participating organization who drives a vehicle with a device installed. The driver selection process is left to the fleet owner's normal Human Resources processes.
Pedestrians: Must be a visually impaired resident who regularly crosses the streets in the equipped study areas. Participants will be selected by the City of New York's support services.

6. Explain briefly the criteria for exclusion of any population from the study.

No criterion has been established for exclusion.

7. Describe plans to identify and recruit subjects, including how the population(s) will be identified, and how initial contact will be made with prospective subjects by those having legitimate access to the subjects' identity and the subjects' information.

Any fleet driver who is an employee of a participating organization and drives a vehicle with a device installed will be a pilot project participant. No formal recruitment or consent will be conducted. Fleet owners/managers will require any driver of the installed vehicle to utilize the information provided regarding safety warnings and alerts.

Pedestrians will be recruited from groups that NYCDOT has worked with in the past in order to recruit a diverse group of individuals with disabilities.

8. Will participants receive incentives, including monetary or other compensation? ☒ No ☐ Yes

If Yes, describe:

a) the type and amount of incentive as well as any schedule for pay-out
b) the conditions that must be fulfilled to receive full or partial payments
c) why the incentive(s) is reasonable.

9. Will participation in the study impose any costs that are the subjects' responsibility? ☒ No ☐ Yes

If yes, describe the costs.

10. Are there non-English speaking subjects or subjects from a foreign culture? ☒ No ☐ Yes

If yes, describe how information about the study will be communicated to potential subjects appropriate for their culture and, if necessary, how new information about the research may be relayed to subjects during the study?

NOTE: Any Informed Consent Form written in a non-English language will require a translation certificate. See Section D.

Commented [SGM4]: Will Smartphones be made available to pedestrians that don't have them? What about DAS' installed in driver-owned taxi cabs?
If so, will there be any fiscal obligations to return equipment upon end of study?
If so, this should be communicated during training/consent process.

Commented [SGM5]: I expect that there will be a considerable number of participants from a foreign culture who are not native English speakers. Project should anticipate resources to include these individuals or include inclusion/exclusion criteria for a fluent English speaker.

B. DATA COLLECTION PROCEDURES

1. Provide a brief, sequential description of the data collection procedures, including any procedures that are experimental. Include the anticipated length of time that it will take for subjects to complete each procedure.

CV Pilot Deployment participants will drive in their respective vehicles as they normally would. The only difference is that during the pilot deployment, they will receive warnings and alerts via an aftermarket safety devices providing information pertaining to managing speed, reducing vehicle- to-vehicle crashes, reducing vehicle-to-pedestrian crashes, reducing vehicle-to-infrastructure crashes, and informing drivers of serious incidents.

In-Vehicle Aftermarket Safety Devices (ASDs) will log relevant information surrounding a triggered event. The trigger will be configurable and will include the CV application warnings, acceleration criteria, brake system status, etc. The time periods for collected data before and after the trigger event will be configurable for each event trigger. The relevant information (data) will be limited to what the ASD provides and it may include vehicle data when the ASD is connected to the vehicle's data bus. Each event log entry will include locations (i.e., latitude, longitude, elevation, 3-axis acceleration), indicated warnings, and the action (i.e., lights, wipers, turn signals, steering angles, brakes) of the vehicle. This event log will be encrypted and stored on the vehicle for later retrieval when the vehicle returns to its fleet terminal where the data will be offloaded. The definition of an event will be configurable so it can be used to collect short-term driver behavioral data for aggregation and performance measures.

An anonymous driver survey instrument will be developed. The exact modalities of the survey instrument have not been developed, but it is anticipated that it would be a combination of web forms (over the internet) and mobile apps on tablet devices positioned at select locations where CV vehicles are serviced/stored and where the vehicle operators will start or stop shifts (taxi barn, MTA Depot, etc.).

Commented [SGM6]: When developed, should include assurances and a description of privacy and data confidentiality measures

2. Will all data collection be conducted in the United States? ☐ No ☒ Yes
   If No, identify other country(ies)/location(s)

3. Identify all types of Data Collection(s) that may apply:

Survey or Interview / Focus Group	☐ **No** ☒ **Yes**	☐	**Mail return**
		☒	**Self-administered at site**
		☐	**Telephone/CATI questionnaire**
		☐	**In-person interview/CAPI**
		☒	**Other, specify: Online at home**
Existing Data Records Review or Abstraction	☐ No ☒ Yes	☒	Electronic data
		☐	Print / Hard copy data
		☐	Other, specify:

Commented [SGM7]: IRB of record will require data collection instruments before issuing any approval.

Commented [SGM8]: Same

Biological Specimen Collection	☒No ☐ Yes	Describe Type of Specimen(s): -Will specimens be obtained directly from subjects? ☐ No ☐ Yes -Will specimens be provided by clients or collaborators? ☐ No ☐ Yes -Will specimens be linked to original human donor(s)? ☐ No ☐ Yes -Will specimens be utilized for follow-on research? ☐ No ☐ Yes -Will specimens be destroyed after study is completed? ☐ No ☐ Yes
Collection of data through non-invasive clinical procedures	☒No ☐ Yes	Describe the procedures, if not described above: -Do procedures require general anesthesia or sedation? ☐ No ☐ Yes
Observation	☒No ☐ Yes	-Will participants be aware of observation? ☐ No ☐ Yes -Is observation in a public location? ☐ No ☐ Yes
Environmental Specimen Collection/ Measurements	☒No ☐ Yes	Type of Specimen(s): ☐ Air; ☐ Soil; ☐ Water; ☐ Food; ☐ Other; specify: -Are specimens collected from subjects' homes or possessions? ☐ No ☐ Yes
Taste, Food Quality- Consumer acceptance	☒No ☐ Yes	
Audio, Video or Image Recording	☒No ☐ Yes	
Electronic interaction or monitoring, e.g. FACEBOOK, GPS, or website activity tracking/responses?	☒No ☐ Yes	-Will informed consent be obtained from subjects ☐ No ☐ Yes Describe the procedures, if not described above:
Collection of data through non-commercially available software?	☐ No ☒ Yes	-Will informed consent be obtained from subjects ☐ No ☒ Yes Describe the procedures, if not described above: Red light cameras may take a photos, but this system is external to the current system and reflects established protocols. Data will also be likely collected through questionnaires online.

OTHER	☐ No ☒ Yes	OTHER, specify: Aftermarket Safety Device Data from in-vehicle devices and pedestrian devices.

C. PRIVACY AND DATA CONFIDENTIALITY PROCEDURES

1. Specify where data/specimens will be stored and how the investigator will protect both the data and the specimens with respect to privacy and confidentiality. Describe the:

   a. Physical Security (e.g., secured locations; file cabinets; restricted access; workstation use and security)

   The participant contact information will be stored in a secure file at the NYCDOT Traffic Management Center.

   b. E-Data Security (e.g., unique passwords or user identifications; data encryption; firewall)

   Data collected and all personal information will be collected in encrypted files and processed within 7 days to remove all personal information or time and location information that could be matched with other data to identify specific drivers or vehicles.

   c. Administrative Security (e.g. institutional security and clearance procedures in place; staff members trained; only authorized study personnel have access to subject data):

   Only authorized research team staff will have access to the list of participant contact information during the study. This list will not be linked to any participant or vehicle data – it will be used purely for scheduling the installation and removal of the equipment and for tracking its reliability and operational integrity.

   d. Safeguards to protect identifiable research information (e.g., coding, links, Subject I.D.s, NIH Certificate of Confidentiality, de-identification, separation and storage of study documents containing subject identifiers away from study data associated with Subject I.Ds.).

   Event log data will be cleansed of any traceable personal data (exact location and time) to prevent from being correlated to other records, such as police reports.

   Vehicle IDs will be anonymized based on the ASD device. The anonymization will be updated regularly to prohibit tracking a single vehicle throughout the study, even with an anonymized ID number. No driver ID will ever be recorded in the ASD unit or recorded data.

   Time and date information will be obfuscated and recorded to have exact date and time scrubbed from records and instead will be registered in different categories or bins of date and time. For example, an action log data set recorded on Tuesday, January 5, 2015 starting at 8:35 am may instead be recorded as January Tuesday 8-9am or January Weekday 8-9am.

Commented [SGM9]: Consider:
_Who will have access?
-Does this include all participant information?
–Won't more than one stakeholder own this data?

Commented [MRK10]: Will employers have access to any IDs?

Detailed latitude and longitude data recorded by the ASD will be scrubbed and converted to an undefined Cartesian coordinate system for storage and later evaluation. Each event data set will be recorded with full precision for all trajectory points relative to each other in the same event data set, but will not be tied to an exact real-world coordinate. The obfuscation of location will be done independently for each event action log data set recorded.

The exact level of scrubbing or obfuscation to time, date, and location data has not yet been finalized and cannot be fully be finalized until the deployment is underway.

Pedestrian Aftermarket Safety Devices / Smartphone Applications will follow the same data privacy and data obfuscation that exist with the in-vehicle ASDs and similar solutions to ensure the safety and privacy of the pedestrians will be utilized.

e. Procedures the project will use if subject data will be shared with contractors, collaborators, or others outside the research team during or after the research (e.g. "honest broker, if applicable", written agreement with recipient not to re-identify).

Collaborators and those outside of the research team will only have access to disaggregated obfuscated data and aggregated processed performance metrics. All raw data will be destroyed following the obfuscation process.

Commented [SGM11]: Is there a timeframe to destroy the raw data?

f. Procedures the project will use to procure, store or share bio-specimens or data expressly for use in in current or future research.

N/A

2. Will identifiers from living human subjects be recorded for the research? ☒ No ☐ Yes

If yes, list the identifiers that will be recorded and explain why this information is needed to conduct the study.

3. Will the study generate electronic data (E-data)? ☐ No ☒ Yes

If yes, where will actual study e-data be stored (e.g., locally on mobile devices, local PCs, networked PCs, e-media like thumb drives or CDs, local Battelle servers, client-owned and administered servers, cloud-based servers)?

The obfuscated data will be hosted on servers in the NYC DOT Traffic Management Center. Portions of the obfuscated data will be shared with USDOT and its contractors and with the larger transportation research community via the USDOT's Research Data Exchange website.

4. Will mobile devices (laptops, wireless phones, thumb drives, etc.) be used to collect or store study data? ☐ No ☒ Yes

If yes, describe safeguards to assure that mobile devices remain secure (e.g. encryption, user password, always in the user's possession except when secured in a locked location.)

During configuration, the OBEs will be provided with a public encryption key for the Data Collection functionality entity. This will not change throughout the lifetime of the project. OBEs are not expected to provide an interface to change this key. The purpose of encryption is to protect staff at intermediate points in the connection between the Data Collection functional entity and the OBE from being required to collect the log files. The OBE uploads encrypted log files to the TMC; the TMC passes them to the Data Collection functional entity. Hence, the server running the Data Collection functional entity is the only node within the system that has access to the log file contents. If the public encryption key is compromised, it cannot be replaced. We consider this risk to be acceptable. Consider two scenarios:

- The decryption private key is obtained by a bad actor who does not have ongoing access to the Data Collection functional entity or to network connections to it. In this case, the bad actor can only read log files off OBEs that they have physical access to.
- The decryption key is obtained by a bad actor who does not have ongoing access to the TMC but has access to the network connections to it. In this case, the bad actor can read log files off the network. We consider this risk remote and not important to mitigate.
- The Data Collection functional entity itself is compromised, either by a hacker, by an insider or by some kind of law enforcement access. In this case, changing the keys is no help. However, the amount of time that the data is "held" in the analysis server is expected to be relatively short (days) before it is normalized aggregated, and truncated thus eliminating the possibility that any of the data collected will contain anything that can be merged with other databases to reconstruct PII.

All log files will be signed with the Basic Safety Message signing key that is currently in use. Log file entries will be encapsulated in a leee1609Dot2Data as defined in IEEE 1609.2, of type signed, using the PSID (0x28) for misbehavior detection. The PSID is included in the BSM signing certificates in the current Security Credential Management System.

5. Will Web-based Surveys or similar methods be used to collect data? ☐ No ☒ Yes

   If yes, is the survey hosted by a third-party vendor? ☐ No ☒ Yes

   If yes, identify the vendor: TBD

   Does the third-party vendor has adequate privacy and security provisions, including a commitment to NOT capture and save subjects' IP addresses? ☐ No ☐ Yes

6. Are data being collected that would identify someone who is not the target study participant ("third parties"), e.g., family members, friends? ☒ No ☐ Yes

   If yes, identify:

7. Is there a data analysis plan? ☐ No ☒ Yes

Commented [SGM12]: IRB of record will require drafts for review

Commented [SGM13]: Consider Vendor's published privacy policy and whether or not vendor itself will have access to any collected studydata.

If yes, describe.
The primary method of evaluating the ASD action log data for the impacts of the CV technology will be to assess the changes in the vehicle trajectory and CAN bus metrics in response to the CV issued warning. The aggregate change in driver behavior will not only be assessed, but the different ranges of response will be tracked to arrive at a distribution of the driver responses in reaction to the deployed CV technology.

8. Is there a data sharing plan? ☐ No ☒ Yes

If yes, describe what is being done with the data and who will have access to the data during and after the study.

The data being collected by the NYC CV Pilot is owned by the individual stakeholders. The use and sharing of the data will be governed by the agreements (MOUs) between NYCDOT and the stakeholders. The guiding principles of these agreements are that the data will be obfuscated to remove any personally identifiable information (PII) and that the data is being collected to evaluate the system performance related to safety, consistent with NYCDOT's Vision Zero initiatives. The use of the data by the USDOT and the research community via the USDOT Research Data Exchange (RDE) should also respect the principles of privacy contained within those signed agreements.

9. If data leave Battelle, are all identifiers removed? ☐ No ☒ Yes

10. Is there a data retention plan? ☐ No ☒ Yes

If YES, describe where samples are being stored, when the data are destroyed, what data are being returned to the client, etc.

Obfuscated data will be hosted on servers in the NYCDOT Traffic Management Center. The data or selected subsets of the data will then be transferred to either the USDOT and their contractors and/or to the USDOT Research Data Exchange.

Commented [MRK14]: Eventually describe data destruction

If NO, provide a time table for destroying the study data/specimens and identify how they will be destroyed OR provide rationale for perpetual maintenance.

11. If not described above, describe the procedures for protecting against or minimizing any risks for **breach of confidentiality** or **invasion of privacy**, e.g., medical or professional interventions, data monitoring.

D. INFORMED CONSENT PROCEDURES

1. Describe how participants will be informed and how their questions will be answered.

The only participants that will be consented will be the pedestrians using the Mobile Accessible Pedestrian Signal System. Participants will have access to a copy of the consent form prior to scheduling an appointment to have complete the consent process. During the informed consent appointment, participants will be provided with ample time to read through the consent form. Once the participant has read the consent form, a trained member of the research team will discuss the Informed Consent form with each prospective participant and ask them questions about the content of the consent form to gauge their understanding of the study and its requirements. Each prospective participant will have an opportunity to ask questions about the study and will be provided with ample time to make the decision about whether or not to participate.

2. Is there any waiting period between informing the prospective subject and obtaining consent?
☒No ☐ Yes

3. How and by whom will it be determined if the subjects or their legally authorized representatives understand the information provided during the consent briefing?

Participant consent will be obtained in-person. Qualified research team staff members will be authorized to obtain informed consent. Participants must be functional enough to hold a valid driver's license. If we are uncertain about their ability to understand the informed consent form, we will ask them questions about the content of the consent form to gauge their understanding.

4. Will any information about the research study be withheld from human subjects? ☒No ☐ Yes

If Yes, describe the deception. Explain why it is necessary to accomplish the research aims and describe the plans for a post-study debriefing of the subjects?

5. If third parties may be identified during the research study, will consent be obtained from the third party(ies)? ☒No ☐ Yes
If Yes, describe how consent will be obtained.

6. Is a copy of the Informed Consent form(s) given to the human subject? ☐ No ☒ Yes

7. Is translation of the informed consent/assent/parental permission documents required? ☒ No ☐ Yes
If Yes, a translation certificate must be provided to the IRB.

8. Does the project request a Waiver of Documented Informed Consent? ☒No ☐ Yes

Commented [SGM15]: Fleet Drivers will not volunteer nor consent. IRB of record may issue a waiver of Informed Consent process (see IRB write-up for specifics), but the IRB will not issue a waiver unless the project meets specific regulatory criteria.

Commented [SGM16]: Given parameters of participant involvement, this is a reasonable process.

Commented [MRK17]: Depending on impairment severity, accommodations for blindness may need to be made

Commented [SGM18]: Phase 2 collaborators to determine how "qualified" is determined.
-IRB of record may require a specific course of HS training or other assurances.
-IRB of record (assumed to be an NYU IRB) may require Individual Investigator Agreements for investigators not employed by NYU.

Commented [MRK19]: True for pedestrians too?

Commented [SGM20]: May be Yes…depending on prevalence of

If Yes, do one of the following conditions apply?

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.	☐ **No** ☐ **Yes**
That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.	☐ No ☐ Yes

POTENTIAL RISKS

1. Describe any potential risks that subjects may encounter as a result of their participation in the study, including physical, psychological, social, legal, or other risks, e.g., breach of confidentiality. Assess the risks' likelihood and seriousness.

There is minimal physical, psychological, social, and legal risk associated with the study. The first potential risks are the risks that come with driving. However, the risks involved in the study are no different than what participants would encounter in their day-to-day driving without the benefit of the warnings and alerts.

Second, a potential risk is that the ASD equipment that will be mounted in the cab of the vehicle might cause distraction. The system should be designed in a way that it does not cause the driver any distraction. This is planned to provide audio alerts and warnings only using threat conditions; there are no plans for a visual display to cause further distraction.

Third, since the driver vehicle data and pedestrian data are being collected in three distinct areas in the boroughs of Manhattan and Brooklyn and obfuscated as soon as it is created, there is potential risk of breach of the data even though it is encrypted when collected and uploaded to the NYCDOT Traffic Management Center. However, confidentiality would not be compromised in this event since the data being collected does not contain any personal identifying information.

Finally, the risk of incorrect information being provided to the driver or a false alarm is possible. The appropriate measures will be taken to make the likelihood of this occurring as small as possible.

2. If not described in other sections of this application, what specific steps will be taken to prevent/minimize potential risks or discomfort?

All study participants will receive training on the applications and information that they will be provided via the ASD and pedestrian application as well as instruction on how to report issues and feedback on the applications to the research team. By providing training, participants will have a better chance of knowing when the ASD is providing incorrect information and will be able to report this to the research team.

3. What, if any, is the relationship between the client/sponsor/investigator team and the subject population?

For some subject populations, like privately-owned fleets (e.g., taxis and UPS vehicles), there is not a relationship with the client/sponsor/investigator team. However, for city-owned fleets, like sanitation vehicles, city vehicles, and Metro Transit Agency bus operators, the subject population are employees of the client/sponsor/investigator team.

Commented [MRK21]: Assumes identity of drivers in city-owned fleets are protected from their employers (or are not uniquely identified through route and time). It's clear from this application that this has been considered, but how it occurs in practice still needs to be determined.

Commented [SGM22]: System training should include actual, audible examples of tones/alerts/etc.

Commented [MRK23]: Questionnaires set up so that they do not require multi-tasking while operating a vehicle

Commented [SGM24]: May also add that encryption key is separate from uploaded data.

Commented [SGM25]: Will the mechanism for this reporting be captured through the driver online survey or will there be a separate process?
If so, will need to include a description in the training as well as some method to assure continued visibility/compliance.

4. Is there any potential for perceived coercion or undue influence of the subject population? ☒
No ☐ Yes If Yes, describe.

Commented [SGM26]: There is no volunteer aspect for fleet drivers. Their participation is mandated as a company policy. While apparent risks to drivers are low, IMO, be advised that the IRB of record may question this practice.

Commented [MRK27]: To me this is the biggest risk for participants – a fleet driver is caught disregarding the system (or breaking the law or a policy). I think the data protections and obfuscations offer a lot of protection, but it's still hard to know who will have access to the data.

5. Will the study require use of recombinant DNA, use of toxic, hazardous, regulated or otherwise controlled materials, use of pressurized vessels, use of radioactive materials or radiation producing devices, or use of animals in research? ☒ No ☐ Yes
If Yes, describe.

If Yes, has the Battelle internal review committee[4] approved the proposed use? ☐ No ☐ Yes

6. How will UNFORESEEN EVENTS[5] be handled and by whom?

Adverse events would consist of crashes. Participants will be instructed to contact local emergency or law enforcement personnel in this scenario

Another adverse event could be a vehicle break-in due to the addition of the ASD. While it is expected that this will be infrequent, participants again will be instructed to contact law enforcement personnel.

The system includes security measures that will minimize or eliminate the possibility that theft of any in-vehicle or roadside equipment could be used to provide false information to the subject vehicles. The system is operable 24x7x365 and responds immediately to any loss of infrastructure signal; security credentials time-out within a week.

Commented [SGM28]: Recommend that participants be advised that they are not required to disclose that the vehicle contains a DAS. Phase 2 project Legal should advise on this aspect.

[4] *Battelle Internal Review Committees could include: Institutional Biosafety Committee (IBC), Biosafety Committee (BC), Pressure Vessel Committee (PVC), Radiation Safety Committee (RSC), or Institutional Animal Care and Use Committee (IACUC). Contact Battelle Environment, Safety & Health (ESH) for assistance.*

[5] *UNFORESEEN EVENTS include Adverse Events, Serious Adverse Events, Unanticipated Problems Involving Subjects and Others, and Nonconformances.*

E. POTENTIAL BENEFITS

1. Describe any benefit from the information provided to study participants.

- [x] No direct benefit
- [ ] Medical or physical data
- [ ] Sociological data
- [ ] Psychological data
- [ ] Environmental data
- [ ] Other, specify:

2. Describe any benefit from the services provided to study participants.

- [x] No direct services provided
- [ ] Medical or rehabilitation treatment
- [ ] Social/economic service
- [ ] Psychological counseling
- [ ] Environmental cleanup or correction
- [ ] Other, specify:

3. What are the benefits, if any, to society that may be expected from this research study?

The primary benefit is evidence that will hopefully contribute to the CV technologies body of knowledge by showing that the use of these technologies can help with speed management, reducing vehicle-to-vehicle crashes, reducing vehicle-to-pedestrian crashes, reducing vehicle-to-infrastructure crashes, and informing drivers of serious incidents. Each of these efforts can help contribute to the Vision Zero goal of eliminating injuries and fatalities due to traffic crashes. This is the first large scale implementation of this technology in an enclosed area (Manhattan) that will provide the opportunity to measure the benefits and serve as a baseline for other urban markets as they could consider the deployment of connected vehicle technology.

F. PROTECTION OF SUBJECTS

1. Summarize the protections assured to human subjects from all study documents, including the Informed Consent or Minor Assent form.

- [x] Anonymity (no link between individual and data)
- [ ] Confidentiality (links between individual and data may exist, but are adequately safeguarded)
- [ ] Data and Safety Monitoring Board / Plan
- [ ] Medical treatment or Counseling

- ☐ Environmental remediation
- ☐ Certificate of Confidentiality (CoC)
- ☐ Other, specify:

G. RISK/BENEFIT RATIO

1. Describe why the risks to subjects are reasonable in relation to the anticipated benefits to subjects/society and in relation to the importance of the knowledge that may reasonably be expected to result.

The risks to subjects are reasonable in relation to the anticipated benefits to subjects/society because the technology augments information about the complex traffic environment and does not attempt to eliminate the risks normally associated with driving as subjects drive as part of their regular duties. Also, as the proposed benefits are expected to help drivers in managing speed, reducing vehicle-to-vehicle crashes, reducing vehicle-to-pedestrian crashes, reducing vehicle-to-infrastructure crashes, and informing drivers of serious incidents, the risks seems reasonable, as a successful pilot deployment will provide evidence showing that CV technology can directly benefit society.

2. If the study requires participation of vulnerable populations, justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them.

By including visually impaired pedestrians, this pilot deployment can potentially show that CV technology can help visually impaired pedestrians navigate traffic intersection more safely than they are currently able. As such, the pedestrian application should receive the greatest attention during design and the greatest rigor in testing, which will help reduce the risks to the participants.

3. Describe any available alternative treatment(s) for the human subjects, if they choose not to participate in the study. NOTE: Alternative may be to NOT participate in the study.

Alternatives are up to the fleet owner since drivers are not fleet owners.

4. Assess the level of risk / benefit to human subjects.

- ☐ Minimal risk, minimal benefit
- ☒ Minimal risk, substantial benefit
- ☐ Substantial risk, substantial individual benefit
- ☐ Substantial risk, substantial research/society benefit
- ☐ Other, describe:

H. HIPAA-REGULATED STUDY NOTE: See MyProcess "Using PHI" Procedure Area.

1. Will the study require collection or access to a medical patient's Protected Health Information[6]? ☒ No ☐ Yes

   If Yes, has/will Battelle enter into a Business Associate Agreement ☐ No ☐ Yes

   If Yes, will Battelle disclose patients' PHI to any subcontractors or collaborators? ☐ No ☐ Yes

   If Yes, will the study develop a Patient's Authorization for Release of PHI or request an IRB Waiver of HIPAA Authorization? ☐ No ☐ Yes

   If Yes, will electronic PHI (ePHI) be managed in the Battelle HIPAA Compliant Environment (BHCE or BISC), in an external HIPAA-compliance cloud-based server controlled by Battelle, or in a HIPAA-compliant environment managed by another entity? Describe how ePHI will be managed:

I. FDA-REGULATED or NIH CLINICAL RESEARCH STUDY

a. Will the study be subject to FDA regulations or be categorized as NIH-sponsored Clinical Research or as a FDA-sponsored Clinical Investigation? ☒ No ☐ Yes

If NO, DO NOT complete this section.

i. Does the study involve the use of a DRUG in a human other than the use of an approved drug in the course of medical practice? ☐ **No** ☐ **Yes**

If Yes, the IRB may follow up with additional questions.

ii. Does the study involve the use of a BIOLOGIC in a human other than the use of an approved biologic in the course of medical practice? ☐ **No** ☐ **Yes**

If Yes, the IRB may follow up with additional questions.

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[6] ***Protected Health Information*** *or* ***PHI*** *is individually identifiable health information that is transmitted or maintained in any form or medium by a Covered Entity or Business Associate.* ***Individually Identifiable Health Information*** *or* ***IIHI*** *is information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual*

iii. Does the study evaluate the safety or effectiveness of a DEVICE in research subjects, a control group, or their biological specimens? ☐ **No** ☐ **Yes**

If Yes, the IRB may follow up with additional questions.

iv. Will results of the study be submitted to or held for inspection by FDA as part of an application for a future permit for research or marketing? (See 21 CFR 50.3(c))
☐ **No** ☐ **Yes**

If Yes, the IRB may follow up with additional questions.

b. Will results of this study be posted to www.ClinicalTrials.gov? ☐ **No** ☐ **Yes**
If Yes, why?

If Yes, will Battelle be identified as the "Responsible Party" for reporting? ☐ **No** ☐ **Yes**
NOTE: Typically, the SPONSOR is the Responsible Party, but may defer to the PI.

Appendix D: IRB Recommendations

A. CV Pilot Deployment Program Phase 1 – Training and Stakeholder Education
   a. P.6 Participant Group Trainers
      i. RECOMMEND Add Bullet – Human Subjects/Ethics briefing to include aspect of voluntariness, assurances of no personal liability arising from participation in the pilot program

   b. P.8, Section 3.3.1 – Fleet drivers MUST participate as a condition of their employment. Fleet Owners to include in their organizational policies:
      i. RECOMMEND an evaluation with future IRB of record to determine if the FLEET Driver(s)-related tasks must be considered to be human subjects research. It's possible that Fleet Driver activities could be ruled Exempt from regulation. Human Subjects Regulations at 45 CFR .46.116 require a human subject's voluntary informed consent for all non-exempt research. The future IRB of record will have the authority to waive all elements of Informed Consent, but this requires the project to prove four discrete elements to IRB of record. I'm not certain that the project can satisfactorily demonstrate the following:

         (1) The research involves no more than minimal risk to the subjects (CAN BE MET);

         (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (CAN LIKELY BE MET)

         (3) The research could not practicably be carried out without the waiver or alteration; (MUST Be DEMONSTRATED) and

         (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation. (CAN LIKELY BE MET)

      ii. RECOMMEND Add
         1. Assurance of no personal liability arising from participation in the pilot program (when there is no violation of company policy). Collective Bargaining units will require this.
         2. Confirm whether or not CV systems can be deactivated and, if so, whether or not participants will be aware that system(s) are inactive.
         3. Acknowledgement that pilot study data is only for purposes of research/evaluation. See Section 4.1 – Security Management Operating Concept-NYC

        a. Brief summary of PII controls, e.g., data held temporarily, no expectation during pilot study for stakeholders of logs, aggregation of data,

    c. P.9. Section 3.3.2 – Pedestrians
        i. Consent document(s) and consent process not available for review. Assure that any issue of personal and municipal liability is addressed.

    d. Section 4.1
        i. RECOMMEND that CV Pilot Program develop a short, informational presentation/briefing (online or video) for relevant groups, i.e., trainers. Presentation to acknowledge:
            1. Some phases of the project are human subjects research
            2. Participants deserve appropriate information so they have a reasonable basis to make an informed decision about whether or not to participate.

B. CV Pilot Deployment Phase 1 – Security Management Operating Concept-NYC
    a. Section 4. Privacy and PII Data Protection
        i. See A.b.i.2. above. Provide appropriate assurances to Pilot study participants and their respective organizations.

C. CV Pilot Deployment Program – Safety Management Plan-NYC
    a. No IRB Comments

D. CV Pilot Deployment Program Phase 1 – Performance Measurement and Evaluation Support Plan – NYC
    a. Section 7.2. Acknowledge that police (accident report) data cannot be correlated to study data.
    b. Section 11.2. Multiple stakeholders "own" study data; through MOUs, will be required to remove PII. RECOMMEND appropriate assurances be provided to study participants, whether participation is voluntary or not.

E. CV Pilot Deployment Program Phase 1 – Concept of Operations (ConOps)-NYC
    a. Sections 4.3.2 and 4.3.3 Acknowledge privacy requirements for stakeholders.

Commented [MRK29]: I'm really surprised that no payment will be given to pedestrians. Some payment seems appropriate given that participation will involve some time and compliance commitment, and they are not employees like most other subjects in the study

Commented [MRK30]: Strongly agree

Appendix E: IRB Notice of Approval

Battelle Memorial Institute
Federalwide Assurance FWA0004696
Battelle Institutional Review Board - No.IRB00000284

INSTITUTIONAL REVIEW BOARD NOTICE OF FULL APPROVAL – PRELIMINARY ONLY

Principal Investigator/Project Manager(s):	Chris Stanley		
Proposal/Project Title :	New York City Connected Vehicle (NYC CV) Pilot Deployment Program, Phase 1		
Client/Funding Agency :	JHK Engineering / TransCore (Prime) Funding: DOT Federal Highway Administration/JPO		
IRB Number:	IRB AAAA-100072168 Rev 0.0	**Date of Submission to IRB:**	9 June 2016
OPP No:	N/A	**Project No:**	100072168
Subcontract to Battelle from	JHK Engineering / TransCore		
Subcontract from Battelle to	N/A		

The federal sponsor mandated that this project shall undergo IRB review, approval and oversight.

While Battelle will not be engaged in research for Phase II or other phases of this project, Battelle's IRB agreed to assist Battelle's project team to meet its deliverables by considering a preliminary "IRB Application", proposing and defining an IRB review pathway(s), and issuing a Preliminary Notice of Approval. This document is the Preliminary Notice of Approval – this Notice of Approval DOES NOT authorize the conduct of human subjects research.

The review considered the entire CV pilot project as presented in documents:

- Connected Vehicle Pilot Deployment Program Phase 1, Concept of Operations (ConOps) – New York City; FHWA-JPO-16-299; Final ConOps – April 8, 2016
- Connected Vehicle Pilot Deployment Program Phase 1, Performance Measurement and Evaluation Support Plan – New York City; FWHA-JPO-16-302, Draft Report – May 20, 2016
- NYC Connected Vehicle (CV) Pilot Deployment Program Safety Management Plan - New York City; FHWA-JPO-16-301, Report – April 22, 2016
- Connected Vehicle (CV) Pilot Deployment Phase 1: Security Management Operating Concept - New York City; FHWA-JPO-16-300, Final Report – Undated
- Connected Vehicle (CV) Pilot Deployment Phase 1: Participant Training and Stakeholder Education Plan - New York City; FHWA-JPO-16-306, Draft Report – May 23, 2016
- Application for IRB Review and Approval of Human Subjects Research

In this "Preliminary" ruling, the Battelle IRB has considered all recommendations published in the USDOT Guidance Summary for Connected Vehicle Pilot Site Deployers: Human Use Approval (Draft Report – Sept 2015)

Level of Review: Full IRB Approval – PRELIMINARY ONLY

This Preliminary Notice of Approval is intended to describe the decision logic for a future ruling by an IRB of Record. In future, Battelle will not interact or intervene with human subjects or have access to information collected about a human subject. Battelle will not be engaged in future research.

This project involves a comprehensive data collection effort that involve many discrete tasks. The Battelle IRB has reviewed pilot project documents (see listing above) that describe proposed interactions with human subjects on a programmatic level – the Battelle IRB has **NOT** reviewed specific recruiting, screening, consent, data collection instruments, and other relevant study documents as these study documents have not yet been developed. Depending upon scope of task, individuals' participation in the research may or may not be voluntary. At least one or more tasks meet regulatory criteria at 45 CFR 46.102 for categorization as human research.

INSTITUTIONAL REVIEW BOARD NOTICE OF FULL APPROVAL – PRELIMINARY ONLY

*This Preliminary Notice of Approval does not authorize the conduct of human subjects research.
This Preliminary Notice of Approval describes the IRB's anticipated basis for approval, if/when ALL study documents are available for IRB review, approval, and oversight.

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The Battelle IRB strongly recommends that:

- Any future IRB of Record should re-evaluate if it is possible that one or more tasks may not require categorization as human subjects research (failing DHHS OHRP (DOT under the Common Rule – 45 CFR 46, Subpart A; definition of "human subject"), or could reasonably be ruled human subjects research, but exempt. This could be the case for the Fleet Drivers-related tasks.
- For Phase 2, JHK/Transcore and collaborating institution(s) engage the designated IRB of record to assess entire scope of work to determine if it is appropriate ONLY to rule on those tasks that clearly can be defined as "human subjects research."

Expedited per 45 CFR 46.110 (b) (1) (Category 7). 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. Study population(s) will consist of legal adults in the State of New York.

All data collection activities described are considered to minimal risk to human subjects regardless of the status of voluntariness. Study participants will receive training in study systems, requirements, and established safeguards. Measures to protect subjects' privacy and confidentiality of study data are appropriate for printed or electronic data. Study data will only be available to the research team; study data provided for collaborators/stakeholders' use will be provided without PII and in aggregate. Anticipated benefits of the research outweigh perceived risks to subjects.

*At this time, the IRB has considered, but has NOT APPROVED a waiver of Informed Consent process per 45 CFR 46.116(d). Not subject to regulation under HIPAA. Does not require an NIH Certificate of Confidentiality. Does not require an IDE/IND and is not otherwise subject to FDA regulations.

☐ Copy of IRB approved informed consent form(s) attached. **NOT Available for the IRB's Review at this time.**

Type of Approval – See Page 2 of 3 for Additional Requirements and Restrictions

☒ Preliminary Approval* – (Preliminary) approval continues to 10 June 2017.

Rosalee Meyer Rader — 6/17/2016
Signature — Date
Co-Chair, Battelle Institutional Review Board

Rosalee Meyer Rader, Ph.D.

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Requirements and Restrictions

A. The Principal Investigator / Project Manager(s) must assure that all study investigators have completed initial training in human subjects ethics, regulations and applicable policies and that all investigators complete human subjects re-training at required intervals.
B. Per 45 CFR 46.109(e), the IRB has the authority to observe or to have a third party observe the consent process and the research.
C. Per 45 CFR 46.113, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Continuing Review/Approval. Federal regulations require that human subjects research protocols maintain IRB approval for the entire duration of the research study, including data analysis and report writing. If the formal study remains open/active, apply for continuing approval of IRB AAAA-100072168 Rev 0.0 at least three weeks prior to 10 June 2017, the final day of approval.

Approval for Amendments. Obtain IRB approval for any proposed amendments/ revisions to the protocol, including changes to study documents and recruiting materials. Federal regulations require that the IRB re-review and re-approve human subjects research prior to implementing any proposed amendments or revisions. Complete and submit an application for amendment to the IRB manager.

Reporting. The following events must always be reported to the IRB:

- Adverse Events, Unanticipated Problems Involving Subjects or Others, or a Nonconformance (within four (4) hours of discovery).
- Protocol violations that
  - Placed a human subject at risk, or
  - Were caused by the action or inaction of a researcher
- New or changed risks to human subjects, including new findings
- Failure to follow regulations or IRB requirements
- Unresolved complaint by a human subject
- Audit, inspection, or inquiry by a federal agency
- Breach of confidentiality
- Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a human subject
- Incarceration of a human subject.

Documentation Control Requirements. Federal regulations require that research study documents and records, e.g., signed informed consent documents and data collection instruments, be maintained in accordance with the confidentiality measures described in the IRB's approved protocol, application and Informed Consent document(s). These documents must be retained for at least three (3) years after a study is formally closed. Battelle policy or client requirements may require a longer retention.

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Definitions

Expedited Review – Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal regulations at 45 CFR 46.110 permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Only the IRB can determine if a proposed research activity meets the requirements for regulation.

Adverse Event - An event or incident not previously known or not anticipated to result from:

- The interactions or interventions used in the research;
- The collection of privately identifiable information under the research;
- An underlying disease, disorder or condition of a human subject, and/or,
- Other circumstances unrelated to the research or any underlying disease, disorder or condition of the subject.

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Depending upon applicable regulations, "minimal risk" may be defined differently for minors and other vulnerable populations.

Nonconformance - A determination that some aspect of a research study has not been performed in accordance with applicable laws and regulations, ethical standards, Battelle policies, IRB requirements, or contractual obligations.

Unanticipated Problem Involving Subjects or Others - An event in a human research study that is not expected given the nature of the research procedures and the subject population being studied, and suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

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