SMART COLUMBUS

Human Use Approval Summary

for the Smart Columbus Demonstration Program

UPDATED REPORT | November 9, 2020

Produced by City of Columbus

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Abstract

This Human Use Approval Summary describes the Smart Columbus institutional review board (IRB) process as it is applied at the program and project levels during both demonstration and performance measurement. The IRB process assures that research involving human participants is designed and conducted in an ethical manner and in accordance with applicable laws and regulations. This report (1) provides background on the importance of Human Use Approval and IRB oversight; (2) documents the IRB application and review process from IRB selection through approval, including feedback and revisions; (3) describes coordination between IRB activity and other program tasks, including Concept of Operations, System Requirements, and Performance Measurement; (4) identifies dependencies, constraints, and key challenges; and (5) identifies events or situations that could affect potential future IRB activities in the program. Because planning and deployment timing varies by project and needs may change as projects proceed through different phases, this should be considered a living document that may be revised as program and project needs evolve.

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Executive Summary

As the winner of the U.S. Department of Transportation's (USDOT's) Smart City Challenge (SCC), Smart Columbus will demonstrate how advanced technologies can be integrated into other operational areas within the City using advancements in intelligent transportation systems (ITS), connected vehicles (CV), autonomous vehicles (AV), and electric vehicle (EV) technologies while integrating data from various sectors and sources to power these technologies, simultaneously leveraging the new information they provide. The Smart Columbus Program includes eight projects grouped into three overarching themes: Enabling Technologies, Enhanced Human Services (EHS), and Emerging Technologies. One of the eight projects is the Smart Columbus Operating System (Operating System), the integral backbone and heart of all current and future Smart City projects.

In accordance with USDOT Cooperative Agreement No. DTFH6116H00013 (Cooperative Agreement), the Smart Columbus Program is expected to improve safety, enhance mobility, increase opportunity, and address climate change through demonstrations of ITS and innovative mobility solutions. Involvement of human subjects is an integral part of demonstrating project technologies' potential to achieve these outcomes.

This Human Use Approval Summary describes the Smart Columbus institutional review board (IRB) process as applied at the program and project levels to assure research and activities involving human participants are designed and conducted in an ethical manner and in accordance with applicable laws and regulations. This report (1) provides background on the importance of Human Use Approval and IRB oversight; (2) documents the IRB application and review process from IRB selection through approval, including feedback and revisions; (3) describes coordination between IRB activity and other program tasks, including Concept of Operations, System Requirements, and Performance Measurement; (4) identifies dependencies, constraints, and key challenges; and (5) identifies events or situations that could affect potential future IRB activities in the program. Because planning and deployment timing varies by project and needs may change as projects proceed through different phases, this Human Use Approval Summary should be considered a living document that may be revised as program and project needs evolve.

Chapter 1. Smart Columbus Introduction

1.1. PROGRAM OVERVIEW

The U.S. Department of Transportation (USDOT) pledged $40 million to Columbus, Ohio, as the winner of the Smart City Challenge (SCC). With this funding, Smart Columbus will demonstrate how advanced technologies can be integrated into other operational areas within the City, using advancements in intelligent transportation systems (ITS), connected vehicles (CVs), autonomous vehicles (AVs), and electric vehicles (EVs) while integrating data from various sectors and sources to power these technologies while simultaneously leveraging the new information they provide. Community and customer engagement will be present throughout the program, driving the requirements and outcomes for each project. This end-user engagement reinforces the idea that the residents of Columbus are ultimately the owners and co-creators of the Smart Columbus Program. Columbus intends to define what it means to be a "Smart City" and to serve as a model for other cities wishing to fully integrate the innovative technologies and community development that will be deployed in the Smart Columbus Program.

The Smart Columbus Program includes eight projects grouped into three overarching themes: Enabling Technologies, Enhanced Human Services (EHS), and Emerging Technologies. One of the eight projects is the Smart Columbus Operating System (Operating System), the integral backbone and heart of all current and future Smart City projects.

Figure 1 shows the Smart Columbus Program and each project.

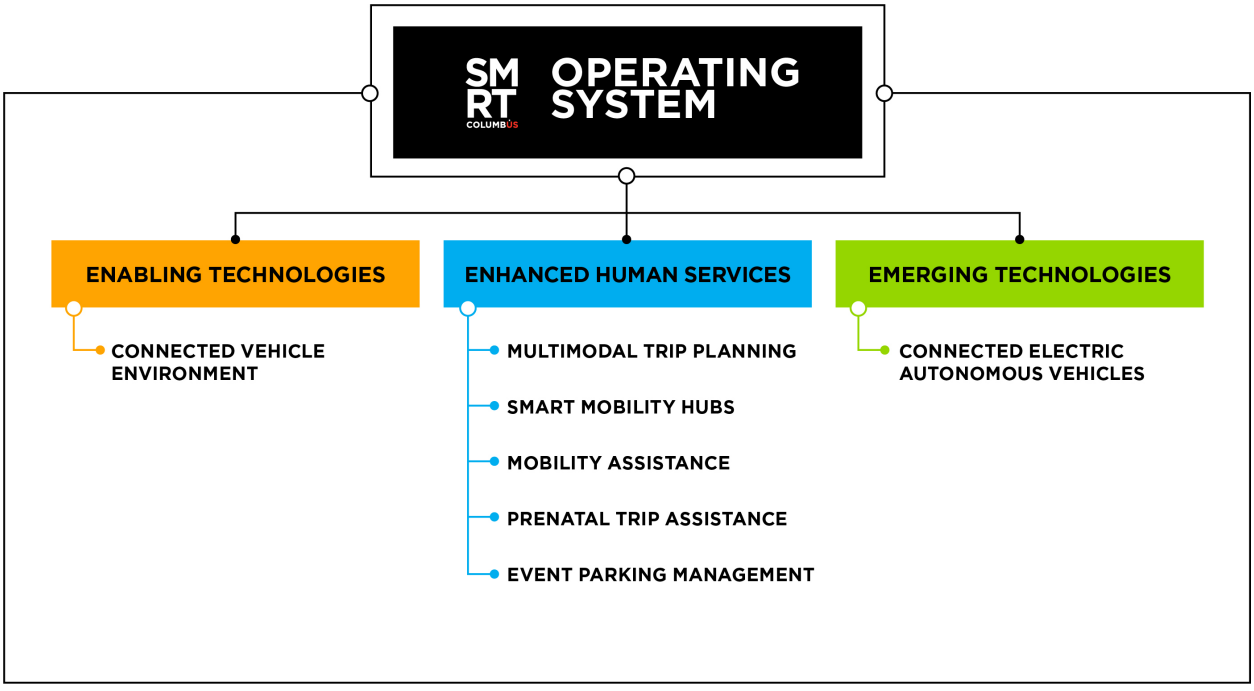

Figure 1: Smart Columbus Projects

Source: City of Columbus

1.2. ENABLING TECHNOLOGIES

These technologies leverage today's foundation in innovative ways to greatly enhance the safety and mobility of the transportation infrastructure. These advanced technologies empower deployments that increase a city's capabilities because of rich data streams and infrastructure that are designed to handle on-demand responses. The Connected Vehicle Environment (CVE) project is an enabling technology that will improve safety, mobility, and the environment by leveraging cutting-edge technology to advance the sustainable movement of people and goods.

1.3. ENHANCED HUMAN SERVICES

EHS projects meet human needs with technology-based solutions that focus on preventing and remediating problems, maintaining a commitment to improving the overall quality of life for users. EHS projects create opportunities to improve access to jobs, healthcare, and events. The Smart Columbus Program includes the following EHS projects: Multimodal Trip Planning Application (MMTPA), Smart Mobility Hubs (SMH), Mobility Assistance for People with Cognitive Disabilities (MAPCD), Prenatal Trip Assistance (PTA), and Event Parking Management (EPM).

1.4. EMERGING TECHNOLOGIES

Emerging technologies are applications that are in development or that will be developed during the next five to 10 years that will substantially alter the business and social environment. By focusing on key emerging technologies, the City will be able to exhibit potential solutions to address and mitigate future transportation and data collection challenges. The Connected Electric Autonomous Vehicles (CEAV) project will demonstrate how emerging technologies can link people to transit and improve mobility access to jobs and services.

1.5. OUTCOMES

The Smart Columbus Program will reorient the City of Columbus to deliver more diversified and nimble transportation options by using data and a connected, complete network that supports healthy activity and a more attractive and sustainable urban form. **Figure 2** introduces outcomes associated with the projects and how they are tied to the vision and outcomes for the Smart Columbus Program.

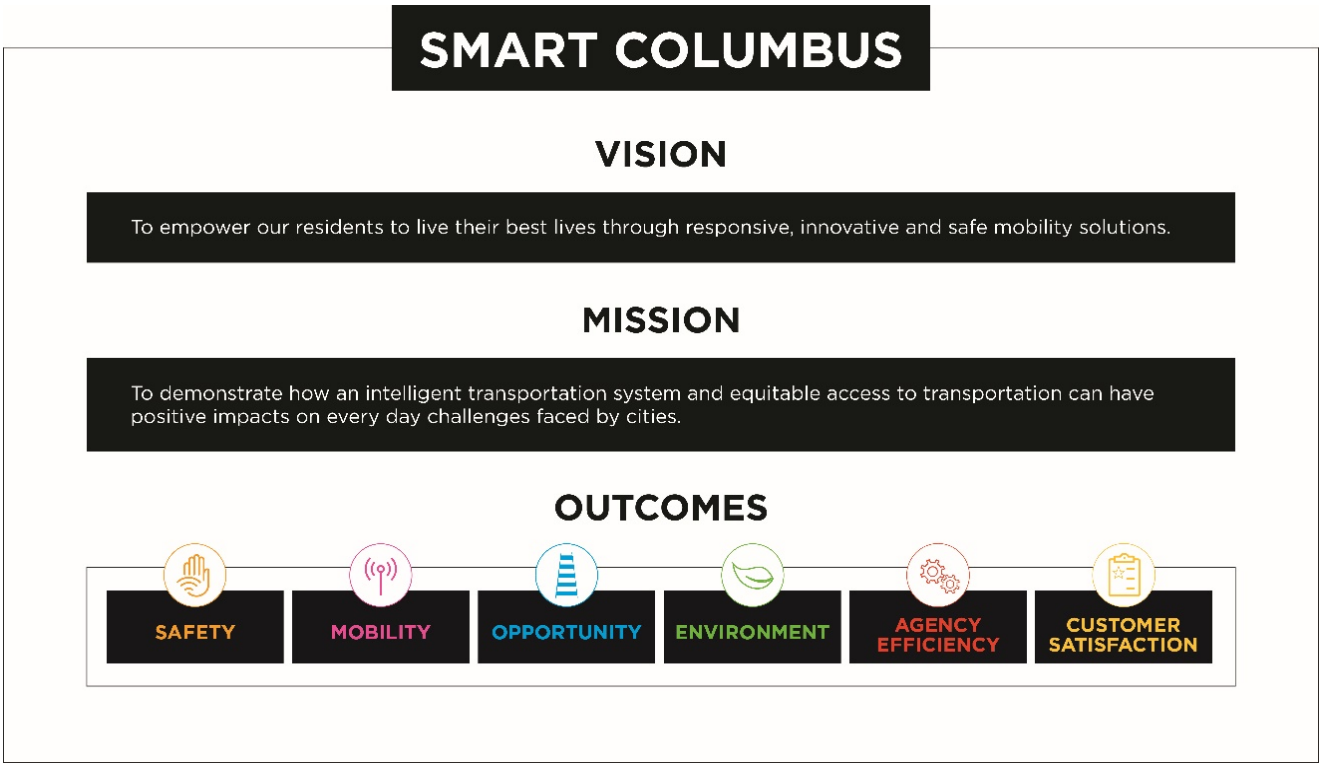

Figure 2: Smart Columbus Vision, Mission, and Outcomes

Source: City of Columbus

Chapter 2. Document Overview

2.1. DOCUMENT OBJECTIVE

This document provides a summary of the Human Use Approval (HUA) process, which is required for all Smart Columbus Program projects that include a human research component. All eight Smart Columbus Program projects involve human subjects in some way during testing, execution, and performance measurement phases, so all require HUA. This document describes the IRB process and HUA components by project, including:

- Project synopsis and Concept of Operations (ConOps)
- Dependencies and constraints
- HUA
  - IRB process and application
  - IRB submittals and determinations
  - Supporting documentation
  - Future needs

Implementing and documenting the HUA process is part of complying with the City's agreement with USDOT and federal regulations. Specifically, the Smart Columbus HUA process is in accordance with Task F, Safety Management and Safety Assurance of the Cooperative Agreement. The HUA process, in which an accredited institutional review board (IRB) oversees projects involving human research subjects, is important for protecting the rights and welfare of human research subjects.

Information used in the IRB application for each project was derived from activities and documents planned, ongoing, or completed under Tasks A through J in the Cooperative Agreement:

- Task A: Program Management
- Task B: Systems Engineering Approach
- Task C: Performance Measurement
- Task D: Data Privacy Requirements
- Task E: Data Management and Support for Independent Evaluation
- Task F: Safety Management and Safety Assurance
- Task G: Communications and Outreach
- Task H: International Collaboration
- Task I: Participation in Relevant ITS Architecture and Standards Development Efforts
- Task J: Interim and Final Reporting

2.2. ORGANIZATION OF THE REPORT

This document outlines the HUA process, including IRB functions and current review status by project. It is organized as follows:

- Introduction to the Smart Columbus Program

- Overview of this document
- Background on the use of human subjects, the rationale for oversight, and research principles, rules, and guidance
- Summary of the HUA process, including scope, benefits and risks, and roles and responsibilities
- Dependencies and constraints, including references to other Smart Columbus systems engineering documents
- HUA information by program-level performance measurement outcome and project, including synopsis of project or outcome, dependencies and constraints, IRB submittals, approvals and exemptions, and future HUA needs
- Conclusions

Chapter 3. Background on Use of Human Subjects

3.1. RATIONALE FOR GOVERNING HUMAN RESEARCH

Throughout history, there have been gross abuses of human test subjects in the name of science or the greater good, often carried out by force, without consent and without due consideration for test subject safety and welfare. An egregious example of such abuse is the Nazi medical experiments conducted on concentration camp prisoners during World War II (WWII). After WWII, the Allied forces held a series of trials to prosecute war criminals, including physicians who conducted unethical medical experiments. One result of these trials was the passing of the Nuremberg Code in 1947, an international code of ethics governing human experimentation and research and requiring the informed consent of participants.[1] In the 1970s, it was discovered that unwitting subjects in the United States had been allowed to suffer syphilis for 40 years as part of the Tuskegee experiment. Study subjects were never given adequate treatment, even when penicillin became the drug of choice for treating syphilis in 1947.

To prevent further abuses, various efforts were made over time to provide guidance for and oversight of research involving human subjects. In 1974, the National Research Act went into effect, requiring all research funded by the Department of Health, Education, and Welfare to be reviewed by an IRB. In 1979, Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research was issued, establishing three principles for the treatment of human subjects: Respect, Beneficence, and Justice. In 1991, 16 government agencies adopted the Common Federal Policy for the Protection of Human Subjects (Common Rule), which still applies today. The Common Rule is codified in Code of Federal Regulations (CFR) Title 10, Part 745 (10 CFR Part 745). Federally funded research involving human subjects is governed by this rule.[2]

Because the Smart Columbus projects are federally funded and involve human subjects, they are subject to IRB review governed by the Common Rule and 49 CFR Part 11, which applies to the use of human subjects and transportation, as well as the human subjects research principles outlined below.

3.1.1. Human Subjects Research Principles

The human research principles followed in the Smart Columbus Program align with federal regulations and exemplify the three critical principles for conducting ethical research outlined in the 1979 Belmont Report.[3]

3.1.1.1. RESPECT FOR PERSONS: INFORMED CONSENT

The principle of Respect states that individuals should be treated with autonomy and afforded additional protections where such autonomy is limited. This includes obtaining the research subjects' informed consent to demonstrate that they are sufficiently informed, that they understand the potential risks of participating in the research, and that their consent is voluntary. Informed consent is documented by project, where applicable, by collecting signed informed consent documents (ICDs) from all participants.

3.1.1.2. BENEFICENCE: BENEFITS VS. RISKS

The principle of Beneficence prioritizes that research "do no harm" to subjects and maximize research benefits while minimizing risks to subjects. This involves systematically identifying and assessing research

[1] https://history.nih.gov/research/downloads/nuremberg.pdf

[2] https://history.nih.gov/about/timelines_laws_human.html

[3] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#xbenefit

risks to ensure unacceptable risks are not taken and necessary risks are minimized as much as possible while achieving research objectives. Risks to vulnerable populations require additional scrutiny and justification.

3.1.1.3. JUSTICE: EQUITY OF DISTRIBUTION OF BENEFITS/RISKS

The principle of Justice establishes that risks and burdens should not be placed disproportionally on disadvantaged populations and vulnerable populations should not be exploited for administrative convenience.

3.2. HUMAN USE RULES AND GUIDANCE

3.2.1. Common Rule

The Common Rule 10 CFR Part 745 provides guidance on defining when research is subject to this rule; what research activities are covered by or exempt from this rule; and requirements for approvals, oversight, and IRB involvement. Because federally funded programs are governed by this rule, and Smart Columbus is funded by USDOT, Smart Columbus program activities are also governed by this rule.

3.2.1.1. DEFINITIONS

3.2.1.1.1 Covered Research

Covered research is “all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States” (49 CFR 11).

3.2.1.1.2 Institutional Review Board

In this document, “IRB” is defined as any accredited IRB established in accord with and for the purposes expressed in 49 CFR Part 11.

3.2.1.1.3 Exemptions and Expedited Review

Some forms of research involving human subjects are exempt from oversight in accordance with 49 CFR 11 guidelines, including certain educational research and research and demonstration projects conducted by or subject to the approval of department or agency heads that are designed to study, evaluate, or examine public benefit or service programs. For a project to receive an IRB exemption, it must pose a “less than minimal risk” to participants and/or fall into one of the exempt categories specified in 49 CFR 11. More information on Smart Columbus projects that received or are expected to receive an exemption is in **Chapter 6.**

Chapter 4. Human Use Approval Process

4.1. INSTITUTIONAL REVIEW BOARD

4.1.1. Institutional Review Board Role

IRBs are charged with protecting the health and welfare of human participants in research, testing, and experiments and ensuring their ethical treatment. IRBs also enhance the quality of research by requiring rigorous processes and documentation in compliance with applicable federal, state, and local guidance. IRB review is needed at various stages of a research project and IRB approval or exemption from oversight must be obtained prior to recruitment or involvement of human subjects in covered research.

4.1.2. Federal Assurance

Federal regulations for human use in research require institutions conducting research involving human subjects to provide formal written assurance certifying that they will comply with those regulations. There are three types of assurances:

- Federal-wide assurance (FWA), applicable to all federally sponsored projects
- Multiple project assurance
- Single project assurance

All Smart Columbus program-level outcomes and projects will provide assurance using their designated IRB's FWA. An IRB provider has been designated for each Smart Columbus project based on project needs. The two IRB providers selected are Advarra and the Ohio State University (OSU). OSU's IRB was selected for projects and outcomes for which OSU researchers were contracted as principal investigators (PIs) for demonstration or measure performance. While OSU researchers are required to use OSU's internal IRB if they are the PI, they are not permitted to do so if not the PI. Therefore, a commercial IRB, Advarra, was selected for projects and outcomes for which the City or other contractors/consultants are the PIs. In addition, for some projects (MMTPA and CEAV) in which surveys were used to assist in marketing and recruiting, the commercial IRB was used to review and provide IRB approval or exemption. In these cases, survey data from project demonstration will still supplement performance measurement.

IRB providers are shown for each program-level outcome in **Table 1.** IRB providers are shown by project in **Table 2**.

Table 1: IRB and Federal-wide Assurance by Program-Level Performance Measure

Program-level Outcome	IRB for Performance Measurement
Environment	Advarra
Mobility	OSU
Opportunity	OSU
Customer satisfaction	OSU

Source: City of Columbus

Table 2: IRB and Federal-wide Assurance by Project-Level Performance Measure

Project	IRB	
	Performance Measurement	Project Demonstration
CVE	Advarra	Advarra
MMTPA	OSU	Advarra
MAPCD	OSU	OSU
PTA	OSU	OSU
SMH	OSU	OSU
EPM	Advarra	Advarra
CEAV	OSU	Advarra

Source: City of Columbus

4.2. SCOPE OF HUMAN USE APPROVAL TASK

The scope of the HUA task includes understanding project-specific IRB requirements, processes, and timelines. An accredited IRB and PI were selected for each project, to oversee the IRB and HUA processes and coordinate with other tasks as needed. IRB selection by outcome is shown in **Table 1** (above). IRB selection by project is shown in **Table 2** (above). PI by project is shown in **Table 3**.

4.2.1. Components of Human Use Approval Task

HUA task components include the IRB application and feedback, application amendments and IRB determinations, and participant recruitment and informed consent.

4.2.1.1. IRB APPLICATION AND FEEDBACK

The initial IRB application may be a request for exemption from oversight, or it may include research protocols (with or without supporting documentation) for expedited or full review. If exemption is granted, additional oversight is not needed unless there is a change to the study protocol. At any stage of review, an IRB may provide feedback requesting clarification, additional information, or modifications to protocols and supporting documents. If revisions to the application are required, they are made, and the revised materials are then submitted to the IRB for further review, after which the IRB may determine to exempt a project or grant approval.

4.2.1.2. PARTICIPANT RECRUITMENT AND INFORMED CONSENT

Research subject recruitment plans are included in the research protocol or supporting documentation. In addition to the plans, all materials to be used to recruit human research subjects undergo IRB review. Recruitment materials vary by project and may include items such as flyers, TV or radio advertisements, e-newsletters, a website, emails, recruitment scripts, and social media messaging.

The ICD is a crucial part of the human use approval process, providing important information about the study and what to expect during participation, if consent is given. In addition to describing the study's purpose, timeline, and scope of activities, the ICD:

- Specifies that participation is voluntary
- Explains the risks and benefits to study participants

- Addresses confidentiality
- Explains participant rights

Contact information is also included, indicating where to send questions and whom to contact in case participants believe themselves to have been harmed through participation in the study. ICDs are developed for each project, and multiple versions may be needed for various stakeholders. ICDs may also include additional topics such as incentives for participation or consent for audio/video recording.

4.3. BENEFITS AND RISKS

Project PIs and research team members are obliged to proactively anticipate risks to participants and take efforts to minimize them, while maximizing potential benefits to participants and society at large. Consideration of risks and benefits plays a critical role in demonstrations and performance measurement, from recruitment design and materials through informed consent procedures and documentation. PIs are tasked with ensuring participants fully understand the risks associated with participation and documenting their consent. Risks and benefits are explained in the ICD for each project. In addition, the Smart Columbus Program Management Office maintains a risk register to proactively identify and mitigate potential program-level and project risks that impact scope, budget, and schedule. More information is in the Smart Columbus Safety Management Plan (SMP), the Smart Columbus Data Privacy Plan[4] (DPP), and the Smart Columbus Data Management Plan[5] (DMP).

4.4. PRINCIPAL INVESTIGATOR

A PI has been assigned to each project to interface with the IRB and project team. The PI is responsible for actively monitoring the HUA process, developing this Human Use Approval Summary, updating IRB applications and amendments as needed, and coordinating with other project and program-level activities.

PIs are also tasked with ensuring all relevant project staff understand the HUA and helping guide them through the process. PI responsibilities include understanding and fulfilling application and documentation requirements, addressing training needs for team members on the IRB process, managing the timeline for IRB review and approval or exemption, and addressing IRB feedback and amending applications as needed.

[4] https://d2rfd3nxvhnf29.cloudfront.net/2020-09/SCC-D-DataPrivacyPlan-AnnualUpdate-V2.pdf

[5] https://d2rfd3nxvhnf29.cloudfront.net/2020-08/SCC-E-DataManagementPlan-Update-v1_0.pdf

Chapter 5. Dependencies and Constraints

The HUA task relies on guidance and information from other program activities and tasks, including dependencies and constraints found in various program documentation. For example, survey questions used during one project's demonstration activities may produce data needed for program-level performance measurement. Integration with the MMTPA project or the Operating System may impact data collection or processing. Many demonstration and performance measurement activities involve data privacy or safety management considerations. Therefore, close, continuing coordination with other project teams and performance measurement teams is needed so that evolving project needs and activities are captured in the IRB review and documentation. More information on coordination with other tasks is provided in project-specific sections in **Chapter 6**.

5.1. PROGRAM SCHEDULE

The overall program schedule determines the timing of IRB document submittal for each project, because the planning, demonstration, and performance measurement schedule varies by project. Timely preparation of IRB documentation and review is key to maintaining project milestones, as many activities require IRB approval or exemption before they begin.

5.2. PROJECT CONCEPT OF OPERATIONS

The ConOps for each project conveys a high-level look at the system to be implemented from the viewpoint of each stakeholder and can be found on the Smart Columbus website[6]. A project's ConOps frames the overall system, sets the technical course for the project, and serves as a bridge between early project motivations and technical requirements. As the basis for a specific project, each ConOps focuses on the functionality of the proposed system and is technology independent. The ConOps also communicate users' needs and expectations for the proposed system. The ConOps gives stakeholders the opportunity to give input on how the proposed system should function, which will help build consensus and create a single vision for the system moving forward.

Some projects did not prepare a traditional ConOps. Neither the MAPCD nor the CEAV project team developed a traditional ConOps. For the MAPCD project, the team prepared a Trade Study; as with the ConOps of other projects, the Trade Study[7] documented the user needs and issues the system sought to resolve. Unlike the ConOps, however, the Trade Study examines and compares specific technologies that can solve these issues and evaluates them to determine a recommended solution. For the CEAV project, the team developed an Operational Concept.[8] This document provided a high-level view of the system to be deployed. It was used by the project team, stakeholders, and potential vendors to create a consistent understanding of project needs, process framework, and other system attributes.

Regardless of whether a traditional ConOps, a Trade Study, or an Operational Concept is developed, documentation about user needs are a key input for assessing what might drive human-subject-related needs and activities, such as the need to recruit private-sector participants for the CVE project.

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[6] https://smart.columbus.gov/

[7] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Mobility%20Assistance%20for%20People%20with%20Cognitive%20Disabilities%20Trade%20Study.pdf

[8] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Smart%20Columbus%20Connected%20Electric%20Autonomous%20Vehicle%20Operational%20Concent.pdf

5.3. DEMONSTRATION SITE MAP AND INSTALLATION SCHEDULE

The Demonstration Site Map and Installation Schedule[9] document identifies the specific geographic areas for the projects and indicates locations related to key issues, current and proposed roadside technology locations, connected and autonomous vehicle operations, and other explanatory features to support efforts that align with the City's proposed strategies. Public use of the physical infrastructure will not be permitted until IRB approval or exemption is received.

5.4. SAFETY MANAGEMENT PLAN

The Smart Columbus Safety Management Plan[10] (SMP) provides guidance on identifying safety scenarios and risk mitigation for the Smart Columbus program and is closely integrated with the HUA process. The SMP identifies safety scenarios at program and project levels, assesses the level of risk for each scenario, and provides safety operational concepts for high- to medium-risk scenarios.

5.5. DATA MANAGEMENT PLAN

The Smart Columbus Data Management Plan[11] (DMP) describes how data will be collected, managed, integrated, and disseminated before, during, and after the Smart City Challenge demonstration. Smart Columbus will not collect, use, or share personally identifiable information (PII) without the data subject's knowledge and informed consent. The program will collect and use the minimum amount of PII necessary to satisfy the purposes of the demonstration. Where possible, the Smart Columbus Program team will provide timely, clear, and specific notice of its collection, use, and sharing of PII. The notice will be provided at the point of collection to the individuals furnishing the PII. When notice at the point of collection is not possible, Smart Columbus will provide clear and specific notice as soon as practicable. If data are to be collected from the participants, an informed consent process will be followed that describes in detail what data will be collected.

5.6. DATA PRIVACY PLAN

The Smart Columbus Data Privacy Plan[12] (DPP) provides an overarching framework for the ways in which Smart Columbus will protect the security of personal information the program collects and uses, and how the program will protect the privacy of the individuals to whom this information pertains. Smart Columbus is committed to be a responsible steward of this personal information. The DPP document applies to all individuals who use or share data with Smart Columbus, including all Smart Columbus employees, partners, independent evaluators, and consultants. Where applicable, contract and other acquisition-related documents will include terms providing for compliance with the requirements of the DPP.

5.7. PERFORMANCE MEASUREMENT PLAN

The Smart Columbus Performance Measurement Plan[13] (PfMP) describes the desired outcomes of the Smart Columbus Program and how the objectives of each project relate to them. The plan identifies and explains the methodology proposed to evaluate the indicators for each project. Evaluations will provide

[9] https://d2rfd3nxvhnf29.cloudfront.net/2020-07/SCC-B-DSP%26IS-UPDATED.pdf

[10] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[11] https://d2rfd3nxvhnf29.cloudfront.net/2020-08/SCC-E-DataManagementPlan-Update-v1_0.pdf

[12] https://d2rfd3nxvhnf29.cloudfront.net/2020-09/SCC-D-DataPrivacyPlan-AnnualUpdate-V2.pdf

[13] https://d2rfd3nxvhnf29.cloudfront.net/2020-08/SCC-C-PfMP-Update-v1.pdf

insight into the performance of a project in meeting the objectives. The plan also describes the data necessary to evaluate the objectives and the required reporting frequency and contents.

Chapter 6. Human Use Approval by Project

6.1. HUA OVERVIEW

All eight Smart Columbus projects use human test subjects as part of the demonstration and/or performance measurement and thus, require submission of study protocol to the IRB for determination of oversight. Program-level performance measurement also requires IRB oversight, as surveys, interviews, and focus groups with human subjects are involved. For some projects, the demonstration is exempt from IRB oversight because of either the nature of the research itself or the way it is conducted.[14]

Table 3 provides the PIs, IRB oversight requirements and IRB determination and status by project. Because demonstrations and performance measurement are ongoing, **Table 3** may be updated periodically as project and performance measurement needs evolve. Updates may also indicate IRB status designation if additional documentation is submitted.

[14] https://nij.ojp.gov/funding/human-subjects-protection

Table 3: IRB Oversight, Principal Investigator, and IRB Status by Project

Project/Program-level Outcome	IRB Oversight Required?		Principal Investigator *(PfM = performance measurement)*	IRB Status
	Demonstration Activities	Performance Measurement		
Program Level				
Environment	N/A	Yes	*PfM*: Rama Boyapati/Battelle	*PfM:* In progress
Mobility			*PfM:* OSU	*PfM:* In progress
Opportunity			*PfM: OSU*	*PfM:* Exempt
Project Level				
Operating System	No; exemption received; informed consent not required.	Yes	*Demo:* Andy Wolpert/Accenture *PfM:* Rama Boyapati/Battelle	*Demo:* Exempt *PfM:* Exempt
CVE	Yes; subjects and activities for demo and PfM integrated		*Demo:* Alyssa Chenault, City of Columbus *PfM:* Dr. Chris Toth/WSP	*Demo:* Approved *PfM:* Approved
MMTPA	No; exemption received; informed consent not required	Yes	*Demo:* Andy Wolpert, City of Columbus *PfM:* Dr. Rabi Mishalani/OSU	*Demo:* Exempt *PfM:* Exempt
MAPCD	Yes; subjects are from a protected class; activities for demo and PfM integrated		*Demo:* Dr. Carmen DiGiovine/OSU *PfM:* Dr. Carmen DiGiovine/OSU	*Demo:* Approved *PfM:* Approved
PTA	Yes; subjects are from a protected class; activities for demo and PfM integrated		*Demo:* Dr. Courtney Lynch/Dr. Erinn Hade/OSU *PfM:* Dr. Courtney Lynch/Dr. Erinn Hade/OSU	*Demo:* Approved *PfM:* Approved
SMH	No; exemption expected;	Yes	*Demo*: Jeff Kupko, MBI *PfM:* Dr. Elena Irwin/OSU	*Demo:* Exempt *PfM:* In progress
EPM	No; exemption received	Yes	*Demo:* Alyssa Chenault, City of Columbus *PfM:* Sherry Kish/HNTB	*Demo:* Exempt *PfM:* Exempt
CEAV	No; exemption received; informed consent not required	Yes	*Demo:* Jeff Kupko, MBI *PfM:* Jason Reece/OSU	*Demo:* Exempt *PfM:* Exempt

Source: City of Columbus

6.1.1. Elements of the HUA Task

Project and performance measurement research protocols and associated IRB documentation provide information about the project-specific elements of the HUA task, including:

- Protocol
  - Participant and vulnerable populations protections
  - Participant recruitment, selection, and training
  - Data collection and management
    - Protecting PII
    - Privacy and data security
- Informed consent and documentation
  - Information on what will happen during the study
  - What the participant needs to know
  - Potential risks to participants
  - Benefits of the study
  - Payment and incentives for participation (if applicable)
  - Injury and legal rights
  - Voluntary nature of participation
  - Whom to contact with questions, concerns, complaints, injuries, or incidents
- Participant-facing materials
  - Survey, interview, and focus group design, implementation, and results
  - Recruiting Materials
  - Training materials

6.1.2. Future Needs

Future IRB documentation and review needs vary by project; they are described in each project's section below. Elements that affect potential future needs include:

- **Project timing:** In keeping with project schedules, performance measurement surveys are under development or IRB review for some projects. In such cases, protocols and/or supporting documentation, such as surveys, training scripts, or outreach materials, are planned future IRB review.
- **IRB feedback:** During document development or routine review of projects, the IRB may provide feedback that prompts response, including protocol, document, and/or process changes.
- **Policy changes:** If federal, state, or local rules and guidelines governing HUA were to change during the program period, protocol or process changes might be needed. Policy changes by project stakeholders, such as medical transportation or parking providers, might also impact interactions with human subjects.
- **Technology:** Many project activities involve software or hardware; human subjects might be affected by these technologies' performance or capabilities, or by the process of training for their use.

- **Participation rates:** To gather sufficient data for project evaluation, many projects have set target participation rates. If planned recruiting efforts do not produce expected participation rates, changes to locations, methods, eligibility criteria, and materials may be needed. Any change in the way participants are recruited would need to be approved by the IRB.
- **COVID-19 pandemic:** The global COVID-19 pandemic has impacted and will likely continue to impact the Smart Columbus program in various ways. In March 2020, the State of Ohio implemented a stay-at-home order, travel restrictions and a state of emergency that were in effect through May 2020. As a result, traveler behavior and needs, travel patterns, transit offerings, data collection, project timelines, and analysis approach were altered throughout the Central Ohio region. These alterations persist even as the City, state and region slowly re-open, which has affected both the development and deployment of the projects, as well as the analysis and performance measurement of them. The Updated PfMP[15] published in August 2020 describes the impact of the pandemic on each program outcome and project.
    1. **Impact to projects**. At a minimum, the pandemic has caused delays in developing and launching projects, whether a result of delays due to travel and production because of the pandemic (as with CVE) or continued reduction in ridership and transit (as with SMH and MMTPA). The pandemic has sharply affected transit and mobility everywhere, not just in Columbus; the impact of this on COTA, a major stakeholder in the MMTPA project, was significant enough to result in a change to the project concept. This changed resulted in the removal of the CPS project from the program, and a revised approach to the MMTPA project where trips are booked through a deep link to mobility providers to enable payment directly to them. This revised architecture is supported by the project's major stakeholders and enables project launch within the current schedule. In the case of CEAV, public health and social distancing guidelines may prohibit re-launching passenger service within the grant timeframe. The CEAV project launched an alternate use case, using the CEAV for food pantry box delivery starting on July 28, 2020, and will continue through the duration of the grant.
    2. **Impact to project performance measurement:** Social distancing guidelines have also led to protocol, recruiting, survey, or other modifications requiring additional IRB review and approval or exemption. For most projects, the content and timing of the survey has been adjusted due to both delays in launching the project amid times of reduced travel and the time necessary by the project teams to revise survey content and questions.

6.2. PROGRAM-LEVEL PERFORMANCE MEASUREMENT

6.2.1. Scope

As shown in **Table 3** above, program-level performance will be measured across four high-level outcomes: environment, mobility, and opportunity.

- **Environment:** Smart Columbus will reduce transportation's negative impacts on the environment through implementing advanced technologies and policies that support a more sustainable transportation system.
- **Mobility:** Enhancing the mobility of Columbus' citizens within the context of Smart Columbus means providing new ways to connect to local destinations and transportation services. To improve mobility, the City considers demographic, economic, geographic, cultural, and technological trends affecting

[15] https://d2rfd3nxvhnf29.cloudfront.net/2020-08/SCC-C-PfMP-Update-v1.pdf

travel demand, personal and commercial mobility across all transportation modes, and the effects of those trends on quality of life and access to economic and educational opportunities.

- **Opportunity:** Providing opportunities for improved access to transportation options for Columbus' citizens is of vital importance to Smart Columbus. This outcome aims to increase access for underserved communities to a wide variety of services through transportation solutions focused on improved access to places of employment, education, healthcare, and other services, as well as increasing the use of the transportation network by bringing available services and users together. Opportunity is created with the implementation of transportation infrastructure in communities that connects people with jobs, housing, and an improved quality of life.

In addition to analyzing project data and other relevant datasets, program-level outcomes will be measured by developing and implementing surveys, questions, focus groups and/or interviews. Projects that are expected to contribute to each program-level outcome are shown in **Table 4**.

Table 4: Program-level Outcomes and Contributing Projects

	Project				
Outcome	CVE	MMTPA	SMH	EPM	CEAV
Environment	X	X		X	
Mobility	X	X		X	X
Opportunity		X	X		X

Source: City of Columbus

6.2.1.1. PARTICIPANTS

Program-level outcomes will be measured, in part, based on feedback from participants in the CVE, MMTPA, SMH, EPM and CEAV projects, as well as employers and agencies supporting these projects. Further details on participants can be found in the corresponding project section below.

6.2.1.2. INFORMED CONSENT

Individuals surveys, questionnaires, focus groups and interviews include consent language explaining the purpose, how results will be used and any privacy protections that are in place.

6.2.2. Dependencies and Constraints

At the program-level, all Smart Columbus activities, including performance measurement, are subject to the guidelines and descriptions in the SMP[16], DPP[17], and PfMP[18], which can be found on the Smart Columbus website.[19]

[16] https://d2rfd3nxvhnf29.cloudfront.net/2020-03/SCC-F-Safety%20Management%20Plan_12-05-2019_FINAL.PDF

[17] https://d2rfd3nxvhnf29.cloudfront.net/2020-09/SCC-D-DataPrivacyPlan-AnnualUpdate-V2.pdf

[18] https://d2rfd3nxvhnf29.cloudfront.net/2020-08/SCC-C-PfMP-Update-v1.pdf

[19] https://smart.columbus.gov/

6.2.3. Human Use Approval

6.2.3.1. IRB PROCESS AND APPLICATION

Program-level protocols and supporting materials are under development or undergoing IRB review. Program-level performance measurement activities are expected to receive IRB exemption because they pose less than minimal risk to participants. The PI for the Environmental outcome is Scott Lowry at HNTB. The PI for the Mobility and Opportunity outcomes is Harvey Miller at OSU. A summary of IRB submittals and determinations by program-level outcome is shown in **Table 5.** This table will be updated as needed as performance measurement progresses.

Table 5: Program-level IRB Submittal and Determination Summary

Outcome	No.	Date	Determination	Subject
Environment	0			[under development]
Mobility	1	3/2/20	Exempt	CEAV Mobility Survey
	2	TBD	In progress	Surveys of SMH users (also in SMH project)
Opportunity	1	9/25/19	Exempt	Pre-deployment survey
	2	4/28/20	Exempt	Pandemic opportunity survey
	3	10/28/20	Exempt	Post pandemic opportunity survey
	4	11/6/20	Exempt	Recontact permission for April 2020 survey

Source: City of Columbus

6.2.3.2. IRB FEEDBACK

Currently, no feedback has been received for the program-level outcomes as protocol and supporting documentation are under development. If feedback is received in the future, this section will be updated to include:

- IRB feedback
- Insights and lessons learned from feedback
- Actions taken as a result of feedback

6.2.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project's IRB for review are provided in **Appendix B** and IRB determinations are provided in **Appendix C**. Documentation currently includes:

- IRB exemption
- Protocol
- Performance measurement surveys

This section, **Appendix B** and **Appendix C** will be updated as additional documents are submitted to and/or approvals or exemptions are received from the IRB.

6.2.3.4. FUTURE NEEDS

As program-level performance measurement progresses, its needs evolve. If IRB feedback is received, the protocol and/or accompanying documents may need to be modified. If such a need arises, the PI will submit amendments to the IRB for review and gain approval or exemption before implementing the changes.

Events that could drive potential future amendments may include:

- Receipt of IRB feedback
- Changes to the performance measurement survey
- Changes in stakeholder policies on privacy, security, access, or other issues

6.3. THE SMART COLUMBUS OPERATING SYSTEM

6.3.1. Project Synopsis and Concept of Operations

6.3.1.1. SCOPE

The Operating System is envisioned as a web-based, dynamic, governed data delivery platform built on a federated architecture. The Operating System is at the heart of the Smart Columbus system. It will ingest and disseminate data while providing access to data services from multiple sources and users, including the planned Smart Columbus technologies, traditional transportation data, and data from other community partners, such as food pantries and medical services. The Operating System will embody open-data, best-of-breed technologies including open-source and commercial off-the-shelf concepts that enable better decision-making and problem solving for all users.

The Operating System will be the source for performance metrics for program monitoring and evaluation. It will serve the needs of public agencies, researchers, and entrepreneurs, and it will help health and human services organizations, and other agencies provide more effective services to their clients. The Operating System will be scalable and demonstrate potential for serving City of Columbus (City) and private sector needs well beyond the life of the SCC award period.

6.3.1.2. RESEARCH CONCEPT DESIGN

The Operating System is the essence of Smart Columbus; it brings to life the innovation. The Operating System is being designed and built to collect data from a variety of inputs, including public, nonprofit, education-based, and private-sector contributors. These inputs may come from other systems, from devices, and from people. All of these are a critical part of building this ecosystem of innovation. Data will be available for analytics and visualization. The Operating System is designed for Big Data, machine learning and artificial intelligence, analytics, and complex data exchange. It will capture the data and provide a means for multitenant access to aggregate, fuse, and consume data.

The Operating System website makes data accessible to people throughout the Columbus community and beyond. It supports users' ability to discover, access, query, visualize, and download data. For new visitors, the Operating System website offers stories on how data are currently being used in real-life scenarios, as well as ways to navigate the datasets available to the public. It also provides links through which users can contribute data, and a "Contact Us" form to provide feedback or suggestions.

6.3.1.3. PARTICIPANTS

Columbus residents and regional agencies will use the Operating System to access and share data. In addition, because the Operating System is the backbone of the Smart Columbus projects, Operating

System users will include project teams, implementation partners, and performance evaluators. Because this project will be open to the general public and it poses less than a minimal risk to participants, it received an IRB exemption.

6.3.1.4. INFORMED CONSENT

To use the Operating System, participants create an account with third-party authentication provided by Auth0 authorization platform. When prompted to create this account, users see consent language that is consistent with the City of Columbus Vendor Services portal consent language, as this portal also uses Auth0 for a similar purpose. The consent language explains how the user's data will be used and any privacy protections that are in place. Before finalizing account creation, users must indicate they give their consent to provide their data and understand what they are consenting to.

6.3.2. Dependencies and Constraints

6.3.2.1. SAFETY MANAGEMENT

The following safety scenarios related to the Operating System are discussed in the SMP Final Report.

- Data re-identification
- Data collection and storage
- Data anonymization
- Authorized users' access to restricted data
- Data breaches
- Restricted data loss and notification of participants
- Data evaluation and data validation
- Data patching and updates
- Security controls and measures
- Security logs
- System recovery

The safety scenarios and the proposed mitigation strategies for the Operating System project are described further in the SMP Final Report. That document is on the Smart Columbus website.[20]

The SMP also discusses the functional safety requirements and safety management for the Operating System project. Safety management involves overseeing all the activities necessary to ensure the project's safe execution. Functional safety requirements include:

- **Equipment procurement –** No equipment will be installed as part of this project.
- **Device installation –** No devices will be installed as part of this project.
- **Quality training –** All system operators, system maintainers, installers/maintainers, and owners of a response plan will receive adequate approved training depending on their point of interface with the system. The training will be documented as it occurs as part of the Smart Columbus Program.

[20] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

The Smart Columbus SMP Final Report, which is on the Smart Columbus website,[21] includes details on the safety operational concept.

6.3.2.2. DATA PROTECTION AND PRIVACY

The Smart Columbus DPP[22] provides program-level oversight and guidance for the privacy and security controls for any data collected as part of the Smart Columbus Program and stored on the Smart Columbus Operating System. The current version of the DPP is on the Smart Columbus website.[23]

The Smart Columbus team will maintain a public website with current information about the Operating System, including educational material on using and sharing data in the portal, all policies and procedures for Operating System operation, any appropriate related public meeting minutes or reports, and information about the datasets on the Operating System, including risk assessments.

The Smart Columbus Operating System collects PII through surveys and potentially through account sign-ups. The Smart Columbus team will apply the security and privacy controls listed in the DPP to all Smart Columbus data throughout the demonstration's entire data life cycle and will require all sub-awardees and contractors to do the same. Each dataset will be reviewed before being fed into the Operating System to ensure that it does not include PII, in compliance with the DPP.

While the DPP provides overarching guidance for every project on privacy and security controls for data, detailed information on privacy and security controls for the Smart Columbus Operating System will be maintained in the IRB protocol and contracts with user organizations.

6.3.2.3. PERFORMANCE MEASUREMENT

Desired outcomes for the Operating System are increased agency efficiency and customer satisfaction.

Agency efficiency performance will be measured by determining how well the project provides:

- Useful data
- A method for improved data-sharing
- Easily discoverable data
- Easily accessible data exchange to providers and consumers of data

Customer satisfaction performance will be measured by determining how well the project:

- Establishes and enhances customer satisfaction with the Operating System
- Provides easily discoverable data

For all the objectives that will provide insight into this project's performance, detailed information is in the Smart Columbus PfMP Final Report on the Smart Columbus website.[24] Specific information in that document includes hypotheses, indicators, design of experiment, data collection, and impact evaluation. Battelle will measure performance, and Advarra will provide IRB review of surveys and the evaluation protocol.

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[21] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[22] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

[23] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

[24] https://d2rfd3nxvhnf29.cloudfront.net/2019-08/Smart%20Columbus%20Performance%20Measurement%20Plan.pdf

6.3.3. Human Use Approval

6.3.3.1. IRB PROCESS AND APPLICATION

This project received an IRB exemption for the demonstration because human subjects are not directly involved. IRB oversight is required, however, for performance measurement. The PI for this project's demonstration activities is Andy Wolpert from the City of Columbus and Katie Robinson from Accenture; the PI for performance measurement is Rama Boyapati, a transportation researcher at Battelle in Columbus. A summary of IRB submittals and determinations for the project is shown in **Table 6.** This table will be updated as needed as the project progresses.

Table 6: OS IRB Submittal and Determination Summary

No.	Date	Determination	Subject
0	5/22/2019	Exempt	Initial submission of IRB protocol
1	5/11/2020	Approved	Consumer survey modification
2	5/14/2020	Approved	Agency survey
3	9/11/20	Exempt	Agency survey modification

Source: City of Columbus

6.3.3.2. IRB FEEDBACK

Currently, no feedback has been received for this project. If feedback is received in the future, this section will be updated to include:

- IRB feedback
- Insights and lessons learned from feedback
- Actions taken as a result of feedback

6.3.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project's IRB for review are provided in **Appendix B** and IRB determinations are provided in **Appendix C**. Documentation currently includes:

- IRB exemption
- Protocol
- Performance measurement surveys

This section, **Appendix B** and **Appendix C** will be updated as additional documents are submitted to and/or approvals or exemptions are received from the IRB.

6.3.3.4. FUTURE NEEDS

As the project progresses, its needs evolve. If IRB feedback is received, the protocol and/or accompanying documents may need to be modified. If such a need arises, the PI will submit amendments to the IRB for review and gain approval or exemption before implementing the changes.

Events that could drive potential future amendments may include:

- Receipt of IRB feedback
- Changes to the performance measurement survey
- Changes in stakeholder policies on privacy, security, access, or other issues

6.4. CONNECTED VEHICLE ENVIRONMENT

6.4.1. Project Synopsis and Concept of Operations

6.4.1.1. SCOPE

The CVE project plays a role in achieving the goal of better connecting Columbus residents to safe, reliable transportation that is accessible to all. Specific CVE objectives that have been developed based on the needs of CVE stakeholders are:

- Improve reliability of adherence to transit vehicle schedules
- Improve emergency response times
- Reduce truck wait time at signalized intersections
- Increase number of times trucks must turn per day
- Improve motorists' obeyance of red lights
- Improve obeyance of speed limits in school zones
- Improve traffic management capability

The CVE project will leverage planned improvements to build a safe, optimal demonstration of the system. The CVE project will meet these objectives by deploying CV technology in vehicles and on the roadside. This technology will allow data to be exchanged among multiple vehicles and between vehicles and infrastructure to improve transportation system safety, mobility, and data collection capability.

Detailed information on the current system is in the CVE ConOps Final Report on the Smart Columbus website.[25]

6.4.1.2. RESEARCH CONCEPT DESIGN

The CVE project addresses needs in the enabling technologies focus area. The CVE project will integrate smart traveler applications, AVs, CVs, and smart sensors into its transportation network by focusing on deploying CV infrastructure and applications as follows:

- **CV infrastructure** – The CVE project will focus on building out the physical and logical CV infrastructure, which will consist of CV hardware and software (e.g., roadside units (RSUs), onboard units (OBUs), front and backhaul communications, and equipment interfaces). The CVE project will generate the transportation-related data the Smart Columbus applications will use.
- **CV applications and data –** The CVE project scope includes deploying CV-specific applications that will leverage the data generated by the infrastructure to deliver real-time safety and mobility services. Data will be collected, related, stored, and made available for use in other Smart Columbus project applications.

[25] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Connected%20Vehicle%20Environment%20Concept%20of%20Operations.pdf

The CVE project is expected to enhance safety and mobility for vehicle operators and improve pedestrian safety in school zones by deploying CV infrastructure on roadsides and CV equipment in vehicles. The CVE project will also provide high-quality data for traffic management and safety.

In-vehicle devices will be deployed to target populations near frequently used infrastructure deployment corridors. The CVE project will connect up to 1,100 vehicles and 90 intersections across the region. The project team plans to install safety applications for multiple vehicle types including transit buses, first responder vehicles, City and partner fleet vehicles, and private vehicles. Deployments aim to ensure that the Central Ohio Transit Agency (COTA) bus rapid transit (BRT) fleet can prioritize traffic signals as needed to increase efficiency, and that emergency vehicles can pre-empt traffic signals as needed to increase safety.

Further details on the proposed solution are discussed in the CVE ConOps Final Report on the Smart Columbus website.[26]

6.4.1.3. PARTICIPANTS

The CVE project includes multiple user classes, each made up of one or more stakeholder groups that show common responsibilities, skill levels, work activities, and modes of interaction with the system. A given group of stakeholders can be involved in one or more user classes. Prospective private participants will primarily be residents or employees of the University District or the Linden, Northland, or Easton neighborhood who frequently drive in these four areas.

Participants are grouped into the following user classes: light-duty vehicle operators, emergency vehicle operators, heavy-duty vehicle operators, traffic managers, transit vehicle operators, and transit managers. Stakeholder groups include private vehicle owners in the Linden area; City of Columbus light duty vehicle operators; logistics companies; COTA; City of Columbus fire, emergency medical services (EMS), and police departments; City of Columbus Department of Public Service traffic managers; and the City of Columbus Department of Technology.

While the IRB application is under development (it is being modified in response to IRB feedback to the initial application), the CVE project poses no greater than minimal risk to participants and is requesting expedited IRB review.

6.4.1.4. INFORMED CONSENT

ICDs are under development for participating private drivers, COTA, Franklin County and City of Columbus fleets, and heavy-duty vehicle operators and will be submitted for IRB review. Fleet and heavy-duty vehicle drivers will not be required to sign individual ICDs because their consent is covered by their contract with the agency. In these cases, verbal consent will be obtained. The ICDs will include the study's purpose and activities as well as information relevant to participants including potential risks and benefits, injury and legal rights, the voluntary nature of participation, and contact information.

6.4.2. Dependencies and Constraints

6.4.2.1. SAFETY MANAGEMENT

The SMP Final Report states that the vehicle operator must always be in full control of the vehicle and must assess any situation that arises and react appropriately. This statement will also be included in the ICD.

The following safety scenarios related to the CVE project are discussed in the SMP Final Report:

[26] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Connected%20Vehicle%20Environment%20Concept%20of%20Operations.pdf

- De-identification of PII
- Unauthorized access to CVE system or OBU
- Equipment malfunction and improper installation
- Communication failures
- Participant misconception, distraction, and confusion
- Vehicle position errors, such as lane assignment
- Weather-related issues, such as power loss

Further information on the safety scenarios and mitigation strategies identified for the CVE project is in the SMP Final Report.

The SMP discusses functional safety requirements and safety management for the CVE project. Safety management involves overseeing all the activities necessary to ensure the safe execution of the project.

Functional safety requirements include:

- **Equipment procurement –** OBUs will be installed in transit, private, emergency, fleet, and freight vehicles. In addition, a human machine interface (HMI) will also be deployed in private vehicles that consists of a head-up display (HUD).
- **Device installation –** CVE RSUs and OBUs will be installed by trained and qualified manufacturer installers. The OBU installations will require the most planning, as OBUs will need to be retrofitted to a variety of privately-owned vehicles and COTA buses. The OBU manufacturer will submit an installation plan that will meet the CVE user needs and system requirements. Installers will need to follow the installation safety requirements. Lessons learned in the USDOT CV pilot programs will be applied as appropriate to the CVE installation process.
- **Fail-safe system mode –** The CVE system will revert to a fail-safe mode if it fails to meet essential operational capabilities as defined in each project's system requirements documentation.
- **Quality training –** All system operators, system maintainers, installers, maintainers, and owners of a response plan will receive adequate approved training depending on their point of interface with the system. This training will be documented as it occurs, as part of the Smart Columbus Program.

Further details on equipment procurement and device installation are in the Demonstration Site Map and Installation Schedule Final Report on the Smart Columbus website.[27] Further details on the safety operational concept are in the Smart Columbus SMP Final Report on the Smart Columbus website.[28]

6.4.2.2. DATA PROTECTION AND PRIVACY

The Smart Columbus DPP[29] provides program-level oversight and guidance for the privacy and security controls for any data that are collected as part of the Smart Columbus Program and stored on the Smart Columbus Operating System.

For the CVE project, prospective participants will receive a clear presentation covering the privacy risks associated with joining the project. Only data necessary to get the participant into the informed consent process will be collected before the informed consent is executed, in accordance with procedures that have

[27] https://d2rfd3nxvhnf29.cloudfront.net/2020-01/SCC-B-DSP-IS-FINAL-20200124.pdf

[28] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[29] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

received advance approval from the demonstration's IRB. The informed consent process followed will depend on:

- Data that will be collected
- The intended use and recipients of the data

All informed consent processes will include:

- Clear notice of any privacy risks of participating and of opportunities to opt out
- Information on the general controls used to mitigate risks
- An explanation of all rights participants will hold over their own data

While the DPP provides overarching guidance for every project on privacy and security controls for data, detailed information on privacy and security controls for the CVE project will be maintained in the IRB protocol and contracts with participating organizations, such as equipment providers and installers, as needed.

6.4.2.3. PERFORMANCE MEASUREMENT

Desired outcomes for the CVE project are increased safety and mobility.

Safety-related performance will be measured by determining how well the project provides:

- A reduction of emergency response times in the CVE corridor
- An increase in drivers' awareness of signal status
- An increase in drivers' awareness of speed limits in school zones

Mobility-related performance will be measured by determining how well the project:

- Demonstrates dedicated short-range communications (DSRC) technology for transit signal priority (TSP) application
- Reduces truck wait (delay) time at signalized intersections

Detailed information is available on hypotheses, indicators, the design of the experiment, the data collection plan, and the impact evaluation plan for all the objectives listed above. These details are discussed in the Smart Columbus PfMP Final Report on the Smart Columbus website.[30] Performance measurement will be carried out by WSP and undergo Advarra IRB review for surveys and evaluation protocol.

6.4.3. Human Use Approval

6.4.3.1. IRB PROCESS AND APPLICATION

IRB oversight is required for the CVE project because it involves human subjects during both the demonstration and performance measurement. The PI for this project's demonstration activities is Alyssa Chenault from the City of Columbus. The PI for performance measurement is Chris Toth, from WSP. Dr. Toth will oversee both the demonstration and the performance measurement for the project. A summary of IRB submittals and determinations for the CVE project is shown in **Table 7**, which will be updated as needed as the project progresses.

[30] *https://d2rfd3nxvhnf29.cloudfront.net/2019-08/Smart%20Columbus%20Performance%20Measurement%20Plan.pdf*

Table 7: CVE IRB Submittal and Determination Summary

No.	Date	Determination	Subject
0	6/24/2020	Approved	Revised protocol, informed consent forms, and recruitment and training materials
1	6/26/2020	Approved	Emailed communication materials
2	7/21/2020	Approved	Revised protocol and informed consent forms
3	8/5/2020	Approved	Recruiting materials, including: CVE one pager Email campaign copy including warm lead email Text reminders copy Finalized wallet card Finalized mailer Sanitation card
4	8/10/20	Approved	Training Video Script and Informed Consent Video Scripts
5	9/9/20	Approved	Recruiting materials, including: Billboard, "Join the Study" POS Wallet Card Poster, "DRIVE CONNECTED" Radio Commercial Scripts
6	11/3/20	Approved	Updated protocol and consent forms
7	11/4/20	Approved	PfMP surveys for LDV and HDV

Source: City of Columbus

6.4.3.2. IRB FEEDBACK

IRB feedback was received in response to the initial IRB document submission. The feedback received is shown in **Table 8**. This table will be updated as needed.

Table 8: CVE IRB Feedback Summary

Category	IRB Feedback	Current Status
Process	All protocol components must be included prior to review.	In progress.
Amendment	Add “Key Information” section to ICD.	Modified ICD.
Clarification	Clarify equipment value and removal costs to participant, if they opt to keep equipment after the demonstration period.	Drafting response; will include revised ICD in future IRB submission.
Clarification	Elaborate on PI’s research experience.	Provided qualifications over email.
Clarification	Clarify setting and plan for IC discussion at automotive shops.	Modified ICD.

Category	IRB Feedback	Current Status
Documentation	Include device privacy policy and/or Terms of Use, if applicable.	No device privacy policy; separated Terms of Use from ICD.
Clarification/ Documentation	Are different IC forms needed for different target participant groups? If so, provide forms or explain why not needed.	Added ICD form for COTA/City fleet.
Clarification	Provide detailed description of OBU (including mounting location, message display, and warning delivery).	Added to protocol.
Clarifications	Eleven questions were asked on a variety of topics including: contents of training materials and software agreements; collection and use of PII, the use of an ICD for fleet drivers, the need for a National Institute of Health Certificate of Confidentiality, and the type of signature required on the ICD.	Protocol was revised to reflect physical signature on the ICDs. Responses were provided for other questions.
Amendment	Added informed consent video, driver training video, participant packet, participant wallet card, and the incentive mailer to submission.	Materials reviewed by the board on 3/6/20.
Clarification	Clarify the process and cost for device removal from both private and fleet vehicles.	Provided explanation and response over email.
Clarification	Clarification on ICDs for fleet and heavy-duty vehicles: how is device removal handled for fleet vehicles and will a separate ICD be submitted for heavy duty vehicles?	Fleet ICD updated and resubmitted. Heavy duty vehicle ICD drafted and submitted.
Clarification	Please ensure ICD updates (see previous clarification) were made to the correct version.	Versions reconciled and resubmitted.

Source: City of Columbus

6.4.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project's IRB for review are provided in **Appendix B** and IRB determinations are provided in **Appendix C**. Documentation currently includes:

- Initial IRB submission
- Amended IRB submissions:
    - Revised protocols (including recruiting plan, clarifications listed in **Table 8**)
    - Prequalification survey
    - Private ICD
    - City of Columbus ICD
    - Fleet (Franklin County, COTA, Heavy Duty Vehicle) ICD
- Informed consent video and scripts:

    - Private
    - City of Columbus
    - Fleet (Franklin County, COTA supervisors, and heavy-duty vehicles)
- Participant packet
- Participant wallet card
- Participant incentive mailer
- Recruiting materials, including:
    - CVE one pager
    - Email campaign copy including warm lead email
    - Text reminders copy
    - Finalized wallet card
    - Finalized mailer
    - Sanitation card
- Training video and scripts:
    - Private
    - City of Columbus
    - Fleet (Franklin County, COTA supervisors, and heavy-duty vehicle)
- Equipment training video and scripts:
    - Private
    - City of Columbus
    - Fleet (Franklin County, COTA supervisors, and heavy-duty vehicle)
- Performance measurement surveys:
    - LDV
    - HDV

This section, **Appendix B** and **Appendix C** will be updated as additional documents are submitted to and/or approvals or exemptions are received from the IRB.

6.4.3.4. FUTURE NEEDS

As the project progresses, project needs evolve. If feedback is received from the IRB, the research protocol and/or accompanying documents may need to be modified or additional documents must be submitted for review. As such needs arise, the PI will submit additional materials and/or amendments to the IRB for review and gain approval or exemption prior to implementing the proposed modifications.

Events that could drive the need for potential future amendments may include:

- Performance measurement protocol or materials
- Receipt of IRB feedback
- Development of surveys

- **Participation rates –** The need for changes to participant eligibility criteria and recruiting methods or materials to reach targets
- **Policy –** Changes to stakeholder policies, including policies of equipment installers and technology providers
- **Technology –** Changes to equipment that impact the study protocol

6.5. MULTIMODAL TRIP PLANNING APPLICATION

6.5.1. Project Synopsis and Concept of Operations

6.5.1.1. SCOPE

The MMTPA project addresses a challenge Columbus residents and visitors currently face because there is no system to seamlessly plan or pay for a trip involving multiple transportation options. Motivation for the MMTPA project focused on the lack of access to coordinated multimodal options, the inability to compare prices across modes, and the need for payment for multiple modes of a single trip. The MMTPA will provide this functionality and improve on the existing functionality.

The main goals for the MMTPA project for achieving positive social outcomes are:

1. Enhanced mobility
2. Enhanced access to opportunities and services
3. Increased customer satisfaction

Detailed information on the current system is in the MMTPA/CPS ConOps Final Report. The document is on the Smart Columbus website.[31] Please note that when published in 2018, the MMTPA project included the Common Payment System (CPS). As described in Section 6.1.2, the concept of the project has been revised due to COVID-19; the PfMP[32] and other systems engineering documents will be updated to describe the revised approach to trip payment.

6.5.1.2. RESEARCH CONCEPT DESIGN

MMPTA is a complete multimodal trip planning and payment solution that provides a single source for multimodal trip planning and payment for all travelers in the Columbus region. Travelers can download and install the MMTPA from public app stores and begin using it immediately to plan trips.

Mobility providers will integrate with the Operating System through application programming interfaces (APIs) in order to be available to travelers in the MMTPA. Providers will be paid for services immediately through a deep link to MMTPA.

Further details on the proposed solution are in the MMTPA/CPS ConOps Final Report on Smart Columbus website.[33] Please note that when published in 2018, the MMTPA project included the Common Payment System (CPS). As described in Section 6.1.2, the concept of the project has been revised due to COVID-19;

[31] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Multi-Modal%20Trip%20Planning%20System%20Concept%20of%20Operations.pdf

[32] https://d2rfd3nxvhnf29.cloudfront.net/2020-08/SCC-C-PfMP-Update-v1.pdf

[33] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Multi-Modal%20Trip%20Planning%20System%20Concept%20of%20Operations.pdf

the PfMP and other systems engineering documents will be updated to describe the revised approach to trip payment.

6.5.1.3. PARTICIPANTS

The MMTPA application is intended for public use to plan and pay for multimodal trips. Other primary project stakeholders include COTA, the Mid-Ohio Regional Planning Commission, the OSU, the City of Columbus, and other transportation providers. Because this project is open to the public and poses less than a minimal risk to participants, it received an IRB exemption.

6.5.1.4. INFORMED CONSENT

The MMTPA project received an exemption from the IRB before the MMTPA component was launched; therefore, it currently does not require a signed consent from application users. A second IRB protocol was made before the production MMTPA system was launched in fall 2020, in November 2020. It was also deemed exempt.

6.5.2. Dependencies and Constraints

6.5.2.1. SAFETY MANAGEMENT

The following safety scenarios related to the MMTPA project are discussed in the SMP Final Report:

- Traffic and emergencies
- Unavailability of recommended modes
- Application unavailability due to maintenance or failure
- De-identification and PII exposure

Further information on the safety scenarios and proposed mitigation strategies identified for the MMTPA project is in the SMP Final Report.

The SMP discusses functional safety requirements and safety management for the project. Safety management involves overseeing all the activities necessary to ensure safe execution of the project. Functional safety requirements include:

- **Equipment procurement –** No equipment will be installed as part of the MMTPA project. An application will be deployed to help travelers with comprehensive trip planning.
- **Device installation –** No devices will be installed as part of this project.
- **Fail-safe system mode –** MMTPA will have a fail-safe system mode. The application will revert to a fail-safe mode if it fails to meet essential operational capabilities as defined in the project's system requirements documentation.
- **Quality training –** All system operators, system maintainers, installers, and owners of a response plan will receive adequate approved training depending on their point of interface with the system. This training will be documented as it occurs, as part of the Smart Columbus Program.

Further details on the safety Operational Concept are in the Smart Columbus SMP Final Report on the Smart Columbus website.[34]

[34] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

6.5.2.2. DATA PROTECTION AND PRIVACY

The Smart Columbus DPP[35] provides program-level oversight and guidance for the privacy and security controls for any data collected as part of the Smart Columbus Program and stored on the Smart Columbus Operating System.

Travelers may wish to create an account within the MMTPA to store preferences that could simplify planning subsequent multimodal trips. Account information may include username; email address; addresses for work, school, and home; addresses of common destinations; and whether an accessible vehicle will be needed. Travelers may also allow the MMTPA to know their current location to simplify entering the origin when planning a multimodal trip. Traveler account information will not be distributed outside of the MMTPA. The MMTPA will use industry-standard security mechanisms to protect the traveler's account information and privacy. Account information will not be allowed to be accessed or used without the traveler's authorization.

While the DPP provides overarching guidance for every project on privacy and security controls for data, detailed information on privacy and security controls for the MMTPA project will be maintained in the IRB protocol and contracts with participating organizations, such as integrated transportation providers and payment processors, as needed.

6.5.2.3. PERFORMANCE MEASUREMENT

Desired outcomes for the MMTPA project are increased mobility, opportunity, and customer satisfaction.

Mobility-related performance will be measured by determining how well the project:

- Provides a single point of access to multimodal trip information to plan, book, and pay for multimodal trips

Opportunity-related performance will be measured by determining how well the project:

- Facilitates access to jobs and services

Customer-satisfaction-related performance will be measured by determining how well the project:

- Improves customer satisfaction

Detailed information on the hypotheses, indicators, design of the experiment, data collection, and impact evaluation for all the objectives is provided in the Smart Columbus PfMP Final Report on the Smart Columbus website.[36] Performance measurement will be carried out by OSU and undergo OSU IRB review for surveys and the evaluation protocol.

6.5.3. Human Use Approval

6.5.3.1. IRB PROCESS AND APPLICATION

The MMTPA project received an exemption from the IRB for the demonstration because human subjects are not directly involved. A second submittal for the demonstration may be made when the final application launches in fall 2020, although an exemption is likely then, as well. Please note, the schedule was delayed due to the impact of COVID-19 on the project concept and launch date, as detailed in Section 6.1.2. IRB oversight is required, however, for performance measurement. The PI for this project's demonstration

[35] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

[36] https://d2rfd3nxvhnf29.cloudfront.net/2019-08/Smart%20Columbus%20Performance%20Measurement%20Plan.pdf

activities is Andrew Wolpert, from the City of Columbus. The PI for performance measurement is Rabi Mishalani, from OSU.

A summary of IRB submittals and determinations for the project is shown in **Table 9.** Initial submittals (numbers 0-2) and exemptions are for the MMTPA project as part of the beta launch of the trip planning functionality. Subsequent submittals (3-4) are for performance measurement..

Table 9: MMTPA IRB Submittal and Determination Summary

No.	Date	Determination	Subject
0	2/20/2019	Exempt	Protocol – MMTPA Phase 1, usability survey
1	4/30/2019	Exempt	Protocol – MMTPA Phase 2, usability survey, user testing
2	7/8/2019	Exempt	Protocol – MMTPA Phase 3, usability survey
3	7/10/20	Exempt	PfM Survey - pre-marketing revision
4	11/6/20	Exempt	Protocol – MMTPA in-app survey

Source: City of Columbus

6.5.3.2. IRB FEEDBACK

Currently, no feedback has been received for the MMTPA project from the IRB and the project received an exemption. If feedback is received in the future, this section will be updated to include a summary of:

- IRB feedback
- Insights and lessons learned from feedback
- Actions taken as a result of feedback

6.5.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project's IRB for review are provided in **Appendix B** and IRB determinations are provided in **Appendix C**. Documentation currently includes:

- MMTPA research protocol for Phases 1, 2, and 3
- MMTPA beta tester surveys for Phases 1, 2, and 3
- MMTPA exemptions
- MMTPA performance measurement pre-marketing launch survey
- Updated MMTPA protocol
- MMTPA in-app survey

This section, **Appendix B** and **Appendix C** will be updated as additional documents are submitted to and/or approvals or exemptions are received from the IRB.

6.5.3.4. FUTURE NEEDS

As the project progresses, project needs evolve, or feedback is received from the IRB, the research protocol and/or accompanying documents may need to be modified and additional materials submitted for review. As

such needs arise, the PI for either the demonstration or the performance measurement (for the MMTPA, these are two different individuals) will submit amendments to the IRB for review and gain approval or exemption prior to implementing the proposed changes.

Events that could drive potential future amendments may include:

- Receipt of IRB feedback
- Changes to survey questions
- Changes to stakeholder policies on issues such as privacy, security, or access

6.6. MOBILITY ASSISTANCE FOR PEOPLE WITH COGNITIVE DISABILITIES

6.6.1. Project Synopsis and Concept of Operations

6.6.1.1. SCOPE

The goals of the Americans with Disabilities Act (ADA) are to promote the independence, integration, and self-sufficiency of people with disabilities. Consistent with these goals and ADA regulations, COTA offers origin-to-destination shared ride (paratransit) services, called Mainstream, for eligible riders who are unable to ride fixed-route bus service because of their disabilities.

The MAPCD project seeks to allow people with cognitive disabilities to safely transition from using paratransit services to using fixed-route bus service, as well as to attract new users with cognitive disabilities who are not already using bus or paratransit services. To do these things, the project provides a solution that offers accurate, turn-by-turn navigation, along with other support features so that users with cognitive disabilities can safely and accurately complete a trip using fixed-route bus service.

More detailed information about the project background and scope is in the MAPCD Trade Study Final Report[37] on the Smart Columbus website.

6.6.1.2. RESEARCH CONCEPT DESIGN

The project team decided on a "caregiver response model" to help users. In this model, a relative or caregiver of the traveler monitors the trip and intervenes as necessary.

WayFinder “Plus” was the preferred solution for Smart Columbus since AbleLink was able to successfully integrate the functionality to actively track an individual on a route. The mobile application features a highly accurate, turn-by-turn navigator designed to be sufficiently intuitive such that people with cognitive disabilities and visual impairments can use it to travel independently.

This project provides an opportunity for users to empower themselves, gaining mobility independence instead of relying on caregivers or the COTA paratransit system for transportation.

Further information on the proposed solution and options considered is provided in the MAPCD Trade Study Final Report[38] on the Smart Columbus website.

[37] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Mobility%20Assistance%20for%20People%20with%20Cognitive%20Disabilities%20Trade%20Study.pdf

[38] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Mobility%20Assistance%20for%20People%20with%20Cognitive%20Disabilities%20Trade%20Study.pdf

6.6.1.3. PARTICIPANTS

MAPCD stakeholders include travelers from a vulnerable class (e.g., individuals with disabilities and older adults), travel partners (e.g., caregivers), and travel trainers. The target population was selected because lack of efficient transportation for individuals with cognitive disabilities creates social exclusion and poses a significant barrier to maintaining employment or accessing services and opportunities. Because participants are from a protected class, full IRB review is required for this project.

6.6.1.4. INFORMED CONSENT

ICDs were developed for study participants or their legally authorized representatives, as well as for traveler caregivers. Signed written consent is required for all participants. ICDs include information about study purpose and tasks, potential risks and benefits, the voluntary nature of participation, photo and video consent and authorization, duration, confidentiality, incentives, participant rights, and contact information.

6.6.2. Dependencies and Constraints

6.6.2.1. SAFETY MANAGEMENT

The following safety scenarios related to the MAPCD project are discussed in the SMP Final Report:

- Inaccurate or incomplete traveler instructions
- Out of date maps or traffic information
- Communication failures
- Traveler distraction or confusion
- Application unavailability due to maintenance or failure
- De-identification and exposed PII
- Non-ADA compliant route recommendations

Information on the safety scenarios and proposed mitigation strategies for the MAPCD project is in the SMP Final Report.

The SMP also discusses functional safety requirements and safety management for the project. Safety management involves overseeing all the activities necessary to ensure the safe execution of the project.

Functional safety requirements include:

- **Equipment procurement –** WayFinder application-equipped Smartphones were purchased from AbleLink and distributed to participants to enable WayFinder application deployment, as specified in project protocol approved by IRB.
- **Device installation –** No devices will be installed as part of this project.
- **Fail-safe system mode –** The MAPCD system will revert to a fail-safe mode if it fails to meet essential operational capabilities as defined in the project's system requirements documentation.
- **Quality training –** All system operators, system maintainers, installers, maintainers, and owners of a response plan will receive adequate approved training depending on their point of interface with the system. This training will be documented as it occurs as part of the Smart Columbus Program.

Further details on the safety Operational Concept are in the Smart Columbus SMP Final Report on the Smart Columbus website.[39]

6.6.2.2. DATA PROTECTION AND PRIVACY

The Smart Columbus DPP[40] provides program-level oversight and guidance for the privacy and security controls for any data collected as part of the Smart Columbus Program and stored on the Smart Columbus Operating System.

As part of the MAPCD project, travelers willing to use the MAPCD application may have to provide information that could include username, email address, home address, addresses of common destinations, caregiver information, and an indication of preferred methods for receiving notifications. Travelers will also be able to allow the MAPCD application to know their current location, so the program can help when travelers are lost or need assistance. Requirements for storing PII in the MAPCD will be addressed in the DPP and vendor contract. Traveler account information will not be distributed outside of the MAPCD. The MAPCD will use industry-standard security mechanisms to protect users' account information and privacy. Account information will not be allowed to be accessed or used without the traveler's or their authorized representative's authorization.

While the DPP provides overarching guidance for every project regarding privacy and security controls for data, detailed information on privacy and security controls for MAPCD will be maintained in the IRB protocol and contracts with participating organizations, as needed.

6.6.2.3. PERFORMANCE MEASUREMENT

Desired outcomes for the MAPCD project are increased mobility, opportunity, and agency efficiency.

Mobility-related performance will be measured by determining how well the project:

- Improves access to and use of COTA fixed-route bus service for MAPCD participants

Opportunity-related performance will be measured by determining how well the project:

- Improves independence of MAPCD participants by using fixed route bus service

Agency efficiency-related performance will be measured by determining how well the project:

- Reduces COTA expenditures

Detailed information on the hypotheses, indicators, the design of the experiment, the data collection, and the impact evaluation for all the objectives is provided in the Smart Columbus PfMP Final Report, which is on the Smart Columbus website.[41] OSU will measure performance, and the OSU IRB will review surveys and evaluation protocols.

6.6.3. Human Use Approval

6.6.3.1. IRB PROCESS AND APPLICATION

IRB oversight is required because the MAPCD project involves human subjects during both the demonstration and performance measurement. The PI for this project is Carmen DiGiovine from OSU, who

[39] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[40] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

[41] https://d2rfd3nxvhnf29.cloudfront.net/2019-08/Smart%20Columbus%20Performance%20Measurement%20Plan.pdf

will oversee both the demonstration itself and the performance measurement for the project. A summary of IRB submittals and determinations for the project is shown in **Table 10.**

Table 10: MAPCD IRB Submittal and Determination Summary

No.	Date	Determination	Subject
0	1/24/2019	Approved	2018B0494 - Approval of Requested Personnel Change for Study - 2019-01-24.pdf
01	2/18/2019	Approved	2018B0494 - Approval of Requested Personnel Change for Study - 2019-02-18.pdf
02	3/21/2019	Approved	2018B0494 - Amendment #2 Approved - 2019-03-21.pdf
03	4/26/2019	Approved	2018B0494 - Approval of Requested Personnel Change for Study - 2019-04-26.pdf
04	5/14/2019	Approved	2018B0494 - Amendment #4 Approved - 2019-05-14.pdf
05	5/20/2019	Approved	2018B0494 - Approval of Requested Personnel Change for Study - 2019-05-30.pdf
06	5/22/2019	Approved	2018B0494 - Approval of Requested Personnel Change for Study - 2019-05-22.pdf
07	7/11/2019	Approved	2018B0494 - Approval of Requested Personnel Change for Study - 2019-07-11.pdf
08	7/22/2019	Approved	2018B0494 - Approval of Requested Personnel Change for Study - 2019-07-22.pdf
09	8/9/2019	Approved	2018B0494 - Approval of Requested Personnel Change for Study - 2019-08-09.pdf
10	9/4/2019	Approved	2018B0494 - Approval of Request Personnel Change for Study - 2019-09-04.pdf
11	12/23/2019	Approved	2018B0494 - Amendment #12 Approved - 2019-12-23.pdf
12	1/17/2019	Approved	2018B0494 - Initial Submission Approved - 2019-01.pdf

Source: City of Columbus

6.6.3.2. IRB FEEDBACK

IRB feedback was received in response to the IRB document submission. The feedback received is shown in **Table 11**.

Table 11: MAPCD IRB Feedback Summary

Category	IRB Feedback	Current Status
Protocol	Rename/reorganize study phases, clarify WayFinder objective and description, increase number of participants, change incentive amount, revise consent to reflect changes	Completed
Data Collection	Provide details on data collected and potential confidentiality breaches related to assent	Completed

Category	IRB Feedback	Current Status
Protocol	Revise protocol for consistency with requested revisions	Completed
Protocol	Please submit tracked changes and clean copy	Completed

Source: City of Columbus

This table will be updated as needed. If additional feedback is received, this section will be updated to include:

- IRB feedback
- Insights and lessons learned from feedback
- Actions taken as a result of feedback

6.6.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project's IRB for review are provided in **Appendix B** and IRB determinations are provided in **Appendix C**. Documentation currently includes:

- Initial IRB submission
- Amendments
- Approvals
- Grant application
- Research protocol
- Data collection forms and/or other instruments
- Surveys and/or questionnaires
- Recruitment materials
- Consent process and documents

This section, **Appendix B** and **Appendix C** will be updated as additional documents are submitted to and/or approvals or exemptions are received from the IRB.

6.6.3.4. FUTURE NEEDS

The MAPCD project went live in April 2019 and concluded in May 2020. As such, it is unlikely that additional IRB submissions will be required. However, if additional feedback is sought as part of the performance measurement evaluation, the research protocol and/or accompanying documents may need to be reviewed. If such a need arises, the PI will submit amendments to the IRB for review and gain approval or exemption prior to implementing the proposed changes.

Events that could drive potential future amendments may include:

- **Technology –** Changes to the mobile application that affect issues such as privacy or security
- **Performance Measurement Methodology –** Changes to the indicators used for performance measurement that may result in additional interview or survey requirements

6.7. PRENATAL TRIP ASSISTANCE

6.7.1. Project Synopsis and Concept of Operations

6.7.1.1. SCOPE

Motivation for the PTA project is focused on providing more reliable non-emergency medical transportation (NEMT) services for prenatal travelers and filling gaps in the current system such as delays in pickup, lack of multiple reminders, inability to schedule from a smartphone or computer, and integration with a trip optimization system. The PTA project will solve these problems and improve the current system's functionality.

Further details on the current system, as well as on the background and scope of the project, are in the PTA ConOps Final Report on the Smart Columbus website.[42]

6.7.1.2. RESEARCH CONCEPT DESIGN

The proposed PTA system is a technologically advanced and user-friendly solution for prenatal Medicaid members to schedule NEMT trips. Prenatal travelers can download and install the PTA application from public app stores and begin using it immediately to plan trips. They will also be able to visit a website or contact a call center to schedule their NEMT trip. Managed care organizations (MCOs) will integrate the solution, so all payment information will be handled between the MCOs and the technology vendor/transportation broker.

More information on the system proposed for the PTA project is in the PTA ConOps Final Report on the Smart Columbus website.[43]

6.7.1.3. PARTICIPANTS

As outlined in the IRB-approved project protocol, participants will be pregnant women aged 18+ years who are at less than 32 weeks of gestation and enrolled in a participating Medicaid managed care plan. They must need NEMT and live in Franklin County at the time of enrollment, with no plans to move out of Franklin County prior to delivery. Because participants are from a protected class, full IRB review is required for this project. Recruiting on the PTA project concluded in June 2020.

6.7.1.4. INFORMED CONSENT

Signed written consent was required for all participants. The ICD includes information about study purpose, number of participants, what is asked of participants, study duration, potential risks and benefits, the voluntary nature of participation, photo and video consent and authorization, duration, confidentiality, incentives, participant rights, what happens in case of injury, de-identification and data sharing information, Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorization to use and disclose information, and contact information.

[42] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Prenatal%20Trip%20Assistance%20Concept%20of%20Operations.pdf

[43] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Prenatal%20Trip%20Assistance%20Concept%20of%20Operations.pdf

6.7.2. Dependencies and Constraints

6.7.2.1. SAFETY MANAGEMENT

The following safety scenarios related to the PTA project are discussed in the SMP Final Report:

- Trip delay or cancellation
- Communication limitations
- Application unavailability due to maintenance or failure
- De-identification and exposed PII
- Unsafe driver behavior
- Lack of or improperly installed car seats

Further information on the safety scenarios and proposed mitigation strategies for the PTA project is in the SMP Final Report.

The SMP also discusses functional safety requirements and safety management. Safety management involves overseeing all the activities necessary to ensure safe execution of the project. Functional safety requirements include:

- **Equipment procurement –** No equipment will be installed as part of this project. An application will be deployed to help prenatal travelers with scheduling their doctor visits.
- **Device installation –** No devices will be installed as part of this project.
- **Fail-safe system mode –** The PTA system will revert to a fail-safe mode if it fails to meet essential operational capabilities as defined in the project's system requirements documentation.
- **Quality training –** All system operators, system maintainers, installers, and owners of a response plan will receive adequate approved training depending on their point of interface with the system. This training will be documented as it occurs, as part of the Smart Columbus Program.

Further details on the safety Operational Concept are in the Smart Columbus SMP Final Report on the Smart Columbus website. [44]

6.7.2.2. DATA PROTECTION AND PRIVACY

The Smart Columbus DPP[45] provides program-level oversight and guidance for the privacy and security controls for any data collected as part of the Smart Columbus Program and stored on the Smart Columbus Operating System.

Prenatal travelers who use the PTA application may have to provide information that could include username; email address; addresses for work, school, and home; and addresses of common destinations, as well as an indication of their preferred method for receiving notifications. The prenatal traveler will also be able to allow the PTA application to know her current location, so it is simpler to enter her origin when she schedules an on-demand trip. Requirements for storing PII in the PTA application will be addressed in the DPP and vendor contract. End-user account information will not be distributed outside of the PTA application. The PTA application will use industry-standard security mechanisms to protect the account

[44] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[45] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

information and the end user's privacy. Account information will not be allowed to be accessed or used without the authorization of the prenatal traveler.

Some medical information will also be collected to screen participants, facilitate project activities, and evaluate project impacts. Collection and use of medical data are governed by the DPP and agreements between medical entities, as applicable. One such instance of medical information collection and sharing is the referral form OSU receives from the call center, Physician's Care Connection (PCC). Information shared between these two medical entities is based on their Business Associate Agreement, which is a contractual data sharing agreement.

While the DPP provides overarching guidance for every project on privacy and security controls for data, detailed information on privacy and security controls for the PTA project will be maintained in the IRB protocol and contracts with participating organizations, such as MCOs, as needed.

6.7.2.3. PERFORMANCE MEASUREMENT

Desirable outcomes for the PTA project are increased mobility, opportunity, and customer satisfaction.

Mobility-related performance will be measured by determining how well the project:

- Improves pregnant women's access to NEMT

Opportunity-related performance will be measured by determining how well the project:

- Increases use of NEMT benefits

Customer-satisfaction-related performance will be measured by determining how well the project:

- Improves customer satisfaction

Detailed information on the hypotheses, indicators, design of the experiment, data collection, and impact evaluation for all the objectives is provided in the Smart Columbus PfMP Final Report on the Smart Columbus website.[46] OSU will measure performance, and the OSU IRB will review surveys and evaluation protocols.

6.7.3. Human Use Approval

6.7.3.1. IRB PROCESS & APPLICATION

Because the PTA project involves human subjects from a protected class, IRB oversight for human use is required for both the demonstration and performance measurement. The PIs for this project are Drs. Courtney Lynch and Erinn Hade from OSU, who oversee both the demonstration and performance measurement for the project. A summary of IRB submittals and determinations for the project is shown in **Table 12**. This table will be updated as the project progresses, as needed.

Table 12: PTA IRB Submittal and Determination Summary

No.	Date	Determination	Subject
0	4/18/2019		Initial submission of IRB document and participant recruitment plan

[46] *https://d2rfd3nxvhnf29.cloudfront.net/2019-08/Smart%20Columbus%20Performance%20Measurement%20Plan.pdf*

No.	Date	Determination	Subject
01	5/20/2019	Approved	Amendment to included Health Insurance Portability and Accountability Act of 1996 (HIPAA) language and minor changes to document
02	5/28/2019	Approved	Amendments to typeset ads, document (minor), informed consent language, transportation survey provider surveys, recruitment flow and data transfer to Medicaid plans, and eligibility criteria
03	5/31/2019	Approved	Personnel amendment
04	6/04/2019	Approved	Amendment to Medicaid ride benefit language (minor)
05	6/14/2019	Approved	Personnel amendment
06	7/16/2019	Approved	Amendments to questionnaires, protocol for participant reminders, and advertisements
07	6/14/2019	Approved	Personnel amendment
08	6/19/2019	Approved	Personnel amendment
09	N/A	Approved	Deleted
10	8/30/2019	Approved	Amendment to protocol to enable expanded recruitment and eligibility criteria
12	1/5/2020	Approved	Amendment to advertising materials, welcome letter, final interview; expanded recruitment to include Women, Infants, and Children clinics
13	1/22/2020	Approved	Removed two students that moved on.
14	3/12/2020	Approved	Reclassified two staff members as key personnel.
15	3/17/2020	Approved	Because of COVID-19, requested permission to complete informed consent, HIPAA authorization procedures, and study interviews over the telephone (rather than in person) while public health restrictions remain in place. Incentives will be mailed.

Source: City of Columbus

6.7.3.2. IRB FEEDBACK

Currently, no feedback has been received for this project from the PTA IRB. All documents submitted to date have been approved. The project will be reviewed by the IRB annually from the date of initial approval. If feedback is received in the future, this section will be updated to include a summary of those submittals:

- IRB feedback
- Insights and lessons learned from feedback
- Actions taken as a result of feedback

6.7.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the IRB for review and IRB responses is provided in **Appendix B**. Approved documents include:

- Initial IRB submission

- Amendments
- Approvals
- Recruitment and outreach materials
- PCC referral forms
- Participant application materials
- Surveys/questionnaires/interview scripts
- Participant communications
- Authorization forms for use and disclosure of information
- MCO benefits information
- Mobile application user guide
- Website language
- Project evaluation protocol
- ICD

This section and **Appendix B** will be updated as additional documents are submitted to and/or approvals are received from the IRB. Future submissions may include:

- Recruitment protocol and/or materials changes

6.7.3.4. FUTURE NEEDS

As the project progresses, project needs evolve, or feedback is received from the IRB, the research protocol and/or accompanying documents may need to be modified. If such a need arises, the PI will submit amendments to the IRB for review and gain approval prior to implementing the proposed changes.

Events that could drive potential future amendments may include:

- Receipt of IRB feedback
- **Policy changes –** Changes in MCO, NEMT provider, or other stakeholder policies
- **Performance Measurement Methodology –** Changes to the indicators used for performance measurement that may result in additional interview or survey requirements

6.8. SMART MOBILITY HUBS

6.8.1. Project Synopsis and Concept of Operations

6.8.1.1. SCOPE

Currently, no enhanced mobility or multimodal features alleviate first-mile/last-mile (FMLM) challenges in the Linden area or along the Cleveland Avenue corridor. Columbus is working to make mobility the great equalizer in part by embracing multimodal transportation and making it as accessible and easy to use as possible.

The purpose of the SMH project is to deploy transportation facilities that provide travelers with consolidated transportation amenities. These amenities include interactive kiosks that provide access to comprehensive

trip-planning tools (via MMTPA) and real-time transportation information. The services are designed to accommodate multiple modes of transportation from a single location including bike-share, scooter-share, and other mobility options. These services are particularly useful in helping travelers complete the FMLM portions of trips and in enabling multimodal trip options.

Further details on the background, scope, and current system of the SMH project are in the SMH ConOps Final Report on the Smart Columbus website.[47]

6.8.1.2. RESEARCH CONCEPT DESIGN

As part of the SMH project vision, some COTA bus stops and transit centers along the BRT CMAX corridor will be transformed into smart mobility hubs that use technology to improve access to mobility options. At these hubs, travelers getting on or off the bus can easily access the next leg of their trip. Public Wi-Fi will be a key enabler for hubs and their points of connection, as Wi-Fi is also present in COTA's stations and on the entire fleet's vehicles. The City plans to outfit the smart mobility hubs with interactive kiosks to help with comprehensive trip-planning and expanded transportation options using other modes, such as bike-sharing and car-sharing. The SMH project will allow residents and visitors to access multiple modes of travel to solve FMLM challenges.

Further details of the proposed system's concept and the geographic scope of the project are in the SMH ConOps Final Report on the Smart Columbus website.[48]

6.8.1.3. PARTICIPANTS

The SMH project is open to the public. Research subjects include travelers and anyone else who interacts with the SMH, from operational users and system operators to operational support personnel, software maintainers, and trainers. Because this project is open to the public and poses less than a minimal risk to participants, it received an IRB exemption.

6.8.1.4. INFORMED CONSENT

The SMH project has not yet undergone IRB review, but because it is expected to receive an exemption, a requirement for SMH users' written consent is not anticipated.

6.8.2. Dependencies and Constraints

6.8.2.1. SAFETY MANAGEMENT

The following SMH safety scenarios related to the SMH project are discussed in the SMP Final Report:

- Difficulty locating the emergency call button
- Emergency response delays
- Kiosk unavailable due to maintenance or failure
- Exposure of PII
- Hub access restricted due to host site hours of operation
- Unsafe traveler behavior

[47] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Smart%20Mobility%20Hubs%20Concept%20of%20Operations.pdf
[48] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Smart%20Mobility%20Hubs%20Concept%20of%20Operations.pdf

- Unavailable or inaccurate mode recommendations
- Kiosk inaccessibility because of weather

Further information on the safety scenarios and proposed mitigation strategies identified for the SMH project is in the SMP Final Report[49].

The SMP also discusses functional safety requirements and safety management. Safety management involves overseeing all the activities necessary to ensure the safe execution of the project. Functional safety requirements include:

- **Equipment procurement –** As part of the SMH project, interactive kiosks, concrete pads, bike-sharing docking stations, bikes, signage, and pavement makings will be installed at six SMH locations in Columbus to facilitate FMLM connections.
- **Device installation –** Smart mobility hubs will have interactive kiosks openly available to the public and installed according to the system design requirements. They will also be tested in a closed environment prior to being opened to the public.
- **Fail-safe system mode** – Interactive kiosks installed at the SMH locations will have a fail-safe system mode. The system will revert to a fail-safe mode if it fails to meet necessary and essential operational capabilities as defined in the project's system requirement documentation.
- **Quality training –** All system operators, system maintainers, installers, and owners of a response plan will receive adequate, approved training based on their point of interface with the system. This training will be documented as it occurs, as part of the Smart Columbus Program.

Further details on equipment procurement and device installation are in the Demonstration Site Map and Installation Schedule Final Report on the Smart Columbus website.[50] Further details on the safety operational concept are in the Smart Columbus SMP Final Report on the Smart Columbus website.[51]

6.8.2.2. DATA PROTECTION AND PRIVACY

The Smart Columbus DPP[52] provides program-level oversight and guidance for the privacy and security controls for any data collected as part of the Smart Columbus Program and stored on the Smart Columbus Operating System.

As part of the SMH project, the Wi-Fi network at SMH facilities has been developed in accordance with best practices in data security and privacy. For this project, no PII given on the kiosk will be stored by the kiosk or held by the vendor.

While the DPP provides overarching guidance for every project on privacy and security controls for data, detailed information on privacy and security controls for SMH will be maintained in the IRB protocol and contracts with participating organizations, such as kiosk provider, as needed.

6.8.2.3. PERFORMANCE MEASUREMENT

Desired outcomes for the SMH project are increased mobility and customer satisfaction.

Mobility-related performance will be measured by determining how well the project:

- Provides physical access to multimodal trip planning and payment options

[49] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[50] https://d2rfd3nxvhnf29.cloudfront.net/2020-01/SCC-B-DSP-IS-FINAL-20200124.pdf

[51] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[52] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

Customer-service-related performance will be measured by determining how well the project:

- Improves customer satisfaction

Detailed information on the hypotheses, indicators, design of the experiment, data collection, and impact evaluation for all the objectives is provided in the Smart Columbus PfMP Final Report on the Smart Columbus website.[53] OSU will measure performance, and the OSU IRB will review surveys and evaluation protocols.

6.8.3. Human Use Approval

6.8.3.1. IRB PROCESS AND APPLICATION

The SMH project does not require IRB oversight for demonstration activities. IRB oversight is required, however, for performance measurement (specifically, the survey that will be distributed). The PI for this project's demonstration activities is Jeff Kupko, from MBI. The PI for performance measurement is Elena Irwin, from OSU. **Table 13** will be updated once IRB documents are submitted for review.

Table 13: SMH IRB Submittal and Determination Summary

No.	Date	Determination	Subject
0	TBD	In progress	SMH performance measurement survey

Source: City of Columbus

6.8.3.2. IRB FEEDBACK

Currently, no feedback has been received for this project from the IRB because the project has not yet undergone IRB review. If feedback is received in the future, this section will be updated to include a summary of:

- IRB feedback
- Insights and lessons learned from feedback
- Actions taken as a result of feedback

6.8.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project's IRB for review will be provided in **Appendix B** and IRB determinations in **Appendix C** once available. Documentation may include:

- IRB exemption
- Protocol
- Performance measurement surveys

This section, **Appendix B** and **Appendix C** will be updated as documents are submitted to and/or approvals or exemptions are received from the IRB.

[53] https://d2rfd3nxvhnf29.cloudfront.net/2019-08/Smart%20Columbus%20Performance%20Measurement%20Plan.pdf

6.8.3.4. FUTURE NEEDS

As described in Section 6.1.2, the SMH project launch was delayed by COVID-19. The original launch was scheduled for April 2020 but was delayed until July 28, 2020. The performance measurement team at OSU is currently revising the survey methodology and instrument to accommodate pandemic-related public health guidelines and impacts. In addition, the performance measurement team is coordinating their survey effort with a planned survey effort of key stakeholder, COTA. The team will launch a combined survey effort in January 2021.

A submission to IRB is expected in November 2020. As the project has not yet undergone IRB review, the performance measurement protocol will be submitted to IRB at a future date. Depending on IRB review, the protocol or supporting documentation may need modification.

6.9. EVENT PARKING MANAGEMENT

6.9.1. Project Synopsis and Concept of Operations

6.9.1.1. SCOPE

The City of Columbus lacks an integrated system for residents and visitors to easily and efficiently view the available parking spaces at parking garages, surface lots, and parking meters, especially during large events. Indirect routing of travelers causes congestion and inefficiency in the transportation network.

The objective of the EPM project is to support and simplify access to information about parking availability and reservation services in downtown and the Short North. The EPM system will allow users to identify currently projected parking availability near their target destination and help reduce the additional driving required to find suitable parking. Ideally, users of this system will be able to use it to reserve and pay for parking. The goals of this project are to reduce congestion, frustration, and emissions in the Downtown and Short North areas of Columbus.

Further details on the project's background, scope, and current system are in the EPM ConOps Final Report on the Smart Columbus website.[54]

6.9.1.2. RESEARCH CONCEPT DESIGN

An EPM application will be deployed that will address the functional requirements that motivate the project. This project will integrate parking information from multiple providers into a single availability and reservation services solution. This will allow travelers to plan and search for parking options at certain locations to reserve and book a parking space. More direct routing of travelers during large events is expected to reduce congestion during those times.

Further details on the proposed system for the project are in the EPM ConOps Final Report on the Smart Columbus website.[55]

6.9.1.3. PARTICIPANTS

Participants include the public (travelers who use the app to park) and participating parking facilities and operators, including City of Columbus parking meters and private parking facilities. As this project is open to

[54] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Event%20Parking%20Management%20Concept%20of%20Operations.pdf

[55] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Event%20Parking%20Management%20Concept%20of%20Operations.pdf

the public and poses less than a minimal risk to participants, IRB provided an exemption from oversight in October 2020.

6.9.1.4. INFORMED CONSENT

Since the IRB provided an exemption, EPM users' written consent is not anticipated.

6.9.2. Dependencies and Constraints

6.9.2.1. SAFETY MANAGEMENT

The following safety scenarios are discussed in the SMP Final Report:

- Application unavailability due to maintenance or failure
- PII exposure
- Parking facility inaccessibility after hours

Further information on the safety scenarios and proposed mitigation strategies identified for the EPM project is in the SMP Final Report.

The SMP also discusses functional safety requirements and safety management. Safety management involves overseeing all the activities necessary to ensure the project's safe execution. Functional safety requirements include:

- **Equipment procurement –** No equipment will be installed as part of this project. An application will be deployed to help travelers with parking. The application can be downloaded from the public app stores on mobile phones.
- **Device installation –** No devices will be installed as part of this project.
- **Fail-safe system mode –** The EPM system will revert to a fail-safe mode if it fails to meet essential operational capabilities as defined in project's system requirements documentation.
- **Quality training –** All system operators, system maintainers, installers, maintainers, and owners of a response plan will receive adequate approved training depending on their point of interface with the system. This training will be documented as it occurs, as part of the Smart Columbus Program.

Further details on the safety operational concept are in the Smart Columbus SMP Final Report on the Smart Columbus website.[56]

6.9.2.2. DATA PROTECTION AND PRIVACY

The Smart Columbus DPP[57] provides program-level oversight and guidance for the privacy and security controls for any data collected as part of the Smart Columbus Program and stored on the Smart Columbus Operating System.

As part of the EPM project, travelers will be able to create an account within the EPM application to store preferences and simplify planning of subsequent parking needs. Account information may include username; email address; work, school, and home addresses; and addresses of other common destinations, as well as an indication of whether an EV charging station or accessible vehicle parking is needed. Traveler account information will not be distributed outside of the EPM system without being de-

[56] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[57] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

identified. The EPM system will use industry-standard security mechanisms to protect the account information and travelers' privacy. Account information will not be allowed to be accessed or used without the traveler's authorization. The EPM system, provided by ParkMobile, is PCI compliant. While transaction data will be shared with the Operating System, it will be de-identified in compliance with the Smart Columbus DPP.

While the DPP provides overarching guidance for every project on privacy and security controls for data, detailed information on privacy and security controls for EPM will be maintained in the IRB protocol and the contract with ParkMobile.

6.9.2.3. PERFORMANCE MEASUREMENT

The desired outcome for the EPM project is increased customer satisfaction, which will be measured using the following objective:

- Increased knowledge of available parking in the downtown and Short North areas during events

Detailed information on the hypotheses, indicators, design of the experiment, data collection, and impact evaluation for all the objectives is provided in the Smart Columbus PfMP Final Report on the Smart Columbus website.[58] Performance measurement will be carried out by HNTB and undergo Advarra IRB review for surveys and evaluation protocol.

6.9.3. Human Use Approval

6.9.3.1. IRB PROCESS AND APPLICATION

The EPM project has received an exemption from the IRB for the demonstration and performance measurement (surveys) because human subjects are not directly involved. The PI for this project's demonstration activities is Alyssa Chenault, from the City of Columbus. The PI for performance measurement is Sherry Kish, from HNTB. A summary of IRB submittals and determinations for the project are shown in **Table 14**. This table will be updated as the project progresses, as needed.

[58] *https://d2rfd3nxvhnf29.cloudfront.net/2019-08/Smart%20Columbus%20Performance%20Measurement%20Plan.pdf*

Table 14: EPM IRB Submittal and Determination Summary

No.	Date	Determination	Subject
0	10/6/2020	Exempt	Protocol and supporting materials (survey, marketing materials, SMP, and DPP)

Source: City of Columbus

6.9.3.2. IRB FEEDBACK

Currently, no feedback has been received for the EPM project from the IRB and the project received an exemption. If feedback is received in the future, this section will be updated to include a summary of:

- IRB feedback
- Insights and lessons learned from feedback
- Actions taken as a result of feedback

6.9.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project's IRB for review are provided in **Appendix B** and IRB determinations are provided in **Appendix C**. Documentation currently includes:

- Protocol
- Surveys
- Marketing materials

This section, **Appendix B** and **Appendix C** will be updated as additional documents are submitted to and/or approvals or exemptions are received from the IRB. Future submissions may include:

- Protocol modifications
- Survey modifications and new surveys (post-deployment)
- Recruitment material modifications

6.9.3.4. FUTURE NEEDS

As the project progresses, project needs evolve, or feedback is received from the IRB, the research protocol and/or accompanying documents may need to be modified. If such a need arises, the PI will submit amendments to the IRB for review and gain approval or exemption prior to implementing the proposed changes.

Events that could drive potential future amendments may include:

- Demonstration and performance measurement IRB modifications
- Receipt of IRB feedback
- **Participation rates –** The need for changes to participant eligibility criteria and recruiting methods/materials to reach target levels
- **Policy changes –** Changes in stakeholder policies on issues such as privacy, security, or access
- **Technology –** Changes to the mobile application that impact issues such as privacy or security

6.10. CONNECTED ELECTRIC AUTONOMOUS VEHICLES

6.10.1. Project Synopsis and Concept of Operations

6.10.1.1. SCOPE

Use of connected and automated shuttles has been widely proposed as a solution to the FMLM challenge. In response, this project will develop solutions to the social and technical challenges associated with use of CEAV technology for safer and more efficient access to jobs and services in the city. Passenger service was suspended on February 20, 2020 following an incident where the CEAV made a sudden stop and a passenger fell from their seat. Following an incident investigation, safety mitigations were proposed to and approved by NHTSA in May 2020. As described in Section 6.1.2, due to the ongoing COVID-19 pandemic, passenger service has remained suspended, as public health and social distancing guidelines cannot be met. Smart Columbus proposed and USDOT approved an alternate use case for the CEAV in late May to use the CEAV for delivery of food pantry boxes from St. Stephens Community House to Rosewind Community Center. This service launched on July 28, 2020 to improve community access to food.

Further details on the project background and scope are in the CEAV Operational Concept Final Report on the Smart Columbus website.[59]

6.10.1.2. RESEARCH CONCEPT DESIGN

The proposed CEAV technology solution involves vehicles with Level 4 automation, as defined in a standard put forth by SAE International (SAEJ30161). Electric and connected, these vehicles can serve the public on short trips when other modes are not available or convenient. The fleet is expected to operate in a way similar to that of traditional transit service, with predetermined routes and signed stops along the routes for passengers to board and alight.

The CEAV team will conduct the project with partners from the Ohio Department of Transportation (ODOT), OSU, and the Columbus Partnership to plan, implement, and evaluate deployment of automated vehicles in the city. Working with these partners allows various use cases to be generated, which will result in deployment of CEAVs in various settings.

This project will provide an opportunity for residents and visitors to access cutting-edge mobility technologies to solve FMLM challenges. Further details of the proposed system are in the CEAV Operational Concept Final Report on the Smart Columbus website.[60]

6.10.1.3. PARTICIPANTS

The CEAV shuttles are open to the public; who is likely to participate depends on route location. The Smart Circuit shuttle was used by participants traveling the Scioto Mile route. The Linden LEAP shuttle is in the underserved Linden community to provide service between key Linden locations, including transit and community centers. Prior to the service pause, the CEAV project (passenger service use case) had received an IRB exemption.

[59] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Smart%20Columbus%20Connected%20Electric%20Autonomous%20Vehicle%20Operational%20Concent.pdf

[60] https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Smart%20Columbus%20Connected%20Electric%20Autonomous%20Vehicle%20Operational%20Concent.pdf

Food pantry delivery began on July 28, 2020 and the performance measurement team is currently working on the IRB submission for the survey. It will be submitted in August 2020 and is expected to be launched that same month.

6.10.1.4. INFORMED CONSENT

The CEAV project's Smart Circuit and Linden LEAP demonstrations received IRB exemptions; therefore, users' written consent is not needed. Since there are no passengers on the CEAV for the food pantry service, informed consent is not an anticipated requirement for that use case.

6.10.2. Dependencies and Constraints

6.10.2.1. SAFETY MANAGEMENT

The SMP Final Report states that vehicle operators must always be present when the vehicle is in operation. Operators must be in full control of the vehicle at all times and must assess situations that arise and react appropriately. The following safety scenarios (relevant to passenger service) are discussed in the SMP Final Report:

- Vulnerable road users, such as pedestrians, bikes, and scooters
- Unsafe human behaviors
- Issues operating in higher-speed traffic
- Operator distraction or inadequate training
- Passengers stranded during CEAV maintenance

Further information on the safety scenarios and proposed mitigation strategies identified for the CEAV project is in the SMP Final Report. Please note, the SMP will be updated with the results of the CEAV incident report from February 2020 as well as any changes identified in conjunction with the food pantry service use case as part of the Annual Safety Review in November 2020. The SMP also discusses functional safety requirements and safety management. Safety management involves overseeing all the activities necessary to ensure the safe execution of the project.

Functional safety requirements include:

- **Equipment procurement –** Automated vehicles will be deployed along specific routes within the City's Linden neighborhood. The Operational Concept document lists the routes the CEAVs would be operating along with connected infrastructure that will be installed as part of the project.
- **Device installation –** CEAVs will come prepackaged and tested at the manufacturer's plant. Any related equipment external to the vehicles will be installed according to the safety requirements of the CEAV quality management plan. The vehicles and related equipment will also be tested in a closed-course environment prior to deployment on the route.

Further details on equipment procurement and device installation are in the Demonstration Site Map and Installation Schedule Final Report on the Smart Columbus website.[61]

- **Fail-safe system mode –** CEAV system will have a fail-safe system mode. The system will revert to a fail-safe mode if it fails to meet necessary and essential operational capabilities as defined in each project's system requirements documentation.

[61] https://d2rfd3nxvhnf29.cloudfront.net/2020-01/SCC-B-DSP-IS-FINAL-20200124.pdf

- **Quality training –** All system operators, system maintainers, installers/maintainers, and owners of a response plan will receive adequate, approved training based on their point of interface with the system. This training will be documented as it occurs, as part of the Smart Columbus Program.

Further details on equipment procurement and device installation are in the Demonstration Site Map and Installation Schedule Final Report on the Smart Columbus website. Further details on the safety operational concept are in the Smart Columbus SMP Final Report, also on the Smart Columbus website.[62]

6.10.2.2. DATA PROTECTION AND PRIVACY

The Smart Columbus DPP[63] provides program-level oversight and guidance for the privacy and security controls for any data collected as part of the Smart Columbus Program and stored on the Smart Columbus Operating System.

Smart Columbus will not collect any PII from travelers who ride CEAVs. If the project begins collecting PII, the privacy and security controls in the Smart Columbus DPP will be consulted.

While the DPP provides overarching guidance for every project on privacy and security controls for data, detailed information on privacy and security controls for the CVE will be maintained in the IRB protocol and contracts with participating organizations, as needed.

6.10.2.3. PERFORMANCE MEASUREMENT

Desired outcomes for the CEAV project are increased mobility, opportunity, and customer satisfaction.

Mobility-related performance will be measured by determining how well the project:

- Provides convenient, reliable FMLM transit options

Opportunity-related performance will be measured by determining how well the project:

- Provides more access to jobs and services to residents from underserved communities. Please note, the addition of the food pantry use case in July 2020 did not result in additional outcomes; however, indicators were added to this objective related to this use case.

Customer-satisfaction-related performance will be measured by determining how well the project:

- Improves user experience

Detailed information on the hypotheses, indicators, design of the experiment, data collection, and impact evaluation for all the objectives is provided in the Smart Columbus PfMP Final Report on the Smart Columbus website.[64] OSU will measure performance, and the OSU IRB will review surveys and evaluation protocols.

6.10.3. Human Use Approval

6.10.3.1. IRB PROCESS AND APPLICATION

This project received an exemption from the IRB for the demonstration because human subjects are not directly involved. IRB oversight is required, however, for performance measurement. The PI for this project's demonstration activities is Jeff Kupko, from MBI. The PI for performance measurement is Jason Reece,

[62] https://d2rfd3nxvhnf29.cloudfront.net/2019-11/SCC-F-Safety%20Management%20Plan_11-07-2019_FINAL.pdf

[63] https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf

[64] https://d2rfd3nxvhnf29.cloudfront.net/2019-08/Smart%20Columbus%20Performance%20Measurement%20Plan.pdf

from OSU. A summary of IRB submittals and determinations for the Smart Circuit Passenger Demonstration part of the project is shown in **Table 15**, and similar information is shown for the Linden LEAP Passenger Demonstration in **Table 16** and for the Linden LEAP Food Pantry Demonstration in **Table 17**.

Table 15: CEAV IRB Submittal and Determination Summary for Smart Circuit Passenger Demonstration

No.	Date	Determination	Subject
0	4/25/2019	Exempt	Survey Protocol
01	11/30/2018	Approved	Protocol modification

Source: City of Columbus

Table 16: CEAV IRB Submittal and Determination Summary for Linden LEAP Passenger Demonstration

No.	Date	Determination	Subject
0	1/15/2020	Exempt	Survey Protocol

Source: City of Columbus

Table 17: CEAV IRB Submittal and Determination Summary for Linden LEAP Food Pantry Demonstration

No.	Date	Determination	Subject
0	3/2/20	Exempt	Protocol
1	9/15/20	Exempt	Food pantry survey (modification of protocol and new survey); changes did not meet fit the “study modifications in response to COVID” exception, thus not requiring an amendment and subsequently, review and approval or exemption.

Source: City of Columbus

6.10.3.2. IRB FEEDBACK

Currently, no feedback has been received for this project from the IRB and the project received an exemption. If feedback is received in the future, this section will be updated to include a summary of:

- IRB feedback
- Insights and lessons learned from feedback
- Actions taken as a result of feedback

6.10.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project’s IRB for review are provided in **Appendix B** and IRB determinations are provided in **Appendix C**. Documentation currently includes:

- Exemptions

- Survey protocols
- Survey questions
- Survey QR code (business card)

This section, **Appendix B** and **Appendix C** will be updated as additional documents are submitted to and/or approvals or exemptions are received from the IRB. Future submissions may include:

- Changes to protocol or other documents, if needed

6.10.3.4. FUTURE NEEDS

As the project progresses, project needs evolve, or feedback is received from the IRB, the research protocol and/or accompanying documents may need to be modified. As such needs arise, the demonstration and/or performance measurement PI will submit amendments to the IRB for review and gain approval or exemption prior to implementing the proposed changes.

Events that could drive potential future submissions and amendments may include:

- Updates to performance measurement protocol and materials
- Receipt of IRB feedback.
- **Policy changes –** Changing stakeholder policies on privacy, security, access, and so forth.

Chapter 7. Conclusions

The Smart Columbus Program Management Office, project teams, and PIs are working diligently to protect the welfare and safety of human subjects, follow all applicable rules and regulations, and conduct this research in accordance with the Belmont Report's three research principles: Respect for Persons (informed consent), Beneficence (benefits vs. risks), and Justice (equity of distribution of benefits and risks). This document will be updated periodically to reflect the latest HUA status and documentation.

7.1. SUMMARY OF UPDATES (MAY TO NOVEMBER 2020)

This subsection is intended to summarize the major updates to this HUAS from the time the Final version was submitted in May 2020. The bullets below provide a high-level summary by project.

7.1.1. Program

The PfMP was revised in August 2020 to reflect the impact of COVID-19 on all outcomes for the program and projects. It also contains an archive of submittals and IRB reviews for the mobility and opportunity outcomes; there were several surveys submitted by OSU that are now captured in this document. At the program level, the main impact has been revisions to the survey methodology and content. There may be additional IRB submissions required for these outcomes, which will be captured in future quarterly updates to the HUAS.

7.1.2. SCOS

The SCOS team created additional user surveys for both public users and agency users in early 2020. These surveys were provided for IRB review in May 2020 and received an exemption. An update to the agency survey was made in September 2020, was submitted to IRB for review and received an exemption. This activity is captured in this update of the HUAS.

7.1.3. CVE

The CVE project had a lot of IRB activity between August and November 2020, which is captured in this update of the HUAS. The tables in Chapter 6 and Appendix B contain the details of each submission and IRB correspondence.

- The team received IRB approval of the initial submission of the protocol and informed consent documents in June 2020.
- Revised protocol and consent documents were submitted to IRB and approved in July 2020.
- The team received IRB approval of participant recruitment materials in August 2020.
- Training and consent video scripts have been submitted to IRB and received IRB approval in August 2020.
- Additional recruiting materials were approved by IRB in September 2020.
- Revised research protocol and consent forms were approved by IRB in November 2020.
- Initial versions of the performance measurement surveys were approved by IRB in November 2020.

7.1.4. MMTPA

The 3rd quarter 2020 update to this document includes the submittal of the updated project research protocol and in-app survey for performance measurement. Both of these items were submitted and received IRB approval in early November 2020.

7.1.5. MAPCD

There was no IRB activity for this project captured in this update.

7.1.6. PTA

There was no IRB activity for this project captured in this update.

7.1.7. SMH

There was no IRB activity for this project captured in this update. However, this version of the HUAS does highlight that the performance measurement survey has begun development and will be submitted to IRB for review in November. It is anticipated that the next update will contain the IRB determination for the performance measurement survey.

7.1.8. EPM

This update captures the submission of the initial research protocol and baseline performance measurement survey, both of which were reviewed by IRB. IRB provided an exemption from oversight upon review. Future versions of the HUAS may contain an update for post-deployment surveys for performance measurement.

7.1.9. CEAV

There was no IRB activity for this project captured in this update. However, this version of the HUAS does contain the OSU study team's determination that the food pantry survey did not require an IRB amendment or subsequent review. It is not anticipated that there will be any further updates for the project and performance measurement, unless the survey methodology changes significantly to meet the criteria for an amendment.

Chapter 8. References

Table 18 contains references consulted in writing this document.

Table 18: References

Doc. No	Title	Rev.	Pub. Date
–	Smart Columbus Website https://smart.columbus.gov/programs/smart-city-demonstration	–	
–	Smart Columbus Program Operating System https://smart.columbus.gov/projects/smart-columbus-operating-system	–	
–	Smart Columbus Program EPM Concept of Operations https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Event%20Parking%20Management%20Concept%20of%20Operations.pdf	–	Jun 27, 2018
–	Smart Columbus Program SMH Concept of Operations https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Smart%20Mobility%20Hubs%20Concept%20of%20Operations.pdf	–	Jul 30, 2018
–	Smart Columbus Program CVE Concept of Operations https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Connected%20Vehicle%20Environment%20Concept%20of%20Operations.pdf	–	Aug 7, 2018
–	Smart Columbus Program MMTPA/CPS Concept of Operations https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Multi-Modal%20Trip%20Planning%20System%20Concept%20of%20Operations.pdf	–	Aug 10, 2018
–	Smart Columbus Program PTA Concept of Operations https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Prenatal%20Trip%20Assistance%20Concept%20of%20Operations.pdf	–	Sept 11, 2018
–	Smart Columbus Program MAPCD Trade Study https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Mobility%20Assistance%20for%20People%20with%20Cognitive%20Disabilities%20Trade%20Study.pdf	–	Mar 19, 2019
–	Smart Columbus Program CEAV Operational Concept https://d3hzplpmmz6qe4.cloudfront.net/2019-07/Smart%20Columbus%20Connected%20Electric%20Autonomous%20Vehicle%20Operational%20Concent.pdf	–	Mar 29, 2019

Doc. No	Title	Rev.	Pub. Date
–	Smart Columbus Program Performance Measurement Plan https://d2rfd3nxvhnf29.cloudfront.net/2020-08/SCC-C-PfMP-Update-v1.pdf	–	Aug 28, 2020
–	Smart Columbus Program Data Management Plan https://d2rfd3nxvhnf29.cloudfront.net/2020-08/SCC-E-DataManagementPlan-Update-v1_0.pdf	–	Aug 6, 2020
–	Smart Columbus Program Data Privacy Plan https://d2rfd3nxvhnf29.cloudfront.net/2020-09/SCC-D-DataPrivacyPlan-AnnualUpdate-V2.pdf	–	Sept 24, 2020
–	Smart Columbus Operating System De-Identification Policy https://d2rfd3nxvhnf29.cloudfront.net/2019-10/Smart%20Columbus%20Operating%20System%20De-Identification%20Policy.pdf	–	Sept 17, 2019
–	Smart Columbus Program Safety Management Plan https://d2rfd3nxvhnf29.cloudfront.net/2020-03/SCC-F-Safety%20Management%20Plan_12-05-2019_FINAL.PDF	–	Dec 5, 2019
–	Smart Columbus Program Demonstration Site Map and Installation Schedule https://d2rfd3nxvhnf29.cloudfront.net/2020-07/SCC-B-DSP%26IS-UPDATED.pdf	–	June 19, 2020

Source: City of Columbus

Appendix A. Acronyms and Definitions

Table A-1 contains project specific acronyms used throughout this document.

Table A-1: Acronyms

Abbreviation/Acronym	Definition
API	Application programming interface
ADA	Americans with Disabilities Act
AV	Autonomous vehicle
BRT	Bus rapid transit
CEAV	Connected Electric Autonomous Vehicles
CFR	Code of Federal Regulations
City	City of Columbus
Common Rule	Common Federal Policy for the Protection of Human Subjects
ConOps	Concept of Operations
Cooperative Agreement	USDOT Cooperative Agreement No. DTFH6116H00013
COTA	Central Ohio Transit Agency
CPS	Common Payment System
CV	Connected vehicle
CVE	Connected Vehicle Environment
DMP	Data Management Plan
DPP	Data Privacy Plan
DSRC	Dedicated short-range communications
EHS	Enhanced Human Services
EMS	Emergency medical services
EPM	Event Parking Management
EV	Electric vehicle
FMLM	First-mile/last-mile
FWA	Federal-wide assurance
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMI	Human machine interface
HUA	Human Use Approval
HUD	Head-up display
ICDs	Informed consent documents

Abbreviation/Acronym	Definition
IRB	Institutional review board
ITS	Intelligent transportation system
MAPCD	Mobility Assistance for People with Cognitive Disabilities
MCO	Managed care organization
MMTPA	Multimodal Trip Planning Application
NEMT	Non-emergency medical transportation
OBU	Onboard unit
Operating System	Smart Columbus Operating System
ODOT	Ohio Department of Transportation
OSU	Ohio State University
PCC	Physician's Care Connection
PCI	Payment Card Industry
PfM	Performance measurement
PfMP	Performance Measurement Plan
PI	Principal investigator
PII	Personally identifiable information
PTA	Prenatal Trip Assistance
RSU	Roadside unit
SCC	Smart City Challenge
SCOS	Smart Columbus Operating System
SMHs	Smart Mobility Hubs
SMP	Safety Management Plan
TSP	Transit signal priority
USDOT	U.S. Department of Transportation
WWII	World War II

Source: City of Columbus

Appendix B. Supporting Documentation List

Table B-1: Program-level Performance Measurement—Environment Outcome

Date	Description	File Name
TBD	Protocol	[Under development]

Source: City of Columbus

Table B-2: Program-level Performance Measurement—Mobility and Opportunity Outcomes

Date	Description	File Name
9/10/2019	Protocol	08_SC-Protocol-Sept_10.docx
9/9/2019	Survey	06_SC-Booklet-Sept9.docx
9/9/2019	Survey	07_SC-Booklet-Sept9-Wave2.docx
9/24/2019	Survey	09_SC-Survey-Cover-WAVE2-Sept24-CLEAN.docx
9/25/2019	Survey	10_SC-Survey-Cover-Sept24-CLEAN.docx
N/A	Survey	02_SC-Survey-Cover.docx
N/A	Survey	03_SC-Survey-Cover-WAVE2.docx
9/25/2019	Travel Diary	11_SC-Diary-Consent-Wave1-Sept25-CLEAN.docx
9/25/2019	Travel Diary	12_SC-Diary-Consent-Wave2-Sept25-CLEAN.docx
N/A	Travel Diary	04_SC-Diary-Wave1.docx
N/A	Travel Diary	05_SC-Diary-Wave2.docx
3/2/2020	Survey	ProposedLindenShuttleSurveyQuestions_20200110.pdf (CEAV Mobility Survey)
3/2/2020	Survey (resubmittal not needed due to COVID-19 special guidelines)	CEAVFoodPantry_QualtricsSurvey_Draft2_20200814_OSU.PDF
TBD	Survey	Surveys of SMH users (also in SMH project)
4/28/2020	Survey	Pandemic Opportunity Survey
10/28/2020	Survey	Post-pandemic Opportunity Survey

Source: City of Columbus

Table B-3: OS Supporting Documentation

Date	Description	File Name
5/23/2019	Protocol	SCOS Research Protocol User Authorization.docx

Date	Description	File Name
5/5/2020	Protocol	Research Protocol Agency Survey.docx
5/7/2019	Survey	PFMP Survey Questions 05072019.docx
4/1/2020	Survey	PFMP Agency Survey Questions 04012020.docx
4/1/2020	Survey	PFMP Agency Survey Questions 04012020_adw.docx
4/1/2020	Survey	PFMP Consumer Survey Questions 04012020.docx
5/4/2020	Survey	PFMP Agency Survey Questions 05042020_Clean Version.docx
9/11/2020	Survey	PfMP Agency Survey Modification

Source: City of Columbus

Table B-4: CVE Supporting Documentation

Date	Description	File Name
8/10/2020	Recruiting Materials	CVE Driver Training Video Script for Private Drivers 8.7.20_CLEAN
8/10/2020	Recruiting Materials	CVE Driver Training Video Script for City County Fleet and COTA Supervisors 8.7.20_CLEAN
8/10/2020	Recruiting Materials	CVE Driver Training Video Script for Freight 8/7/20_CLEAN
8/10/20	Recruiting Materials	CVE_PrivateICD_Videoscript_8.7.20_CLEAN
8/10/20	Recruiting Materials	CVE_Transit County Freight ICD Script 8.7.20_CLEAN
8/10/20	Recruiting Materials	CVE City ICD_Videoscript 8.7.20_CLEAN
7/31/2020	Recruiting Materials	CVE Text Reminder Copy(0.01)
7/31/2020	Recruiting Materials	Sanitation Card (0.01)
7/31/2020	Recruiting Materials	Incentive Mailer – FINAL (0.01)
7/31/2020	Recruiting Materials	CVE Wallet Card (0.01)
9/9/2020	Recruiting Materials	Recruiting materials, including: Billboard, "Join the Study" POS Wallet Card Poster, "DRIVE CONNECTED" Radio Commercial Scripts
7/31/2020	Flyer, poster or bulletin board	CVE One Pager (0.01)
7/31/20	Other	CVE Email Campaign Copy V2(0.01)

Date	Description	File Name
6/23/2020	Advertisement	2020 0623 CVE_AwarenessFacebookInstagramAds v1_rev.docx
6/23/2020	Advertisement	2020 0623 CVE_AwarenessGoogleAds V1_rev.docx
6/23/2020	Communication	2020 0623 CVE_IncentiveMailer – DOC_rev.docx
6/23/2020	Communication	2020 0623 CVE_ParticipationPacket – DOC_rev.docx
N/A	Communication	200219_CVE_ParticipationPacket
N/A	Communication	ColumbusConnectedCars Email Capture Form Auto Responder Email-v1.docx
N/A	Communication	CVE Email Campaign Copy.docx
N/A	Communication	OTIC Presentation Background.JPG
3/9/2020	ICD	Chenault Drivers ICF Pro00040123 Mar0920 – tc.docx
4/16/2020	ICD	Chenault City and Transit Fleet LDV Operators ICF Pro00040123 Apr1620 – tc.docx
6/23/2020	ICD	Chenault City Vehicle Operators ICF Pro00040123 Jun2320.docx
6/23/2020	ICD	Chenault Drivers ICF Pro00040123 Jun2320.docx
6/23/2020	ICD	Chenault Transit_County_HDV_ICF Pro00040123 Jun2320.docx
7/20/2020	ICD	Chenault City Vehicle Operators ICF Pro00040123 Jul2020.docx
7/20/2020	ICD	Chenault Transit_County_HDV_ICF Pro00040123 Jul2020.docx
N/A	ICD (Fleet)	CVE City and COTA Fleet LDV ICD_Draft_v1.docx
N/A	ICD (Fleet)	CVE City and COTA Fleet LDV ICD_Draft_v2.docx
N/A	ICD (Fleet)	CVE City COTA and County Fleet LDV ICD_Final_v3_Clean.docx
N/A	ICD (Heavy duty)	CVE HDV ICD_Draft.docx
N/A	ICD (Heavy duty)	CVE HDV ICD_Draft_v2_Clean.docx
N/A	ICD (Private)	CVE Private LDV ICD_Draft v6.docx
N/A	ICD (Private)	CVE Private LDV ICD_Draft V7.docx
6/23/2020	ICD/Training Video	2020 0623 CVE_ICD_VideoScript_rev.docx
N/A	ICD/Training Video	Informed Consent and Driver Training Video
11/3/2020	ICD	Updated ICDs
N/A	Incentive Mailer	200219_CVE_IncentiveMailer
2/19/2020	Participant Wallet Card	200219_CVE_folder_Wallet_cards-v3.pdf
N/A	Prequalification Survey	CVE Prequalification Survey_v7_wLogic and Prompts – Clean (1).docx
N/A	Prequalification Survey	CVE Prequalification Survey_v7_wLogic and Prompts – Clean.docx

Date	Description	File Name
N/A	Prequalification Survey	Prequalification Survey_v7_wLogicandPrompts_Clean.docx
12/6/2019	Protocol	SCC-F-CVE-RPD-Draft_V7_12-6-19.docx
1/8/2020	Protocol	SCC-F-CVE-RPD-Draft_V8_1-8-20.docx
2/10/2020	Protocol	SCC-F-CVE-RPD-Draft_V9_2-10-20.docx
3/16/2020	Protocol	SCC-F-CVE-RPD-Draft_V10_3-16-20.docx
4/2/2020	Protocol	SCC-F-CVE-RPD-Draft_v10-4-2-20.docx
5/19/2020	Protocol	SCC-F-CVE-RPD-Draft_V11_5-19-20.docx
5/20/2020	Protocol	SCC-F-CVE-RPD-Draft_V12_5-20-20.docx
N/A	Protocol	SCC-F-CVE-RPD-Draft_V2.docx
N/A	Protocol	SCC-F-CVE-RPD-Draft_V5_Edited.docx
N/A	Protocol	Smart Columbus CVE Protocol and ICF MOD 1 Summary and Rationale.docx
11/3/2020	Protocol	Updated protocol
6/9/2020	Questionnaire	Prequalification Questionnaire V4 6.9.2020-CLEAN.docx
N/A	Recruitment Video	Smart Columbus Connected Vehicle Environment Educational Video Script
11/6/2019	Survey	Prequalification Survey – FINAL 11.6.19
11/6/2020	Survey	PfMP surveys for LDV and HDV
6/23/2020	Training	2020 0623 Smart Columbus Connected Vehicle Environment Educational Video Script – DOC_rev.docx
N/A	Training	CVE_EquipmentTrainingVideo_Script.docx
N/A	Vendor Software Customer Use Agreement (with ICD)	Smart Columbus CVE ICD_Vendor Software Customer Use Agreement.docx
12/2/2019	Website	Connected Vehicle Environment Website for IRB approval 12.2.91
6/9/2020	Website	Smart Columbus Vehicle Installation Scheduling Website Screenshots 6.9.2020.docx
N/A	Website	Columbus Connected Cars Website – V4.docx
7/31/20	Flyer, Poster or Bulletin Board	Flyer, poster, or bulletin board, "DRIVE CONNECTED, Join the study!" (not dated)
7/31/20	Other	CVE Recruiting Email Copy (Updated July 16, 2020)
7/31/20	Other	CVE Text Message Reminders (Last updated: July 31, 2020
7/31/20	Other	CVE Wallet Card (not dated)
7/31/20	Other	CVE Participant Incentive Mailer, “Smart Columbus Thanks You” (not dated)

Date	Description	File Name
7/31/20	Other	CVE Sanitation Card (not dated)

Source: City of Columbus

Table B-5: MMPTA Supporting Documentation

Date	Description	File Name
2/20/2019	Protocol	MMTPA Research Protocol Release 1.docx
4/30/2019	Protocol	MMTPA Research Protocol Release 2.docx
7/8/2019	Protocol	MMTPA Research Protocol Release 3.docx
11/3/2020	Protocol	[Under IRB review] Research Protocol for MMTPA_11032020_clean.pdf
2/20/2019	Survey	MMTPA Release 1 User Survey.docx
4/30/2019	Survey	MMTPA Release 2 User Survey.docx
7/8/2019	Survey	MMTPA Release 3 User Survey.docx
7/10/2020	Survey	Pre-marking Launch Survey (OSU)
11/6/2020	Survey	Pivot User Survey.pdf

Source: City of Columbus

Table B-6: MAPCD Supporting Documentation

Date	Description	File Name
1/23/2019	Amendment	2018h0494_2019_01_23_Personnel Amendment 01_Approved_1_23_19.pdf
2/15/2019	Amendment	2018H0494_2019_02_15_Amendment 02_Incomplete_2_15_2019.pdf
2/15/2019	Amendment	2018H0494_2019_02_15_Personnel Amendment 03_Approved_2_15_19.pdf
3/4/2019	Amendment	2018H0494_2019_03_04_Amendment 02_Modifications Requested_03_04_2019.pdf
3/11/2019	Amendment	2018H0494_2019_03_11_Personnel Amendment 05_Approved_03_11_2019.pdf
3/18/2019	Amendment	2018H0494_2019_03_18_Amendment 02_Approved_03_18_2019.pdf
4/15/2019	Amendment	2018H0494_2019_04_15_Amendment 04_Incomplete_04_15_2019.pdf
4/25/2019	Amendment	2018h0494_2019_04_25_Amendment 04_Incomplete_04_25_2019.pdf
4/29/2019	Amendment	2018h0494_2019_04_29_Amendment 04_Modifcations Requested_04_29_2019.pdf
5/14/2019	Amendment	2018H0494_2019_05_14_Amendment 04_Approved_05_14_2019.pdf
5/21/2019	Amendment	2018H0494_2019_05_21_Personnel Amendment 06_Approved_5_21_2019.pdf

Date	Description	File Name
5/29/2019	Amendment	2018H0494_2019_05_29_Personnel Amendment 07_Approved_5_29_2019.pdf
7/10/2019	Amendment	2018H0494_2019_07_10_Personnel Amendment 08_Approved_7_10_2019.pdf
7/18/2019	Amendment	2018H0494_2019_07_18_Amendment 12_Incomplete_7_18_2019.pdf
7/18/2019	Amendment	2018H0494_2019_07_22_Personnel Amendment 09_Approved_7_22_2019.pdf
7/22/2019	Amendment	2018H0494_2019_07_29_Personnel Amendment 10_Approved_7_29_2019.pdf
7/29/2019	Amendment	2018H0494_2019_09_03_Personnel Amendment 11_Approved_9_3_2019.pdf
10/16/2019	Amendment	2018H0494_2019_10_16_Amendment 12_Incomplete_10_16_2019.pdf
10/24/2019	Amendment	2018H0494_2019_10_24_Amendment 12_Modifications Requested_10_24_2019.pdf
12/17/2019	Amendment	2018H0494_2019_12_17_Amendment 12_Modifications Requested_12_17_2019.pdf
12/19/2019	Amendment	2018H0494_2019_12_19_Amenment 12_Approved_12_19_2019.pdf
1/10/2020	Annual Status	2018B0494 - Annual Status Report Confirmed - 2020_01_10.pdf
5/14/2019	Assent	32_AssentTransportationStudy_2019_05_14 - Clean.docx
N/A	Assessment	02_Task Analysis Assessment of WayFinder App_final.docx
N/A	Assessment	05_Initial Assessment of Abilities FINAL.docx
N/A	Assessment	13_Appendix I - Task Analysis Assessment of WayFinder - Clean.docx
N/A	Assessment	15_Appendix M - Task Analysis Assessment Smartphone.docx
N/A	Assessment	26_Appendix A - Initial Assessment of Abilities - Clean.docx
4/12/2019	Consent	30_Consent_Travel Partner_2019_04_12 - Clean.docx
4/12/2019	Consent	31_Consent_Individuals with IDD OR Legally Authorized Representatives_2019_04_12 - Clean.docx
12/19/2019	Current	2018H0494_2019_12_19_Current Document_12_19_2019.pdf
12/18/2009	Feedback	2018B0494 - Incomplete Modifications Response Required -2019-12-18.pdf
11/7/2010	Feedback	2018B0494 - Amendment #12 Modifications Required - 2019-11-07.pdf
12/26/2018	Feedback	2018B0494 - Initial Submission Modifications Required - 2018-12-26.pdf
3/15/2019	Feedback	2018B0494 - Amendment #2 Modifications Required - 2019-03-15.pdf
5/13/2019	Feedback	2018B0494 - Amendment #4 Modifications Required - 2019-05-13.pdf
N/A	Focus Group	04_Focus Group Questions FINAL.docx
10/3/2019	Individual Investigator Agreement	04_REF IIA Andrew Wolpert 2018B0494.pdf

Date	Description	File Name
10/16/2019	Individual Investigator Agreement	03_REF IIA Jeffrey Kupko 2018B0494 NEW.pdf
1/14/2019	Initial Submission	2018H0494_2019_01_14_Initial Submission_Approved_01_14_19.pdf
N/A	Intake Form	06_Travel Intake Form for Indivdiuals with a Disability FINAL.docx
N/A	Intake Form	25_Appendix B - Travel Intake Form - Traveler - Clean.docx
11/26/2018	Letter of Support	02_LOS COTA IRB.pdf
N/A	Letter of Support	01_LOS Arc North IRB.pdf
9/25/2019	Permission	33_ParentalPermissionTemplate_BSS_SmarCbus_2019_09_25.doc
10/9/2018	Protocol	2018H0494_2018_10_09_Initial Submission_Incomplete_10_09_18.pdf
11/7/2018	Protocol	2018H0494_2018_11_07_Initial Submission_Incomplete_11_07_18.pdf
11/28/2018	Protocol	2018H0494_2018_11_28_Initial Submission_Modifcations Requested_11_28_18.pdf
12/21/2019	Protocol	34_SMARTColumbus Personal Navigation for Individuals with Disabilities_2019_12_21 - Clean.docx
N/A	Protocol	01_Community Wayfinding for Individuals with Disabilities and Older Adults - Final.pdf
N/A	Recruiting	11_Recruitment Scripts IRB.docx
N/A	Recruiting	16_SmarCityWayfinder_Recruit_e-newsletter.docx
N/A	Recruiting	17_SmarCityWayfinder_Recruitment_website.docx
N/A	Recruiting	18_SmartCityWayfinder_Recruitment_Flier.docx
N/A	Recruiting	19_SmarCityWayfinder_Recruitment_email.docx
N/A	Recruiting	20_SmarCityWayfinder_Recruit_Social Media.docx
3/6/2019	Submission Received	2018B0494 - Amendment #2 Completeness Verified - 2019-03-06.pdf
5/1/2019	Submission Received	2018B0494 - Amendment #4 Completeness Verified - 2019-05-01.pdf
10/24/2019	Submission Received	2018B0494 - Amendment #12 Completeness Verified - 2019-10-24.pdf
N/A	Survey	03_Satisfaction Surveys_final.docx
N/A	Survey	21_Appendix D - Satisfaction Survey - Safety Training - Traveler - Clean.docx
N/A	Survey	22_Appendix F - Satisfaction Survey - COTA Transportation Training - Traveler - Clean.docx
N/A	Survey	23_Appendix G - Satisfaction Survey - Smartphone Training - Traveler - Clean.docx

Date	Description	File Name
N/A	Survey	24_Appendix N - Check-in Survey - Traveler.docx
N/A	Survey	27_Appendix J - App Satisfaction Survey - Traveler - Clean.docx
N/A	Survey	28_Appendix H - Satisfaction Survey - Wayfinder App Training - Traveler - Clean.docx
N/A	Survey	29_Appendix L - App and Portal Satisfaction Survey - Travel Partner.docx
10/17/2018	System Notification	2018B0494 - Olivia Vega - Training Required IRB - 2018-10-17.pdf
10/23/2018	System Notification	2018B0494 - Sandra Metzler - Signature Required IRB - 2018-10-23.pdf
10/30/2018	System Notification	2018B0494 -Incomplete Response Required - 2018-10-30.pdf
11/3/2018	System Notification	2018B0494 - Incomplete Response Required - 2018-11-13.pdf
12/18/2018	System Notification	2018B0494 - Initial Submission Completeness Verified - 2018-12-18.pdf
2/15/2019	System Notification	2018B0494 - Carmen DiGiovine - IRB Amendment Ready - 2019-02-15.pdf
2/26/2019	System Notification	2018B0494 - Incomplete Response Required - 2019-02-26.pdf
4/24/2019	System Notification	2018B0494 - Incomplete Response Required - 2019-04-24.pdf
4/26/2019	System Notification	2018B0494 - Incomplete Response Required - 2019-04-26.pdf
5/21/2019	System Notification	2018B0494 - Carmen DiGiovine - Personnel Change Ready - 2019-05-21.pdf
5/29/2019	System Notification	2018B0494 - Carmen DiGiovine - Personnel Change Ready - 2019-05-29.pdf
8/6/2019	System Notification	2018B0494 - Carmen DiGiovine - IRB Amendment Ready - 2019-08-06.pdf
9/3/2019	System Notification	2018B0494 - Carmen DiGiovine - Personnel Change Ready - 2019-9-03.pdf
10/3/2019	System Notification	2018B0494 - Incomplete Response Required - 2019-10-03.pdf
10/16/2019	System Notification	2018B0494 - Incomplete Response Required- 2019-10-16.pdf
10/19/2019	System Notification	2018B0494 - Continuing Review Submission Reminder - 2019-10-19.pdf
10/23/2019	System Notification	2018B0494 - D Michele Basso - Signature Required IRB - 2019-10-23.pdf
10/30/2019	System Notification	2018B0494 - Incomplete Response Required- 2018-10-30.pdf

Date	Description	File Name
12/3/2019	System Notification	2018B0494 - Continuing Review Submission Reminder - 2019-12-03.pdf
12/31/2019	System Notification	2018B0494 - Carmen DiGiovine - IRB Annual Status Report Ready - 2019-12-31.pdf
N/A	Training	07_Training Quizzes FINAL IRB.docx
N/A	Training	08_WayFinder App Training IRB.pptx
N/A	Training	09_Smartphone Training IRB.pptx
N/A	Training	10_Online Training Materials IRB.docx
N/A	Training	12_Appendix C - Training Quiz - Safety - Traveler - Clean.docx
N/A	Training	14_Appendix E - Training Quiz - COTA Transportation - Traveler - Clean.docx

Source: City of Columbus

Table B-7: PTA Supporting Documentation

Date	Description	File Name
5/2/2019	Form	07_Rides 4 Baby Screener fillable_5_2_2019.pdf
5/2/2019	Form	08_Prenatal Care Application -Combined Assessment_5_2_2019.pdf
N/A	Form	03_FDEATH11-03finalACC.pdf
N/A	Form	04_birth11-03final-acc.pdf
N/A	Form	05_death11-03final-acc.pdf
N/A	Form	09_StepOne_ROI.pdf
8/12/2019	ICD	62_30_Combined ICF and parental permission and HIPAA_8_12_2019_nosignature_block_clean.docx
6/2/2019	Interview script	39_Script_for_final_interview_over_phone_6_2_2019.docx
6/2/2019	Interview script	56_Script_for_final_interview_over_phone_6_2_2019.docx
N/A	Interview script	PTA Script_for_final_interview_over_phone.docx
3/23/2019	Outreach	06_Business Cards_Magnets_3_23_19r.docx
9/18/2018	Protocol	01_Rides4Baby_Protocol_Draft_v1.4_(9_18_2018).pdf
8/6/2019	Protocol	40_Rides4Baby_Protocol_v6.0_8_6_19_clean.docx
8/6/2019	Protocol	PTA_Rides4Baby_Research Protocol_v6.0_8_6_19.docx
3/17/2020	Protocol	COVID19_amendment.pdf
4/6/2020	Protocol	R4B_protocol_v9_04062020.docx
N/A	Protocol	R4B_protocol_v9_clean.docx
6/13/2019	Questionnaire	33_R4B_final_questionnaire_6_13_19_clean.docx
8/3/2019	Questionnaire	54_17_R4B_followup_questions_8_3_2019_clean.docx

Date	Description	File Name
8/5/2019	Questionnaire	57_R4B baseline questionnaire_8_5_19_clean.docx
8/6/2019	Questionnaire	55_R4B_screening_questions_8_6_2019_clean.docx
6/21/2017	Recruitment/Communication	21_OH-MMED-1295 Transporation Benefit Flier_2017-06-21_PROOF FINAL.pdf
4/30/2019	Recruitment/Communication	10_043019_PTA_Outreach_Education_Materials_Part6 (MCO postcard).pdf
4/30/2019	Recruitment/Communication	11_043019_PTA_Outreach_Education_Materials_Part13 (Newspaper Ads).pdf
4/30/2019	Recruitment/Communication	12_043019_PTA_Outreach_Education_Materials_Part2 (Church Ads).pdf
4/30/2019	Recruitment/Communication	13_043019_PTA_Outreach_Education_Materials_Part4 (Office Outreach).pdf
4/30/2019	Recruitment/Communication	14_043019_PTA_Outreach_Education_Materials_Part3 (Widescreen Church).pdf
4/30/2019	Recruitment/Communication	15_043019_PTA_Outreach_Education_Materials (Wallet Card).pdf
5/9/2019	Recruitment/Communication	18_190509_PTA_Flyer_8.5x11APPROVEDCO.pdf
5/13/2019	Recruitment/Communication	20_190513_PTA_COTA Bus AdV2APPROVED.pdf
5/13/2019	Recruitment/Communication	23_190513_PTA_WelcomeLetter_8.5inx11inAPPROVED.pdf
5/14/2019	Recruitment/Communication	25_190514_PTA_Benefits_8.5inx11inAPPROVED.pdf
5/15/2019	Recruitment/Communication	17_Rides4Baby work flow and trip data summary 05.15.19.docx
5/16/2019	Recruitment/Communication	19_190516_PTA_Rides4Baby_Table SignsAPPROVED.pdf
5/23/2019	Recruitment/Communication	27_OSU_website_5_23_19.pdf
6/6/2019	Recruitment/Communication	30_190606 SO screenshot- Approved.pdf
6/6/2019	Recruitment/Communication	31_190606 PTA CO screenshot -Approved.pdf
6/7/2019	Recruitment/Communication	32_190607 Radio + TV Crawl scripts - approved.docx
6/14/2019	Recruitment/Communication	29_Ad_table_6_14_19_clean.docx
7/15/2019	Recruitment/Communication	38_Appointment_Reminder_revised_071519.pdf
7/24/2019	Recruitment/Communication	41_190724_PTA_COTA_BusAd.pdf
7/24/2019	Recruitment/Communication	42_190724_PTA_CTVAd.pdf
7/24/2019	Recruitment/Communication	43_190724_PTA_Hotcard_5.5x8.5.pdf
7/24/2019	Recruitment/Communication	46_190724_PTA_CelebrateOne_Invitation_8.5x11.pdf
7/24/2019	Recruitment/Communication	47_190724_PTA_MCO_Invitation_5x7.pdf
7/24/2019	Recruitment/Communication	49_190724_PTA_ColsComm_PrintAd.pdf
7/24/2019	Recruitment/Communication	50_190724_PTA_Flyer_ContactStrips_8.5x11.pdf
8/6/2019	Recruitment/Communication	44_R4B Step1 Website_8_6_2019.docx

Date	Description	File Name
8/6/2019	Recruitment/Communication	45_R4B Celebrate1 Website_8_6_2019.docx
8/6/2019	Recruitment/Communication	48_R4B Radio + TV Crawl + PSA scriptsv3_8_6_2019.docx
8/6/2019	Recruitment/Communication	52_R4B Welcome letter 08_06_2019_clean.docx
8/6/2019	Recruitment/Communication	58_R4B_MCO_FAQs_8_6_2019.docx
8/6/2019	Recruitment/Communication	59_R4B_PreDeliveryCheckIn_Text_8_6_2019.pdf
8/6/2019	Recruitment/Communication	60_R4B_Appointment_Reminder_Text_8_6_2019.pdf
8/6/2019	Recruitment/Communication	61_Updated_Welcome_Packet_Cards_8_6_2019.pdf
N/A	Recruitment/Communication	02_R4B MCO postcard.docx
N/A	Recruitment/Communication	16_SMSTestMessage_Rides4Baby.pdf
N/A	Recruitment/Communication	22_MHO-1241 13290501 Medicaid Transportation Benefit Brochure_DRAFT.pdf
N/A	Recruitment/Communication	28_Molina_MHO-1422 Medicaid Transportation Benefit_June_2019.pdf
N/A	Recruitment/Communication	34_PreDeliveryCheckInSMS__text.pdf
N/A	Recruitment/Communication	35_PCC2_website2.jpg
N/A	Recruitment/Communication	36_PCC1_website1.jpg
N/A	Recruitment/Communication	53_MHO-1241 13290501 Medicaid Transportation Benefit Brochure.pdf
N/A	Screening	PTA R4B_screening_questions.docx
5/22/2019	Survey	26_Kaizen Satisfaction Surveys_5_22_19.docx
6/26/2019	Survey	37_190626_PTA_CareSource_Eblastv3-APPROVED.docx
8/6/2019	Survey	51_R4B_CareSource_Eblast_8_6_2019.docx
N/A	Survey	PTA Kaizen Satisfaction Surveys.docx
N/A	Survey	PTA PFMP Survey Questions.docx
N/A	Survey	PTA R4B baseline questionnaire.docx
N/A	Survey	PTA R4B_final_questionnaire.docx
N/A	Survey	PTA R4B_followup_questions.docx
5/7/2019	User Guide	24_2019_05_07_rides4baby_app_guide.pdf

Source: City of Columbus

Table B-8: SMH Supporting Documentation

Date	Description	File Name
N/A	Protocol	[Under development]

Source: City of Columbus

Table B-9: EPM Supporting Documentation

Date	Description	File Name
N/A	Protocol	EPM Research Protocol Release 1 Final.docx
N/A	Recruitment Material	Marketing Material For IRB Submission.docx
N/A	Recruitment Material	ParkColumbus survey email to users.docx
11/6/2020	Protocol	EPM Research Protocol Release 1 Final.docx
11/6/2020	Survey	User survey
11/6/2020	Marketing Materials	Marketing Material For IRB Submission.docx
12/5/2019	SMP	SCC-F-Safety Management Plan_12-05-2019_FINAL.pdf
9/2020	DMP	SCC-E-Data Management Plan-UPDATE-20200805.pdf

Source: City of Columbus

Table B-10: CEAV Supporting Documentation for Smart Circuit Demonstration

Date	Description	File Name
N/A	Communication	CEAV QR Business Card V3.pdf
N/A	Protocol	CEAV Smart Circuit Survey Protocol.pdf
N/A	Survey	CEAV Proposed Smart Circuit Survey Questions-IRB_rev.pdf

Source: City of Columbus

Table B-11: CEAV Supporting Documentation for Linden LEAP Passenger Demonstration

Date	Description	File Name
N/A	Communication	QR Business Card.pdf
1/15/2020	Exemption	Kupko Protocol Exempt Determination Notice Jan1520.pdf
1/10/2020	Protocol	Linden Shuttle Survey Protocol.pdf
N/A	Survey	ProposedLindenShuttleSurveyQuestions_20200110.pdf

Source: City of Columbus

Table B-12: CEAV Supporting Documentation for Linden LEAP Food Pantry Demonstration

Date	Description	File Name
3/2/2020	Protocol	Linden Shuttle Survey Protocol.pdf
8/14/2020	Survey	CEAVFoodPantry_QualtricsSurvey_Draft2_20200814_OSU.PDF

Source: City of Columbus

Appendix C. IRB Approvals and Exemptions

Table C-1: List of Included Documentation

Project	Date	Description	Individual File Name
Program-level	10/28/2020	Exemption	**Subject:** Study Determined Exempt for #2020E1146
Program-level	4/28/2020	Exemption	SC-AfterCOVID-IRB.pdf
Program-level	9/25/2020	Exemption	Survey-TravelDiary-2Waves-IRBexempt-Sept25.pdf
Program-level	11/3/2020	Exemption	SC-AfterCOVID-Oct2020-IRB.pdf
Program-level	11/6/2020	Exemption	Fw: Study Determined Exempt for #2020E1177 (recontact permission for April 2020 survey participants)
SCOS	5/22/2019	Exemption	Protocol NHSR Determination Notice Pro00034104 May2219.pdf
SCOS	5/11/2020	Exemption	Robinson Subject Materials NHSR Determination Notice May1120.pdf
SCOS	5/14/2020	Exemption	Robinson Protocol NHSR Determination Notice May1420.pdf
SCOS	9/11/2020	Exemption	Robinson Modification NHSR Determination Notice Sep1120.pdf
CVE	6/24/2020	Approval	Chenault Protocol Approval with Modifications Notice Jun2420.pdf
CVE	6/26/2020	Approval	Chenault Subject Material Notice Jun2620.pdf
CVE	7/21/2020	Approval	Chenault Protocol and ICFs Modification Approval Notice Jul2120.pdf
CVE	8/5/2020	Approval	Chenault Recruitment and Subject Material Notice Aug0520.pdf(0.01)
CVE	11/3/2020	Exemption	Chenault Protocol and ICFs Approval Notice Nov0320.pdf
CVE	11/4/2020	Exemption	Chenault Subject Material Notice Nov0420.pdf
MMTPA	2/20/2019	Exemption	Wolpert Protocol NHSR Determination Notice Feb2019.pdf
MMTPA	4/30/2019	Exemption	Wolpert Protocol NHSR Determination Notice Apr3019.pdf
MMTPA	7/8/2019	Exemption	Wolpert Protocol NHSR Determination Notice Jul0819.pdf
MMTPA	7/10/2020	Exemption	E-mail IRB approval 2020 July 10.pdf (Pre-marketing launch phase (revised questionnaire))

Project	Date	Description	Individual File Name
MMTPA	11/6/2020	Exemption	Wolpert Protocol NHSR Determination Notice Nov0620.pdf
MAPCD	1/24/2019	Approval	2018B0494 - Approval of Requested Personnel Change for Study - 2019-01-24.pdf
MAPCD	2/18/2019	Approval	2018B0494 - Approval of Requested Personnel Change for Study - 2019-02-18.pdf
MAPCD	3/21/2019	Approval	2018B0494 - Amendment #2 Approved - 2019-03-21.pdf
MAPCD	4/26/2019	Approval	2018B0494 - Approval of Requested Personnel Change for Study - 2019-04-26.pdf
MAPCD	5/14/2019	Approval	2018B0494 - Amendment #4 Approved - 2019-05-14.pdf
MAPCD	5/22/2019	Approval	2018B0494 - Approval of Requested Personnel Change for Study - 2019-05-22.pdf
MAPCD	5/30/2019	Approval	2018B0494 - Approval of Requested Personnel Change for Study - 2019-05-30.pdf
MAPCD	7/11/2019	Approval	2018B0494 - Approval of Requested Personnel Change for Study - 2019-07-11.pdf
MAPCD	7/22/2019	Approval	2018B0494 - Approval of Requested Personnel Change for Study - 2019-07-22.pdf
MAPCD	8/9/2019	Approval	2018B0494 - Approval of Requested Personnel Change for Study - 2019-08-09.pdf
MAPCD	9/4/2019	Approval	2018B0494 - Approval of Request Personnel Change for Study - 2019-09-04.pdf
MAPCD	12/23/2019	Approval	2018B0494 - Amendment #12 Approved - 2019-12-23.pdf
MAPCD	1/17/2019	Approval	2018B0494 - Initial Submission Approved - 2019-01.pdf
PTA	4/18/2019	Approval	Initial_approval.pdf
PTA	5/20/2019	Approval	Amend_1.pdf
PTA	5/28/2019	Approval	Amend_2.pdf
PTA	5/31/2019	Approval	Amend_3.pdf
PTA	5/31/2019	Approval	Amend_5.pdf
PTA	6/4/2019	Approval	Amend_4.pdf
PTA	6/14/2019	Approval	Amend_7.pdf
PTA	6/19/2019	Approval	Amend_8.pdf
PTA	7/16/2019	Approval	Amend_6.pdf
PTA	8/30/2019	Approval	Amend_10.pdf
PTA	1/6/2020	Approval	Amend_12.pdf
CEAV-Smart Circuit	4/25/2019	Approval	CEAV Kupko AM 1 Modification Approval Notice Apr2519.pdf

Project	Date	Description	Individual File Name
CEAV-Smart Circuit	11/30/2018	Exemption	CEAV Kupko Protocol Exempt Determination Notices Nov3018.pdf
CEAV-Linden LEAP Passenger Deployment	1/15/2020	Exemption	Kupko Protocol Exempt Determination Notice Jan1520.pdf
CEAV – Linden LEAP Passenger and Food Pantry Deployments	3/2/2020	Exemption	CEAV Exemption_Buck-IRB _ Office of Research.pdf

Source: City of Columbus

From: Herziger, Atar
To: Diane Newton
Cc: Wolpert, Andrew D.; Akar, Gulsah
Subject: Fw: Study Determined Exempt for #2020E1146
Date: Tuesday, November 3, 2020 3:30:45 PM

FYI

From: OR IRB Info <IRBInfo@osu.edu>
Sent: Wednesday, October 28, 2020 11:37 AM
To: Akar, Gulsah <akar.3@osu.edu>
Cc: Herziger, Atar <herziger.1@osu.edu>
Subject: Study Determined Exempt for #2020E1146

The Ohio State University

Office of Responsible Research Practices

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

10/28/2020
Study Number: 2020E1146
Study Title: Smart Columbus Impacts - Wave1 and 2 - Amendment for Wave 2
Principal investigator: Gulsah Akar
Date of determination: 10/28/2020
Qualifying exempt category: #2b
Dear Gulsah Akar,
The Office of Responsible Research Practices has determined the above referenced project exempt from IRB review.

Administrative Note:

- As the university moves to a staged approach to restarting research activities, refer to Human Subjects Guidance and FAQs. If after reviewing this information and working through your college you have additional questions, please direct emails to research@osu.edu.

Please note the following about this determination:

- Retain a copy of this correspondence for your records.
- Only the Ohio State staff and students named on the application are approved as Ohio State investigators and/or key personnel for this study.
- Simple changes to personnel that do not require changes to materials can be submitted for review and approval through Buck-IRB.
- No other changes may be made to exempt research (e.g., to recruitment procedures, advertisements, instruments, protocol, etc.). If changes are needed, a new application for

exemption must be submitted for review and approval prior to implementing the changes.

- Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.
- It is the responsibility of the investigators to promptly report events that may represent unanticipated problems involving risks to subjects or others.

This determination is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Human research protection program policies, procedures, and guidance can be found on the ORRP website.
Please feel free to contact the Office of Responsible Research Practices with any questions or concerns.

Jacob Stoddard
stoddard.13@osu.edu
(614) 292-0526

AAHRPP


For information on the staged approach to restarting human subjects research, read Guidance and FAQs.

2020E1177

Study Determined Exempt for #2020E0449

Sent Date

04/28/2020 2:16 pm

From

Jacob Stoddard <stoddard.13@osu.edu>

To

Gulsah Akar <akar.3@osu.edu>

THE OHIO STATE UNIVERSITY

Office of Responsible Research Practices

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

04/28/2020

Study Number: 2020E0449
Study Title: Smart Columbus Impacts - After COVID

Principal investigator: Gulsah Akar
Date of determination: 04/28/2020

Qualifying exempt category: #2b

Dear Gulsah Akar,

The Office of Responsible Research Practices has determined the above referenced project exempt from IRB review.

Administrative Note:

- All investigators must adhere to Office of Research issued interim guidance on human subjects-related research during the COVID-19 outbreak. The guidance addresses new participant enrollment and interactions with currently enrolled participants.
- Investigators requesting to engage in COVID-related research must follow Wexner Medical Center, College of Medicine, and Comprehensive Cancer Center (CCC) policies and/or procedures. Investigators outside the Medical Center or CCC must follow university and/or departmental policies and/or procedures.

Please note the following about this determination:

- Retain a copy of this correspondence for your records.
- Only the Ohio State staff and students named on the application are approved as Ohio State investigators and/or key personnel for this study.
- Simple changes to personnel that do not require changes to materials can be submitted for review and approval through Buck-IRB.
- No other changes may be made to exempt research (e.g., to recruitment procedures, advertisements, instruments, protocol, etc.). If changes are needed, a new application for exemption must be submitted for review and approval prior to implementing the changes.
- Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.
- It is the responsibility of the investigators to promptly report events that may represent unanticipated problems involving risks to subjects or others.

This determination is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Please feel free to contact the Office of Responsible Research Practices with any questions or concerns.

Jacob Stoddard
stoddard.13@osu.edu
(614) 292-0526


Association for the Accreditation of
Full
Accreditation
Human Research Protection Programs, Inc.

Subject: Study Determined Exempt for #2019E0846
Date: Wednesday, September 25, 2019 at 2:13:53 PM Eastern Daylight Time
From: OR IRB Info
To: Akar, Gulsah
CC: Herziger, Atar

Office of Responsible Research Practices

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

09/25/2019

Study Number: 2019E0846
Study Title: Smart Columbus Impacts - Wave1 and 2

Principal investigator: Gulsah Akar
Date of determination: 09/25/2019

Qualifying exempt category: #2b

Dear Gulsah Akar,

The Office of Responsible Research Practices has determined the above referenced project exempt from IRB review.

Please note the following about this determination:

- Retain a copy of this correspondence for your records.
- Only the Ohio State staff and students named on the application are approved as Ohio State investigators and/or key personnel for this study.
- Simple changes to personnel that do not require changes to materials can be submitted for review and approval through Buck-IRB.
- No other changes may be made to exempt research (e.g., to recruitment procedures, advertisements, instruments, protocol, etc.). If changes are needed, a new application for exemption must be submitted for review and approval prior to implementing the changes.
- Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.
- It is the responsibility of the investigators to promptly report events that may represent unanticipated problems involving risks to subjects or others.

This determination is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Please feel free to contact the Office of Responsible Research Practices with any questions or concerns.

Jacob Stoddard
stoddard.13@osu.edu
(614) 292-0526

For information on the staged approach to restarting human subjects research, read Guidance and FAQs.

Study Determined Exempt for #2020E1149

Sent Date

11/03/2020 5:05 pm

From

Anthony Dent <dent.56@osu.edu>

To

Gulsah Akar <akar.3@osu.edu>

THE OHIO STATE UNIVERSITY

Office of Responsible Research Practices

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

11/03/2020

Study Number: 2020E1149
Study Title: Smart Columbus Impacts - After COVID Oct 2020

Principal investigator: Gulsah Akar
Date of determination: 11/03/2020

Qualifying exempt category: #2b

Dear Gulsah Akar,

The Office of Responsible Research Practices has determined the above referenced project exempt from IRB review.

Administrative Note:

- As the university moves to a staged approach to restarting research activities, refer to Human Subjects Guidance and FAQs. If after reviewing this information and working through your college you have additional questions, please direct emails to research@osu.edu.

Please note the following about this determination:

- Retain a copy of this correspondence for your records.
- Only the Ohio State staff and students named on the application are approved as Ohio State investigators and/or key personnel for this study.
- Simple changes to personnel that do not require changes to materials can be submitted for review and approval through Buck-IRB.
- No other changes may be made to exempt research (e.g., to recruitment procedures, advertisements, instruments, protocol, etc.). If changes are needed, a new application for exemption must be submitted for review and approval prior to implementing the changes.
- Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.
- It is the responsibility of the investigators to promptly report events that may represent unanticipated problems involving risks to subjects or others.

This determination is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Please feel free to contact the Office of Responsible Research Practices with any questions or concerns.

Anthony Dent
dent.56@osu.edu
(614) 292-4502


Association for the Accreditation of
Full
Accreditation
Human Research Protection Programs, Inc.

From: Diane Newton
To: Casey Cooper-Fenske
Subject: FW: Study Determined Exempt for #2020E1177
Date: Friday, November 6, 2020 2:46:46 PM

Casey,
One more for you!

Diane

Tel (317) 332-3020 **Email** dnewton@hntb.com

From: Herziger, Atar <herziger.1@osu.edu>
Sent: Friday, November 6, 2020 2:29 PM
To: Diane Newton <dnewton@HNTB.com>
Cc: Akar, Gulsah <akar.3@osu.edu>; Wolpert, Andrew D. <ADWolpert@columbus.gov>
Subject: Fw: Study Determined Exempt for #2020E1177

Hi Diane,

FYI the below is an additional IRB exemption for the current COVID survey; it allows us to re-contact folks from the April wave who opted-in for the opportunity to take part in another survey.

Have a great weekend!
Atar

From: OR IRB Info <IRBInfo@osu.edu>
Sent: Friday, November 6, 2020 1:45 PM
To: Akar, Gulsah <akar.3@osu.edu>
Subject: Study Determined Exempt for #2020E1177

The Ohio State University

Office of Responsible Research Practices
300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

11/06/2020

Study Number: 2020E1177
Study Title: Smart Columbus Impacts - After COVID Oct 2020 - April Contacts

Principal investigator: Gulsah Akar
Date of determination: 11/06/2020

Qualifying exempt category: #2b

Dear Gulsah Akar,

The Office of Responsible Research Practices has determined the above referenced project exempt from IRB review.

Administrative Note:

- As the university moves to a staged approach to restarting research activities, refer to Human Subjects Guidance and FAQs. If after reviewing this information and working through your college you have additional questions, please direct emails to research@osu.edu.

Please note the following about this determination:

- Retain a copy of this correspondence for your records.
- Only the Ohio State staff and students named on the application are approved as Ohio State investigators and/or key personnel for this study.
- Simple changes to personnel that do not require changes to materials can be submitted for review and approval through Buck-IRB.
- No other changes may be made to exempt research (e.g., to recruitment procedures, advertisements, instruments, protocol, etc.). If changes are needed, a new application for exemption must be submitted for review and approval prior to implementing the changes.
- Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.
- It is the responsibility of the investigators to promptly report events that may represent unanticipated problems involving risks to subjects or others.

This determination is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Please feel free to contact the Office of Responsible Research Practices with any questions or concerns.

Jacob Stoddard
stoddard.13@osu.edu
(614) 292-0526

AAHRPP

ADVARRA
advancing better research

NON-HUMAN SUBJECT RESEARCH DETERMINATION

DATE: 23 May 2019

TO: Katie Robinson

PROJECT: City of Columbus - Research Protocol for Smart Columbus Operating System (Pro00034104)

DOCUMENTATION REVIEWED:

Protocol Version:
- Research Protocol for Smart Columbus Operating System (Not Dated)

Other Material:
- Questionnaire Submitted as "PFMP Survey Questions Modified 05072019"

Using the Department of Health and Human Services regulations at 45 CFR 46, the IRB determined that your research project does not constitute research under 45 CFR 46.102(d) and the Revised Common Rule, as it does not involve human subjects, and, therefore, does not require IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.102(d), you will resubmit revised materials for IRB review.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

NON-HUMAN SUBJECT RESEARCH DETERMINATION

DATE:	11 May 2020
TO:	Katie Robinson
PROJECT:	City of Columbus - Research Protocol for Smart Columbus Operating System (Pro00034104)

DOCUMENTATION REVIEWED:

Other Material:

- PFMP Consumer Survey Questions (Not Dated)

The IRB has reviewed and approved the above referenced documentation.

Using the Department of Health and Human Services regulations at 45 CFR 46, the IRB determined that your research project remains Non-Human Subject Research under 45 CFR 46.102(d). All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.102(d), you will resubmit revised materials for IRB review.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

NON-HUMAN SUBJECT RESEARCH DETERMINATION

DATE: 14 May 2020

TO: Katie Robinson

PROJECT: Katie Robinson - Research Protocol for Smart Columbus Operating System (Pro00043759)

DOCUMENTATION REVIEWED:

Protocol Version:
- Protocol (Not Dated)

Other Material:
- PFMP Agency Survey Questionnaire (Not Dated)

Using the Department of Health and Human Services regulations at 45 CFR 46, the IRB determined that your research project does not constitute research under 45 CFR 46.102(d) and, therefore, does not require IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.102(d), you will resubmit revised materials for IRB review.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

NON-HUMAN SUBJECT RESEARCH DETERMINATION

DATE:	11 Sep 2020
TO:	Katie Robinson
PROJECT:	Katie Robinson - Research Protocol for Smart Columbus Operating System (Pro00043759)

DOCUMENTATION REVIEWED:

Other Material:

- Questionnaire: PfMP Agency Survey (Dated: 8/6/2020)

Using the Department of Health and Human Services regulations at 45 CFR 46, the IRB determined that the submission of the above reference documentation does not change the original non-human research determination under 45 CFR 46.102(d) and, therefore, still does not require IRB oversight.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.102, you will resubmit revised materials for IRB review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

PROTOCOL APPROVAL WITH MODIFICATIONS

DATE: 24 Jun 2020

TO: Alyssa Chenault

PROTOCOL: City of Columbus -, Connected Vehicle Environment (CVE) Research Protocol for Protecting Human Research Participants (Pro00040123)

APPROVAL DATE: 9 Mar 2020

IRB APPROVED DOCUMENTATION:

Protocol Version:

- Protocol (Dated June 2020)

Consent Forms:

- Informed Consent Form For Drivers (Advarra IRB Approved Version 23 Jun 2020)
- Informed Consent Form For City Vehicle Operators (Advarra IRB Approved Version 23 Jun 2020)
- Informed Consent Form For COTA, Franklin County and Heavy Duty Vehicle Operators (Advarra IRB Approved Version 23 Jun 2020)

Recruitment Material:

- Smart Columbus Connected Vehicle Environment Educational Video Script (Not Dated)
- Awareness Facebook and Instagram Advertisements (Not Dated)
- ColumbusConnectedCars.com Email Capture Auto-Responder (Not Dated)
- Awareness Google Search Advertisements (Not Dated)
- Smart Columbus Vehicle Installation Scheduler (Not Dated)
- Connected Vehicle Environment Research Prequalification Survey (Not Dated)
- Prospective Participant Website (Not Dated)

Other Material:

- Connected Vehicle Environment – Equipment Training Script (Not Dated)
- CVE Participant Incentive Mailer, "Smart Columbus Thanks You" (Not Dated)
- CONNECTED VEHICLE ENVIRONMENT User Manual (Not Dated)
- CVE Wallet Card (Not Dated)
- Connected Vehicle Environment – Informed Consent Document Video Script (Not Dated)

- Safety Management Plan (SMP) (FINAL REPORT, Dated November 7, 2019)
- Data Privacy Plan (FINAL REPORT, Dated SEPTEMBER 6, 2019)
- Data Management Plan (FINAL REPORT, Dated AUGUST 22, 2019)
- Smart Columbus Connected Vehicle Environment Project: VENDOR SOFTWARE CUSTOMER USE AGREEMENT FOR PARTICIPANTS (Not Dated)

The IRB approved the above referenced protocol and your site with the modifications listed below on 9 Mar 2020:

- **Modifications to the Informed Consent Forms**
- **Modifications to the Informed Consent and Driver Training Video**
- **Modifications to the Pre-Qualification Survey**

The IRB granted a Waiver of Documentation of Consent for drivers other than drivers of personal vehicles (emergency, municipal, freight and transit vehicle drivers), and City and COTA employees completing the required surveys.

On 23 Jun 2020, the IRB reviewed and approved the revised Protocol.

Additionally, on 23 Jun 2020, the IRB reviewed and approved with modifications additional edits to the Informed Consent Forms. the CVE Educational Recruitment Video; the CVE Participant Incentive Mailer, the CVE User Manual, the CVE Social Media Posts, the CVE Google Search Ads and the CVE Informed Consent Document Video Script.

On 23 Jun 2020, the IRB reviewed and approved additional edits to the CVE Driver Training Video, the CVE Participant Wallet Card, the Capture Form Auto Responder Email, the Online Appointment Scheduling Website, the Pre-qualification Survey, and the Prospective Participant Website.

The IRB approved the use of the following terms for interchangeable use in the recruitment and subject facing materials: study device/technology/alert, research device/technology/alert, investigational device/technology/alert, study-related device/technology/alert, research-related device/technology/alert. All other changes to recruitment or subject facing materials must be approved by the IRB prior to use.

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform under the "IRB Issued Documents" tab.

If there are any changes to the IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

Please submit a final formatted copy of all recruitment material approved in script format only (e.g. television or radio script in .mp3, .wav, or .wmf format). The final format must be in the format potential subjects will see and hear.

There is no expiration date for this study, and it is not subject to requirements for continuing review under the revised Common Rule (2018 Requirements). However, a termination report must be submitted upon termination of the study.

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Approved investigators and sites are required to submit to Advarra for review, and await a response prior to implementing, any amendments or changes in the protocol; informed consents; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to provide oversight for your research project.

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SUBJECT MATERIAL APPROVAL

MOD00708855

DATE:	26 Jun 2020
TO:	Alyssa Chenault
PROTOCOL:	City of Columbus, Connected Vehicle Environment (CVE) Research Protocol for Protecting Human Research Participants (Pro00040123)
APPROVAL DATE:	26 Jun 2020

IRB APPROVED:

Documentation:

- CVE Email Copy (Updated: June 25, 2020)

The IRB reviewed and approved the above referenced material.

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform under the "IRB Issued Documents" tab.

If there are any changes to IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for continuing to use Advarra IRB to provide oversight for your research project.

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APPROVAL NOTICE

MOD00722476

DATE:	21 Jul 2020
TO:	Alyssa Chenault
PROTOCOL:	City of Columbus -, Connected Vehicle Environment (CVE) Research Protocol for Protecting Human Research Participants (Pro00040123)
APPROVAL DATE:	20 Jul 2020

IRB APPROVED:

Documentation:	• Protocol (Dated July 2020) • Protocol Summary of Changes (Not Dated)
Consent Forms:	• Informed Consent Form For City Vehicle Operators (Advarra IRB Approved Version 20 Jul 2020) • Informed Consent Form For COTA, Franklin County and Heavy Duty Vehicle Operators (Advarra IRB Approved Version 20 Jul 2020)

The IRB has reviewed and approved the above referenced documentation.

The Consent Forms referenced above are now available on your Advarra CIRBI Platform workspace. **The IRB determined new subjects need to sign the above referenced Consent Forms.**

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for continuing to use Advarra IRB to provide oversight for your research project.

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RECRUITMENT/SUBJECT MATERIAL APPROVAL

MOD00736002

DATE: 5 Aug 2020

TO: Alyssa Chenault

PROTOCOL: City of Columbus -, Connected Vehicle Environment (CVE) Research Protocol for Protecting Human Research Participants (Pro00040123)

APPROVAL DATE: 4 Aug 2020

IRB APPROVED:

Documentation:

- Flyer, poster, or bulletin board, "DRIVE CONNECTED, Join the study!" (Not Dated)
- CVE Email Copy (Updated: July 16, 2020)
- CVE Text Message Reminders (Last updated: July 31, 2020)
- CVE Wallet Card (Not Dated)
- CVE Participant Incentive Mailer, "Smart Columbus Thanks You" (Not Dated)
- Sanitation Card (Not Dated)

The IRB reviewed and approved the above referenced material.

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform under the "IRB Issued Documents" tab.

If there are any changes to IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for continuing to use Advarra IRB to provide oversight for your research project.

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APPROVAL NOTICE

MOD00805668

DATE:	3 Nov 2020
TO:	Alyssa Chenault
PROTOCOL:	City of Columbus, Connected Vehicle Environment (CVE) Research Protocol for Protecting Human Research Participants (Pro00040123)
APPROVAL DATE:	2 Nov 2020

IRB APPROVED:

Documentation:

- Protocol (Dated October 2020)
- Summary and Rationale for the Changes to the Research Protocol (Not Dated)

Consent Forms:

- Informed Consent Form For Drivers (Advarra IRB Approved Version 2 Nov 2020)
- Informed Consent Form For City Vehicle Operators (Advarra IRB Approved Version 2 Nov 2020)
- Informed Consent Form For COTA, Franklin County and Heavy Duty Vehicle Operators (Advarra IRB Approved Version 2 Nov 2020)

The IRB has reviewed and approved the above referenced documentation.

The Consent Forms referenced above are now available on your Advarra CIRBI Platform workspace. **The IRB determined new and currently enrolled subjects receiving applicable study treatment/drug need to sign the above referenced Consent Forms.**

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for continuing to use Advarra IRB to provide oversight for your research project.

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SUBJECT MATERIAL APPROVAL

MOD00809539

DATE:	4 Nov 2020
TO:	Alyssa Chenault,
PROTOCOL:	City of Columbus, Connected Vehicle Environment (CVE) Research Protocol for Protecting Human Research Participants (Pro00040123)
APPROVAL DATE:	4 Nov 2020

IRB APPROVED:

Documentation:

- Connected Vehicle Environment Evaluation Survey (Not Dated)
- Connected Vehicle Environment Post-Deployment Survey (Not Dated)

The IRB reviewed and approved the above referenced material.

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform under the "IRB Issued Documents" tab.

If there are any changes to IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for continuing to use Advarra IRB to provide oversight for your research project.

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NON-HUMAN SUBJECT RESEARCH DETERMINATION

DATE: 20 Feb 2019

TO: Andrew Wolpert, PE
City of Columbus

PROJECT: City of Columbus, Research Protocol for Multimodal Trip Planning Application (Pro00032482)

DOCUMENTATION REVIEWED:

Protocol Version:
- Research Protocol for Multimodal Trip Planning Application (Not Dated)

Other Material:
- MMTPA Usability Survey | First App Launch (Not Dated)

Using the Department of Health and Human Services regulations at 45 CFR 46 the IRB determined that your research project does not constitute research under 45 CFR 46.102(d) and, therefore, does not require IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.102(d), you will resubmit revised materials for IRB review.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

NON-HUMAN SUBJECT RESEARCH DETERMINATION

MOD00417784

DATE:	30 Apr 2019
TO:	Andrew Wolpert, PE
PROTOCOL:	City of Columbus, Research Protocol for Multimodal Trip Planning Application (Pro00032482)
APPROVAL DATE:	29 Apr 2019

DOCUMENTATION REVIEWED:

Documentation:

- Research Protocol for Multimodal Trip Planning Application - Release 2 (Not Dated)
- Summary of Changes for Multimodal Trip Planning Application – Release 2 (Not Dated)
- MMTPA Usability Survey (Not Dated)
- Smart Columbus MMTPA User Testing – Phase 2 | Screener (Dated April 19, 2019)

Using the Department of Health and Human Services regulations at 45 CFR 46 the IRB determined that your research project still does not constitute research under 45 CFR 46.102(d) and, therefore, does not require IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.102(d), you will resubmit revised materials for IRB review.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

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NON-HUMAN SUBJECT RESEARCH DETERMINATION

MOD00451172

DATE:	8 Jul 2019
TO:	Andrew Wolpert, PE
PROTOCOL:	City of Columbus, Research Protocol for Multimodal Trip Planning Application (Pro00032482)
APPROVAL DATE:	3 Jul 2019

DOCUMENTATION REVIEWED:

Documentation:

- Summary of Changes for Multimodal Trip Planning Application – Release 3 (Not Dated)
- Research Protocol for Multimodal Trip Planning Application - Release 3 (Not Dated)
- Revised MMTPA Usability Survey (Not Dated)

Using the Department of Health and Human Services regulations at 45 CFR 46 the IRB determined that your research project still does not constitute research under 45 CFR 46.102(d) and, therefore, does not require IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.102(d), you will resubmit revised materials for IRB review.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

Subject: Study Determined Exempt for #2020E0710
Date: Friday, July 10, 2020 at 1:16:20 PM Eastern Daylight Time
From: OR IRB Info
To: Mishalani, Rabi
CC: Carrel, Andre, McCord, Mark

Office of Responsible Research Practices

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

07/10/2020

Study Number: 2020E0710
Study Title: Evaluating the impact of a new Multi-Modal Trip Planning Application (MMTPA) on travel behavior - Pre-marketing launch phase (revised questionnaire)

Principal investigator: Rabi Mishalani
Date of determination: 07/10/2020

Qualifying exempt category: #2b

Dear Rabi Mishalani,

The Office of Responsible Research Practices has determined the above referenced project exempt from IRB review.

Administrative Note:

- As the university moves to a staged approach to restarting research activities, refer to Human Subjects Guidance and FAQs. If after reviewing this information and working through your college you have additional questions, please direct emails to research@osu.edu.

Please note the following about this determination:

- Retain a copy of this correspondence for your records.
- Only the Ohio State staff and students named on the application are approved as Ohio State investigators and/or key personnel for this study.
- Simple changes to personnel that do not require changes to materials can be submitted for review and approval through Buck-IRB.
- No other changes may be made to exempt research (e.g., to recruitment procedures, advertisements, instruments, protocol, etc.). If changes are needed, a new application for exemption must be submitted for review and approval prior to implementing the changes.
- Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.
- It is the responsibility of the investigators to promptly report events that may represent unanticipated problems involving risks to subjects or others.

This determination is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Please feel free to contact the Office of Responsible Research Practices with any questions or concerns.

Jacob Stoddard
stoddard.13@osu.edu
(614) 292-0526

NON-HUMAN SUBJECT RESEARCH DETERMINATION

MOD00809963

DATE: 6 Nov 2020

TO: Andrew Wolpert, PE

PROTOCOL: City of Columbus, Research Protocol for Multimodal Trip Planning Application (Pro00032482)

DOCUMENTATION REVIEWED:

Documentation:

- Summary of Changes for Multimodal Trip Planning Application – Release 4 (Not Dated)
- Protocol for Multimodal Trip Planning Application - Release 4 (Not Dated)
- Colombus Trip Planning App Usability Survey/Fall 2020 (Not Dated)

Using the Department of Health and Human Services regulations at 45 CFR 46 the IRB determined that your research project still does not constitute research under 45 CFR 46.102(d) and, therefore, does not require IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.102(d), you will resubmit revised materials for IRB review.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

01/24/2019 11:37 am

From

Joni Barnard <barnard.15@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

01/24/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 01/24/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #1

ADDED:

- Kaetlyn Culter

MODIFIED:

- NONE

REMOVED:

- NONE

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Policies, procedures, and guidance can be found on the ORRP website - orrp.osu.edu. Please feel free to contact ORRP with any questions or concerns.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB.

Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

02/18/2019 1:08 pm

From

Meliha Rahmani <rahmani.3@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

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02/18/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 02/18/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #3

ADDED:

- Lauren Jeunnette

MODIFIED:

- NONE

REMOVED:

- NONE

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Policies, procedures, and guidance can be found on the ORRP website - orrp.osu.edu. Please feel free to contact ORRP with any questions or concerns.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB.

Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

Amendment #2 Approved for #2018B0494

Sent Date

03/21/2019 6:40 am

From

Nicola Hettler <hettler.6@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>
Julie Faieta <faieta.7@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

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03/21/2019

Study Number: 2018B0494
Study Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Type of Review: Amendment #2

Review Method: Expedited

Request to amend the research dated February 15, 2019 (revise protocol to rename and re-organize study phases, add implementation phase during the SmartColumbus Go Live period, WayFinder portal objective and describe the WayFinder system, increase number of participants to 80, and incentive amount; add new consent form for travel partners and revise assent and consent form for consistency with the proposed changes).

Date of IRB Approval: 03/20/2019
Date of IRB Approval Expiration: 01/17/2020

Dear Carmen DiGiovine,

The Ohio State Behavioral and Social Sciences IRB **APPROVED** the above referenced research.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378 and is valid until the expiration date listed above. ***Without further review, IRB approval will no longer be in effect on the expiration date.*** To continue the study, a continuing review application must be approved before the expiration date to avoid a lapse in IRB approval and the need to stop all research activities. A final study report must be provided to the IRB once all research activities involving human subjects have ended.

Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.

Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB


Association for the Accreditation of
Full
Accreditation
Human Research Protection Programs, Inc.

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

04/26/2019 2:44 pm

From

Joni Barnard <barnard.15@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>
Julie Faieta <faieta.7@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

04/26/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 04/26/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #5

ADDED:

- Sarah Anderson

MODIFIED:

- NONE

REMOVED:

- NONE

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Policies, procedures, and guidance can be found on the ORRP website - orrp.osu.edu. Please feel free to contact ORRP with any questions or concerns.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB.

Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

Amendment #4 Approved for #2018B0494

Sent Date

05/14/2019 10:33 am

From

Ryan Liersemann <liersemann.1@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>
Julie Faieta <faieta.7@osu.edu>
Sandra Metzler <metzler.136@osu.edu>
Ryan Liersemann <liersemann.1@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

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05/14/2019

Study Number: 2018B0494
Study Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Type of Review: Amendment #4

Review Method: Expedited

Request to amend the research dated April 15, 2019 (update the protocol, consent forms, instrument documents and include new recruitment material to reflect based on their experiences with the initial set of participants (multiple changes)).

Date of IRB Approval: 05/14/2019
Date of IRB Approval Expiration: 01/17/2020

Dear Carmen DiGiovine,

The Ohio State Behavioral and Social Sciences IRB **APPROVED** the above referenced research.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

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Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB


Association for the Accreditation of
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Human Research Protection Programs, Inc.

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

05/22/2019 9:41 am

From

Joni Barnard <barnard.15@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>
Julie Faieta <faieta.7@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

05/22/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 05/22/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #6

ADDED:

- Isabelle Maher

MODIFIED:

- NONE

REMOVED:

- NONE

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Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

05/30/2019 12:27 pm

From

Joni Barnard <barnard.15@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>
Julie Faieta <faieta.7@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

05/30/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 05/30/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #7

ADDED:

- Ashley Stojkov

MODIFIED:

- NONE

REMOVED:

- NONE

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Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

07/11/2019 12:22 pm

From

Joni Barnard <barnard.15@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>
Julie Faieta <faieta.7@osu.edu>

THE OHIO STATE UNIVERSITY

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1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

07/11/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 07/11/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #8

ADDED:

- Mersadies Coles
- D Michele Basso

MODIFIED:

- NONE

REMOVED:

- NONE

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Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

07/22/2019 9:44 am

From

Joni Barnard <barnard.15@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>
Julie Faieta <faieta.7@osu.edu>
Mersadies Coles <coles.85@osu.edu>
D Michele Basso <Michele.Basso@osumc.edu>

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Columbus, OH 43210-1063

orrp.osu.edu

07/22/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 07/22/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #9

ADDED:

- Erika Kemp

MODIFIED:

- NONE

REMOVED:

- Olivia Vega

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Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

To better align with the OSU security framework and safeguard your accounts, BuckeyePass will be enforced for all users when accessing Office of Research applications starting February 1st, 2020. If you have not enrolled in BuckeyePass, visit http://buckeyepass.osu.edu.

Contact: OR Helpdesk at orhelpdesk@osu.edu

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

08/09/2019 3:36 pm

From

Joni Barnard <barnard.15@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Julie Faieta <faieta.7@osu.edu>
Mersadies Coles <coles.85@osu.edu>
D Michele Basso <Michele.Basso@osumc.edu>

THE OHIO STATE UNIVERSITY

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300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

08/09/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 08/09/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #10

ADDED:

- Theresa Berner

MODIFIED:

- NONE

REMOVED:

- NONE

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Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

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Contact: OR Helpdesk at orhelpdesk@osu.edu

Approval of Requested Personnel Change for Study #2018B0494

Sent Date

09/04/2019 10:25 am

From

Joni Barnard <barnard.15@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Julie Faieta <faieta.7@osu.edu>
Mersadies Coles <coles.85@osu.edu>
D Michele Basso <Michele.Basso@osumc.edu>

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orrp.osu.edu

09/04/2019

Protocol Number: 2018B0494
Protocol Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Review Method: Expedited

Dear Carmen DiGiovine,

On 09/04/2019, the Ohio State Behavioral and Social Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #11

ADDED:

- Elizabeth Mance

MODIFIED:

- NONE

REMOVED:

- NONE

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Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

Amendment #12 Approved for #2018B0494

Sent Date

12/23/2019 9:57 am

From

Michael Donovan <donovan.6@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Julie Faieta <faieta.7@osu.edu>
D Michele Basso <Michele.Basso@osumc.edu>
Sandra Metzler <metzler.136@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

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12/23/2019

Study Number: 2018B0494
Study Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Type of Review: Amendment #12

Review Method: Expedited

Request to amend the research dated September 25, 2019 (Remove Lauren Jeunnette as key personnel; Add Andrew Wolpert and Jeffrey Kupko as external collaborators; Add Children as participants with expanded age range (from 18-90 to 14-90); Add parent permission form; Revise research protocol to reflect changes).

Date of IRB Approval: 12/23/2019
Date of IRB Approval Expiration: 01/17/2020

Dear Carmen DiGiovine,

The Ohio State Behavioral and Social Sciences IRB **APPROVED** the above referenced research.

In addition, the following were also approved for this study:

- Children (permission of one parent sufficient)

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

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Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB


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Initial Submission Approved for #2018B0494

Sent Date

01/17/2019 1:24 pm

From

Jessica Mayercin-Johnson <mayercin-johnson.1@osu.edu>

To

Carmen DiGiovine <digiovine.1@osu.edu>

Cc

Olivia Vega <vega.76@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

01/17/2019

Study Number: 2018B0494
Study Title: SMARTColumbus Personal Navigation for Individuals with Disabilities - Pilot Study

Type of Review: Initial Submission

Review Method: Expedited

Date of IRB Approval: 01/17/2019
Date of IRB Approval Expiration: 01/17/2020

Expedited category: #6, #7

Dear Carmen DiGiovine,

The Ohio State Behavioral and Social Sciences IRB **APPROVED** the above referenced research.

In addition, the following were also approved for this study:

- Adults with Decisional Impairment
- Consent by Legally Authorized Representative

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

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Ohio State Behavioral and Social Sciences IRB


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Biomedical Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

05/20/2019

Study Number: 2019H0009
Study Title: Evaluation of the Prenatal Trip Assistance Project

Type of Review: Amendment #1

Review Method: Expedited

Request to amend the research dated May 5, 2019 (Add alteration of HIPAA research authorization; add recruitment materials; add wallet cards; revise questionnaires; revise welcome letter; add instruments [information disclosure, SMS text, referral form, prenatal care application]; revise protocol).

Date of IRB Approval: 05/20/2019
Date of IRB Approval Expiration: 04/18/2020

Dear Courtney Lynch,

The Ohio State Biomedical Sciences IRB **APPROVED** the above referenced research.

In addition, the following were also approved for this study:

- Alteration of HIPAA research authorization

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

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Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB


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THE OHIO STATE UNIVERSITY

Biomedical Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

05/28/2019

Study Number: 2019H0009
Study Title: Evaluation of the Prenatal Trip Assistance Project

Type of Review: Amendment #2

Review Method: Expedited

Request to amend the research dated May 23, 2019 (add new work flow, IRB table, recruitment materials [brochures, flyers, COTA bus ads, and website screenshot], Kaizen satisfaction surveys, subject materials [app user guide, instructions, welcome letter, and wallet cards]; revise protocol to indicate that participants must have access to phone (mobile or landline), computer, or tablet and consent to communication by phone/text/email and that bus passes will be provided for study interviews if necessary; revise and add questions/possible answers in screening, baseline, and final questionnaires; revise consent/parental permission and HIPAA authorization form to state that participants are responsible for the cost of receiving text messages and that they agree to calls/texts that may be automatically generated, and clarify the Medicaid health plan/providers that may obtain data).

Date of IRB Approval: 05/24/2019
Date of IRB Approval Expiration: 04/18/2020

Dear Courtney Lynch,

The Ohio State Biomedical Sciences IRB **APPROVED** the above referenced research.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

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Karla Zadnik

Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB


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Biomedical Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

05/31/2019

Protocol Number: 2019H0009
Protocol Title: Evaluation of the Prenatal Trip Assistance Project

Review Method: Expedited

Dear Courtney Lynch,

On 05/31/2019, the Ohio State Biomedical Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #5

ADDED:

- Holly Heffer

MODIFIED:

- NONE

REMOVED:

- NONE

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Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB

THE OHIO STATE UNIVERSITY

Biomedical Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

06/04/2019

Study Number: 2019H0009
Study Title: Evaluation of the Prenatal Trip Assistance Project

Type of Review: Amendment #4

Review Method: Expedited

Request to amend the research dated May 30, 2019 (Add temporary ride benefit information sheet from Molina).

Date of IRB Approval: 06/04/2019
Date of IRB Approval Expiration: 04/18/2020

Dear Courtney Lynch,

The Ohio State Biomedical Sciences IRB **APPROVED** the above referenced research.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

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Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB


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300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

05/31/2019

Protocol Number: 2019H0009
Protocol Title: Evaluation of the Prenatal Trip Assistance Project

Review Method: Expedited

Dear Courtney Lynch,

On 05/31/2019, the Ohio State Biomedical Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #5

ADDED:

- Holly Heffer

MODIFIED:

- NONE

REMOVED:

- NONE

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Policies, procedures, and guidance can be found on the ORRP website - orrp.osu.edu. Please feel free to contact ORRP with any questions or concerns.

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Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB

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300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

07/16/2019

Study Number: 2019H0009
Study Title: Evaluation of the Prenatal Trip Assistance Project

Type of Review: Amendment #6

Review Method: Expedited

Request to amend the research dated June 14, 2019 (Protocol v 5.1: allow for final questionnaire to be conducted by phone and for gift card to be mailed to these subjects, and add phone script; revise screening questions, baseline questionnaire, and final questionnaire for clarity; add two SMS text messages; add radio/tv ad, web ads for StepOne, CelebrateOne, and Physicians CareConnection sites, and a CareSource recruitment email; revise recruitment ad table accordingly).

Date of IRB Approval: 07/16/2019
Date of IRB Approval Expiration: 04/18/2020

Dear Courtney Lynch,

The Ohio State Biomedical Sciences IRB **APPROVED** the above referenced research.

Administrative notes:

- TV & radio ads: The IRB approved the scripts for these ads; however, the final recording(s) must be submitted for IRB review via a future amendment before they are aired.
- During review the amendment, the IRB made a determination of minor noncompliance for one of the ads being posted to a live website prior to IRB approval. An educational noncompliance letter will be sent separately.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

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Karla Zadnik, OD, PhD, Chair

Ohio State Biomedical Sciences IRB

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1960 Kenny Road
Columbus, OH 43210-1063

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06/14/2019

Protocol Number: 2019H0009
Protocol Title: Evaluation of the Prenatal Trip Assistance Project

Review Method: Expedited

Dear Courtney Lynch,

On 06/14/2019, the Ohio State Biomedical Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #7

ADDED:

- Jordan Gilbert

MODIFIED:

- NONE

REMOVED:

- NONE

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Ohio State Biomedical Sciences IRB

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06/19/2019

Protocol Number: 2019H0009
Protocol Title: Evaluation of the Prenatal Trip Assistance Project

Review Method: Expedited

Dear Courtney Lynch,

On 06/19/2019, the Ohio State Biomedical Sciences IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #8

ADDED:

- Heather Lansky
- Hannah Blumenfeld
- Rachel Steger

MODIFIED:

- NONE

REMOVED:

- NONE

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Policies, procedures, and guidance can be found on the ORRP website - orrp.osu.edu. Please feel free to contact ORRP with any questions or concerns.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB.

Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB

THE OHIO STATE UNIVERSITY

Biomedical Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

08/30/2019

Study Number: 2019H0009
Study Title: Evaluation of the Prenatal Trip Assistance Project

Type of Review: Amendment #10

Review Method: Expedited

Request to amend the research dated August 19, 2019 (update to recruit materials; expansion of women in Franklin county instead of CelebrateOne zip; addition of one day bus pass; increase in incentive for online satisfaction survey; addition of reminder interview texts; addition of Medicaid transportation information sheet; update to the consent and HIPAA form to outline the City of Columbus review of study data; protocol changes accordingly)

Date of IRB Approval: 08/29/2019
Date of IRB Approval Expiration: 04/18/2020

Dear Courtney Lynch,

The Ohio State Biomedical Sciences IRB **APPROVED** the above referenced research.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378 and is valid until the expiration date listed above. ***Without further review, IRB approval will no longer be in effect on the expiration date.*** To continue the study, a continuing review application must be approved before the expiration date to avoid a lapse in IRB approval and the need to stop all research activities. A final study report must be provided to the IRB once all research activities involving human subjects have ended.

Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.

Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB


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01/06/2020

Study Number: 2019H0009
Study Title: Evaluation of the Prenatal Trip Assistance Project

Type of Review: Amendment #12

Review Method: Expedited

Request to amend the research dated November 19, 2019 (Revise research protocol expanding recruitment to include WIC clinics, include new business card ads, wallet cards, and text messages, update script for final interview, include new shorter version of the final questionnaire, update welcome letter and PTA flyer)

Date of IRB Approval: 01/05/2020
Date of IRB Approval Expiration: 04/18/2020

Dear Courtney Lynch,

The Ohio State Biomedical Sciences IRB **APPROVED** the above referenced research.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

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04/18/2019

Study Number: 2019H0009
Study Title: Evaluation of the Prenatal Trip Assistance Pilot Project

Type of Review: Initial Submission

Review Method: Expedited

Date of IRB Approval: 04/18/2019
Date of IRB Approval Expiration: 04/18/2020

Expedited category: #7

Dear Courtney Lynch,

The Ohio State Biomedical Sciences IRB **APPROVED** the above referenced research.

In addition, the following were also approved for this study:

- Pregnant Women/Fetuses
- Children
- Waiver of Parental Permission Documentation
- Waiver of Consent Documentation

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378 and is valid until the expiration date listed above. ***Without further review, IRB approval will no longer be in effect on the expiration date.*** To continue the study, a continuing review application must be approved before the expiration date to avoid a lapse in IRB approval and the need to stop all research activities. A final study report must be provided to the IRB once all research activities involving human subjects have ended.

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Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical Sciences IRB


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EXEMPT DETERMINATION

MOD00415673

DATE: 25 Apr 2019

TO: Jeffrey Kupko, PI

PROTOCOL: US DOT -, Smart Circuit AV Shuttle (Pro00031234)

APPROVAL DATE: 25 Apr 2019

DOCUMENTATION REVIEWED:

Documentation:

- Protocol (Amendment 1 – April 25, 2019)

Using the Department of Health and Human Services regulations found at 45 CFR 46.101(b)(2), the IRB determined that your research project continues to be exempt from IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.101(b), you will resubmit revised materials for IRB review.

3. It is the responsibility of the investigator to ensure that the project meets the ethical standards of the institution. Specifically, the research involves no more than minimal risk to participants, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed that the activity involves research, a description of the procedures, participation is voluntary, and the contact information for the researcher.

The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform .

Thank you for continuing to use Advarra IRB to provide oversight for your research project.

> 6940 Columbia Gateway Dr., Suite 110
Columbia, MD 21046
410-884-2900 OFFICE
ADVARRA.COM

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EXEMPT DETERMINATION

DATE: 30 Nov 2018

TO: Jeffrey Kupko, P.E., PTOE
Michael Baker International

PROJECT: US DOT - Smart Circuit AV Shuttle (Pro00031234)

DOCUMENTATION REVIEWED:

Protocol Version:
- Protocol (Not Dated)

Recruitment Material:
- Smart Circuit Survey Questions (Not Dated)
- QR CODE CARD (Not Dated)

Using the Department of Health and Human Services regulations found at 45 CFR 46.101(b)(2), the IRB determined that your research project is exempt from IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.101(b), you will resubmit revised materials for IRB review.

3. It is the responsibility of the investigator to ensure that the project meets the ethical standards of the institution. Specifically, the research involves no more than minimal risk to participants, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed that the activity involves research, a description of the procedures, participation is voluntary, and the contact information for the researcher.

The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform .

Thank you for selecting Advarra IRB to review your research project.

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EXEMPT DETERMINATION

DATE:	15 Jan 2020
TO:	Jeffrey Kupko
PROJECT:	City of Columbus -, US DOT - Linden LEAP AV Shuttle (Pro00041337)

DOCUMENTATION REVIEWED:

Protocol Version:	• Protocol (Dated January 10, 2020)
Recruitment Material:	• Flyer, poster, or bulletin board, QR Business Card (Not Dated)
Other Material:	• Linden Shuttle Survey Questions (Not Dated)

Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(2) the IRB determined that your research project is exempt from IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.104(d)(2), you will resubmit revised materials for IRB review.

3. It is the responsibility of each investigator to ensure that the project meets the ethical standards of the institution. Specifically, the research involves no more than minimal risk to participants, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed that the activity involves research, a description of the procedures, participation is voluntary, and the contact information for the researcher.

The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform.

Thank you for selecting Advarra IRB to review your research project.

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For information on the staged approach to restarting human subjects research, read Guidance and FAQs.

Study Determined Exempt for #2020E0033

Sent Date

03/02/2020 7:28 am

From

Jacob Stoddard <stoddard.13@osu.edu>

To

Jason Reece <reece.35@osu.edu>

THE OHIO STATE UNIVERSITY

Office of Responsible Research Practices

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

03/02/2020

Study Number: 2020E0033
Study Title: Evaluation of Autonomous Shuttle Introduction Into the Linden Community

Principal investigator: Jason Reece
Date of determination: 03/02/2020

Qualifying exempt category: #2b

Dear Jason Reece,

The Office of Responsible Research Practices has determined the above referenced project exempt from IRB review.

Please note the following about this determination:

- Retain a copy of this correspondence for your records.
- Only the Ohio State staff and students named on the application are approved as Ohio State investigators and/or key personnel for this study.
- Simple changes to personnel that do not require changes to materials can be submitted for review and approval through Buck-IRB.
- No other changes may be made to exempt research (e.g., to recruitment procedures, advertisements, instruments, protocol, etc.). If changes are needed, a new application for exemption must be submitted for review and approval prior to implementing the changes.
- Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.
- It is the responsibility of the investigators to promptly report events that may represent unanticipated problems involving risks to subjects or others.

This determination is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Please feel free to contact the Office of Responsible Research Practices with any questions or concerns.

Jacob Stoddard
stoddard.13@osu.edu
(614) 292-0526

THE CITY OF
COLUMBUS
ANDREW J. GINTHER, MAYOR