Human Use Approval Summary

for the Smart Columbus Demonstration Program

DRAFT REPORT | February 11, 2020
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Acknowledgments

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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 activities. 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, Systems Engineering, and Performance Measurement; (4) identifies dependencies, constraints, and key challenges; and (4) identifies events or situations that could affect potential future IRB activities in the program. Because planning and deployment timing varies by project and there is potential for changing needs as projects proceed through different phases, this document should be considered a preliminary, living document that may be revised as program needs evolve.
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Executive Summary

As the winner of the U.S. Department of Transportation’s (USDOT) 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 System (ITS), Connected Vehicles (CV), Autonomous Vehicles (AV), and electric vehicles (EV) technologies to meet these challenges while integrating data from various sectors and sources to simultaneously power these technologies while 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, as well as the Smart Columbus Operating System (Operating System), the integral backbone and heart of all current and future Smart City projects.

In accordance with a Cooperative Agreement with USDOT, the Smart Columbus program is expected to improve safety, enhance mobility, increase opportunity, and address climate change through demonstrations of Intelligent Transportation Systems (ITSs) 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) documents the IRB application and review process from IRB selection through approval, including feedback and revisions; (2) describes coordination between IRB activity and other program tasks, including the Concept of Operations, Systems Engineering, and Performance Measurement; (3) identifies dependencies and constraints; and (4) identifies events or situations that could drive potential future IRB activities. Because planning and deployment timing varies by project and there is potential for changing needs as projects proceed through different phases, this Human Use Approval Summary should be considered a preliminary, living document that may be revised as program 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, utilizing advancements in Intelligent Transportation System (ITS), Connected Vehicles (CV), Autonomous Vehicles (AV), and electric vehicles (EV) to meet these challenges, while integrating data from various sectors and sources to simultaneously power these technologies while 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 owner and co-creator of the Smart Columbus Program. Columbus intends to define what it means to be a “Smart City” and serve as a model for other cities wishing to fully integrate 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. The program also includes the Smart Columbus Operating System (the Operating System), the integral backbone and heart of all current and future Smart City projects. Figure 1 shows the Smart Columbus Program including each project.

![Smart Columbus Projects Diagram](source: City of Columbus)
1.2. **ENABLING TECHNOLOGIES**

These technologies leverage today’s foundation in new and 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) 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)/Common Payment System (CPS), 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 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 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 Demonstration 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, including a human research component. All eight Smart Columbus Program projects involve human subjects in some way during testing, execution, and performance measurement phases. 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 approvals
  - 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 USDOT Cooperative Agreement No. DTFH6116H00013 (Cooperative Agreement). The HUA process, in which an accredited Institutional Review Board (IRB) oversees projects involving human research subjects, is important 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 project, including synopsis of project, dependencies and constraints, IRB submittals, approvals and exemptions, and future HUA needs
• Conclusion
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. In the 1970s, it was discovered that unwitting subjects 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 (DHEW) 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. Federally funded research involving human subjects is governed by this rule.

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.

3.1.1.1. 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 informed consent by research subjects 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 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.

---

2 [https://history.nih.gov/about/timelines_laws_human.html](https://history.nih.gov/about/timelines_laws_human.html)
3.1.1.3. **JUSTICE: EQUITY OF DISTRIBUTION OF BENEFITS/RISKS**

The principle of Justice establishes that risks and burdens should not be placed disproportionately 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, codified in 49 CFR Part 11, 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, institutional review board (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 the policies in 49 CFR 11, 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. Some Smart Columbus projects have received or expected to receive such an exemption.
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 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 (MPA)
- Single project assurance (SPA)

All Smart Columbus programs and projects will provide assurance using an FWA. An IRB provider has been designated for each Smart Columbus project based on project needs. The two IRB providers selected were Advarra and the Ohio State University (OSU). IRB providers are shown for each project in Table 4.1.

Table 4.1: IRB and Federal Assurance by Project

<table>
<thead>
<tr>
<th>Project</th>
<th>Program Level Performance Management</th>
<th>Project Level Performance Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment</td>
<td>Advarra (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Mobility</td>
<td>OSU</td>
<td></td>
</tr>
<tr>
<td>Opportunity</td>
<td>OSU</td>
<td></td>
</tr>
<tr>
<td>Customer satisfaction</td>
<td>OSU</td>
<td></td>
</tr>
<tr>
<td>CVE</td>
<td>Advarra</td>
<td></td>
</tr>
<tr>
<td>MMTPA/CPS</td>
<td>OSU</td>
<td></td>
</tr>
<tr>
<td>MAPCD</td>
<td>OSU</td>
<td></td>
</tr>
<tr>
<td>PTA</td>
<td>OSU</td>
<td></td>
</tr>
<tr>
<td>SMH</td>
<td>OSU</td>
<td></td>
</tr>
<tr>
<td>EPM</td>
<td>Advarra</td>
<td></td>
</tr>
<tr>
<td>CEAV</td>
<td>Advarra</td>
<td></td>
</tr>
</tbody>
</table>
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 principal investigator (PI) were selected for each project, to oversee the IRB and HUA processes and coordinate with other tasks as needed. HUA task components include the IRB application and feedback, application amendments and IRB approvals, and participant recruitment and informed consent.

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. PI’s are tasked with ensuring participants fully understand the risks associated with participation and documenting their consent.

4.4. **PRINCIPAL INVESTIGATOR**

A PI was or will be 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. PI’s also are 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, potential training needs for team members on the IRB process, managing the timeline for IRB review and approval, and addressing IRB feedback and amending applications as needed.
Human Use Approval by Project
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 MMTPA/CPS or the OS 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 so activities are captured in the IRB review and documentation. More information on coordination with other tasks is in 0 and project-specific sections in Chapter 6.

5.1. PROGRAM SCHEDULE

Overall program schedule determines 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 in maintaining project milestones, as many activities require IRB approval 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. 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. Consequently, the ConOps for each project drives of human-subject-related needs and activities, such as the need to recruit private-sector participants for the CVE project.

5.3. DEMONSTRATION SITE MAP AND INSTALLATION SCHEDULE

The Demonstration Site Map and Installation Schedule 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 and/or exemption is received.

5.4. SAFETY MANAGEMENT

The Smart Columbus Safety Management Plan (SMP) provides guidance on identifying safety scenarios and risk mitigation for the Smart Columbus demonstration 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 high- to medium-risk scenarios.
5.5. DATA MANAGEMENT

The Smart Columbus Data Management Plan (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, the informed consent process will be followed that describes in detail what data will be collected from the participants.

5.6. DATA PRIVACY

The Smart Columbus Data Privacy Plan (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

The Smart Columbus Performance Measurement Plan (PfMP) describes the outcomes of Smart Columbus 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 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 itself is exempt from IRB oversight because of either the nature of the research itself or the manner in which it is conducted.\textsuperscript{4}

Table 6.1 provides the PIs, IRB oversight requirements and exemptions, and status of already-submitted IRB documents by project. Because demonstrations and performance measurement activities are ongoing, Table 6.1 may be updated periodically as project and performance measurement needs evolve. Updates may also indicate IRB Status designation if additional documentation is submitted.

\textsuperscript{4} https://nij.ojp.gov/funding/human-subjects-protection
Table 6.1: IRB Oversight, Principal Investigator, and IRB Status by Project

<table>
<thead>
<tr>
<th>Project</th>
<th>IRB Oversight Required?</th>
<th>Demonstration Activities</th>
<th>Performance Measurement (PfM) Efforts</th>
<th>Principal Investigator</th>
<th>IRB Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment</td>
<td></td>
<td>N/A</td>
<td>Yes</td>
<td><em>PfM</em>: Rama Boyapati/Battelle</td>
<td>In progress</td>
</tr>
<tr>
<td>Mobility</td>
<td></td>
<td></td>
<td></td>
<td><em>PfM</em>: Jinhyung Lee/OSU</td>
<td>In progress</td>
</tr>
<tr>
<td>Economic</td>
<td></td>
<td></td>
<td></td>
<td>TBD</td>
<td></td>
</tr>
<tr>
<td>Behavior/Satisfaction</td>
<td></td>
<td></td>
<td></td>
<td>TBD</td>
<td></td>
</tr>
</tbody>
</table>

**Program Level PfM**

<table>
<thead>
<tr>
<th>Project</th>
<th>IRB Oversight Required?</th>
<th>Demonstration Activities</th>
<th>Performance Measurement (PfM) Efforts</th>
<th>Principal Investigator</th>
<th>IRB Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCOS</td>
<td>No; Exempt</td>
<td>Yes</td>
<td></td>
<td><em>Dem</em>: Katie Robinson/Accenture</td>
<td><em>PfM</em>: In progress</td>
</tr>
<tr>
<td>CVE</td>
<td>Yes; subjects and activities for demo and PfM integrated</td>
<td>Yes</td>
<td><em>Dem</em>: Dr. Chris Toth/WSP</td>
<td><em>PfM</em>: Dr. Chris Toth/WSP</td>
<td><em>PfM</em>: In progress</td>
</tr>
<tr>
<td>MMTPA/ CPS</td>
<td>No; exemption received; informed consent not required</td>
<td>Yes</td>
<td><em>Dem</em>: Andy Wolpert, City of Columbus</td>
<td><em>PfM</em>: Dr. Rabi Mishalani/OSU</td>
<td><em>PfM</em>: In progress</td>
</tr>
<tr>
<td>MAPCD</td>
<td>Yes; subjects are from a protected class; activities for demo and PfM integrated</td>
<td></td>
<td></td>
<td><em>Dem</em>: Dr. Carmen DiGiovine/OSU</td>
<td><em>PfM</em>: Approved</td>
</tr>
<tr>
<td>PTA</td>
<td>Yes; subjects are from a protected class; activities for demo and PfM integrated</td>
<td></td>
<td></td>
<td><em>Dem</em>: Dr. Courtney Lynch/Dr. Erinn Hade/OSU</td>
<td><em>PfM</em>: Approved</td>
</tr>
<tr>
<td>SMH</td>
<td>No; exemption received; informed consent not required</td>
<td>Yes</td>
<td></td>
<td><em>Dem</em>: Jeff Kupko, MBI</td>
<td><em>PfM</em>: In progress</td>
</tr>
<tr>
<td>EPM</td>
<td>No; exemption expected</td>
<td>Yes</td>
<td></td>
<td><em>Dem</em>: Allyssa Chenault, City of Columbus</td>
<td><em>PfM</em>: In progress</td>
</tr>
<tr>
<td>Project</td>
<td>IRB Oversight Required?</td>
<td>Principal Investigator</td>
<td>IRB Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-------------------------</td>
<td>-------------------------</td>
<td>------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Demonstration Activities</td>
<td>Performance Measurement (PfM) Efforts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEAV</td>
<td>No; exemption received; informed consent not required</td>
<td>Yes</td>
<td>Demo: Jeff Kupko, MBI PfM: Elena Irwin/OSU</td>
<td>Demo: Exempt PfM: In progress</td>
<td></td>
</tr>
</tbody>
</table>

*Source: City of Columbus*
6.1.1. Elements of HUA Task

Project and performance measurement research protocol 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

6.1.2. Future Needs

Future IRB documentation and review needs vary by project and are included in each project’s section below. Elements that impact potential future needs include:

- **Project Timing**: EPM, for example, has not yet submitted a protocol to IRB, and CVE has not yet developed surveys, in keeping with project schedules. Performance measurement activities for many projects have also not yet begun. In such cases, protocols and/or supporting documentation such as surveys, training scripts, or outreach materials may be still under development to be submitted for IRB review in the future.

- **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 to the way participants are recruited would need to be approved by the IRB.

### 6.2. THE SMART COLUMBUS OPERATING SYSTEM

#### 6.2.1. Project Synopsis and Concept of Operations

##### 6.2.1.1. SCOPE

The Smart Columbus Operating System (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, 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.

##### 6.2.1.2. 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, devices, and people. All of which are a critical part of building this ecosystem of innovation. Data will be available for analytics and visualization. The Operating System is a platform 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 and download data. For new visitors, the Operating System website offers stories on how data is currently being used in real life scenarios, as well as ways to navigate the datasets available to the public. It also provides links to contribute data, and a “Contact Us” form to provide feedback or suggestions.

#### 6.2.2. Dependencies and Constraints

##### 6.2.2.1. SAFETY MANAGEMENT

The following safety scenarios related to the Operating System are discussed in the Safety Management Plan 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 Safety Management Plan Final Report. That document can be found on the Smart Columbus website.\(^5\)

The Safety Management Plan 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 the following safety functions:

- **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 demonstration program.

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 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.

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More detailed information on the privacy controls and security controls of the data collected and stored can be found in the Smart Columbus DPP, which can be found on the Smart Columbus website.\(^7\)

### 6.2.2.3. 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 Performance Measurement Plan Final Report, which can be found on the Smart Columbus website.\(^8\) Specific information in that document includes hypotheses, indicators, design of experiment, data collection, and impact evaluation.

### 6.2.3. Human Use Approval

#### 6.2.3.1. IRB PROCESS AND APPLICATION

This project received an exemption from its IRB for the demonstration itself, as human subjects are not directly involved. IRB oversight is required, however, for performance measurement. The PI for this project is Ramya Boyapati, a transportation researcher at Battelle in Columbus. A summary of IRB submittals and approvals for the project is shown in Table 6.2. This table will be updated as the project progresses.

<table>
<thead>
<tr>
<th>No.</th>
<th>Approval Date</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>5/23/2019</td>
<td>Exemption received for initial submission of IRB document</td>
</tr>
</tbody>
</table>

*Source: City of Columbus*

#### 6.2.3.2. IRB FEEDBACK

Currently, no feedback has been received for this project from the project’s IRB, because the project received an exemption.

If feedback is received in the future, this section will be updated to include:

- IRB feedback

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\(^7\) [https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf](https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf)

• 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 and IRB responses is provided in Appendix A. Current documents are:
• Protocol and survey submitted for review
• IRB exemption

This section and Appendix A will be updated as additional documents are submitted to and/or approvals received from the IRB.

6.2.3.4. FUTURE NEEDS
As the project progresses, its needs evolve. If IRB feedback is received, 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 before implementing the changes.

Events that could drive potential future amendments may include:
• Receipt of IRB feedback
• Changes to survey
• Changes in stakeholder policies on privacy, security, access, or other issues

6.3. CONNECTED VEHICLE ENVIRONMENT

6.3.1. Project Synopsis and Concept of Operations

6.3.1.1. 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 in 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 of the current system can be found in the CVE Concept of Operations Final Report. The document can be found on the Smart Columbus website.\(^9\)

6.3.1.2. RESEARCH CONCEPT DESIGN

The CVE project addresses needs in the enabling technologies focus area. The CVE project will enable other technologies that will be delivered through the other seven projects. The CVE project will integrate smart traveler applications, AV’s, CVs, and smart sensors into its transportation network by focusing on deploying CV infrastructure and applications.

- **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, on-board equipment (OBE), 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.

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.

The deployment of in-vehicle devices will target populations located near frequently used infrastructure deployment corridors. The CVE project will connect up to 1,800 vehicles and 95 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. Application deployments will ensure that the Central Ohio Transit Agency (COTA) bus rapid transit (BRT) fleet can pre-empt traffic signals as needed to increase efficiency, and that emergency vehicles can pre-empt traffic signals as needed to increase safety.

Further details of the proposed solution are discussed in the CVE Concept of Operation Final Report, which can be found on the Smart Columbus website.\(^10\)

6.3.2. Dependencies and Constraints

6.3.2.1. SAFETY MANAGEMENT

The Safety Management Plan Final Report states that the vehicle operator must be in full control of the vehicle at all times and must assess the situation 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 Safety Management Plan Final Report:

- De-identification of PII
- Unauthorized access to CVE system or OBU
- Equipment malfunction/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 Safety Management Plan Final Report.

The Safety Management Plan 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 the following safety functions:

• **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.

Further details on equipment procurement and device installation can be found in the Demonstration Site Map and Installation Document Final Report, which can be found on the Smart Columbus website.\(^{11}\)

• **Fail-Safe System Mode:** The CVE system will revert to a fail-safe mode when 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 demonstration program.

Further details on the safety operational concept are in the Smart Columbus Safety Management Plan Final Report, which can be found on the Smart Columbus website.\(^{12}\)

### 6.3.2.2. DATA PROTECTION AND PRIVACY

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

• Which data will be collected
• The intended use and recipients of the data

All informed consent processes will include:

\(^{11}\) [https://d2rfd3nxvhlf29.cloudfront.net/2020-01/SCC-B-DSP-IS_FINAL-20200124.pdf](https://d2rfd3nxvhlf29.cloudfront.net/2020-01/SCC-B-DSP-IS_FINAL-20200124.pdf)

• 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

More detailed information on the privacy controls and security controls for the data collected and stored can be found in the Smart Columbus DPP, which can be found on the Smart Columbus website.

6.3.2.3. PERFORMANCE MEASUREMENT

Desired outcomes for the CVE project team 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
• And 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 Performance Measurement Plan Final Report, which can be found on the Smart Columbus website.¹³

6.3.3. Human Use Approval

6.3.3.1. IRB PROCESS AND APPLICATION

IRB oversight is required for the CVE project because it involves human subjects during both the demonstration and the performance measurement activities. The PI for the CVE project is Chris Toth, who is from WSP. Dr. Toth will oversee both the demonstration and the performance measurement for the project. A summary of IRB submittals and approvals for the CVE project is shown in Table 6.3, which will be updated as the project progresses as needed.

Table 6.3: CVE IRB Submittal and Approval Summary

<table>
<thead>
<tr>
<th>No.</th>
<th>Approval</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Pending; feedback received</td>
<td>Initial submission of IRB document</td>
</tr>
</tbody>
</table>

Source: City of Columbus

6.3.3.2. IRB FEEDBACK

IRB feedback was received in response to the initial IRB document submission. The feedback received is shown in **Table 6.4**. This table will be updated as needed.

Table 6.4: CVE IRB Feedback Summary

<table>
<thead>
<tr>
<th>Category</th>
<th>IRB Feedback</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process</td>
<td>All protocol components must be included prior to review.</td>
<td>In progress</td>
</tr>
<tr>
<td>Amendment</td>
<td>Add “Key Information” section to ICD.</td>
<td>Modified ICD</td>
</tr>
<tr>
<td>Clarification</td>
<td>Clarify equipment value and removal costs to participant, if they opt to keep equipment after the demonstration period.</td>
<td>Drafting response; will include revised ICD in future IRB submission</td>
</tr>
<tr>
<td>Clarification</td>
<td>Elaborate on PI’s research experience.</td>
<td>Provided qualifications over email</td>
</tr>
<tr>
<td>Clarification</td>
<td>Clarify setting and plan for IC discussion at automotive shops.</td>
<td>Modified ICD</td>
</tr>
<tr>
<td>Documentation</td>
<td>Include device privacy policy and/or Terms of Use, if applicable.</td>
<td>No device privacy policy; separated Terms of Use from ICD</td>
</tr>
<tr>
<td>Clarification/Documentation</td>
<td>Are different IC forms needed for different target participant groups? If so, provide forms or explain why not needed.</td>
<td>Added ICD form for COTA/City fleet</td>
</tr>
<tr>
<td>Clarification</td>
<td>Provide detailed description of OBU (including mounting location, message display, and warning delivery).</td>
<td>Added to protocol</td>
</tr>
</tbody>
</table>

*Source: City of Columbus*

6.3.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to IRB for review and IRB responses is provided in Appendix A. The document currently in the list is:

- Initial IRB submission

This section and Appendix A will be updated as additional documents are submitted to and/or approvals received from the CVE IRB. Anticipated future submissions may include:

- Revised protocol
- ICD (private drivers and COTA/City fleets)
- ICD review script
- CVE equipment training script
- Surveys

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

- 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 study protocol.

### 6.4. MULTIMODAL TRIP PLANNING APPLICATION AND COMMON PAYMENT SYSTEM

#### 6.4.1. Project Synopsis and Concept of Operations

**6.4.1.1. SCOPE**

The MMTPA/CPS project addresses a challenge Columbus residents and visitors face currently because there is no system to seamlessly plan or pay for a trip involving multiple transportation options. In addition, some residents are unbanked (they do not have a bank account) and therefore cannot use alternative modes of transportation including car- and bike-sharing systems.

Motivation for the MMTPA/CPS project focused on the lack of access to coordinated multimodal options, the inability to compare prices across modes, and the need for integration with a CPS. The MMTPA/CPS will provide this functionality and improve on the existing functionality.

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

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

Detailed information on the current system can be found in the MMTPA/CPS Concept of Operations Final Report. The document can be found on the Smart Columbus website.14

**6.4.1.2. RESEARCH CONCEPT DESIGN**

The MMTPA/CPS system 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. Travelers will be required to create a CPS account to pay for 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 or at a negotiated frequency (weekly or monthly) for all rides paid for using the MMTPA/CPS. Payment for services will be deducted immediately from travelers’ accounts and credited toward the appropriate Mobility

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Provider’s account. Travelers will also have the option of funding their CPS accounts on a fixed schedule or when the existing balances fall below a set threshold.

Further details of the proposed solution can be found in the MMTPA/CPS Concept of Operations Final Report on Smart Columbus website.  

6.4.2. Dependencies and Constraints

6.4.2.1. SAFETY MANAGEMENT

The following safety scenarios related to the MMTPA/CPS project are discussed in the Safety Management Plan Final Report:

- Traffic and emergencies
- Unavailability of recommended modes
- Application unavailability due to maintenance or failure
- De-identification and PII exposure
- Lack of nearby places to fund CPS account

Further information on the safety scenarios and proposed mitigation strategies identified for the MMTPA/CPS project is in the Safety Management Plan Final Report. The Safety Management Plan 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/CPS 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/CPS will have a fail-safe system mode. The application will revert to a fail-safe mode when 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 demonstration program.

Further details on the safety operational concept can be found in the Smart Columbus Safety Management Plan Final Report on the Smart Columbus website.  

6.4.2.2. DATA PROTECTION AND PRIVACY

Travelers may wish to create an account within the MMTPA to store preferences that could simplify planning subsequent multimodal trips. Account information may include user name; email address; addresses for work, school, and home; addresses of common destinations, and whether they need an accessible vehicle. 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

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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.

The CPS will collect financial information from users in the form of payment methods (e.g., credit card number, type, expiration date); that information will be stored in the CPS user account for use by the payment processor. Because it collects and stores financial information, the CPS will be subject to Payment Card Industry (PCI) data security standards.

More detailed information on the privacy and security controls on the data collected and stored can be found in the Smart Columbus DPP, which is on the Smart Columbus website.\(^{17}\)

### 6.4.2.3. PERFORMANCE MEASUREMENT

Desired outcomes for the MMTPA/CPS 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, the design of the experiment, the data collection, and the impact evaluation for all the objectives is provided in the Smart Columbus Performance Measurement Plan Final Report, which can be found on the Smart Columbus website.\(^{18}\)

### 6.4.3. Human Use Approval

#### 6.4.3.1. IRB PROCESS AND APPLICATION

This project received an exemption from the MMTPA/CPS IRB for the demonstration itself, as human subjects are not directly involved. IRB oversight is required, however, for performance measurement activities. The PI for this project is Rabi Mishalani, who is from OSU. A summary of IRB submittals and approvals for the project is shown in Table 6.5.

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\(^{17}\) [https://d2rfd3nxvhnl29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf](https://d2rfd3nxvhnl29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf)

Table 6.5: MMTPA/CPS IRB Submittal and Approval Summary

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<tr>
<th>No.</th>
<th>Approval</th>
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<tbody>
<tr>
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<td>2/20/2019 (exempt)</td>
<td>Protocol – Phase 1</td>
</tr>
<tr>
<td>01</td>
<td>4/30/2019 (exempt)</td>
<td>Protocol – Phase 2</td>
</tr>
<tr>
<td>02</td>
<td>7/8/2019 (exempt)</td>
<td>Protocol – Phase 3</td>
</tr>
<tr>
<td>03</td>
<td>2/20/2019 (exempt)</td>
<td>Survey – Phase 1</td>
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<tr>
<td>04</td>
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<td>Survey – Phase 2</td>
</tr>
<tr>
<td>05</td>
<td>7/8/2019 (exempt)</td>
<td>Survey – Phase 3</td>
</tr>
</tbody>
</table>

Source: City of Columbus

6.4.3.2. IRB FEEDBACK

Currently, no feedback has been received for the MMTPA/CPS project from the IRB because 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

6.4.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the project’s IRB for review and IRB responses is provided in Appendix A. Current documents include:

- Research protocol for phases 1, 2, and 3
- Surveys for phases 1, 2, and 3
- Exemptions

This section and Appendix A will be updated as additional documents are submitted to and/or approvals are received from the IRB. Anticipated future submissions may include surveys.

6.4.3.4. 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
- Changes to survey questions
- Changes to stakeholder policies on issues such as privacy, security, or access
6.5. MOBILITY ASSISTANCE FOR PERSONS WITH COGNITIVE DISABILITIES

6.5.1. Project Synopsis and Concept of Operations

6.5.1.1. 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 can be found in the MAPCD Trade Study Final Report 19, which is on the Smart Columbus website.

6.5.1.2. 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" is the preferred solution for Smart Columbus, provided that AbleLink successfully integrates the functionality to actively track an individual on a route. The mobile application will feature 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 20, which is on the Smart Columbus website.

6.5.2. Dependencies and Constraints

6.5.2.1. SAFETY MANAGEMENT

The following safety scenarios related to the MAPCD project are discussed in the Safety Management Plan 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

For information on the safety scenarios and proposed mitigation strategies for the MAPCD project is in the Safety Management Plan Final Report.

The Safety Management Plan 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 the following safety functions:

• **Equipment Procurement**: No equipment will be installed as part of the MAPCD project. An application will be deployed to help people with cognitive disabilities travel safely and independently.

• **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 when 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 demonstration program.

Further details on the safety operational concept can be found in the Smart Columbus Safety Management Plan Final Report on the Smart Columbus website.\(^\text{21}\)

### 6.5.2.2. DATA PROTECTION AND PRIVACY

As part of the MAPCD project, travelers willing to use the MAPCD application may have to provide information, which could include user name, 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 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. 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 authorization.

More detailed information on the privacy controls and security controls on the data collected and stored is in the Smart Columbus DPP, which is on the Smart Columbus website.\(^\text{22}\)

### 6.5.2.3. 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

\(\text{22} \) https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf
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 Performance Measurement Plan Final Report, which is on the Smart Columbus website.23

### 6.5.3. Human Use Approval

#### 6.5.3.1. IRB PROCESS AND APPLICATION

IRB oversight is required because the MAPCD project involves human subjects during both the demonstration and performance measurement activities. The PI for this project is Carmen DiGiovine from OSU, who will oversee both the demonstration itself and the performance measurement for the project. A summary of IRB submittals and approvals for the project is shown in Table 6.6.

#### Table 6.6: MAPCD IRB Submittal and Approval Summary

<table>
<thead>
<tr>
<th>No.</th>
<th>Approval</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1/14/2018</td>
<td>Initial submission of IRB document</td>
</tr>
<tr>
<td>01</td>
<td>1/23/2019</td>
<td>Amendment 1 (Personnel)</td>
</tr>
<tr>
<td>02</td>
<td>2/15/2019</td>
<td>Amendment 3 (Personnel)</td>
</tr>
<tr>
<td>03</td>
<td>3/18/2019</td>
<td>Amendment 2 (Summary/Background/Objectives, Research Methods &amp; Activities, Duration, Participants [number, population, identification], Informed Consent Process, Monitoring)</td>
</tr>
<tr>
<td>04</td>
<td>5/14/2019</td>
<td>Amendment 4 (External Collaborators, Research Methods and Activities, Duration, Participant Identification, Incentives to Participate, Informed Consent Process)</td>
</tr>
<tr>
<td>05</td>
<td>5/21/2019</td>
<td>Amendment 06 (Personnel)</td>
</tr>
<tr>
<td>06</td>
<td>5/29/2019</td>
<td>Amendment 07 (Personnel)</td>
</tr>
<tr>
<td>07</td>
<td>7/10/2019</td>
<td>Amendment 08 (Personnel)</td>
</tr>
<tr>
<td>08</td>
<td>7/22/2019</td>
<td>Amendment 09 (Personnel)</td>
</tr>
<tr>
<td>09</td>
<td>7/29/2019</td>
<td>Amendment 10 (Personnel)</td>
</tr>
<tr>
<td>10</td>
<td>9/3/2019</td>
<td>Amendment 11 (Personnel)</td>
</tr>
</tbody>
</table>

*Source: City of Columbus*

#### 6.5.3.2. IRB FEEDBACK

IRB feedback was received in response to the IRB document submission. The feedback received is shown in Table 6.7.

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Table 6.7: MAPCD IRB Feedback Summary

<table>
<thead>
<tr>
<th>Category</th>
<th>IRB Feedback</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>Rename/reorganize study phases, clarify WayFinder objective and description, increase number of participants, change incentive amount, revise consent for to reflect changes</td>
<td>Completed</td>
</tr>
<tr>
<td>Data Collection</td>
<td>Provide details on data collected and potential confidentiality breaches related to assent</td>
<td>Completed</td>
</tr>
<tr>
<td>Protocol</td>
<td>Revise protocol for consistency with requested revisions</td>
<td>Completed</td>
</tr>
<tr>
<td>Protocol</td>
<td>Please submit tracked changes and clean copy</td>
<td>Completed</td>
</tr>
</tbody>
</table>

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

6.5.3.3. SUPPORTING DOCUMENTATION

A list of documents submitted to the MAPCD IRB for review and IRB responses is provided in Appendix A. Approved documents are:

- 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 and Appendix A will be updated as additional documents are submitted to and/or approvals are received from the IRB. Anticipated future submissions may include:

- Changes to protocol or other documents, if needed

6.5.3.4. FUTURE NEEDS

As the project progresses, its needs will evolve. If 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.
• Participation Rates: The need for changes to participant eligibility criteria and recruiting methods or materials to reach targets.
• Technology: Changes to the mobile application that impact issues such as privacy or security.

6.6. PRENATAL TRIP ASSISTANCE

6.6.1. Project Synopsis and Concept of Operations

6.6.1.1. SCOPE
Motivation for the PTA project is focused on providing more reliable Non-Emergency Medical Transportation (NEMT) services for prenatal travelers and filling the gaps that are present in the current system, such as the delays in pickup times, lack of multiple reminders, the ability to schedule from a smartphone application or computer, and integration with a trip optimization system. The PTA project will provide solutions for these problems and improve the functionality available with the current system.

Further details on the current system, as well as on the background and scope of the project, can be found in the PTA Concept of Operations Final Report, which is on the Smart Columbus website.

6.6.1.2. 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 be the solution integrator, 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 Concept of Operations Final Report on the Smart Columbus website.

6.6.2. Dependencies and Constraints

6.6.2.1. SAFETY MANAGEMENT
The following safety scenarios related to the PTA project are discussed in the Safety Management Plan Final Report:

• Trip delay or cancellation
• Communication limitations
• Application unavailability due to maintenance or failure
• De-identification and exposed PII
• Unsafe driver behavior

24 https://d3hzplpmmz6ge4.cloudfront.net/2019-07/Prenatal%20Trip%20Assistance%20Concept%20of%20Operations.pdf
• Lack of or improperly installed car seats

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

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 the following safety functions:

• **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 when 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 demonstration program.

Further details on the safety operational concept can be found in the Smart Columbus Safety Management Plan Final Report on the Smart Columbus website.

### 6.6.2.2. DATA PROTECTION AND PRIVACY

Prenatal travelers who use PTA may have to provide information, which could include user name; email address; addresses for work, school, and home; and addresses of common destinations, as well as an indication of preferred method for receiving notifications. The prenatal traveler may also allow the PTA application to know her current location, to simplify entering her origin when scheduling an on-demand trip. Requirements for storing PII in the PTA will be addressed in the DPP. End-user account information will not be distributed outside of the PTA. The PTA application will use industry-standard security mechanisms to protect the account 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.

More detailed information on the privacy and security controls on the data collected and stored is in the Smart Columbus DPP, which is on the Smart Columbus website.

### 6.6.2.3. 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

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27 https://d2rfd3nxvhnt29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf
Detailed information on the hypotheses, indicators, the design of the experiment, data collection, and impact evaluation for all the objectives is provided in the Smart Columbus Performance Measurement Plan Final Report, which can be found on the Smart Columbus website.28

6.6.3. Human Use Approval

6.6.3.1. 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 activities. The PIs for this project are Drs. Courtney Lynch and Erinn Hade from OSU, overseeing both the demonstration itself and performance measurement for the project. A summary of IRB submittals and approvals for the project is shown in Table 6.8. This table will be updated as the project progresses, as needed.

Table 6.8: PTAIRB Submittal and Approval Summary

<table>
<thead>
<tr>
<th>No.</th>
<th>Approval</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4/18/2019</td>
<td>Initial submission of IRB document and participant recruitment plan</td>
</tr>
<tr>
<td>01</td>
<td>5/20/2019</td>
<td>Amendment to included Health Insurance Portability and Accountability Act of 1996 (HIPAA) Language and minor changes to document</td>
</tr>
<tr>
<td>02</td>
<td>5/28/2019</td>
<td>Amendments to typeset ads, document (minor), informed consent language, transportation survey provider surveys, recruitment flow and data transfer to Medicaid plans, and eligibility criteria</td>
</tr>
<tr>
<td>03</td>
<td>5/31/2019</td>
<td>Personnel amendment</td>
</tr>
<tr>
<td>04</td>
<td>6/04/2019</td>
<td>Amendment to Medicaid ride benefit language (minor)</td>
</tr>
<tr>
<td>05</td>
<td>6/14/2019</td>
<td>Personnel amendment</td>
</tr>
<tr>
<td>06</td>
<td>7/16/2019</td>
<td>Amendments to questionnaires, protocol for participant reminders, and advertisements</td>
</tr>
<tr>
<td>07</td>
<td>6/14/2019</td>
<td>Personnel amendment</td>
</tr>
<tr>
<td>08</td>
<td>6/19/2019</td>
<td>Personnel amendment</td>
</tr>
<tr>
<td>09</td>
<td>N/A</td>
<td>Deleted</td>
</tr>
<tr>
<td>10</td>
<td>8/30/2019</td>
<td>Amendment to protocol to enable expanded recruitment and eligibility criteria</td>
</tr>
<tr>
<td>12</td>
<td>1/6/2020</td>
<td>Amendment to advertising materials, welcome letter, final interview; expanded recruitment to include Women, Infants, and Children (WIC) clinics</td>
</tr>
</tbody>
</table>

Source: City of Columbus

6.6.3.2. 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:

• 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 IRB for review and IRB responses is provided in Appendix A. Approved documents include:

• Initial IRB submission
• Amendments
• Approvals
• Recruitment and outreach materials
• Physician 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
• Informed Consent form

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

• Recruitment protocol and/or materials changes

6.6.3.4. 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
• Participation Rates: The need for changes to participant eligibility criteria and recruiting methods or materials to reach target levels
• Policy Changes: Changes in MCO, NEMT provider, or other stakeholder policies
6.7. SMART MOBILITY HUBS

6.7.1. Project Synopsis and Concept of Operations

6.7.1.1. 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/CPS) and real-time transportation information. The services are designed to accommodate multiple modes of transportation from a single location including bike-share, car-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 can be found in the SMH Concept of Operations Final Report on the Smart Columbus website. 29

6.7.1.2. 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 can be found in the SMH Concept of Operations Final Report on the Smart Columbus website. 30

6.7.2. Dependencies and Constraints

6.7.2.1. SAFETY MANAGEMENT

The following SMH safety scenarios related to the SMH project are discussed in the Safety Management Plan Final Report:

- Difficulty locating the emergency call button (ECB).
- Emergency response delays.
- Kiosk unavailable due to maintenance or failure.
- Exposure of PII.
- Hub access restricted due to host site hours of operation.

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29 https://d3hzplpmz6qe4.cloudfront.net/2019-07/Smart%20Mobility%20Hubs%20Concept%20of%20Operations.pdf
30 https://d3hzplpmz6qe4.cloudfront.net/2019-07/Smart%20Mobility%20Hubs%20Concept%20of%20Operations.pdf
• Unsafe traveler behavior.
• Unavailable or inaccurate mode recommendations.
• Kiosk inaccessibility due to weather.

Further information on the safety scenarios and proposed mitigation strategies identified for the SMH project is in the Safety Management Plan Final Report.

The Safety Management Plan 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, signage, and pavement markings 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 upon failure of the system to meet necessary and essential operational capabilities as defined in project’s system requirement documentation.

• **Quality Training**: All system operators, system maintainers, installers/maintainers and owners of a response plan included referenced herein will receive adequate, approved training based on their point of interface with the system. This training will be documented as it occurs as part of the Smart Columbus demonstration program.

Further details on equipment procurement and device installation are in the Demonstration Site Map and Installation Document Final Report, which is on the Smart Columbus website.  

Further details on the safety operational concept can be found in the Smart Columbus Safety Management Plan Final Report on the Smart Columbus website.  

### 6.7.2.2. DATA PROTECTION AND PRIVACY

As part of the SMH project, the Wi-Fi network at SMH facilities will be developed in accordance with best practices in data security and privacy. Data security refers to the tools, policies, practices, and procedures used to protect data from being accessed, manipulated, or destroyed, or from being leveraged by unauthorized people or those with a malicious intent. Data privacy is the reasonable expectation that sensitive data will be kept confidential, sanitized and/or encrypted, and respectfully and responsibly maintained by all users, managers, and collectors of the data, while adhering to applicable laws and regulations, policies, and procedures.

More detailed information on the privacy controls and security controls on the data collected and stored is in the Smart Columbus DPP on the Smart Columbus website.  

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33 [https://d2rd3nxvhf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf](https://d2rd3nxvhf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf)
6.7.2.3. 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

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

Detailed information on the hypotheses, indicators, the design of the experiment, data collection, and impact evaluation for all the objectives is provided in the Smart Columbus Performance Measurement Plan Final Report on the Smart Columbus website.34

6.7.3. Human Use Approval

6.7.3.1. IRB PROCESS AND APPLICATION

The SMH project has not yet undergone IRB review for demonstration activities. IRB oversight is required, however, for performance measurement activities. The PI for this project is Elena Irwin, who is from OSU.

6.7.3.2. 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

6.7.3.3. SUPPORTING DOCUMENTATION

Not documentation has yet been submitted to the IRB.

6.7.3.4. FUTURE NEEDS

As the project has not yet undergone IRB review, protocol will be submitted to IRB at a future date. Depending on IRB review, modifications to protocol or supporting documentation may be needed.

6.8. EVENT PARKING MANAGEMENT

6.8.1. Project Synopsis and Concept of Operations

6.8.1.1. 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 Concept of Operations Final Report on the Smart Columbus website.35

6.8.1.2. 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 with the CPS. 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 Concept of Operations Final Report on the Smart Columbus website.36

6.8.2. Dependencies and Constraints

6.8.2.1. SAFETY MANAGEMENT

The following safety scenarios are discussed in the Safety Management Plan 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 Safety Management Plan Final Report.

The Safety Management Plan 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 the following safety functions:

- **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 when the system 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 included 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 demonstration program.

Further details on the safety operational concept are in the Smart Columbus Safety Management Plan Final Report on the Smart Columbus website.\(^{37}\)

### 6.8.2.2. DATA PROTECTION AND PRIVACY

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 user name; 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 anonymized. 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. However, payment information will not go to the OS from the EPM system. EPM also will not save any PCI information as a result of a payment transaction using the CPS.

More detailed information on the privacy and security controls for the data collected and stored are in the Smart Columbus DPP on the Smart Columbus website.\(^{38}\)

### 6.8.2.3. 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 Performance Measurement Plan Final Report on the Smart Columbus website.\(^{39}\)

### 6.8.3. Human Use Approval

#### 6.8.3.1. IRB PROCESS AND APPLICATION

The EPM project is expected to receive an exemption from the IRB for the demonstration itself, as human subjects are not directly involved. IRB oversight will be required, however, for performance measurement activities. The PI for this project is Alex Kavanagh, from HNTB. A summary of IRB submittals and approvals for the project is shown in Table 6.9.

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38 https://d2rdf3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf
Table 6.9: EPM IRB Submittal and Approval Summary

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<tr>
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<td>In progress</td>
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_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 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

6.8.3.3. SUPPORTING DOCUMENTATION

Currently, no documents have been submitted to the IRB. Once documents are submitted, a list of them and IRB responses will be provided in Appendix A.

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

- Protocol
- Surveys
- Recruitment materials

6.8.3.4. FUTURE NEEDS

As the project progresses, project needs evolve, or feedback is received from the IRB, modifications to the research protocol and/or accompanying documents may be required. 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.
- **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.
6.9. CONNECTED ELECTRIC AUTONOMOUS VEHICLES

6.9.1. Project Synopsis and Concept of Operations

6.9.1.1. SCOPE

The use of connected and automated shuttles has been widely proposed as a solution to the FMLM challenge. In response to that suggestion, this project will develop solutions to the social and technical challenges associated with use of Connected Electric Autonomous Vehicles (CEAV) technology for safer and more efficient access to jobs and services in the city.

Further details on the project background and scope are in the CEAV Operational Concept Final Report on the Smart Columbus website.40

6.9.1.2. 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, OSU, and the Columbus Partnership to plan, implement, and evaluate the deployment of automated vehicles in the City. Working with these partners allows various use cases to be generated, which will result in the 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.41

6.9.2. Dependencies and Constraints

6.9.2.1. SAFETY MANAGEMENT

The Safety Management Plan 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 are discussed in the Safety Management Plan Final Report:

- Vulnerable road user such as pedestrians, bikes, and scooters
- Unsafe human behaviors
- Issues operating in higher-speed traffic
- Operator distraction or inadequate training

Chapter 6. Human Use Approval by Project

- Passengers stranded during CEAV maintenance

Further information on the safety scenarios and proposed mitigation strategies identified for the CEAV project is in the Safety Management Plan Final Report. The Safety Management Plan 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 in 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 can be found in the Demonstration Site Map and Installation Document Final Report, which can be found on the Smart Columbus website.42

- **Fail-Safe System Mode**: CEAV system will have a fail-safe system mode. The system will revert to a fail-safe mode upon failure of the system to meet necessary and 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 based on their point of interface with the system. This training will be documented as it occurs as part of the Smart Columbus demonstration program.

Further details on equipment procurement and device installation are in the Demonstration Site Map and Installation Document Final Report on the Smart Columbus website. Further details on the safety operational concept are in the Smart Columbus Safety Management Plan Final Report, also on the Smart Columbus website.43

6.9.2.2. DATA PROTECTION AND PRIVACY

Smart Columbus will not collect any PII from travelers who ride CEAVs.

More detailed information on the privacy and security controls on the data collected and stored can be found in the Smart Columbus DPP on the Smart Columbus website.44

6.9.2.3. 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

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

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


44 [https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf](https://d2rfd3nxvhnf29.cloudfront.net/2019-09/SCC-D-Data%20Privacy%20Plan-FINAL-20190906%5B1%5D_0.pdf)
• 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 Performance Measurement Plan Final Report, which is on the Smart Columbus website.⁴⁵

6.9.3. Human Use Approval

6.9.3.1. IRB PROCESS AND APPLICATION

This project received an exemption from the IRB for the demonstration itself, as human subjects are not directly involved. IRB oversight is required, however, for performance measurement activities. The PI for this project is Elena Irwin, from OSU. A summary of IRB submittals and approvals for the Smart Circuit Demonstration part of the project is shown in Table 6.10, and similar information is shown for the Linden Demonstration in Table 6.11.

Table 6.10: CEAV IRB Submittal and Approval Summary for Smart Circuit Demonstration

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Source: City of Columbus

Table 6.11: CEAV IRB Submittal and Approval Summary for Linden Demonstration

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<td>1/15/2020</td>
<td>Linden Shuttle Survey Protocol.pdf</td>
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Source: City of Columbus

6.9.3.2. IRB FEEDBACK

Currently, no feedback has been received for this project from the IRB, because 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 IRB for review and IRB responses is provided in Appendix A. Items currently awaiting IRB review include:

Chapter 6. Human Use Approval by Project

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

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

- Changes to protocol or other documents, if needed

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 prior to implementing the proposed changes.

Events that could drive potential future amendments may include:

- Receipt of IRB feedback.
- **Policy Changes:** Changing stakeholder policies on privacy, security, access, and so forth.
Chapter 7. Conclusions

The Smart Columbus Program 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.
# Chapter 8. References and Acronyms

## 8.1. REFERENCES

Table 8.1: References contains acronyms used throughout this document.

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<td>–</td>
<td>Smart Columbus Demonstration Program MAPCD Trade Study</td>
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### Table 8.2: Acronyms

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<th>Definition</th>
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<td>ADA</td>
<td>Americans with Disabilities Act</td>
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<tr>
<td>API</td>
<td>Application Programming Interface</td>
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<tr>
<td>AV</td>
<td>Autonomous Vehicles</td>
</tr>
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<td>BRT</td>
<td>Bus Rapid Transit</td>
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Source: City of Columbus
<table>
<thead>
<tr>
<th>Abbreviation/Acronym</th>
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<td>CEAV</td>
<td>Connected Electric Autonomous Vehicles</td>
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<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
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<td>CITY</td>
<td>City of Columbus</td>
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<td>COTA</td>
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<td>CPS</td>
<td>Common Payment System</td>
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<td>CV</td>
<td>Connected Vehicles</td>
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<td>CVE</td>
<td>Connected Vehicle Environment</td>
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<td>DMP</td>
<td>Data Management Plan</td>
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<td>DPP</td>
<td>Data Privacy Plan</td>
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<td>DSRC</td>
<td>Dedicated Short-Range Communications</td>
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<td>ECB</td>
<td>Emergency Call Button</td>
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<td>Enhances Human Services</td>
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<td>Event Parking Management</td>
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<td>First-mile/Last-mile</td>
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<td>Federal-wide assurance</td>
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<td>HIPAA</td>
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<td>ICD</td>
<td>Informed Consent Document</td>
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<td>Multimodal Trip Planning Application</td>
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<td>MPA</td>
<td>Multiple project assurance</td>
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<td>OBE</td>
<td>On-Board Equipment</td>
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<td>PII</td>
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Source: City of Columbus
Chapter 9. List of Appendices

APPENDIX A. SUPPORTING DOCUMENTATION LIST

APPENDIX B. IRB APPROVALS AND EXEMPTIONS
Appendix A. Supporting Documentation List

Table 1. OS Supporting Documentation

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Table 6. SMH Supporting Documentation

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Table 8.A. CEAV Supporting Documentation for Linden LEAP Demonstration

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<td>Linden Shuttle Survey Protocol.pdf</td>
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Table 9.B. CEAV Supporting Documentation for Smart Circuit Demonstration

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## Appendix B. IRB Approvals and Exemptions

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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: 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.
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.
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>
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
**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>
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.

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.

[Signature]

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>
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.

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
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
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>
**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

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

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
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>
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.

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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
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>
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
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>
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
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>
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

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
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>
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

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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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>
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

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
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>
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

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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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>
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

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
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>
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.

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](https://orapps.osu.edu/buck-irb/index/view-correspondence/study/39761/correspondence/125953) and [Research Data](https://orapps.osu.edu/buck-irb/index/view-correspondence/study/39761/correspondence/125953).

Human research protection program policies, procedures, and guidance can be found on the [ORRP website](https://orapps.osu.edu/buck-irb/index/view-correspondence/study/39761/correspondence/125953).

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