HUMAN USE
APPROVAL SUMMARY
SPEAKERS

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TODAY’S AGENDA

01 | PURPOSE OF THIS WEBINAR
• Share human use activities from Smart Columbus with stakeholders

02 | WEBINAR CONTENT
• Smart Columbus program overview
• Document purpose and overview
• Background on oversight of human use and summary of human use approval process
• Dependencies and constraints
• Human use approval for Smart Columbus (program and project)
• Lessons learned
• How to stay connected
• Stakeholder Q&A

03 | WEBINAR PROTOCOL
• All participant lines have been muted during the webinar in order to reduce background noise
• Questions are welcome via chatbox during the Q&A Section
• The webinar recording and presentation materials will be posted on the Smart Columbus website
$40 MILLION
78 APPLIED • COLUMBUS WON

VISION:
To empower our residents to live their best lives through responsive, innovative and safe mobility solutions.

MISSION:
To demonstrate how an intelligent transportation system and equitable access to transportation can have positive impacts on every day challenges faced by cities.

OUTCOMES:
- SAFETY
- MOBILITY
- OPPORTUNITY
- ENVIRONMENT
- AGENCY EFFICIENCY
- CUSTOMER SATISFACTION

THE CITY OF COLUMBUS
ANDREW J. GINTHER, MAYOR

SMART CITY CHALLENGE

U.S. Department of Transportation
USDOT PORTFOLIO

SMRT OPERATING SYSTEM

ENABLING TECHNOLOGIES
- CONNECTED VEHICLE ENVIRONMENT

ENHANCED HUMAN SERVICES
- MULTIMODAL TRIP PLANNING/
  COMMON PAYMENT SYSTEM
- SMART MOBILITY HUBS
- MOBILITY ASSISTANCE
- PRENATAL TRIP ASSISTANCE
- EVENT PARKING MANAGEMENT

EMERGING TECHNOLOGIES
- CONNECTED ELECTRIC AUTONOMOUS VEHICLES
USDOT PORTFOLIO

Connected Vehicle Environment
- 100+ roadside units
- 1,500-1,800 on-board units
- 1,240 light duty vehicles
  - 430 transit vehicles
  - 110 emergency vehicles
  - 12 freight vehicles

Connected Electric Autonomous Vehicles
- Scioto Mile Deployment (May Mobility)
  - December 2018-September 2019
  - 6 vehicles
- Linden Deployment (EasyMile)
  - January 2020-January 2021
  - 2 vehicles

Smart Mobility Hubs
- 6 locations to facilitate first-mile/last-mile connections
- Anchored by an interactive kiosk
USDOT PORTFOLIO

Operating System

• Big data and complex data exchange
• Analytics and visualization
• Data aggregation, fusion and consumption
• Replicable and scalable

Mobility Assistance

• Research study with app for turn-by-turn navigation
• Increase independence
• Up to 30 participants

Multimodal Trip Planning App

• Publicly available app (Pivot)
• Backed by Common Payment System

Prenatal Trip Assistance

• Research study to improve transportation for moms-to-be
• Up to 500 participants

Event Parking Management

• Publicly available app (ParkColumbus)
• Probability of on-street parking
• Reserve private lot/garage spaces
HUMAN USE APPROVAL SUMMARY: DOCUMENT OVERVIEW
• Summarizes Institutional Review Board (IRB) activities by program and project
• Describes coordination of IRB activities and other project engineering and development activities
• Identifies dependencies and constraints
• Considers events and activities that could create future IRB need

DOCUMENT OBJECTIVE

Provides protection of human subjects
BACKGROUND ON THE USE OF HUMAN SUBJECTS
Key historical examples of gross human test subject abuses in the name of science or the greater good:

- Nazi medical experiments during WWII
- Tuskegee Experiment
**RESEARCH PRINCIPLES**

1979 Belmont Report

- Respect for persons: informed consent
- Beneficence: benefits vs. risks
- Justices: equity of distribution of benefits/risks
Common Rule, 49 CFR Part 11

- Covered research
- Institutional Review Board
- Exemptions and Expedited Review
SUMMARY OF HUMAN USE APPROVAL PROCESS
Institutional Review Board (IRB): Organization authorized to review and monitor research involving human subjects

Human Subject: “...a living individual about whom an investigator (whether professional or student) conducting research obtains information...” (49 CFR Part 11)
ROLES AND RESPONSIBILITIES

Project Manager (PM)
• Planning/execution of project activities
• Develop/maintain schedule
• Support PI requests for information

Principal Investigator (PI)
• Actively monitoring the HUA process
• Updating IRB applications/amendments
• Coordinating with other project- and program-level activities

Program Management Office (PMO)
• Summarizing HUAS process
• Sharing Information (per Cooperative Agreement with USDOT)
• Developing the HUA Summary
Cooperative Agreement Task F: Safety Management and Safety Assurance

- Identification of underlying safety needs associated with the safety of all travelers, subjects and other personnel associated with the Smart City Demonstration
  - Safety Management
  - Human Use Approval for components using human participants
Components of Human Use Approval Task

- Initial application to IRB and supporting documents
  - Recruitment materials
  - Informed consent document
  - Surveys
- Feedback and modifications
- Exemption or approval
**SCOPE**

**IRB Approach:** use of multiple IRBs both public and private:
- If lead by OSU researchers, required to use OSU IRB
- If not by OSU researchers, commercial IRB selected (Advarra)

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<thead>
<tr>
<th>Program-Level Outcomes</th>
<th>OSU</th>
<th>Advarra</th>
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<tbody>
<tr>
<td>Environment</td>
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<td>Mobility</td>
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<td>Opportunity</td>
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<td>Customer Satisfaction</td>
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<table>
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<tr>
<th>Projects</th>
<th>OSU</th>
<th>Advarra</th>
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<tr>
<td>CVE</td>
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<td>MMTPA/CPS</td>
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<td>MAPCD</td>
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<td>PTA</td>
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<td>EPM</td>
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<td>CEAV</td>
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</table>
IRB review type per 49 CFR 11:

**Full:** more than minimal risk; does not fit expedited or exempt categories

**Projects:** PTA, MAPCD

**Expedited:** no greater than minimal risk; fits one of the expedited review categories

**Projects:** CVE

**Exempt:** less than minimal risk; fits one of the exempt categories

**Projects:** SCOS, MMTPA/CPS, SMH, EPM, CEAV
What is submitted

- Research protocol
  - Personnel and qualifications/training
  - Objectives
  - Methodologies
  - Subject recruitment plan/methods
  - Risk vs. benefits
- Surveys/interview scripts
- Communication materials (ads, flyers, etc.)
- Informed consent document (form)
BENEFITS AND RISKS

- Responsibility to minimize risk to human subjects while maximizing benefits to participants and society
- Explanation of risks and benefits included in the ICD for each project

BENEFITS
  - Mobility
  - Opportunity
  - Customer satisfaction
  - Environment

RISKS
  - Physical safety
  - Data privacy
PROCESS

- Initial IRB Application
- Feedback & Modifications
- Determination
- Exemption
  (no IRB oversight required)

- IRB Review
  - Full IRB Review
  - Expedited IRB Review
  - Additional Submissions/ Feedback/Modifications
  - Approval

- Required
- As needed
DEPENDENCIES AND CONSTRAINTS
Cooperative Agreement with USDOT

Systems engineering documents
- Concept of Operations (ConOps)
- System Requirements Specifications (SyRS)
- Demonstration Site Map and Installation Schedule

Program-level documents
- Safety Management Plan (SMP)
- Data Privacy Plan (DPP) and Data Management Plan (DMP)
- Performance Measurement Plan (PfMP)
- Program Schedule
IRB SUMMARY BY PROJECT
### IRB SUMMARY – PROGRAM LEVEL

**Performance Measurement Outcome** | **Is IRB Oversight Needed?**
--- | ---
Environment | Yes; application in progress
Mobility | Surveys planned:
Opportunity | 1. Community survey
Customer Satisfaction | 2. Intercept survey (at SMH kiosks)

**IRB Status**
- Application
- Feedback & Modifications
- Determination
- IRB Review
- Feedback & Modifications
- Approval
PROGRAM-LEVEL PERFORMANCE MEASUREMENT

<table>
<thead>
<tr>
<th>Outcome</th>
<th>PI</th>
<th>Materials for Review</th>
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<tbody>
<tr>
<td>Environment</td>
<td>Battelle</td>
<td>TBD</td>
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<tr>
<td>Mobility</td>
<td>OSU</td>
<td>Protocol, surveys</td>
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<tr>
<td>Opportunity</td>
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<td>Customer Satisfaction</td>
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Dependencies and Constraints
- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

Future IRB Needs
- IRB feedback, changes to project needs

Risks
- Data privacy

IRB Status
- Application (preparation)
- Feedback & Modifications
- Determination
- IRB Review
- Feedback & Modifications
- Approval
Roles And Responsibilities

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<thead>
<tr>
<th>Task</th>
<th>PI</th>
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<tbody>
<tr>
<td>Demonstration</td>
<td>Accenture</td>
<td>Protocol</td>
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<tr>
<td>Performance Measures</td>
<td>Battelle</td>
<td>Surveys</td>
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</tbody>
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Dependencies and Constraints
- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

Future IRB Needs
- Changes to surveys, changes to project needs

Risks
- Data collection, anonymization, re-identification, security, data patching/updates, system recovery

IRB Status
- Application
- Feedback & Modifications
- Determination - Exempt
- IRB Review
- Feedback & Modifications
- Approval
Roles And Responsibilities

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<td>OSU</td>
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<td>Performance Measures</td>
<td>OSU</td>
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Dependencies and Constraints

- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

Future IRB Needs

- IRB feedback, changes to project needs

IRB Status

- Application
- Feedback & Modifications
- Determination
- IRB Review
- Feedback & Modifications
- Approved
### PTA

<table>
<thead>
<tr>
<th>Risks</th>
<th>Materials for review</th>
<th>IRB feedback</th>
</tr>
</thead>
</table>
| • Trip delay/cancellation  
• Mobile app availability  
• PII and de-identification  
• Driver behavior  
• Car seat installation/availability | • Protocol – demo and evaluation  
• Surveys  
• Recruiting materials  
• Medicaid and MCO materials  
• Informed consent document  
• Application user guide | • None received |
## Roles And Responsibilities

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## Dependencies and Constraints
- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

## Future IRB Needs
- IRB feedback, changes to mobile app

## IRB Status
- Application
- Feedback & Modifications
- Determination
- IRB Review
- Feedback & Modifications
- Approved
### Materials for review
- Protocol
- Recruiting materials
- Informed consent document
- Surveys

### IRB feedback
- Reorganize study phases
- Clarify Wayfinder objective/description
- Increase number of participants
- Change participant incentive amount
- Provide additional details on data collected and potential confidentiality breaches

### Risks
- Inaccurate/incomplete traveler instructions
- Out of date maps/traffic info
- Communication failure
- Traveler distraction/confusion
- Mobile app availability
- PII and de-identification
- ADA route compliance
### MMTPA/CPS

#### Roles And Responsibilities

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<tr>
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<td>Protocol, surveys</td>
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<tr>
<td>Performance Measures</td>
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**Dependencies and Constraints**

- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

**Future IRB needs**

- IRB feedback, changes to mobile app

**Risks**

- Traffic/emergencies, mode/mobile app availability, ability to fund CPS account, PII privacy, location data, user account information

#### IRB Status

- Application
- Feedback & Modifications
- Determination - Exempt
- IRB Review
- Feedback & Modifications
- Approval
Roles And Responsibilities

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<td>Performance Measures</td>
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Dependencies and Constraints

- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

Future IRB needs

- IRB feedback, changes to project needs

Risks

- Vulnerable road users, operator/passenger behaviors, higher-speed traffic, maintenance
SMH

Roles And Responsibilities

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Dependencies and Constraints

- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

Future IRB needs

- IRB feedback, survey development, changes to project needs, changes to kiosk

Risks

- Emergencies, kiosk availability, traveler behavior, mode availability/accuracy, weather
- PII, data security tools/processes/policies

IRB Status

- Application (preparation)
- Feedback & Modifications
- Determination
- IRB Review
- Feedback & Modifications
- Approval
CVE

Roles And Responsibilities

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<td>City of Columbus</td>
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<td>Performance Measures</td>
<td>WSP</td>
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Dependencies and Constraints
- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

Future IRB needs
- IRB feedback, development of surveys, and changes to equipment

IRB Status
- Application
- Feedback & Modifications
- Determination
- IRB Review
- Feedback & Modifications
- Approval
Risks
• PII deidentification
• Unauthorized access to system/OBU
• Equipment malfunction
• Communication failure
• Participant misconception/distraction
• Vehicle positioning errors
• Weather-related issues

Materials for review
• Protocol
• Informed consent document
• Equipment information
• Training materials
• Recruitment materials
• Surveys

IRB feedback
• Submit all protocol components prior to review
• Include "Key Information" section in ICD
• Provide detailed equipment info, value/removal costs
• Elaborate on PI's research experience
• Clarify setting/plan for IC discussion at auto shops
• Differentiate IC forms for different audiences
EPM

Roles And Responsibilities

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Dependencies and Constraints

- Program/project documentation and schedule
- SMP, DMP, DPP, PfMP

Future IRB needs

- IRB feedback, changes to system or mobile app

Risks

- Mobile app availability, parking facility accessibility
- PII privacy, account information/ user preferences, anonymization, system security

IRB Status

- Application (preparation)
- Feedback & Modifications
- Determination
- IRB Review
- Feedback & Modifications
- Approval
LESSONS LEARNED
LESSONS LEARNED – IRB PROCESS

• Build in time for IRB review, feedback and modifications in project schedule (ex. IRB review required before survey deployment)

• Identify IRB board meeting interval/frequency upfront and incorporate into schedule
  o Example: do they meet once/month or multiple times per week?

• Clarify training needed for anyone involved in IRB or HUA processes and document completion/certifications
LESSONS LEARNED – IRB PROCESS

• Submit all documentation, including surveys and participant communication materials, with initial application to avoid delay in initial review

• Okay to submit more materials for review than are initially planned for use; approving contingency materials
  o (ex. recruitment materials for different scenarios) in advance helps avoid delay, if they are needed.
LESSONS LEARNED – HUAS PROCESS

• Develop HUA Summary outline early to orient teams and promote proactive information sharing

• Track all submittals, feedback, modifications, approvals and exemptions as they are developed/received to minimize duplication of efforts during HUA Summary development

• Anticipate questions or information needs based on different target audiences
  o Example: research funders, program evaluators, organizations replicating or scaling similar projects, etc.
WRAP UP
Public comment period open for the Human Use Approval Summary is:

- March 26 to April 12

Where to find it:

2. Scroll to Program Plans
3. Click Smart Columbus Human Use Approval Summary
PUBLIC COMMENTS NEEDED

How to comment:
1. Please email comments to: kldepenhart@columbus.gov
2. Subject line: HUAS Comments
3. Include your contact information
4. State whether or not you represent a vendor interest
HOW TO STAY CONNECTED

SMART COLUMBUS INQUIRIES:
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Communications Project Manager
anchenault@columbus.gov

Upcoming Smart Columbus Webinars:

SMH Test Results and Launch

MMTPA/CPS - CPS Test Results + Presentation of Combined MVP + Lessons Learned

Check ITE website for webinar dates at:
https://www.ite.org/events-meetings/event-calendar/

Webinar recording and materials will be available at ite.org and smart.columbus.gov
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Contact:
SmartColumbus@columbus.gov

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This material is based upon work supported by the U.S. Department of Transportation under Agreement No. DTFH6116H00013.

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