COMPLETE TRIP

ITS4US

Task 8 Training:
Human Use Approval Summary
Program Overview
Complete Trip - ITS4US Deployment Program

- A USDOT Multimodal Deployment effort, led by ITS JPO and supported by OST, FHWA and FTA
- Supports multiple large-scale replicable deployments to address the challenges of planning and executing all segments of a complete trip

Vision

Innovative and integrated complete trip deployments to support seamless travel for all users across all modes, regardless of location, income, or disability
Program Goals

- Spur high-impact integrated Complete Trip deployments nationwide
- Identify needs and challenges by populations
- Develop and deploy mobility solutions that meet user needs
- Measure impact of integrated deployments
- Identify replicable solutions and disseminate lessons learned
Complete Trip Phase 1 Awardees

- University of Washington
  OR, WA, MD
- California Association of Coordinated Transportation
  CA, OR, and WA
- Heart of Iowa Regional Transit Agency
  Dallas County, IA
- ICF
  Buffalo, NY
- Atlanta Regional Commission
  Gwinnett County, GA
Deployment Phases

**PHASE 1: Concept Development**
- Concept Development for Complete Trip Deployment
- Establish Cohort Roundtables

**PHASE 2: Design & Test**
- Design, Test and Deploy Complete Trip Solutions
- Evaluation Framework and Planning

**PHASE 3: Operate & Evaluate**
- Demonstrate Multiple Large-Scale Deployments
- Evaluate Deployments
- Share Data & Lessons Learned

**Operations Maintenance**
- Sustain operations for a minimum period of five years after the program is completed with no supplementary federal funds

**Deployment**
- Up to 12 months
- Up to 24 months
- Minimum of 18 months

**Post-Deployment**
- 5 years
COMPLETE TRIP

ITS4US

Task 8 Training:
Human Use Approval Summary
Robert Sheehan

Multimodal ITS Program Manager

Intelligent Transportation Systems
Joint Program Office (ITS JPO)
Agenda

- Human Use Approval Summary (Task 8) Overview
- IRB Preparation and Application Process

- Human Use Approval Summary Template
  - Introduction
  - Human Subjects Research Plans
  - Protocol / Application Summary
  - Human Use Approval
  - Future Steps and Schedule

- Final Thoughts
  - Useful References
  - Stay Connected
Human Use Approval Summary (HUAS) Overview
Human Use Approval

Describes the planned extent and nature of the project relating to research involving human subject participants (i.e., a summary of your Institutional Review Board (IRB) application) and documents the IRB application / process covering the project and Phase 1 outcome (IRB preliminary or full approval).
Human Use Approval Interdependencies

**Inputs**
- Information for Application / Protocol
  - Task 2: ConOps
  - Task 3: Data Mgmt
  - Task 4: Safety Mgmt

**Human Use Approval**
- IRB Preparation
- IRB Application
- Human Use Approval Summary

**Outputs**
- Plans for Phase 2/3
  - Task 9: Training Plan
  - Task 13: ICTD Plan
  - Task 14: Dep. Briefing
## Deliverables

<table>
<thead>
<tr>
<th>ID</th>
<th>BAA Section</th>
<th>Task 8: Human Use Approval Summary</th>
<th>Due Date</th>
<th>Format</th>
<th>Site Specific Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1T08D1</td>
<td>5.8</td>
<td>Human Use Approval Draft Summary</td>
<td>11/29/2021</td>
<td>Word</td>
<td></td>
</tr>
<tr>
<td>P1T08D2</td>
<td>5.8</td>
<td>Human Use Approval Final Summary</td>
<td>12/27/2021</td>
<td>Word</td>
<td></td>
</tr>
</tbody>
</table>
# Human Use Approval Major Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>Review IRB process, identify and document planned components of project relating to human use approval.</td>
</tr>
<tr>
<td>IRB Application</td>
<td>Identify IRB to oversee the project and complete application for IRB approval.</td>
</tr>
<tr>
<td>Human Use Approval Summary</td>
<td>Develop Human Use Approval Summary documenting outcome, status, and future steps.</td>
</tr>
</tbody>
</table>
IRB Preparation & Application
IRB Preparation

- Before documenting Human Use Approval Summary, sites will have engaged with their IRB:
  - Suitability – Federal-Wide Assurance
  - Relationship with Project
  - Understanding Process and Timelines

USDOT cannot serve as the IRB; the IRB independently oversees the human subjects research in the project
IRB Application

- The HUAS documents the preparation and application steps to summarize the interactions with the IRB:
  - Application structure may vary based on specific IRB
  - HUAS should convey the information provided to the IRB
Task 8 HUAS Document Overview

**A Human Use Approval Summary:**
- Explains the Human Subjects Research planning within the project
- Describes the Institutional Review Board (IRB) and interactions for approving and overseeing the research;
- Documents the approval, conditions, and future requirements.

**Major components of the HUAS:**
- Human Subjects Research Plans
- Protocol / Application Summary
- Human Use Approval
- Future Steps and Schedule
Section 1: Introduction

- Section 1 of the HUAS should address:
  - **Document Purpose**: Discuss the purpose and content covered in the deliverable.
  - **Project Overview**: Provide a high-level overview of the project focusing on the evaluation-related goals and elements with participant interactions.
Section 2: Human Subjects Research Plan (1/2)

- Section 2 of the HUAS should address:
  - **Research Questions**: Discuss the key research context for the project.
  - **Interactions with Other Tasks**: Discuss relationship and consistency with other related tasks.
  - **Considerations for Vulnerable Populations**: Discuss any interactions with population covered by supplemental regulations.
  - **Informed Consent**: Discuss key elements of informed consent that need to be understood by participants.
Section 2: Human Subjects Research Plan (2/2)

- Section 2 of the HUAS should address:
  - **Recruitment Design**: Discuss the plan for recruiting participants to achieve performance measurement objectives.
  - **Participant Training**: Discuss key elements of training provided by the project for participants.
  - **Team Training**: Discuss any training for team/partner staff who may engage with participants or their data.
Section 3: Protocol / Application Summary

- Section 3 of the HUAS should address:
  
  - **Institutional Review Board**: Provide information on the IRB supporting review and oversight of project.
  
  - **IRB Review Process**: Give overview of the IRB’s review and approval processes applicable to the project.
  
  - **Ensuring IRB Understanding of Project**: Discuss any methods used to ensure IRB adequately understands project, particularly the elements of project that may be new or novel.
  
  - **Relevant IRB Procedures**: Highlight procedures and timelines applicable to the IRB for this project.
Section 4: Human Use Approval

- Section 4 of the HUAS should address:
  
  □ **Type of Review**: Describe the nature of review conducted by the IRB.
  
  □ **Approval Status**: State the approval status by the IRB and status of supporting documentation
    
    ▪ Supporting materials (e.g., approval letter) can be included in an Appendix
  
  □ **Feedback from IRB Review**: Discuss feedback received from the IRB during the review and approval process.
  
  □ **Conditions**: State future requirements to maintain/renew approval and address changes/updates for the project.
Section 5: Future Steps and Schedule

- Section 5 of the HUAS should address:
  
  - **IRB-Required Future Actions**: Describe the specific required actions for the project team to maintain approval, and planned IRB reviews/renewals/amendments in the future.
  
  - **Phase 2/3 Human Use Approval Confirmation Materials**: Describe the planned documentation to confirm that IRB approvals are maintained during Phase 2/3, including how changes would be addressed through amendments. Include anticipated schedule overview for interactions with IRB and participants.
Final Thoughts
HUAS Useful References

Stay Connected

For more information please contact:

Elina Zlotchenko, ITS JPO
ITS4US Program Manager
Elina.Zlotchenko@dot.gov

Robert Sheehan, ITS JPO
ITS4US Human Use Approval Lead
Robert.Sheehan@dot.gov

Visit the Complete Trip - ITS4US Deployment Program Website and FAQs:
https://its.dot.gov/its4us/
https://www.its.dot.gov/its4us/its4us_faq.htm
Q&A

Any questions?