



U.S. Department of Transportation

## COMPLETE TRIP

---

ITS4US

The logo for ITS4US, where the number '4' is stylized as a blue '4' with a dashed orange line forming a path through it. The path starts at a red location pin at the top, goes down, then left, then down again, ending at another red location pin at the bottom.

**Task 8 Training:**  
Human Use Approval Summary



# Deborah Curtis

Highway Research Engineer

Office of Operations Research and  
Development

# 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

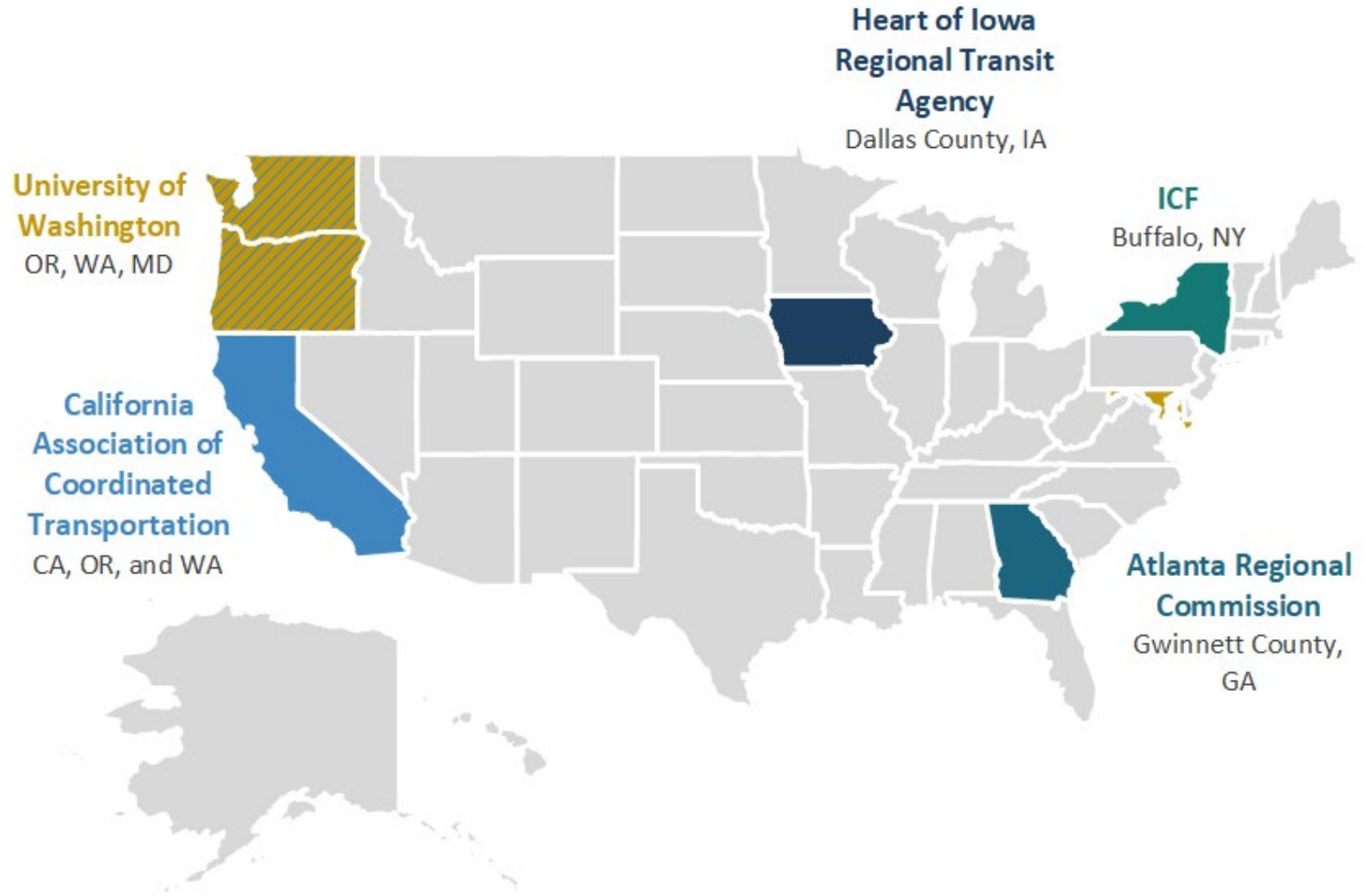


Measure impact of integrated deployments

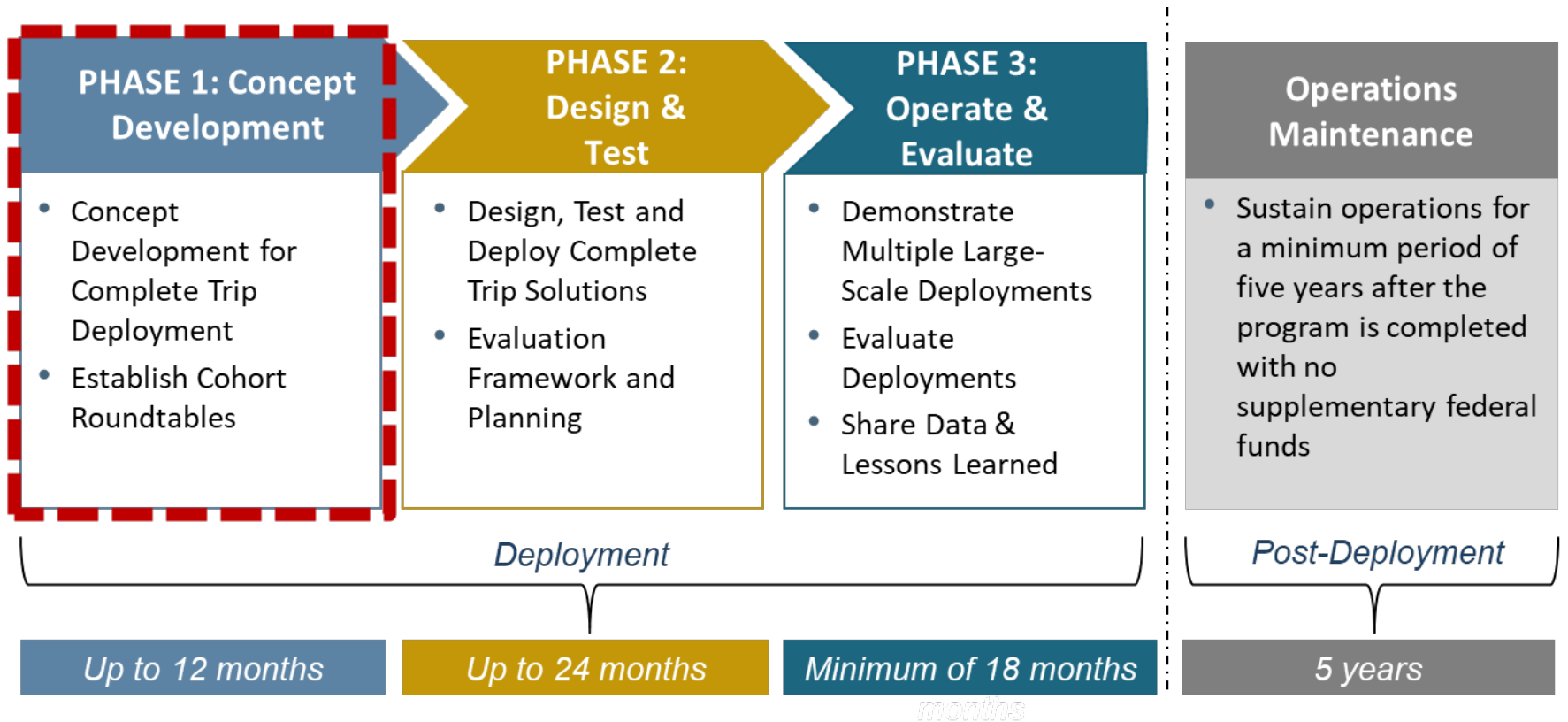


Identify replicable solutions and disseminate lessons learned

# Complete Trip Phase 1 Awardees



# Deployment Phases





U.S. Department of Transportation

## COMPLETE TRIP

---

ITS4US

The logo for ITS4US, where the number '4' is stylized as a blue '4' with a dashed orange line forming a path through it. The path starts at a red location pin at the top, goes down, then left, then down again, ending at another red location pin at the bottom.

**Task 8 Training:**  
Human Use Approval Summary





# Robert Sheehan

Multimodal ITS Program Manager  
Intelligent Transportation Systems  
Joint Program Office (ITS JPO)

# Agenda

---

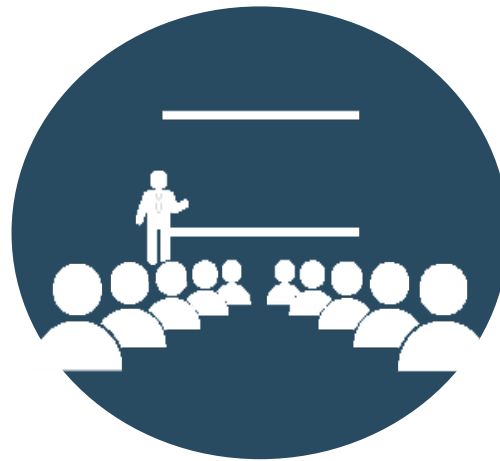
- **Human Use Approval Summary (Task 8) Overview**
- **IRB Preparation and Application Process**
- **Human Use Approval Summary Template**
  - Introduction
  - Human Subjects Research Plans
  - Protocol / Application Summary
  - Human Use Approval
  - Future Steps and Schedule
- **Final Thoughts**
  - Useful References
  - Stay Connected

# Human Use Approval Summary (HUAS) Overview

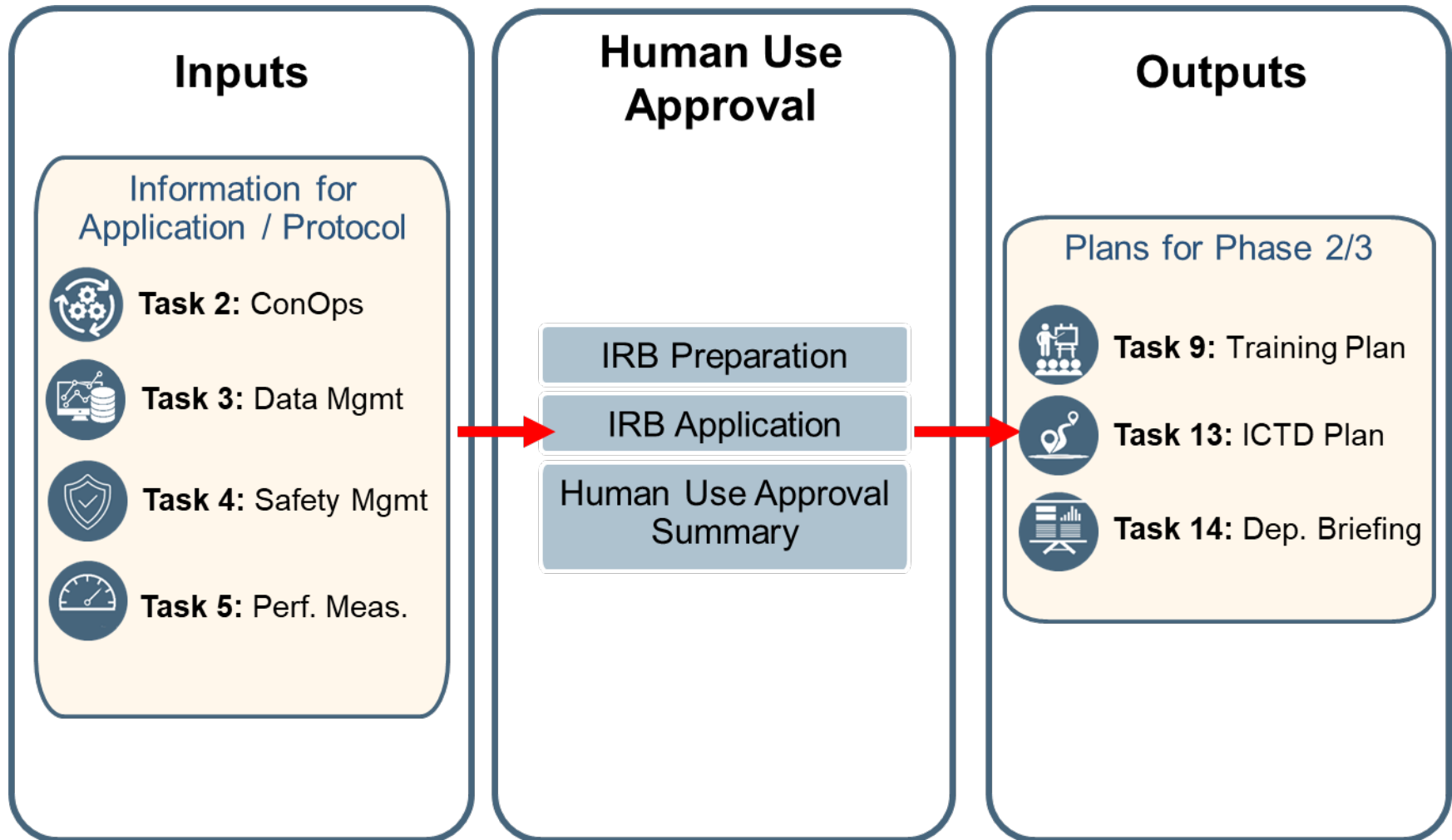
# Human Use Approval

---

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



# Deliverables

---

ID	BAA Section	Task 8: Human Use Approval Summary	Due Date	Format	Site Specific Date
P1T08D1	5.8	Human Use Approval Summary Draft	11/29/2021	Word	
P1T08D2	5.8	Human Use Approval Summary Final	12/27/2021	Word	

# Human Use Approval Major Components

---

## Preparation

Review IRB process, identify and document planned components of project relating to human use approval.

## IRB Application

Identify IRB to oversee the project and complete application for IRB approval.

## Human Use Approval Summary

Develop Human Use Approval Summary documenting outcome, status, and future steps.

# 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

# HUAS Template Sections

# 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)

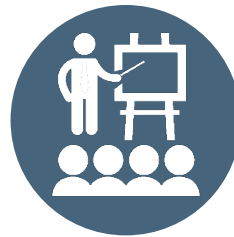
- Section 2 of the HUAS should address:
  - **Research Questions:** Discuss the key research context for the project.
  - **Interactions with Other Tasks:** Discuss relationship and consistency with other related tasks.
  - **Considerations for Vulnerable Populations:** Discuss any interactions with 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

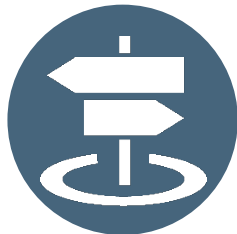
---

- 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

---

- *Code of Federal Regulations, Title 49 – Transportation, Part 11 – Protection of Human Subjects*, October 2019, <https://www.govinfo.gov/content/pkg/CFR-2019-title49-vol1/pdf/CFR-2019-title49-vol1-part11.pdf>
- US Dept. of HHS, Office for Human Research Protections (OHRP), <https://www.hhs.gov/ohrp/>
- US Dept. of HHS, *Revised Common Rule Educational Materials*, <https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html>
- Required Assurance for the Protection of Human Subjects, <http://www.hhs.gov/ohrp/assurances/index.html>
- Status of FWAs, <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html>
- *USDOT Guidance Summary for Connected Vehicle Deployments: Human Use Approval*, July 2016 <https://rosap.ntl.bts.gov/view/dot/31551>

# Stay Connected

---

**For more information please contact:**

Elina Zlotchenko, ITS JPO  
ITS4US Program Manager  
[Elina.Zlotchenko@dot.gov](mailto:Elina.Zlotchenko@dot.gov)

Robert Sheehan, ITS JPO  
ITS4US Human Use Approval Lead  
[Robert.Sheehan@dot.gov](mailto: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](https://www.its.dot.gov/its4us/its4us_faq.htm)

Any questions?

