



# CONNECTED VEHICLE PILOT Deployment Program



Preparing a Human Use Approval  
Summary for Connected Vehicle  
Deployments



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# TODAY'S AGENDA



- Purpose of this Technical Assistance Webinar Series
  - To assist not only the three selected sites, but also other early deployers of connected vehicle technologies to conduct Concept Development activities.
  
- Webinar Content
  - Connected Vehicle Pilot Deployment Program Overview
  - Human Use Approval Background and Concepts
  - Resources to Facilitate Human Use Approval for Pilot Deployments
  - Stakeholder Q&A
  - How to Stay Connected
  
- Webinar Protocol
  - Please mute your phone during the entire webinar
  - You are welcome to ask questions via chatbox at the Q&A Section
  - The webinar will be recorded except the Q&A Section
  - The webinar recording and the presentation material will be posted on the CV Pilots website within a week

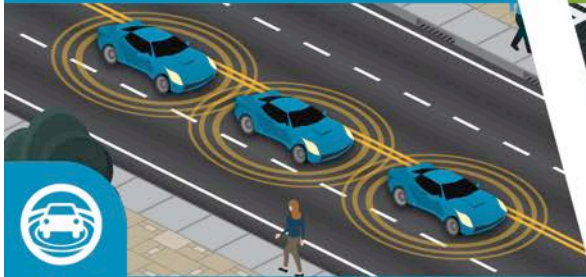




# CV PILOT DEPLOYMENT PROGRAM GOALS



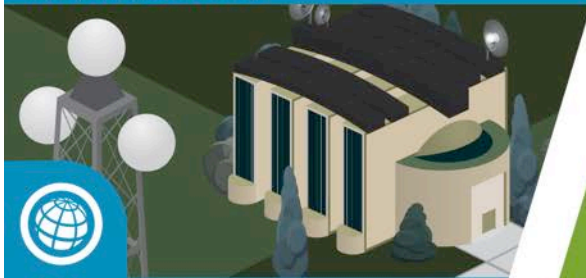
## Spur Early CV Tech Deployment



Wirelessly Connected Vehicles



Mobile Devices



Infrastructure

## Measure Deployment Benefits



Safety

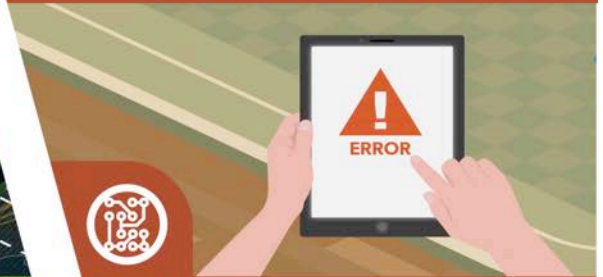


Mobility



Environment

## Resolve Deployment Issues



Technical



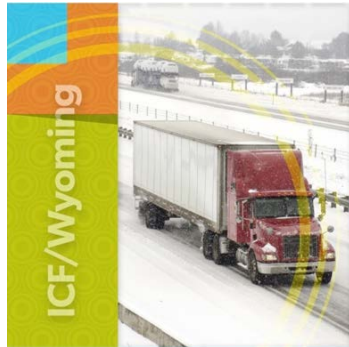
Institutional



Financial



# Sites Selected – 2015 Awards



- Reduce the number and severity of adverse weather-related incidents in the I-80 Corridor in order to improve safety and reduce incident-related delays.
- Focused on the needs of commercial vehicle operators in the State of Wyoming.



- Improve safety and mobility of travelers in New York City through connected vehicle technologies.
- Vehicle to vehicle (V2V) technology installed in up to 10,000 vehicles in Midtown Manhattan, and vehicle to infrastructure (V2I) technology installed along high-accident rate arterials in Manhattan and Central Brooklyn.

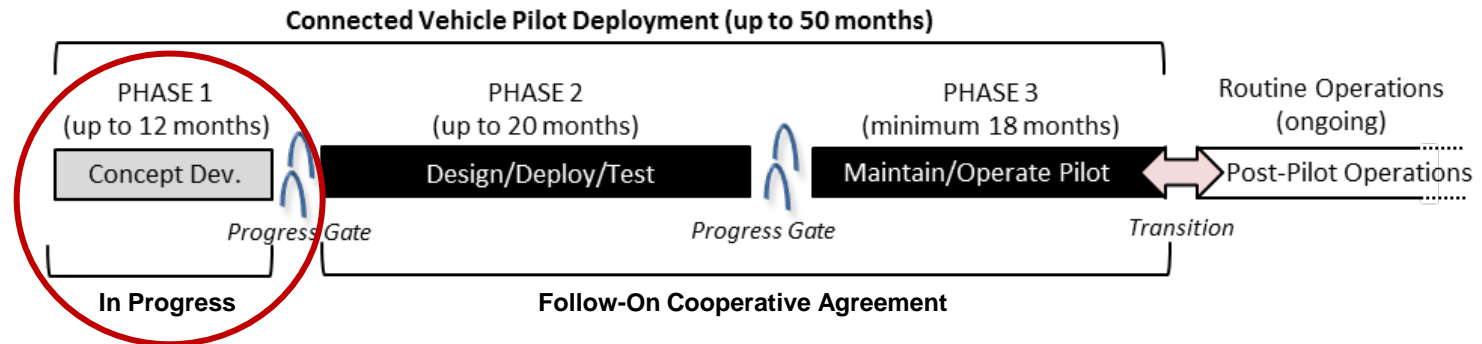


- Alleviate congestion and improve safety during morning commuting hours.
- Deploy a variety of connected vehicle technologies on and in the vicinity of reversible express lanes and three major arterials in downtown Tampa to solve the transportation challenges.





# Deployment Schedule



- Overall Deployment Schedule
  - Phase 1: Concept Development
    - Creates the foundational plan to enable further design and deployment
  - Phase 2: Design/Deploy/Test
    - Detailed design and deployment followed by testing to ensure deployment functions as intended (both technically and institutionally)
  - Phase 3: Maintain/Operate
    - Focus is on assessing the performance of the deployed system
  - Post Pilot Operations (CV tech integrated into operational practice)
- Public webinars to share the concept development activities from the three sites
  - Concept of Operations Webinar (February – March 2016)
  - Performance Measurement Webinar (May – June 2016)
  - Deployment Plan Webinar (August 2016)



# Relationship with CV Pilot Planning



- Understanding Scope / Plans in specific detail
- Research Concept Design
- Safety Management
- Data Protection / Privacy
- Data Collection Use for Independent Evaluation and Research
- Training
- Ongoing Oversight / Revisions





# Human Use Approval Webinar



- Goals:
  - Why?
    - Overview / background on Human Use Approval
  - What/How?
    - Support understanding of processes and issues in HUA application and approval for CV Pilots
- Information of use to connected vehicle pilot deployments, researchers



# Need for Human Use Oversight



- Experiments in the Past
  - Nazi Medical War Crimes
  - Nuremburg Code
  - Tuskegee Syphilis Study
- Research Context
- Data, not just direct interactions





# Human Subjects Research Principles



- Belmont Report
- Key Principles:
  - Respect for Persons
    - Informed Consent
  - Beneficence
    - Design addresses Benefits / Risks
  - Justice
    - Equity in distribution of Benefits / Risks



# Federal Regulations / Guidance



- 49 CFR Part 11 (USDOT)
  
- “Common Rule”
  
- Definitions
  - Covered Research
  - Institutional Review Board
  - Exemptions / Expedited Review



# Institutional Review Board (IRB)



- IRB Role
- Federal Assurance Required
  - Federal-Wide Assurance (FWA) with US Dept. of HHS Office for Human Research Protection (OHRP) or
  - Single / Multiple Project Assurance
- IRB Functions
- Identify and understand project-specific IRB procedures



# Scope of Human Use Approval Task



- Gain understanding of IRB requirements, process, and timing
- Identify IRB affiliated with team member, or search for third-party IRB
- Collect information about your IRB's approval process
  - Review application and requirement for additional documentation required by the IRB as part of the approval process and post-approval (e.g., informed consent form)
  - Determine if training is required before submitting application
  - Determine timeframe for IRB approval, factor in time for review and comment period
- Complete application for IRB approval



# Scope of Human Use Task



- Actively monitor approval process
- Develop Human Use Approval Summary
- Update IRB application/amendments, as required/dictated by project updates
- Coordinate Human Use Approval with other entities as required, and the CV Pilot Independent Evaluator (IE)



# Principal Investigator(PI)'s Role



- Interface with Oversight - Institutional Review Board
- Responsible for ensuring that all relevant project staff understand HUA
- Guide project through Human Use Approval process
- Ensure and coordinate activities that affect or are affected by Human Use oversight



# Human Use Training



- IRB-specific requirements
- Common Resources
  - National Institutes of Health (NIH) free training  
<https://phrp.nihtraining.com/users/login.php>
  - Collaborative Institutional Training Initiative (CITI) Human Subjects Research training used by many IRBs:  
<https://www.citiprogram.org/index.cfm?pageID=88>



# Recruitment / Informed Consent



- Recruitment Design
- Instruments (Informed Consent Form)
- Participant Understanding of Risks
- Documented Consent
- Defined Time Context





# Benefits and Risks



- Articulate Benefits
  - Value of research
  - Benefits to participants
- Describe Risks
  - Safety Risks (Safety Management Plan)
  - Other Risks (e.g., protection of PII, etc.)





# State / Local Considerations

- State / Local Laws, Regulations, Policies also may apply (*NOT LEGAL ADVICE*)
- Particularly on Privacy, Security
- One Example:
  - CA Civil Code §§ [1798.90.5-1798.90.55](#), [1798.29](#), [1798.82](#) regulate the privacy and usage of data collected by automated license plate recognition (ALPR) systems.
  - [California Civil Code section 1798.24](#) and [Welfare and Institutions Code section 10850](#) regulate disclosure of personal information for certain research purposes.
  - <https://oag.ca.gov/privacy/privacy-laws>



# IRB after Concept Development



- Can't start recruiting until IRB approval granted
- Changes require IRB oversight / approval
  - Understand IRB's amendment process
- Establish coordination and information sharing



# Human Use Approval Challenges



- No available “internal” IRB
  - Issue: No members of the project team have an “internal” IRB
  - Possible Strategies: Search for similar institutions/organizations that have an IRB willing to approve your research project (“external” IRB)
- IRB Process Affects Schedule
  - Issue: IRB continues to request additional information, or requires additional time
  - Possible Strategies: Initiate effort early in Phase 1, seek additional information about the approval process, take on-line training, and request in-person meeting to obtain assistance with approval. Identify team member responsible for periodic check in with IRB
- Conflicts with Other Tasks
  - Issue: Activities in other tasks are in conflict with description provided in IRB application
  - Possible Strategy: Determine potential conflicts and interdependencies across tasks at early stage and plan coordination meetings with relevant personnel to ensure consistency.





# Learning from Prior Experiences



- Safety Pilot Model Deployment (SPMD)
  - Large Project, multiple teams – multiple IRB applications and amendments as new needs and challenges met
  - Note nature of amendments
  - Worked with partners for application supporting documents
  - Vital to define and test data sharing requirements and process
- SHRP 2 Naturalistic Driving Study (NDS)
  - Multiple sites, multiple IRBs – communication is essential
  - Be aware of local IRB processes and personnel
  - Consider timing in amendment submittals



# Useful References

- Code of Federal Regulations, Title 49 – Transportation, Part 11 – Protection of Human Subjects, October 2014, <http://www.gpo.gov/fdsys/pkg/CFR-2014-title49-vol1/pdf/CFR-2014-title49-vol1-part11.pdf>
- Required Assurance for the Protection of Human Subjects, <http://www.hhs.gov/ohrp/assurances/index.html>
- Office for Human Research Protections (OHRP) IRB Registration FAQ, <http://archive.hhs.gov/ohrp/IRBfaq.pdf>
- Strategic Highway Research Program (SHRP 2) (2015), Naturalistic Driving Study: (Example Lessons from Naturalistic Driving Study),  
[http://onlinepubs.trb.org/onlinepubs/shrp2/SHRP2\\_S07Report.pdf](http://onlinepubs.trb.org/onlinepubs/shrp2/SHRP2_S07Report.pdf)  
[http://onlinepubs.trb.org/onlinepubs/shrp2/SHRP2\\_S2-S05-RR-1.pdf](http://onlinepubs.trb.org/onlinepubs/shrp2/SHRP2_S2-S05-RR-1.pdf)  
[http://onlinepubs.trb.org/onlinepubs/shrp2/SHRP2\\_S2-S06-RW-1.pdf](http://onlinepubs.trb.org/onlinepubs/shrp2/SHRP2_S2-S06-RW-1.pdf)
- Safety Pilot Model Deployment Test Conductor Final Report, <http://www.nhtsa.gov/DOT/NHTSA/NVS/Crash%20Avoidance/Technical%20Publications/2015/812171-SafetyPilotModelDeployDelTestCondrTmRep.pdf>  
Lessons Learned, <http://umtri.umich.edu/content/2014.GlobalSymposium.Gay.pdf>
- Alternative Models of IRB Review, Workshop Summary Report, November 17-18, 2005, <http://www.hhs.gov/ohrp/archive/sachrp/documents/AltModIRB.pdf>



# Stakeholder Q&A



- Please keep your phone muted
- Please use chatbox to ask questions
- Questions will be answered in the order in which they were received
- This Q&A section will not be recorded, nor posted to the website



# STAY CONNECTED



## Join us for the *Getting Ready for Deployment Series*

- Discover more about the 2015 CV Pilot Sites
- Learn the Essential Steps to CV Deployment
- Engage in Technical Discussion



**Website: <http://www.its.dot.gov/pilots>**

**Twitter: [@ITSJPODirector](https://twitter.com/ITSJPODirector)**

**Facebook:**

**<https://www.facebook.com/DOTRITA>**

## Contact for CV Pilots Program:

Kate Hartman, Program Manager

[Kate.hartman@dot.gov](mailto:Kate.hartman@dot.gov)

## January 2016 Technical Assistance Webinars:

- [1/25/2016, 1:00 – 2:30 pm EST](#)  
*Preparing a Human Use Approval Summary for Connected Vehicle Deployments*
- [1/27/2016, 12:30 – 2:00 pm EST](#)  
*Preparing a Training and Education Plan for Connected Vehicle Deployments*
- [1/28/2016, 2:00 – 3:30 pm EST](#)  
*Utilizing the Open Source Application Development Portal for Connected Vehicle Deployments*

Please visit the CV pilots website for the recording and the briefing material of the previous webinars.

