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**
- **Measure Deployment Benefits**
- **Resolve Deployment Issues**

- **Wirelessly Connected Vehicles**
- **Safety**
- **Technical**

- **Mobile Devices**
- **Mobility**
- **Institutional**

- **Infrastructure**
- **Environment**
- **Financial**

U.S. Department of Transportation 3
Sites Selected – 2015 Awards

ICF/Wyoming

- 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.

New York City

- 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.

Tampa (THEA)

- 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
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
  - Nuremberg 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


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
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  
**Facebook:** https://www.facebook.com/DOTRITA

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**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.