USDOT Guidance Summary for Connected Vehicle Deployments

Human Use Approval

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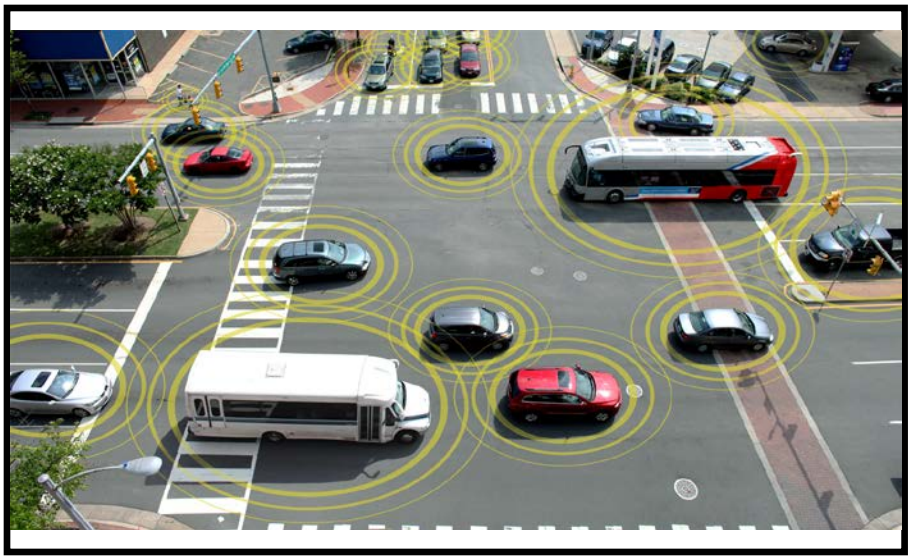

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16. Abstract

This document provides guidance material in regards to human use approval required for the CV Pilots Deployment Concept Development Phase. Background is provided on relevant Federal guidance and Institutional Review Boards, including specific references and resources. Highlights of important considerations are presented to assist pilot teams in planning for and obtaining and documenting required approvals. The document concludes with a summary of USDOT supporting efforts for this area.

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Table of Contents

List of Tables

1 Introduction

1.1 Purpose of the Report

The purpose of this report is to assist Pilot Deployers in the timely and successful completion of Concept Development Phase deliverables. This includes a synthesis of considerations in key topic areas for site orientation (e.g., human use approval), additional background and guidance materials potentially helpful to the preparation of Concept Development Phase deliverables, and a summary of available technical support resources available to CV Pilots sites. This report covers the human use approval process required in the Concept Development Phase in preparation for deployment involving human subjects (e.g., drivers) in the Design/Deploy/Test Phase and the Maintain/Operate Phase. By providing a summary of relevant topics and issues that should be addressed, Pilot Deployer teams can benefit from an early understanding that will assist in planning the execution of Task 8. In particular, advance planning is critical to ensure that schedule impacts are minimized (e.g., when external entities outside the project team are involved) and that risks are effectively managed. While the scope of human use may vary among the CV Pilot sites, all projects must successfully obtain and document necessary approvals before human subjects can participate in CV Pilot testing. This report aims to assist Pilot Deployers in successfully providing the *Draft Human Approval Summary* and *Final Human Approval Summary* deliverables

This document does not replace or alter the work statement defined in the Broad Agency Announcement, it only provides technical assistance to the pilot deployers in completing the tasks and deliverables described in the statement of work.

1.2 Organization of the Report

This report contains four additional sections and a references section. Section 2 provides a general background and concepts in planning for Institutional Review Board (IRB) approval. This includes key concepts to consider, and the most useful references which can be used to learn about the IRB process. Section 3 walks through the relevant deliverables and how each task relates to providing support for the IRB process and developing a successful draft and final Concept Development Phase *Human Approval Summary*. Section 4 summarizes the key challenges that may arise when dealing with obtaining IRB approval, including resources that can be helpful in avoiding or overcoming them. Section 5 provides a technical support summary with examples of how USDOT can help with deliverables and a schedule of technical support events provided by USDOT. Finally, the Reference sections are broken down into documents used in drafting this report, relevant Federal guidance, and potentially useful resources.

2 Background

Federally-sponsored research involving human subjects requires adhering to processes to carefully review the plans for, and execution of, research projects. The general principles behind this requirement serve to protect the interests of participating persons and balance with societal benefits associated with research outcomes. Researchers and sponsors sometimes desire to involve human subjects in projects, due to the nature of the research, or for other purposes. In order to protect the human subjects who may otherwise lack a voice or understanding of their participation in research projects, a set of practices have been established in the research community, over the course of many decades.

2.1 Rationale for Human Use Approval:

In the past, significant abuses have occurred in the conduct of research, most notably the medical experiments conducted on prisoners by the Nazi regime, for which physicians were convicted of war crimes. As a result, various efforts have been made, starting with the Nuremberg Code [1], to establish protections and protocols based on basic moral, ethical, and legal concepts. In the United States, a key milestone in the effort was achieved with the 1979 release of the Belmont Report [2], which identified three critical principles in conducting ethical research involving humans:

- **Respect for Persons**
  Individuals should be treated with autonomy, and those who have limited autonomy should be afforded additional protections. Informed consent needs to be given by subjects, showing that they have sufficient information to make a decision, that they comprehend the nature and risks in the research, and that consent is voluntarily given.

- **Beneficence**
  Design and conduct research to "do no harm" to subjects, and maximize research benefits while minimizing risks to subjects. Research risks should be systematically identified and assessed to ensure that unacceptable risks are not taken, and that risks are reduced to those necessary to achieve the research objective. Risks to vulnerable populations require additional scrutiny and justification.

- **Justice**
  Risks and burdens associated with research should be equitably distributed in relation to the benefits from research results. Subject selection should not result in additional burdens on disadvantaged populations, and vulnerable populations warrant protection from involvement for administrative convenience.

Subsequently, Federal regulations codified the protections in the "Common Rule" developed by the U.S. Department of Health and Human Services (HHS), which was adopted by multiple departments, including the U.S. Department of Transportation. Federally-funded research involving human subjects is governed by this rule.

2.2 Regulatory Guidance:

The Common Rule adopted by the USDOT is codified in 49 CFR Part 11 [3]. The Common Rule provides guidance on defining when research falls under this rule, and associated requirements for approvals, oversight, and Institutional Review Board participation. Key points from the regulations include:

- **Defining research activities covered and excepted from the policy**
  It is anticipated that CV Pilot projects will involve intervention or interaction with human subjects and be subject to this policy. Additional protections and regulations at the state or local level may also apply.
- **Assurances of compliance required**
  Institutions conducting covered research are required to provide written assurance of compliance with the regulation. Existing Federal assurances are acceptable, i.e., Federal Wide Assurance (FWA), or a Single (or Multiple) Project Assurance may be provided.
- **IRB review required**
  The regulations describe the nature and functions of the Institutional Review Board (IRB) which reviews, and approves, requires modifications for, or disapproves research activities. In addition, the IRB provides continued post-approval oversight for the research. Selected categories of research involving no more than minimal risk may be eligible for expedited review, as defined by the regulations [4]. Research falling into certain categories may be exempt from the policy, but this determination is also made and documented by the IRB. All reviews are subject to criteria developed from Belmont Report principles, such as informed consent.
- **Documentation**
  Records shall be maintained for both IRB-related functions as well as participants' informed consent, as prescribed by the regulations and IRB procedures.

In addition to federal regulatory guidance, state and local laws, regulations, and policies may apply to CV pilot research and deployments. Participating organizations may also have internal policies that impact pilot interactions with humans. Since each pilot deployment may be subject to differing jurisdiction and policies, this report recognizes the need for each project team to identify additional steps (e.g., applications, reviews, approvals) required beyond what is given here.

2.3 Key References:

Following are some key reference resources to provide background on Human Use Approval. Additional useful references are noted throughout the report and a list is provided at the end of the document.

- Belmont Report [2]
- 49 CFR Part 11 [3]
- HHS Assurances Website [5]
- HHS Office of Human Research Protections [6]

3 Deliverables

This section describes relevant related deliverables by task as explained in the CV Pilots Broad Agency Announcement. While the main deliverable dealing with human use approval is the *Human Use Approval Summary* of Task 8, elements of human use approval planning will need to be addressed in other deliverables in a number of other tasks. Below are some potential areas where significant coordination of human use approval planning with other tasks are likely to be needed. While the examples are not comprehensive, they should assist in understanding the need to consider the interdependencies in related activities across project tasks. It is likely that relevant content produced in earlier activities will be utilized (either directly, or as input material) as part of the IRB process.

3.1 Task 2: Pilot Deployment Concept of Operations (ConOps)

The *Concept of Operations document* describes the proposed Pilot Deployment and operational practice. In order to plan for Human Use Approval including the IRB application, a detailed understanding of how human subjects will interact with the Pilot Deployment is necessary. In addition, knowledge of the principles behind Human Use protections will help in developing a concept that is feasible and carefully considers the risks to participants.

3.2 Task 3: Privacy and Security Management Operating Concept

The *Privacy and Security Management Operating Concept* shall describe, at a high level, the concepts to be implemented to meet system security and privacy needs. A key consideration in both Privacy and Security Management is how personal information will be gathered, protected, and handled. As the IRB application process will necessitate a thorough review of how information from participants, including but not necessarily limited to PII, is used in the project, early planning is essential to avoid potential conflicts.

3.3 Task 4: Safety Management Plan

The *Safety Management Plan* includes identification of safety needs and scenarios that will also be important in identifying the nature and magnitude of risks to human participants, and the effectiveness of mitigation measures. It is anticipated that the IRB will pay particular attention to any risks that are beyond a minimal level, and will also need to be informed about the nature of connected vehicle technology in order to understand the safety risks. Depending on the nature of the planned pilot deployment, there may be safety risks to humans who are not active project participants, such as other non-participating drivers, pedestrians, etc. It is important to note that the level of protection for those

persons who have not given consent to participate in the project will likely face significantly greater scrutiny in IRB review.

3.4 Task 5: Performance Measurement and Evaluation Support Plan

The *Performance Measurement Plan* will define plans for collecting data associated with assessing the impacts of the pilot deployment. Development of methods for assessing performance that involve humans or have potential for impacts to humans needs to be coordinated with Human Use Approval planning. Relevant considerations include potential for adverse impacts, protection of data, and ensuring that population groups are not treated unfairly. Additionally, Task 5 includes provision of support to the Independent Evaluation effort. Anticipated interactions with the Independent Evaluator (e.g., provision of data, etc.) need to also be considered in the IRB process.

3.5 Task 8: Human Use Approval Summary

IRB approval is a vital aspect in the CV Pilots Deployment (when necessary). The *Human Use Approval Summary* documents not only the IRB approval, but also supporting information needed for USDOT to assess the process used to obtain approval. For example, private data is often necessary when dealing with human subjects in scientific trials. The Human Use Approval Summary should include sufficient information to allow USDOT to observe that the IRB had an adequate understanding of all data planned to be recorded, a plan for its use and safe keeping, etc. While duplicate material from other Task deliverables may be incorporated by reference, an overview including any changes should be included.

3.6 Task 9: Participant Training and Stakeholder Education Plan

One important aspect of IRB approval is the manner in which participants are recruited and informed consent given. The recruitment plan in Task 9 should reflect the requirement for formal IRB approval before any recruitment activity begins. As with Task 5, private data can often be collected from individuals when training participants on technical aspects of the deployment, and planning for these interactions should reflect the understanding gained in the Human Use Approval process. Private data may include name, address, role and activities of participants, and description of their activities. The IRB application and supporting information will likely require describing and assessing the role of participant training and participant data.

3.7 Task 12: Comprehensive Pilot Deployment Plan

Task 12 involves preparation of a Comprehensive Pilot Deployment (CPD) plan, which draws upon the other Tasks. This plan includes describing the steps to ensure the safety and privacy of participants, and therefore will need to be consistent with the application approved by the IRB. Particular attention should be paid to ensure that any modifications and IRB amendments are consistent with the CPD, and that the CPD includes a plan for how future modifications and amendments would be handled, including considerations for necessary IRB oversight.

4 Key Challenges

As stated in the BAA, in Task 8, "The Contractor shall obtain Human Use Approval from an accredited Institutional Review Board (IRB)." As the IRB process requires attention to detail and schedule, and proactive planning and coordination, it is important that the project team engage an accredited IRB at an early stage. The major challenges in obtaining human use approval include making sure the project team proactively understands the IRB process and ensuring that the necessary inputs (e.g., information developed in other Tasks) are consistent with both the principles of human use protections as well as the policies and processes for the specific IRB selected. This section of the orientation material will touch upon just the top few major challenges that may arise during the CV pilots, and what can be done to promote an effective and efficient Human Use Approval process.

4.1 Engagement with an Accredited IRB

Understanding the requirements, process and timelines for the specific IRB(s) governing the research is essential to success. Therefore, engagement with the IRB process, and its requirements, at an early point in time will assist in minimizing the schedule risks in the Concept Development Phase. Based on the composition of the project team, an existing approved IRB may be identified, or an external IRB may be needed. It is not likely that a newly formed IRB for this project can be constituted and gain necessary approvals in a suitable timeframe to effectively support the Concept Development Phase.

4.1.1 Principal Investigator Understanding of IRB Process

The Principal Investigator (PI) serves as a key interface between the project and the IRB. The PI's experience in working through the IRB process will help greatly in avoiding pitfalls and helping coordinate the activities in other Tasks to maximizing the probability of IRB approval. In the event that the PI lacks substantial experience in the IRB process, IRB and Human Protections Training will likely be required for project success. While each IRB may have specific training requirements that must be satisfied, there are several relevant training resources available through HHS and others [7, 8]. Many IRBs that oversee NIH-funded research, which requires human protections training [9, 10], have instituted the same requirement for all research.

Affected Team Members	Training Requirements	Relevant Training
Principal Investigator(s)	Typically defined by IRB	IRB-specific PI training Education on Protection of Human Research Participants (e.g., NIH training [9], CITI [8])
Staff involved in Human Subjects Research Design or Conduct	Typically defined by IRB	Education on Protection of Human Research Participants (e.g., NIH training [9], CITI [8])
Other project staff	As required/determined by PI	As required/determined by PI

4.1.2 Assurances

The Federal regulations for Human Use protections require the institution conducting the research to provide a formal written assurance [5] certifying that it will comply with the regulations. There is an established process to provide this assurance in a manner covering all Federally-sponsored research, through a "Federal-Wide Assurance" (FWA). Project teams that do not have an existing FWA on record will need to provide at least a Single Project Assurance (SPA) [11], and may consider whether a Multiple Project Assurance (MPA) or FWA would better meet project goals.

Assurance Types	Applicability
Federal-Wide Assurance (FWA)	All Federally-sponsored projects
Multiple Project Assurance (MPA)	Multiple Projects
Single Project Assurance (SPA)	Single Project

4.1.3 Responsibilities beyond single IRB

Depending on the planned roles of project team members, including partner organizations, multiple IRBs may be involved. In the case of a single IRB, formal partnership coordination of Human Use Approval responsibilities is required (as specified in Task 10). In addition, other regulations and policies (e.g., state and local laws governing privacy) may need to be satisfied. Experience from past studies [12, 13] may be helpful in establishing or modifying the project team's approach and defining the organizational responsibilities.

4.1.4 Changes and Amendments

During the application process, it is prudent to anticipate questions and feedback from the IRB, and have a proactive approach to modify the research plan and file necessary changes to the application. Since the IRB review process takes time, minimizing the number of changes that are eventually needed will help to manage project schedule risk. In addition, after IRB approval, further changes may require additional engagement and filings, according to the procedures of the specific IRB.

4.2 Ensuring Supporting Information Meets HUA Needs

The IRB approval process may vary depending on local procedures and protocols, but retain certain fundamental characteristics. For example, the IRB members need to be able to understand the research approach and protocols, risks and benefits to participants, and informed consent provisions. In addition, the probability of successful approval will be enhanced by the demonstration that the project team fully and comprehensively understands and has planned for all necessary protections to human participants.

4.2.1 Research Plan

While developing the research plan components in other Tasks, the project team should keep in mind the IRB process to ensure that planned activities are consistent with human use protections. In particular, the project leadership should ensure that project team members who may not be familiar with the principles and regulations behind Human Use Approval do not invest effort in a design that will be incompatible with obtaining IRB approval.

4.2.2 Recruitment / Informed Consent

Depending on the research approach planned, there is the potential need to address how persons who are not formal participants in a study (e.g., other drivers on roadways) would be affected, and any required outreach to these stakeholders as covered in Task 11. This is a particular challenge in that informed consent may not be possible to obtain, and the project team should be prepared to address this in the IRB application process. The research approach should ensure that non-participants are not subjected to risks and that data collection is carefully planned to avoid problems in gaining IRB approval.

4.2.3 Data collection, storage, usage, disposal

As the pilot deployments will require collection of various data (e.g., to support Performance Measurement in Task 5), it is important to ensure that planned data collection and handling can provide the necessary information to satisfy the research goals while remaining in compliance with human use approval and informed consent. Lessons from other projects where data including participants' travel patterns have been collected [12] may be particularly useful, especially with respect to data ownership and governing the use of various data collected during the project.

4.2.4 Benefits / Risks

The CV applications proposed in each pilot deployment vary in the potential benefits and risks. Since connected vehicle technologies are relatively new, IRB members may not have a prior understanding of benefits and risks, and therefore the project team may be required to provide substantiating information to assist the IRB review. Key concerns may include potential for driver distraction, risks of crashes and privacy impacts.

5 Technical Support Summary

Each Connected Vehicle Pilot Deployment will include different technologies and strategies. It is important to plan, at an early stage, the necessary steps required for successful Human Use Approval. The USDOT can assist in identifying relevant resources, but the responsibility for obtaining Human Use Approval lies solely with the project team. CV Pilot Site Leads that lack experience with the IRB process are encouraged to seek assistance from qualified supporting team personnel or partners. The resources listed in the following sections can help with planning for Human Use Approval for the connected vehicle pilot deployment.

Example Training Resources:

- HHS Office for Human Research Protections Training: http://www.hhs.gov/ohrp/education/training/
- NIH PHRP Training: https://phrp.nihtraining.com/users/login.php

Additionally, a series of USDOT-sponsored webinars were developed to assist early deployers of connected vehicle technologies with Concept Development activities. The webinar described below provides support for the development of a Human Use Approval Summary.

1. **Preparing a Human Use Approval Summary for Connected Vehicle Deployments**

This webinar presents the USDOT perspective on the development of a Human Use Approval Summary, a key step in the concept development phase for deployment planning. Govind Vadakpat and Charles Fay of the Federal Highway Administration describe important considerations to assist pilot teams in planning for and obtaining and documenting required approvals from an accredited Institutional Review Board (IRB). By providing a summary of relevant topics and issues that should be addressed, pilot deployer teams can benefit from an early understanding that will assist in preparing for and obtaining human use approval. In particular, advance planning is critical to ensure that schedule impacts are minimized and that risks are effectively managed.

To access the presentation slides and audio recording for this webinar, please visit the technical assistance page of the CV Pilots website: http://www.its.dot.gov/pilots/technical_assistance_events.htm.

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Appendix: List of Acronyms

Table A-1: List of Acronyms

Acronym	Meaning
BAA	Broad Agency Annoucement
CFR	Code of Federal Regulations
CPD	Comprehensive Pilot Deployment
FWA	Federal-Wide Assurance
HHS	U.S. Department of Health and Human Services
HUA	Human Use Approval
IRB	Institutional Review Board
ITS	Intelligent Transportation Systems
JPO	Joint Program Office
MPA	Multiple Project Assurance
NIH	National Institutes of Health
PHRP	Protecting Human Research Participants
PI	Principal Investigator
PII	Personally Identifiable Information
SHRP	Strategic Highway Research Program
SPA	Single Project Assurance

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