ITS4US Human Use Approval Training

August 24, 2021

Speaker – Deb Curtis

So, let us take a few minutes to review the program.

Although most of you are already familiar with it.

Next slide, please.

So, this is a high-level summary of the complete trip ITS4US program.

As you can see there are multiple partners involved with this initiative with the goal of deploying innovative and integrated trips to support mobility for all users with a particular focus on underserved communities.

So, as you can see here, this involves the lead ITS Joint Program Office from the US Department of Transportation, but also involves the Federal Highway Administration and the Federal Transit Speaker: Deb Curtis This will allow us to take revolutionary steps to integrate advanced technologies, especially those that enable Administration. We are looking to make these large-scale deployments that are replicable and address the challenges of planning.

And executing all segments of the complete trip.

We would like to target all users across all modes regardless of location, income, or disability.
Speaker: Deb Curtis
Next slide, please.

So, we have 5 program goals.

And these program goals are spur high impact, integrated complete trip deployments nationwide, this first goal is to assist the transportation industry in tackling the difficult challenge of providing complete trips for all travelers nationwide by streamlining and expediting solution development.

Through pilot deployment.

Yes.

High impact, replicable integrated solutions developed by these pilot deployments.

Will reduce the cost of future deployments of these critical personal mobility enhancements.

The second goal is to identify needs and challenges by populations.

The needs and of the communities to support mobile mobility options for all travelers, regardless of location, income, or disability are important populations within each community have different needs and challenges for accessing transportation options to improve their quality of life.

The third goal is to develop and deploy mobility solutions that meet user needs.

This will allow us to take revolutionary steps to integrate advanced technologies, especially those that enable adaptive and assistive transportation technologies into the management and operations of the transportation network, including non-motorized modes.

Here we are.

Our goal is to engage key partners within the federal government.

The research community, stakeholder organizations, and private industry to support development of potential solutions for all travelers.

The fourth goal is to quantify and evaluate the impact of the integration of these advanced technologies strategies and applications.

The improvement of safety and mobility of all travelers, quantified impact support, communication of technology benefits to future deployers.

And decision makers.

And finally, the fifth goal is to determine which technologies, strategies, applications and institutional partnerships demonstrate the most potential to address identified barriers to providing complete trips to all travelers in a variety of communities and build environments.

This we also.

The goal is to disseminate the lessons learned from replicable solutions developed by the deployment sites to catalyze additional deployment.

The systems engineering process that we are going to talk about is critical to all of these goals.

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The US Department of Transportation has awarded five teams with Phase One funding to support the development of their deployment concepts. These five deployment sites include the University of Washington, California Association of Coordinated Transportation, Heart of Iowa Regional Agency.

ICF International in Buffalo, NY, and the Atlanta Regional Commission. Next slide please.

There are three deployment phases, and one post deployment phase.

Participants are currently in the first phase concept development where they will develop their ideas to ensure future success in later phases.

They will test and evaluate their projects.

The deployments are expected to sustain operation for at least five years after the program is completed. Next Slide Please.

Speaker - Robert Sheehan

Okay, today we are covering Task 8 Training for the Human Use Approval Task and deliverable. My name is Bob Sheehan. Next slide please.

I am the Multimodal Research Program for the ITS Joint Program Office and also the COR for the CALACT site in addition to supporting the Human Use Approval and Performance Measures among a few of the deliverables and tasks. Next slide.

Today, today's agenda will cover the Human Use Approval Summary, the IRB preparation. We'll give a brief reminder of the different activities that were discussed in the Kickoff and before describing the sections of the Human Use Approval Summary we will talk about the IRB preparation and the actual IRB application process. The remaining time will be spent on explaining the major sections of the deliverable template listed here. Next slide.

In this and the next section, we will mostly remind teams of the activities leading up to the deliverable. Next slide.

Human Use Approval task covers all the steps for applying and obtaining approval for research involving participants. Federally funded research requires IRB process or oversite, requires and consideration of human subjects. Research is the key definition. Understanding what parts of the project are governed by Human Use Approval and what, and the nature of the approval that may vary depending on IRB and potential uncertain items in later phases. Deliverables included Draft Human Use Approval Summary and revised, and final version based on USDOT comments. Next slide please.

So as just indicated and most sites know now, you see the relationship between the deliverables and the tasks, and especially for the human use approval and the IRB. The IRB application will need information from the planned system deployment and how it will operate safely. Data for performance measurement needs to be addressed where it involves participant interaction and data collection. Lastly, recruitment and training should be consistent with informed consent developed in the IRB protocol. Next slide.

And the deliverables? As we have done before and you saw in the template, the DOT has shared a template to facilitate the development and efficient completion of the human use approval summary.

So the two deliverables: the draft, due November 29; and the final, due December 27th. So, Happy holidays.

Next slide 10 please.

The major components of the human use approval summary. The major components of the task are centered around the planning of the IRB application and approval. Preparation and lead times for IRB. Familiarize yourself with the process and timing at an early stage - and we discussed this in the beginning - and I know for a fact that some many sites have really receive the benefits of addressing the IRB at an early stage. And lastly, the need to define what aspects of the project are covered and discuss with IRB staff. So those are the major components of the summary.

Next please.

The IRB preparation application. The IRB's essential element of the task, and so we'll talk about the general points to keep in mind as the sites go through the IRB process.

The IRB is the entity that needs to oversee the research components of the projects as they progress through the phases. The human use approval summary is a summary of the activities and the outcomes. Key points to consider in engagement with the IRB include:

1) making sure that they are suitable to provide a federal-wide assurance from the US Department of Health and Human Services to satisfy the regulations.

IRBs that are part of universities typically need to have a related role for the university. For example, university staff are conducting the performance measurement assessment, where the university lead will be the investigator in the research. Discuss early with the team to set expectations if this applies to this particular project.

Keep in mind the timelines for IRBs can sometimes be long. Engage early to understand the process in timing; so you have to understand the meeting frequency, the application review and timing, etc.

The application is the means for the IRB to review and approve the planned work to engage with human participants. Each IRB will have specific application forms and processes, but they are largely similar. The human use approval summary deliverable does not need to copy the whole application, but should convey the important information.

The human use approval summary is the deliverable for this task to summarize the human use approval, so the document should explain the planning, the IRB interactions, and document the approvals and conditions. Please note that the initial IRB approval is expected in phase one, although there may be additional future steps and requirements from the IRB to cover those things for the phase two activities, or things that are still to be determined.

So the template sections, first one: the introduction.

The introduction provides some context for the reader that may have not read the other deliverables. Focus more on attention on the elements where there are planned interaction with participants.

Section 2: the Human Subjects research plan.

Note that the term "human subjects" is not a plain English term, but is used here only to make the connection with the regulatory language. It is to emphasize that there is a specific regulatory definition, and the regulation is in the references at the end of the slides. Within the plan to discuss the context for

the research components involving participants and as we talked about in previous slides and previous discussions, there are interactions across tasks such as data management, the safety management plan, etc. The interactions and outcomes should be described - in this case, at this point, Phase one.

The human subject research regulations, specifically include additional attention for research involving certain groups, to ensure they are not subject to coercion or undue influence, such as children, prisoners, etc. In this particular case is not necessarily all underserved from the ITS point of view. The regulation is defined that the specific groups may be relevant, for example, to people with cognitive or intellectual disabilities, so informed consent is a key principle in human subjects research. Participation that needs to be voluntary and with sufficient understanding of risks and benefits. So please keep in mind the core principles of human subjects research, including 1) respect for persons, 2) beneficence, and 3) justice.

Next slide, please.

The human subjects research plan. Recruitment of participants in training should be explained, consistent with the IRB application. Note that the IRB approval is needed for participant recruitment as part of the research. There may also be training required for team members and staff who will be engaging with participants or their data.

Section 3. Next slide.

Now this section moves into the specifics of the projects' IRB and process. It provides information on the IRB, including relationship with the team. It provides an overview of the processes and how the team has interacted with them. It's important to ensure the IRB sufficiently understands the project to be able to adequately approve and oversee research. Lastly, it highlights procedures, and past and future timelines.

Next slide please, Section 4.

This section documents the formal approval. The IRB will determine the type of review and approval consistent with the regulations in the plan project. Provide a summary of the approval and explain the feedback and issues raised by the IRB. There are likely components that still will be revised and refined.

We need to discuss the conditions for maintaining approval status and how changes will be addressed over the remainder of the project.

Section 5 of the document covers the future supporting activities and actions. You may need to explain what steps will need to be performed to maintain IRB approval in later phases, including a discussion of expected changes or revisions to the project plans.

Next slide.

So here we, as you've seen before, we have templates that provided for the other deliverables. We see the relationships between the different deliverables and the interdependencies to the human use approval.

Next slide please. So we will go back one slide, sorry.

The references that I at least partly addressed during the review are provided here, to address those key points of the human use approval summary and process.

So as always to stay connected to the program, and specifically for this area, you know general questions, always reaching out to Elina; for this particular technical area (human use approval) contact me (Robert Sheehan). We of course reached the complete trip ITS deployment website for that information.

So now we'll take that and apply it to a Q&A.