Phase 1 Human Use Approval Summary

ARC ITS4US Deployment Project

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16. Abstract

The Atlanta Regional Commission Complete Trip - ITS4US Deployment project, Safe Trips in a Connected Transportation Network (ST-CTN), is leveraging innovative solutions, existing deployments, and collaboration to make a positive impact using transportation technology to support safety, mobility, sustainability, and accessibility. The ST-CTN concept is comprised of an integrated set of advanced transportation technology solutions (connected vehicle, transit signal priority, machine learning, predictive analytics) to support safe and complete trips, with a focus on accessibility for those with disabilities, older adults, and those with limited English proficiency.

This document serves as the Human Use Approval Summary (HUAS) for the ST-CTN project. The HUAS consists of summarizing the IRB process, which includes planning for human subject interactions, human subject protocols and data handling for all research components. The HUAS documents the IRB protocol application process and the integration of IRB approvals.

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Phase 1 Human Use Approval Summary - ARC | ii

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U.S. Department of Transportation
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Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary – ARC | i

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

ii | Phase 1 Human Use Approval Summary - ARC

Table of Contents

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | iii

List of Tables

List of Figures

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

iv | Phase 1 Human Use Approval Summary - ARC

1 Introduction

The Safe Trips in a Connected Transportation Network (ST-CTN) project seeks to enhance the traveler's complete trip travel experience by enhancing mobility, accessibility, reliability, and safety for system users, particularly for underserved communities, including those with disabilities, older adults, and users with limited English proficiency (LEP). This is done by leveraging innovative solutions, existing deployments and team collaboration.

The Human Use Approval Summary (HUAS) describes the nature and extent of the ST-CTN project with respect to all research that involves human subjects and personally identifiable information (PII). This HUAS first provides a background on Institutional Review Board (IRB) requirements associated with the implementation of the ST-CTN project. The HUAS also describes the PII, as well as proprietary data that could lead to the disclosure of PII, to be covered by individual IRB protocols for this project. In addition, the HUAS provides a high-level description of the anticipated human interaction with the system through the application being developed, such as recommended trip routes, notifications, and alerts. This document then summarizes the local procedures that must be met to apply for and obtain approval for the implementation of human subject research.

The HUAS is a companion document to the program and project-level systems engineering documents, including the Concept of Operations (ConOps), Data Management Plan (DMP), Safety Management Plan (SMP), and Performance Measurements and Evaluation Support Plan (PMESP). The HUAS will also serves as input into the development of the Participant Training and Stakeholder Education Plan (PTSEP), Integrated Complete Trip Deployment Plan (ICTDP), and Deployment Readiness Summary Briefing (DRSB). Any changes to the project companion documents over time that result in an effective change in the handling of PII or risk to project participants will result in a subsequent modifications to this HUAS, modifications to approved IRB protocols, and the submission of any necessary supplemental IRB protocols. Protection of the interests of all project participants, especially with respect to safety and privacy, is the most important element of this project.

The ST-CTN project team has extensive experience in human subject research and in obtaining IRB approvals and implementing IRB protocols for large research projects. Over the past fifteen years, the team has obtained prior IRB certification for 18 IRB protocols that collectively involve all of the data types that will be employed in this project (from traditional surveys to high-resolution position trace data). Hence, all of the IRB protocols for the ST-CTN project will be based upon prior work.

1.1 Document Purpose

The purpose of the HUAS is to summarize the IRB process by explaining the research components of the project that relate to human participants, incorporate interactions by reference that are contained in other project documents, describe the documentation of human subject protocols, and the implementation of applicable data handling conditions. The HUAS documents

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | 1

the IRB protocol application process and how the team plans to integrate IRB approvals into the project.

Each IRB protocol application requires full disclosure of the research plan, participant burden, potential participant risk, and how all PII data will be handled and used in the project. Each informed consent agreement that flows from an IRB protocol, requires the same disclosures to participants before they opt-in to the ST-CTN project. The team must adhere to the terms of all standing IRB protocols during project implementation. Once a protocol is implemented, it becomes quite difficult to change the terms of the agreement. For example, the IRB will not approve amendments that would increase respondent burden once a participant has been recruited. For example, an amendment to a protocol that would request participants to complete an exit survey will not be granted, because the time required to participate in the exit survey was not disclosed at the time of project recruitment. Hence, it is imperative that IRB protocols be developed very carefully and comprehensively to ensure that all aspects of the project are fully formed and all interrelationships between protocols are documented prior to recruitment and/or participation of any human subjects. No ST-CTN project interaction with human subjects will take place until all applicable protocols are approved, including any required consent and assent documentation. As noted later in this document, any changes that occur during ST-CTN system refinement that could impact any recruited participant will require the team to submit a protocol modification and potential re-consent and re-assent (per standard IRB procedures). Because each modification can take up to two months to complete, it is important that protocols be fully developed based on the refined system so that minimal modifications are required, to avoid any negative impact on project schedule and budget.

1.2 Project Overview

The project overview will discuss the background of the ITS4US ST-CTN project, the ST-CTN system, an overview of the document, and related tasks.

1.2.1 Project Background

The Complete Trip - ITS4US Deployment Program is a multimodal effort – led by the Intelligent Transportation Systems (ITS) Joint Program Office (JPO) – and supported by the Office of the Secretary (OST), Federal Highway Administration (FHWA), and Federal Transit Administration (FTA) – to identify ways to provide more efficient, affordable, and accessible transportation options for underserved communities that often face greater challenges in accessing essential services. The program aims to solve mobility challenges for all travelers with a specific focus on underserved communities, including people with physical or cognitive disabilities, older adults, low-income individuals, and LEP travelers. This program seeks to enable communities to build local partnerships, develop and deploy integrated and replicable mobility solutions to achieve complete trips for all travelers.

The Complete Trip – ITS4US Deployment Program will be executed in three phases. As depicted in **Figure 1**, deployment sites are expected to go through three phases:

- **Phase 1.** Concept Development
- **Phase 2.** Design and Testing
- **Phase 3.** Operations and Evaluation

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

2 | Phase 1 Human Use Approval Summary - ARC

Post deployment, sites are expected to sustain operations for a minimum period of five years without supplementary federal funds.
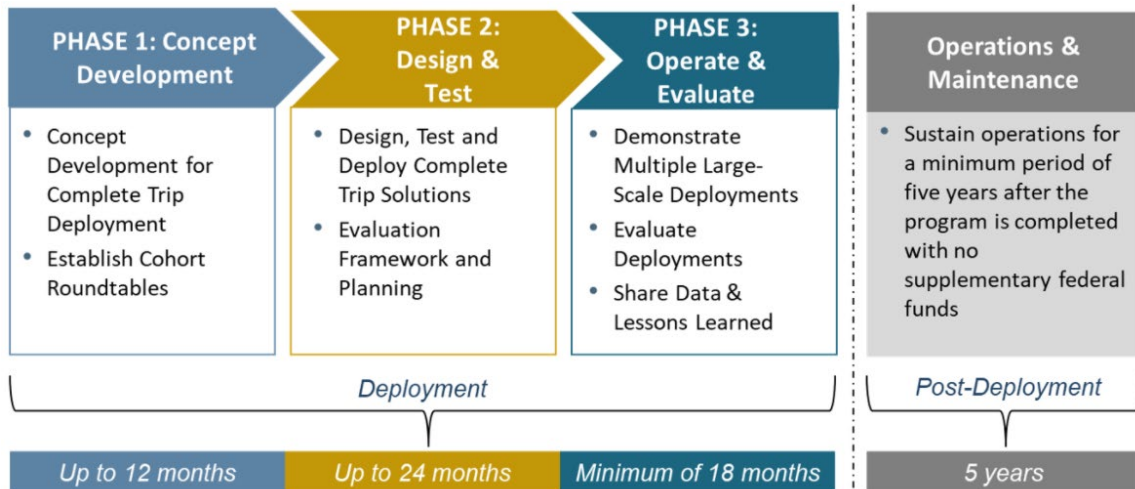
Source: USDOT, 2020

Figure 1. Phases of the Complete Trip – ITS4US Deployment Program

The Atlanta Regional Commission (ARC) was selected by U.S. Department of Transportation (USDOT) as one of the Phase 1 projects to showcase innovative business partnerships, technologies, and practices that promote independent mobility for all travelers regardless of location, income, or disability. The project team intends to address multiple aspects of the Complete Trip by integrating multiple technological innovations. The ST-CTN system will provide Gwinnett County residents with detailed information and step-by-step navigation tailored for users' specific needs along with a range of other features geared to improve trip efficiency and safety. This concept is comprised of an integrated set of advanced transportation technology solutions including connected vehicles, transit signal priority, machine learning, and predictive analytics to support safe and complete trips for all. The ST-CTN system includes a mobile application that will provide users with the ability to create a personalized trip plan with information regarding the navigation of physical infrastructure, the ability to provide safe alternative trip routes when encountering unexpected obstacles, and ensuring users safety throughout the trip. Consistent with the ITS4US Program goals, the ST-CTN project is specifically focused on supporting the following underserved communities:

- **People with Physical Disabilities.** People with physical disabilities are limited in independent, purposeful physical movement of the body or of one or more extremities, and substantially limits one or more major life activities.
- **People with Cognitive Disabilities.** People with cognitive disabilities have a condition that makes it more difficult to interact or participate in the environment around them. Cognitive disabilities may affect a person's thinking, remembering, learning, communicating, mental health, sensory processing, or social interactions.
- **Aging Adults.** Aging adults may have trouble performing specific tasks within a set time (e.g., crossing a road or boarding a transit vehicle), standing for an extended period of time, or be more sensitive to the elements (e.g., waiting for transit in excessive heat). Aging adults are people (typically 60 years of age or older) who have physical or cognitive limitations that impact their ability to perform daily activities.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **3**

- **Limited English Proficiency (LEP) Communities.** A person with LEP refers to a person who is not fluent in the English language. Users who have LEP may have trouble understanding directions and alerts when delivered in their non-native language, may have different culture norms that make it difficult to follow directions others would feel are standard, or may have difficulty understanding wayfinding signs.
- **Low Income Communities.** Users who fall into the low-income category may be single or no-vehicle households, may have trouble accessing different forms of technology (i.e., cellphone or personal computer), may be on reduced payment or fixed payment transit plans, may be unbanked (e.g., not have access to a bank account or credit card), or may use transit as their sole means of transportation. A person who has low income has a median household income that is at or below the Department of Health and Human Services (HHS) poverty guidelines. Poverty guidelines designate $26,500 as the threshold for a household of four in the state of Georgia in 2021.

The ST-CTN project will be implemented in Gwinnett County. Which was chosen partially due to its representative nature. It faces many of the same challenges as much of Metro Atlanta, including suburban land-uses; wide, high-speed roadways; and inconsistent pedestrian infrastructure. This area also was chosen to leverage its implementation readiness and the CV planning work recently completed. A map of the project area can be found in **Figure 2.**
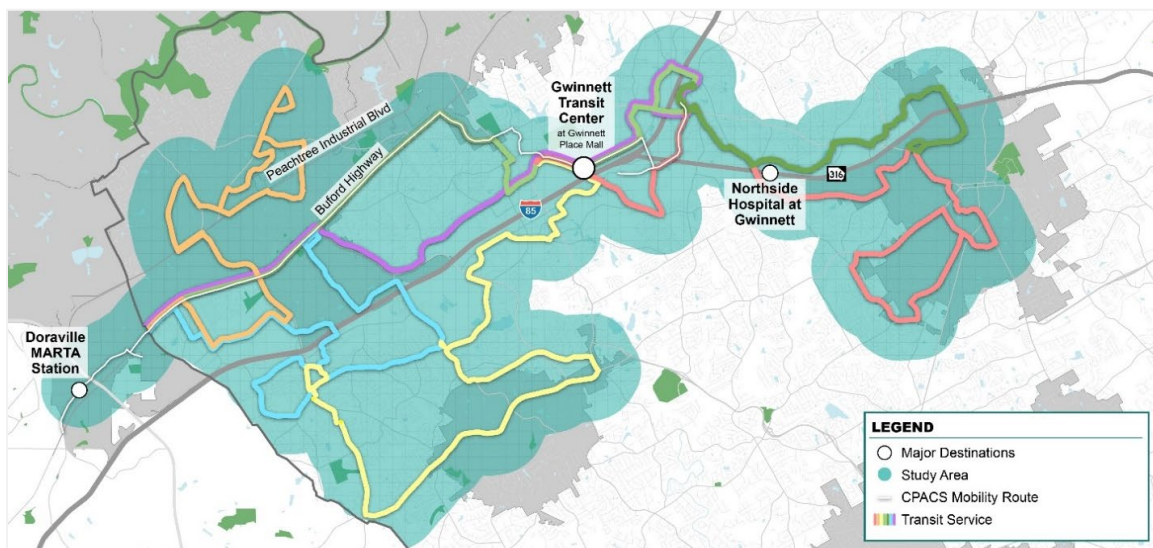
Source: ARC, 2020

Figure 2. ST-CTN Deployment Site Map

1.2.2 System Overview

The ST-CTN system can be thought of as a *system of systems*; the scope of work required to develop, design, and deploy ST-CTN is focused on the expansion or enhancement of current systems and added connectivity between those systems. **Figure 3** provides a simplified context diagram of the proposed system – indicating the system of interest and added subsystem connectivity. Each subsystem is indicated by color and icon: Sidewalk Inventory Collection Tools is burnt orange; space time memory (STM) Platform is peach; CV is green; Atlanta Rider Information and Data Evaluation System (ATL RIDES) is turquoise; and Gwinnett County Transit

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

4 | Phase 1 Human Use Approval Summary - ARC

(GCT) is teal. The STM Platform, ATL RIDES, and CV subsystems will each require expanded capability and added connectivity to support the proposed ST-CTN system. The Sidewalk Inventory Collection Tools and GCT existing independent systems will serve to support the proposed ST-CTN system. Data exchanges between subsystems are denoted by a gray or black line. A gray line indicates an existing and unchanged data exchange between subsystems. A black line indicates a new or upgraded data exchange between subsystems.
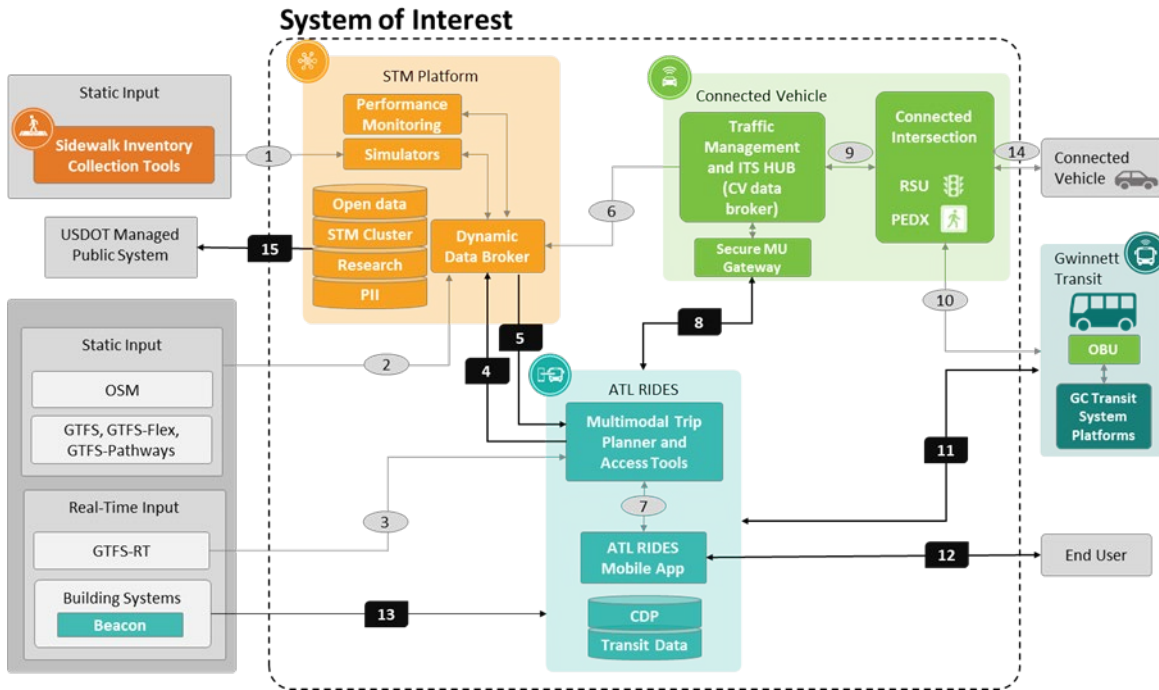
Source: ARC, 2021

Figure 3. ST-CTN Network Data Exchange Flow Diagram and Data Storage Systems

Critical ST-CTN data exchanges are identified by number in the context diagram above and described in **Table 1**. The grey oval labels indicate existing data exchanges that will be utilized with no change to the current data exchange. Black rectangular labels indicate data exchanges that will be new or upgraded to support the ST-CTN system. In addition, dataset storage systems and their access levels (PII confidential, operational, open or research) embedded in the ATL RIDES and STM subsystems are described in the Task 3 DMP.

The ST-CTN system involves interactions between participants and the ATL-RIDES smartphone app as described in the following project planning documents: Concept of Operations (ConOps), Data Management Plan (DMP), Safety Management Plan (SMP), and Performance Measurements and Evaluation Support Plan (PMESP). These plans (as well as this HUAS and other relevant Phase 1 documents) all must be submitted as elements of the IRB protocol applications, along with final detailed specifications of the application interface design and user interactions so that the IRB can assess participant burden and potential risk.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **5**

Table 1. Critical ST-CTN Connection Descriptions

Data Exchange ID	Description
1	Sidewalk inventory data, including accessibility features to the STM Platform simulators
2	Static and dynamic data from various existing sources to the STM Platform dynamic data broker
3	Static and dynamic data from various existing sources to the ATL RIDES multimodal trip planner and access tools
4	Mobile App logs, trip feedback, and crowdsourced data (introduced in the SyRS document as the Asset Condition application programming interface (API))
5	STM Network Impedance API
6	CV and Traffic Operations Messages: signal phasing and timing (SPaT), Map Data (MAP), CV Advanced Traveler Information System (ATIS) broadcast data, NaviGAtor ITS, road characteristics, traffic data
7	Open Trip Planner APIs and ATL RIDES APIs
8	Mobile Accessible Pedestrian Signal System (PED-SIG) / Personal Safety Message (PSM)
9	CV messages
10	Transit signal priority and other CV application messages
11	GCT computer aided dispatch (CAD) application transactions for transit applications including Transit Connection Protection (replacing CV Transit Stop Request (TSR) and Pedestrian Transit Indication (PTI) as described in ConOps Version 1.0)
12	ATL RIDES and Traveler exchange – profile, trip plan, settings, notifications, feedback, etc.
13	Static and dynamic information from building facilities, including beacons, to ATL RIDES
14	CV Data
15	Project data for USDOT-managed Public System

1.2.3 Document Overview

The ST-CTN HUAS is based on the HUAS template provided by the USDOT for the ITS4US-Complete Trip program. The remainder of this document consists of the following sections and content:

- **Section 2** (Human Subjects Research Plan) provides an overview summarizing the project elements that involve or relate to human subjects research, including planned activities later in Phase 1 and through Phase 2 and 3.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

6 | Phase 1 Human Use Approval Summary - ARC

- **Section 3** (Protocol / Application Summary) summarizes the formal IRB application process and documentation.

- **Section 4** (Human Use Approval) documents the formal approval, conditions and feedback resulting from the IRB application.

- **Section 5** (Future Steps and Schedule) explains all currently known future steps (e.g., potential updates, amendments, periodic review, etc.) relating to HUA and serves as a plan for future supporting activities in later Phases. **Table 6** identifies the IRB protocols proposed for this project.
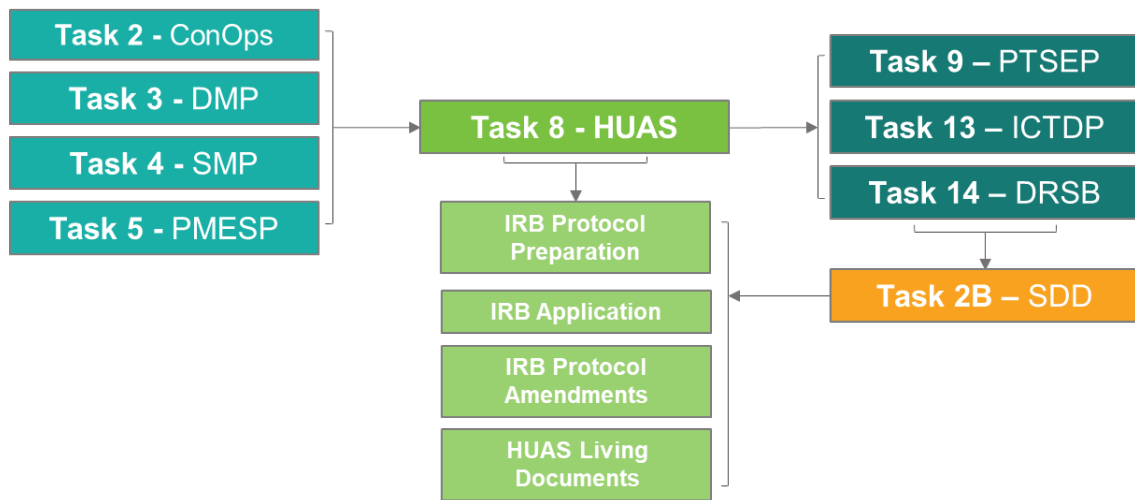
1.2.4 Related Tasks

The ST-CTN project team is required to follow the IRB application and review process due to the nature of the project and the interactions with human subjects. **Table 2** provides a summary of the interactions with participants in other project tasks and key task areas that provide supporting information to (or will be guided by) the HUAS.

Table 2. HUA Related Project Tasks

Related Task	Summary
Task 2 – Concept of Operations (ConOps)	The ConOps is an input for the HUAS. The user group needs and use cases are leveraged to specify where engagement and interactions with participants will occur. As shown in **Figure 3**, ST-CTN users will interact with the system through exchange 12 which includes user profiles, routing information, access to the call center, etc.
Task 3 – Data Management Plan (DMP)	The DMP is an input for the HUAS. Data collection streams and methods identified in the DMP are used for evaluating datasets that will leverage interaction with human participants. The HUAS further defines how the datasets, which rely on human interaction, are collected and therefore can also inform future versions of the DMP.
Task 4 – Safety Management Plan (SMP)	The SMP is an input for the HUAS. The safety needs and scenarios are important considerations for the IRB application process and approval. All human subjects must be aware of potential risks associated with interaction with the system such that they may provide informed consent.
Task 5 – Performance Measurement and Evaluation Support Plan (PMESP)	The PMESP is an input for the HUAS. The measures in the PMESP guide the interactions with participants and guide the process for obtaining data from participants.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **7**

Related Task	Summary
Task 9 – Participant Training and Stakeholder Education Plan (PTSEP)	The PTSEP is an output of the HUAS. The PTSEP outlines the recruitment and training of all travelers and potential caregivers. The interactions defined in the HUAS are used to develop the PTSEP.
Task 13 – Integrated Complete Trip Deployment Plan (ICTDP)	The ICTDP is an output of the HUAS. The HUAS is used to refine the deployment concept and guide any potential changes in the deployment costs or risks.
Task 14 – Deployment Readiness Summary Briefing (DRSB)	The DRSB is an output of the HUAS. Information from the HUAS will be used to assess the project's readiness for deployment in order to begin the Design/Build/Test Phase.

Figure 4 illustrates the key elements and interactions between the HUAS and related project tasks. The HUAS provides information that will support the development of the PTSEP, ICTDP, and DRSB. These Phase 1 tasks will support the development of the Phase 2 System Design Document (SDD) which will then, in-turn support the IRB protocol preparation, IRB application development and approval, and continued HUAS documentation maintenance.

Source: ARC, 2021

Figure 4. HUAS Related Tasks

1.3 Acronyms and Glossary

Below is a list of acronyms and a glossary of terms used in the document.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

8 | Phase 1 Human Use Approval Summary - ARC

1.3.1 Acronyms

API – application programming interface

ARC – Atlanta Regional Commission

ATIS – Advanced Traveler Information System

ATL RIDES – Atlanta Rider Information and Data Evaluation System

CAD – computer aided dispatch

CITI – Collaborative Institutional Training Initiative

CM – Configuration Manager

ConOps – Concept of Operations

CV – connected vehicle

DMP – Data Management Plan

DRSB – Deployment Readiness Summary Briefing

EU – European Union

FHWA – Federal Highway Administration

FTA – Federal Transit Administration

FWA – Federal-Wide Assurance

GA Tech – Georgia Institute of Technology

GCT – Gwinnett County Transit

GDPR – General Data Protection Regulation

HHS – Department of Health and Human Services

HUAS – Human Use Approval Summary

ICTDP – Integrated Complete Trip Deployment Plan

IRB – Institutional Review Board

ITS – intelligent transportation system

JPO – Joint Program Office

LEP – limited English proficiency

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **9**

OHRP – Office of Human Research Protections

ORIA – Office of Research Integrity Assurance

OST – Office of the Secretary of Transportation

PED-SIG – Mobile Accessible Pedestrian Signal System

PII – personally identifiable information

PMESP – Performance Measurement Evaluation Support Plan

PSM – personal safety message

PTSEP – Participant Training and Stakeholder Education Plan

SMP – Safety Management Plan

SPaT – signal phasing and timing

ST-CTN – Safe Trips in a Connected Network

STM – space time memory

TSR – transit stop request

USDOT – U.S. Department of Transportation

1.3.2 Glossary

General Data Protection Regulation (GDPR) – a privacy and security law in effect in the EU that applies to any organization collecting data from persons in the EU. This law discusses data processing principles, informed consent, accountability and data design and default. [GDPR]

Pedestrian Transit Indication (PTI) – indication provides vehicle to device communications to inform pedestrians at a transit stop of an approaching transit vehicle. The indication also informs the transit vehicle operators of pedestrian presence. [PTI]

Personally Identifiable Information (PII) – Information on an individual's identity such as name, address, identifying number, telephone number, email address, etc.

Personal Safety Message (PSM) – A data broadcast by a vulnerable road user (such as pedestrians) to announce their presence to approaching vehicles. [CAV]

Privacy – The ability of an individual or group to seclude themselves or seclude information about themselves, thereby revealing themselves selectively. [CAV]

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

10 | Phase 1 Human Use Approval Summary - ARC

1.4 References

The following table lists the documents that were used to support the development of the ST-CTN HUAS document. References to these documents are identified with the acronym provided in brackets.

Table 3. References

ID	Referenced Documents
[ConOps]	Atlanta Regional Commission. Deliverable Task 2 Concept of Operations. Atlanta: U.S Department of Transportation. (2021).
[DMP]	Atlanta Regional Commission. Deliverable Task 3 Data Management Plan. Atlanta: U.S Department of Transportation. (2021).
[SMP]	Atlanta Regional Commission. Deliverable Task 4 Safety Management Plan. Atlanta: U.S Department of Transportation. (2021).
[PMESP]	Atlanta Regional Commission. Deliverable Task 5 Performance Measurement and Evaluation Support Plan. Atlanta: U.S Department of Transportation. (2021).
[GPS]	Elango, V., S. Koheini, Y. Xu, R. Guensler. Longitudinal GPS Travel Data and Breach of Privacy via Enhanced Spatial and Demographic Analysis. Transportation Research Record Number 2354. Pp. 86-98. Washington D.C.: National Academy of Sciences. (2013).
[VPFP]	Guensler, R., Y. Xu, V. Elango. Value Pricing Fellowship Project. Atlanta: Georgia Department of Transportation. (2013).
[PTI]	The National ITS Reference Architecture. PT 11: Transit Pedestrian Indication. Washington D.C.: U.S. Department of Transportation. (2021).
[IRBa]	Office of Research Integrity Assurance. Exempt IRB Protocol Reviews. Atlanta: Georgia Institute of Technology. (2021). https://researchintegrity.gatech.edu/irb/submitting-protocol/exempt-irb-review.
[IRBb]	Office of Research Integrity Assurance. IRB Protocol Form Templates. Atlanta: Georgia Institute of Technology. (2021). https://researchintegrity.gatech.edu/irb/submitting-protocol/forms
[IRBc]	Office of Research Integrity Assurance. IRB Protocol Informed Consent. Atlanta: Georgia Institute of Technology. (2021). https://researchintegrity.gatech.edu/irb/hsr/irb-informed-consent
[IRBd]	Office of Research Integrity Assurance. IRB Required Training. Atlanta: Georgia Institute of Technology. (2021). https://researchintegrity.gatech.edu/irb-required-training

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | 11

ID	Referenced Documents
[IRBe]	Office of Research Integrity Assurance. IRB Protocol Submission Decision Tree. Atlanta: Georgia Institute of Technology. (2021). https://researchintegrity.gatech.edu/irb/submitting-protocol/submission-decision-tree
[IRBf]	Office of Research Integrity Assurance. IRB Protocol Submission Example and Guidance. Atlanta: Georgia Institute of Technology. (2021). https://researchintegrity.gatech.edu/irb/submitting-protocol/example-protocol-submission
[IRBg]	Office of Research Integrity Assurance. Submitting IRB Protocols. Atlanta: Georgia Institute of Technology. (2021). https://researchintegrity.gatech.edu/irb/submitting-protocol
[CAV]	Park, Hyungjun; Khattak, Zulqarnain; Smith, Brian. Glossary of Connected and Automated Vehicle Terms *Version 1.0*. Charlottesville: University of Virginia Center for Transportation Studies. (2018).
[BAA]	U.S. Department of Transportation, Federal Highway Administration. ITS4US Broad Agency Announcement. Washington D.C.: U.S. Department of Transportation. (2020).
[GDPR]	Wolford, Ben. What is the GDPR, the EU's new data protection law?. Geneva: Proton Technologies. (2021).

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

12 | Phase 1 Human Use Approval Summary - ARC

2 Human Subjects Research Plan

The following sections provide an overview of project elements that involve or relate to human subjects research, including planned activities through Phases 1, 2, and 3. All planning and steps taken to ensure research elements are conducted consistent with human subjects research principles and regulations are discussed.

2.1 Research Questions

Research questions deigned to support the ST-CTN project are outlined in the PMESP. These research questions relate to the participants' complete trip travel experience while using the ST-CTN system, including the system functions and features, how the system impacts their travel experience, and their perception of safety they feel while using the ST-CTN system. These research questions are designed to allow the project team to evaluate if the ST-CTN system has met the goals and objectives identified in the ConOps.

Example survey questions likely to be asked of ST-CTN system users may include:

- Did use of the ST-CTN application enhance your experience while making a trip?
- Was the ST-CTN application easy to use/configure/access?
- Did the ST-CTN application features and functions, including alerts, notification methods, and accessible route selection enhance your complete trip experience?
- Did access to the travelers' caregiver through the ST-CTN application enhance your experience?

Survey instruments designed to answer these research questions will be designed in Phase 2. Survey questions will be written in a way that does not guide the user to an answer but allows the user to respond accurately and provide critical feedback to the ST-CTN project team.

2.2 Interactions with Other Tasks and Consistency

It is necessary that any documentation and activities related to human subjects conducted throughout the life of the ST-CTN project be consistent with the HUAS and IRB approval. **Table 2** summarizes the related Phase 1 tasks that provide supporting information or will be guided by the HUAS and IRB process. A Configuration Manager (CM) will be designated to be responsible for maintaining consistency throughout all relevant documents during Phases 2 and 3 of the project, including the HUAS and IRB approval. This person will be responsible for identifying or receiving impacting changes, documenting those changes, and then revising the necessary related documentation and processes to maintain consistency. Further details pertaining to the configuration management process are provided within the SEMP

In addition, it is anticipated that beyond documentation configuration management, the individual IRB protocols implemented for this project will be refined and updated as necessary based on key design and Agile development activities during Phase 2. These design and development

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **13**

decisions will be reflected in the HUAS and IRB process updates such that all interactions between the system and human subjects and data handling procedures have been accounted for and approved by the IRB.

2.3 Considerations for Vulnerable Populations

Each IRB protocol for the ST-CTN project must clearly identify any vulnerable populations as defined under Title 45, Part 46 that are participating in the project, including pregnant subjects, prisoners, and children (Title 45, Part 46). Furthermore, individuals with impaired decision-making capacity who do not have the capacity to consent for themselves (e.g., individuals with Alzheimer diseases) must be expressly identified in the protocols. Economically disadvantaged persons and educationally disadvantaged persons must also be disclosed and expressly considered in the protocols. Georgia Institute of Technology (GA Tech) protocols require the identification of additional potentially vulnerable populations, including employees or subordinates of investigators, non-native English speakers, patients, students, trainees, and wards of the state. The ST-CTN project team will seek IRB protocol approval to include all participants legally capable of providing informed consent. This will not include those persons with a severe mental disability or children under 18.

The ST-CTN project team will not seek to establish specific end user group cohorts which would require the development of (and IRB approval of) statistically significant numbers of participants within each cohort. The project will not expressly recruit as a cohort, nor exclude from participation, any individuals based upon gender, adult age, employment status or type, income, or other demographic characteristics. The project will not specifically recruit as a cohort, nor exclude from participation, pregnant subjects, prisoners, economically disadvantaged persons, educationally disadvantaged persons, employees or subordinates of investigators, non-native English speakers, patients, students, trainees, and wards of the state. For online surveys and smart phone app use, the IRB has traditionally allowed research to include these classes of vulnerable users into studies, provided that there is no differential treatment and there is only de minimis risk associated with participation. All protocols will provide the rationale as to why pregnant women, workers, and economically disadvantaged persons will experience no additional risk or participant burden. Regional and sub-regional surveys will include random stratified sampling goals based upon demographic characteristics; hence, each survey will receive a separate IRB protocol. All of the ST-CTN protocols are required to take special care with respect to the participation of children who do not legally have the capacity to consent for themselves and individuals that do not have the capacity to consent for themselves (e.g. those with Alzheimer diseases). Informed consent and parental assent (or caregiver assent) are required for the participation of children and individuals with such impaired decision-making capabilities. Caregivers will also participate directly with this program.

The ST-CTN project team will be deployed without the participation of children or individuals that cannot consent for themselves, however caregivers will be included. Hence, all protocols will specifically exclude participation of children and individuals with impaired decision-making capabilities.

The team recognizes that there is a chance that survey respondents could be located within the European Union (EU) at the time of correspondence or completing a survey (e.g., they use the ST-CTN while in Gwinnett County and receive a survey while traveling in the EU). Given the additional requirements associated with the EU General Data Protection Regulation (GDPR), the

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

14 | Phase 1 Human Use Approval Summary - ARC

team will specifically ask whether a participant is located in the EU and will exclude these individuals from participation in any data collection processes. Participants will also specifically acknowledge that they are not located in the EU in all online consent form documents.

2.4 Informed Consent

Prior to participation in any IRB-approved research, participants must execute an informed consent document that clearly explains the goals of the project, the data collection methods, potential participant risk, potential participant burden, data that will be collected, how the data will be used, the anticipated respondent burden (through the entire course of the research effort), and the potential risk to the participant from participation [IRBc]. Informed consent documentation is submitted with the proposed protocol and must be approved by the IRB as part of the protocol. It is expected that the informed consent documents will be comprehensive in nature and tailored as necessary for different use cases or user groups which will be determined during Phase 2. As noted in **Section 2.3**, children and individuals with impaired decision-making capacity will not be included. Informed consent language must be specifically tailored to these vulnerable (as defined within Title 45, Part 46) groups and informed assent documentation must be executed in parallel by a guardian or caregiver. An informed consent (and assent document if needed) must be specifically designed for each protocol to reflect the content of the IRB protocol application, and then approved by the IRB as part of the protocol. The informed consent relies directly upon (and must match) the materials submitted through the online protocol submission form fields [IRBg]. Any project modifications that would change the nature of the research, data use (which must be disclosed to the participant), participant burden, or participant risk require the team to amend the protocol through a similar IRB approval process and will likely require changes to informed consent and assent documents. In general, the IRB will not approve amendments to the protocol that increase respondent risk beyond a de minimis level. The IRB also has a history of not approving any protocol amendments that would increase respondent burden after the participant has agreed to initial participation terms. For example, the team cannot obtain an amendment to add-on an exit survey to an approved protocol after participants have been recruited. Hence, it is critical that the team design the protocols carefully and identify all potential data uses and surveys that may be required as part of the project prior to seeking approval.

2.4.1 Participant Questionnaires / Evaluation

As discussed in the PMESP document and in **Section 5** below, the team will be implementing targeted participant survey questions directly through the ATL RIDES app and application as well online sub-regional before-and-after surveys. Separate protocols will be submitted for each survey type that will ensure that all PII are fully protected. Standard stakeholder review procedures are implemented for all survey designs and questions to help ensure that participants can clearly understand questions and that inherent bias (participant and question non-response bias, auspice bias, etc.) is minimized. In addition, survey design will include consideration of the communication format to ensure it is accessible for participants. Formats may include large print, audible, multiple languages, etc. It is expected that surveys will be conducted solely through the ATL RIDES app or online application. The IRB also reviews each survey instrument and question as part of the protocol approval process. Hence, all survey instruments must be in final form before a protocol will be approved by the IRB. Any change to a survey question requires submission of a protocol amendment for expedited review (which typically takes only a few days).

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | 15

2.4.2 Participant Data

The IRB protocols govern all data handling procedures that relate to data that disclose the identity of a participant or taken in combination with other data that can be obtained publicly, can disclose the identity of a participant. All such data must be handled in accordance with IRB protocols obtained for the ST-CTN project, irrespective of the content of the Phase 1 DMP. Hence, the team will ensure that each protocol reflects the content of the DMP and that any changes to data handling required by the IRB are reflected in an update to the DMP.

The DMP provides an inventory of the datasets and their characteristics related to the ST-CTN system. The inventory includes datasets that are ingested, generated, processed, and exported by the ST-CTN system including static, real-time, and archived datasets. The plan includes information on data governance, management, security and privacy policies, storage, and access.

Each dataset will be assigned a data owner and data steward, as described in Section 4.1 of the DMP, who will be tasked with maintaining the accessibility and integrity of the data. Data access is categorized as either open (i.e., publicly available data) and private. Private data sets contain data that may not be shared with external users due to operational, proprietary, research, or PII restrictions. Operational, proprietary, and research datasets are often able to be shared for project related purposes including performance monitoring or modeling if data licensing agreements are respected. PII data is restricted to hard-wire access points maintained by GA Tech with multiple security protocols in place to prevent external access as described in Section 4.2 of the DMP.

Participants will be required to acknowledge and allow data generated by their use of the ST-CTN system to be used by the ST-CTN project team. Information regarding how the data will be used and secured will be provided to the participant, including the length with which the data will be stored. In some cases, caregivers will be asked to provide consent for data collection for participants unable to provide consent for themselves.

2.5 Recruitment Design

As a user focused system, many of the goals and objectives will only be adequately evaluated by hearing directly from users and their caregivers. The majority of this information will be collected through surveys that will be available through the ATL RIDES application. ST-CTN system users and survey participants will be recruited through outreach conducted with existing advocacy organizations who have interest in sharing the ST-CTN system with their customers, as described in the PTSEP. End user recruitment will primarily leverage already existing programs by working with organizations that serve the ST-CTN target populations, i.e. travel trainings and independent living skills trainings. In addition, recruitment will be performed through outreach activities as described in the Outreach Plan, including local event engagement, sharing user stories through various media platforms, public meetings, and advertisements within transit vehicles or stops. Recruitment will begin early in Phase 2 such that the existing ATL RIDES application can be used to establish baseline data. Anticipated baseline data needs are discussed in the PTSEP and include trip feedback reports, traverse data, mobile app logs, and GCT complaint log.

Additionally, surveys will be conducted with the study participants after their training to gain information of overall UI design, training materials, and procedures. Participants will also be

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

16 Phase 1 Human Use Approval Summary - ARC

asked what level of participation with the study they would like to have in the future, the highest of which will be interviewed for the team to gain a greater understanding of the system from a user perspective. Participants will be recruited through training events conducted with advocacy organizations throughout the study area.

2.6 Training of Participants

Participants will have access to receive training on how to use the ST-CTN system. The PTSEP provides a guide for developing and delivering training to participants and caregivers of the system. Training will be developed to support end users of all target populations, including people with physical or cognitive disabilities, older adults, low-income individuals, and LEP travelers. The document consists of identifying participants, determining eligibility, defining the recruitment and selection process, developing a retention plan, and discussion of training methodology and assessment.

A summary of anticipated participant trainings and methods that will be available to participants include:

- End User:
    - General ST-CTN Use – In-person or live virtual trainings conducted in combination with existing advocacy organization trainings.
    - General ST-CTN Use – Self-directed trainings conducted online through pre-recorded videos.
    - General ST-CTN Use – Self-directed trainings conducted within the ATL RIDES application resources.
    - Crowdsource Data Collection – Self-directed trainings conducted online through pre-recorded videos.
- Infrastructure Owner/Operator (IOO):
    - ST-CTN Transit Signal Priority (TSP) and Connection Protection – In-person or live virtual trainings conducted for Gwinnett County Transit Operators.
    - ST-CTN Call Center Interface – In-person or live virtual trainings conducted for Gwinnett County Transit Call Center Operators.

2.7 Team Human Subjects Research Training

All project managers and all team members that are involved with PII in any way (agency staff, software developers, consultants, students, etc.) will complete the "Responsible Conduct of Research - RCR Basic Course (CITI Curriculum ID 104819)" as well as "Human Research - Group 2 Social / Behavioral Research Investigators and Key Personnel (CITI Curriculum ID 935)" [IRBd]. All team members will renew both training certificates before they expire during Phase 3. Georgia Tech will provide Collaborative Institutional Training Initiative (CITI) accounts to all ST-CTN project staff, so that personnel can take the exams through the university CITI portal. Copies of certificates of completion will be maintained by GA Tech and the ARC and available to the sponsor at any time.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | 17

3 Protocol / Application Summary

This section identifies the IRB for the Atlanta metropolitan area and summarizes the IRB procedures that will be followed by the ST-CTN project team. The Georgia Tech members of the project team will lead all the IRB protocol submissions. The Georgia Tech researchers have extensive experience working with the IRB and have obtained 18 IRB protocols for human subjects research, 13 of which relate to this project as they involve collection and handling of similar demographic data, survey data, and second-by-second GPS-based human mobility data (as described in **Section 5**).

3.1 Institutional Review Board

An IRB is a federally mandated panel charged under federal law with safeguarding the rights and welfare of human subjects in research. For projects in the Atlanta metropolitan area, the Central IRB reviews human subject research activities. The Board is composed of faculty and administrators from Georgia Tech and representatives from the greater Atlanta community. Administrative support for the Board is provided by the Georgia Tech Office of Research Integrity Assurance (ORIA), which reports to the Vice President for Research Development and Operations. ORIA staff members manage all IRB procedures associated with protocol submission and approval. IRB approval must be attained in advance of the implementation of all research projects that include human subjects, regardless of funding source, and regardless of whether the project is a subcontract to or from another institution.

3.1.1 Federal-wide Assurance

ORIA maintains the university's Federal-Wide Assurance (**FWA 00001731**) and Registrations with the Office for Human Research Protections (OHRP) in the HHS.

3.2 IRB Review Process

The IRB requires online submissions of all proposed human subject protocols via the online IRBWISE system through a step-by-step decision tree and online form completion process. Submissions require advance preparation of responses for the online form, so that general information and essay responses may be entered [IRBe]. The detailed essay elements flow from the research plan and are typically the equivalent of approximately eight-to-ten-page summaries per protocol. Essay responses answer IRB questions associated with project benefits, research design and methods, participant recruitment, target sample size, data collection plan, data collection instrument design, potential data bias, statistical analysis plans, start and end dates, data handling, data security, potential participant risk, participant burden, etc. These responses will be developed during Phase 2, once research protocols and human use interface designs are finalized for review. For each protocol, the team is also required to upload an annotated bibliography and all relevant Phase 1 documents: Concept of Operations (ConOps), Data

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **19**

Management Plan (DMP), Safety Management Plan (SMP), Performance Measurements and Evaluation Support Plan (PMESP), and Human Use Approval Summary (HUAS). Once all form fields are populated and each submission is deemed complete by ORIA staff, the proposed protocol is added to the agenda for the next monthly Central IRB meeting for review and consideration. Complex submissions (such as those for this ST-CTN project) typically require the researcher to answer additional questions from the Board, which requires a response to comments submission and final decision review by one or more Board members and ORIA staff [IRBb]. The team expects that the majority of the protocols for the ST-CTN project will be approved within two months of application submission.

3.3 Ensuring IRB Understanding of Project

Before any proposed protocols can be submitted to the IRB, the research team is required to submit comprehensive research plans to the IRB for all project-related activities. Within each protocol submission, the team is also required to summarize the goals and objectives of each project element as they relate to the overall research plan. For the ST-CTN project, this submission will include all Phase 1 plans that relate to participant interaction, data collection, data handling, and data use. Prior to the submission of any specific project-related protocols, the team will submit the following Phase 1 plans to the IRB as project background information to support informed IRB review of all submissions (i.e., all related IRB protocols will reference these background documents):

- Phase 1 Concept of Operations

- Phase 1 Data Management Plan

- Phase 1 Safety Management Plan

- Phase 1 Performance Measurement and Evaluation Support Plan

- Phase 1 Human Use Approval Summary

The IRB will refer to these plans during each protocol review and will keep the research plans on file as reference materials to support approved IRB protocols. Any updates made to these plans during the Phase 2 Agile process that would materially affect any approved protocol will require the submission of a protocol amendment and submission of the updated plan that drove the need for the amendment. The IRB protocol applications will include detailed disclosure of all final research protocols, ST-CTN system designs, and specific system human interactions. Draft protocols will be reviewed by the Executive Management Team (EMT) prior to submittal to the IRB to ensure consistency across all project elements. More detail about anticipated IRB proposed protocols is presented in **Section 5**.

3.4 Relevant IRB Procedures

The IRB requires online submissions of all proposed human subject protocols via the online IRBWISE system, using a step-by-step decision tree (to define review type) and form completion process (to provide all information for Board review of the specific protocol) [IRBf]. The Central IRB approves all research conducted by researchers at the GA Tech. Board members are very familiar with all of the technologies that are being employed in the ST-CTN project. IRB oversight of the protocols is continuous, until the protocol expires or is cancelled.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

20 | Phase 1 Human Use Approval Summary - ARC

Once an IRB protocol is approved, the research team may not deviate from the protocol. Any desired changes to the project that evolve during the Agile process (e.g., research protocols, interface designs, data handling procedures, et.) that would affect the ability of the team to comply with an approved IRB protocol requires the submission of a protocol amendment. Most amendments can be approved quickly, given that the IRB is already familiar with the research project. As each change is made to any of the Phase 1 plans identified in **Section 3.3** during Phase 2 and Phase 3 of the project, the team will revisit the HUAS and each IRB protocol. Relevant IRB protocol amendments will be submitted as soon as a needed change is identified.

Any incidental changes to the project that would result in a deviation from a protocol must be reported immediately to the IRB. The team must work with the IRB to ensure that any deviation is corrected, an amendment is processed to change the protocol (assuming no increase in participant risk or burden has resulted), or the project must halt until a resolution is achieved.

As described in **Section 5** and presented in **Table 4**, the Central IRB has already approved prior research protocols that have collectively covered data collection and use of all of the data types that will be employed in the ST-CTN, as well as app-based human interfaces and map-based routing. Hence, the team anticipates that there will be no major issues encountered with the development and approval or protocols for the ST-CTN project.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **21**

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

22 Phase 1 Human Use Approval Summary - ARC

4 Human Use Approval

This section of the HUA will document the formal approval, conditions, and feedback resulting from the IRB application process discussed in detail in Section 3. Once the modular IRB protocols (individual protocols that can reference each other as required) have been submitted and approved in Phase 2 (see Section 5 and Table 6), approval letters will be included in Appendix A. By submitting IRB protocols through a 'modular' approach, the team will have flexibility to leverage existing approved IRB protocols through amendments and will allow for future use of system elements for expansion or other purposes. Together, all modular IRB protocols will support the full ST-CTN system deployment, evaluation, and research.

4.1 Type of Review

The ST-CTN project team will be submitting a series of modular IRB protocols (for specific data collection methods and data types that will then be incorporated by reference into additional project-specific IRB protocols. The Human Use Approval confirmation materials are outlined below and provided in full detail in **Table 6**.

- Research Server Setup and Operation
- Licensed Municipal and Demographic Data
- Vehicle Registration Data
- Customer Demographic and Preference Data
- Sub-regional Survey Data
- Customer Activity and Trace Data
- Targeted App Customer Survey Data

This modular approach allows the team to propose and obtain approval for simple protocol amendments that apply across multiple projects or project elements, when such changes do not impact participant risk or respondent burden (e.g., changing the location of secure data storage). The majority of the protocols required for the ST-CTN project will require Full Board Review, which generally takes up to two months to process. None of the protocols will qualify as exempt [IRBa]. The Central IRB generally meets on the third Friday of each month. For studies that need to be reviewed by the Full Board Committee, protocol submissions must be received by the first business day of the month to be added to that month's meeting agenda. Proposed protocols can only be added to the month's agenda when the application is deemed complete by the ORIA staff in their review of the IRBWISE online forms submitted for each protocol by the research team (as discussed in **Section 3.2**).

4.2 Approval Status

As discussed in **Section 3**, the Central IRB will only review protocol applications once the applications are deemed complete by ORIA staff members. This requires not only the completion of the Phase 1 planning documentation, but also the development of all final sampling plans,

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **23**

recruitment plans, recruitment documents, survey instruments, human-computer interaction details, consent and assent forms, and data handling protocols. Hence, the team will prepare and submit all of the protocols outlined in **Section 5** (**Table 6**) during the first six months of Phase 2 of the ST-CTN project. Formal approval status of each protocol and protocol amendment will be reported monthly. In addition, the HUAS will be updated to define the approval status of each protocol, content submitted for the protocol, IRB approval letters, and stamped consent forms will be provided in the Appendix for reference.

4.3 Feedback from IRB Review

The ST-CTN project team will receive formal feedback from the Central IRB after each protocol is submitted during Phase 2. On complex studies such as the ST-CTN, the research team anticipates multiple interactions with the IRB and preparation of response to comments documents during the application process. Because the team has previously obtained approvals for protocols that have included the collection of all of the data types that will be employed in the ST-CTN as well as app-based human interfaces and secure PII data routing procedures (see **Section 5**), the team does not anticipate any problems with obtaining full approval for all project-related protocols during Phase 2. The team shared the proposal and discussed the project with OIRA staff members during Phase 1. OIRA staff members are aware that specific IRB protocol applications are forthcoming when Phase 2 is funded. The team acknowledged that no participant interactions nor PII data collection shall proceed until the associated IRB protocols have been approved and consent forms have been stamped as approved by the IRB. As noted above, there are no provisions for pre-approval of protocols. All protocols must be complete, which requires full and detailed disclosure of all research methods, sampling plans, survey instruments, respondent burden estimates/demonstrations, detailed human-computer interaction screens, consent and assent forms, and data security protocols.

4.4 Conditions

As noted earlier, once an IRB protocol is approved, the research team may not deviate from the protocol. When any change is made to a Phase 1 plan over the life of the project, the team will revisit the HUAS and each IRB protocol. Relevant IRB protocol amendments will be submitted as soon as a needed change is identified. Any incidental changes to the project that would result in a deviation from a protocol will be reported immediately to the IRB and project sponsor (per standard reporting requirements). The team will immediately correct the deviation, process an amendment to change the protocol (assuming no increase in participant risk or burden has resulted), or halt the data collection until a resolution is achieved. The IRB has always been very responsive to such submissions and action will be taken immediately.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

24 | Phase 1 Human Use Approval Summary - ARC

5 Future Steps and Schedule

The ST-CTN project involves the development and deployment of complex app-based systems that collect PII from participants, concurrent activity surveys, as well as sub-regional before-and-after surveys, which must be fully designed before IRB approval can be obtained. The IRB does not pre-approve research projects. The ST-CTN project team will be required to submit the entire set of Phase 1 documents to provide the basis for the overall Phase 2 and Phase 3 deployment and research activities to the IRB. The ST-CTN project team will then apply for individual IRB protocols for each ST-CTN subsystem or module that involves the collection of data and handling of PII as outlined in **Table 6.** The Georgia Tech research team has found this process provides a tremendous advantage, because the development of IRB protocols that rely on data sources for which protocols have already been approved can proceed much more quickly. Any individual subsystem protocol can be incorporated by reference into new and modified protocols because they have been pre-approved and have been proven to be successful. For example, the collection of instrumented vehicle data originally approved in 2004 has been updated and then implemented in many other protocols over the last 16 years. The ST-CTN team has already obtained approval for 16 prior protocols (identified in the table below) that have collectively included the data collection of all data types that will be employed in the ST-CTN. As such, the ST-CTN team will be generating new protocols for the ITS4US project that are based upon elements within these previously approved protocols.

Table 4. IRB-Approved Protocols

IRB-Approved Protocol	Relevance to ST-CTN	Protocol ID
Metropolitan Atlanta Commuter Survey (2021)	Survey instrument and implementation (pre-approved questions)	Pending
Clayton County Sidewalk Survey (2021)	Survey instrument and implementation (pre-approved questions)	H21189
SRTA Customer Satisfaction Survey (2020)	Survey instrument and implementation (pre-approved questions)	H20061
Transportation Planning and E-Scooter Use in Atlanta (2019)	Survey instrument and implementation (pre-approved questions)	H19461
Sidewalk Prioritization Public Preferences Survey (2016)	Survey instrument and implementation (pre-approved questions)	H16209

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **25**

IRB-Approved Protocol	Relevance to ST-CTN	Protocol ID
Sidewalk Accessibility Stakeholder Interviews (2016)	Survey instrument and implementation (pre-approved questions)	H16116
Bicycle and Pedestrian Safety Survey and Interviews (2014)	Survey instrument and implementation (pre-approved questions)	H14375
Opinions from the Disability Community for Sidewalk Quality Evaluation (2014)	Survey instrument and implementation (pre-approved questions)	H14223
HOV to HOT Conversion Impacts on Carpooling (2013)	Survey instrument and implementation (pre-approved questions)	H13520
Real-time Travel Tracking with Commute Warrior (2013)	Instrumented vehicle data collection (second-by-second trace data), app user interface, data handling, and use	H13508
Real-Time Tracking and Choice Data Pilot Testing (2013)	Instrumented vehicle data collection (second-by-second trace data), app user interface, data handling, and use	H13119
Using Expert Knowledge to Evaluate Sidewalk Quality (2013)	Survey instrument and implementation (pre-approved questions)	H13082
Web-based Customer Feedback to Improve Public Transit Services (2013)	Survey instrument and implementation (pre-approved questions)	H13070
Bicycle Mapping Tool Research Survey (2012)	Survey instrument and implementation (pre-approved questions)	H12413
Congestion Pricing Impacts on Delivery Fleets and Commercial Services (2007)	Survey instrument and implementation (pre-approved questions)	H07320

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

26 | Phase 1 Human Use Approval Summary - ARC

IRB-Approved Protocol	Relevance to ST-CTN	Protocol ID
Commute Atlanta for Instrumented Vehicle Data Collection and Use (2004)	Instrumented vehicle data collection (second-by-second trace data), web user interface, data handling, and use	H04131
Relationship Between Driver Speed and Crash Probabilities (2001)	Instrumented vehicle data collection (second-by-second trace data), web user interface, data handling, and use	00A041

5.1 IRB-Required Future Actions

During Phase 2 of the ST-CTN project, the team must submit individual protocols for each data collection and analysis element of the project as outlined in **Table 6**. As part of each protocol, all research methods, human interaction, participant risk, survey instruments, data handling and security measures, and informed consent and assent forms must be reviewed and approved by the IRB prior to recruitment and participation of any members of the public in system testing or deployment. The team will begin preparing and submitting all of the protocols during the first six months of Phase 2. The ST-CTN project team anticipates approval of each protocol within 1-2 months from the time of submission, barring any unforeseen issues. IRB approval status for each protocol will be shared with USDOT in the team's progress reports.

Due to the use of the Agile process for this deployment, it is anticipated that the team will go through a round of initial protocol applications early in Phase 2 and will apply for protocol modifications as needed. Minor modifications can often be obtained without a full IRB review, until participants are recruited. Final protocols require full disclosure to the IRB (through the protocol application) and to ST-CTN participants (through the informed consent documentation) of each research plan, participant interaction with systems, participant burden, potential participant risk, and how all PII data will be handled and used in the project. All of these elements must be incorporated into the informed consent document. Hence, protocols will necessarily evolve with the Agile process, alongside any changes in data collection interfaces, data management protocols, data use protocols, and need to expressly account for any potential change participant risk or burden. Once a participant has been recruited, and executes the informed consent document, the protocol cannot be changed for that recruit without renewing their recruitment, under a new/modified protocol. Hence, protocol versioning will be tracked with new IRB-assigned protocol IDs, whenever a substantive change needs to be made by the team.

Table 5 provides those ST-CTN data streams that include PII and will therefore require specific IRB protocols. More specific information about each data set can be found in the DMP. The initial storage date in the table is the date that data will be available in each data storage system. The date is reference to the Phase (P) and its related Quarter (Q). Phase 2 has 8 quarters in the two-

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | 27

year period, and Phase 3 has 6 quarters in the 18-month period. It is possible that approved IRB protocols will need to be amended during Phase 2 as design developments occur in the Agile process. Amendments will be submitted as soon as they are identified as being necessary.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

28 | Phase 1 Human Use Approval Summary - ARC

Table 5. ST-CTN Data Streams for IRB Protocols Development

DMP Data ID	Dataset Name	Data Storage System Name	Data Storage System Subsystem and Status	Data Exchange ID	Initial Storage Date
1	Parcel-level Land Use Data	Research Server	STM; Operational	2	Phase 2 Q3-Q6
48	Customer Demographic Data	PII Server Processed Data on Research Server	STM; Operational	2	Phase 2 Q4-Q6
49	Household Level Licensed Demographic Data	PII Server Processed Data on Research Server	STM; Operational	2	Phase 2 Q4-Q6
50	Household Level Vehicle Registration Data	PII Server Processed Data on Research Server	STM; Operational	2	Phase 2 Q4-Q6
51	Mobile App Logs	PII Server Processed Data on Research Server ATL RIDES Connected Data Platform Module	STM; Operational	4	Phase 2 Q5-Q6
52	Traverse Data	PII Server Processed Data in Research Server and STM Server	STM; Operational	4	Phase 2 Q4-Q6
53	Trip Feedback Reports	PII Server Processed Data on Research Server ATL RIDES Connected Data Platform Module	STM; Operational	4	Phase 2 Q5-Q6

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | **29**

DMP Data ID	Dataset Name	Data Storage System Name	Data Storage System Subsystem and Status	Data Exchange ID	Initial Storage Date
54	Trip Crowdsource Reports	Research Server (Updates to Home Data Sets)	STM; Operational	From 12 to 4	Phase 2 Q5-Q6
56	Business Level Licensed Facility Data	PII Server Processed Data on Research Server	STM; Operational	2	Phase 2 Q4-Q6
58	ST-CTN Performance Measures Data	PII Server Processed Data in Research Server and STM Server	ATL; Operational Research Server	-	Phase 2 Q6
59	STM Communication Logs	PII Server Processed Data in Research Server and STM Server	STM; Operational	-	Phase 2 Q6
60	STM Impedance Calculation Logs	PII Server Processed Data in Research Server and STM Server	STM; Operational	-	Phase 2 Q6
61	Secure MU Gateway Event Logs	PII Server Processed Data in Research Server and STM Server	STM; Operational	-	Phase 2 Q4-Q6
62	Pedestrian Crash Data	External	External	-	Phase 2 Q4
63	Pedestrian Incidents Police Reports	External	External	-	Phase 2 Q4
65	GCT Complaint Log	External	External		Phase 2 Q3

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

30 | Phase 1 Human Use Approval Summary - ARC

5.2 Phase 2/3 Human Use Approval Confirmation Materials

During the first six months of Phase 2, the research team will prepare and submit seven IRB protocols for the ST-CTN project. As described in **Section 4.1**, IRB protocols are submitted online via ORIA's IRBWISE portal. Upon IRB protocol approval, the HUAS will be updated to document the approval status of each protocol, content submitted for the protocol, IRB approval letters, and stamped consent forms which will be provided in the Appendix for reference. These protocols and status are summarized below in **Table 6**.

Table 6. Human Use Approval Confirmation Materials Summary

Planned Submittal to IRB	Confirmation Material	Description	Protocol Dependencies
August 2022	IRB Approval Letter to be provided to USDOT and included within the HUAS Appendix	**Research Server Setup and Operation** - This protocol will govern all transmission, storage, and security of PII data to and from the GT Secure Data Center research server for all ST-CTN activities and related projects [VPFP]. Because all PII will be transferred to, managed, and analyzed on the secure research server, this protocol will be incorporated by reference into all other protocols that employ PII. This allows the team to amend this protocol and have all changes flow automatically into the other project IRB protocols.	Concept Development – Phase 1
September 2022	IRB Approval Letter to be provided to USDOT and included within the HUAS Appendix	**Licensed Municipal and Demographic Data** - This protocol will cover the handling of all licensed data from public and private sources that can be used in combination with project data to reveal the identity of project participants. These data sources include land use data that contain owner information, licensed household demographic data that contain homeowner and renter names and addresses, and licensed business data that contain employer names and addresses. Proprietary data will be protected on the secure server. This protocol will be incorporated by reference into all protocols that employ the use of licensed proprietary data in concert with PII.	Approved Research Server Setup and Operation Protocol

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | 31

Planned Submittal to IRB	Confirmation Material	Description	Protocol Dependencies
January 2023	IRB Approval Letter to be provided to USDOT and included within the HUAS Appendix	**Vehicle Registration Data** - The protocol will cover access to vehicle ownership data (vehicles/household) for use in demographic relationships to sub-regional activity data. The State of Georgia treats such data as PII. A data use agreement must be executed with the State and a protocol must be implemented for any use of these data. The use and treatment of these data must be clearly outlined and the Research Server protocol must be approved by the State as well.	Approved Research Server Setup and Operation Protocol
October 2022	IRB Approval Letter to be provided to USDOT and included within the HUAS Appendix	**Customer Demographic and Preference Data** - All customer data are protected as PII, including any demographic and app preferences selected by the customer. The use of customer demographic and preference data will be delineated in this protocol. These data will be stored, managed, and protected on the secure server in accordance with the research server protocol.	Approved Research Server Setup and Operation Protocol
October 2022	IRB Approval Letter to be provided to USDOT and included within the HUAS Appendix	**Sub-regional Survey Data** - This protocol will cover the collection of survey data designed to track changes in travel that occur between the beginning and end of the project to control for confounding factors (as defined in the PMESP). Survey protocols must include the research design and sampling plan, human-computer interactions, final design of the survey instrument, and the specific questions that will be asked.	Approved Research Server Setup and Operation Protocol

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

32 | Phase 1 Human Use Approval Summary - ARC

Planned Submittal to IRB	Confirmation Material	Description	Protocol Dependencies
November 2022	IRB Approval Letter to be provided to USDOT and included within the HUAS Appendix	**Customer Activity and Trace Data** – All customer activity and interaction with the ST-CTN system through the app and applications will be defined within this protocol, including user settings, generation of routes, capturing trace data, etc. All customer data generated by the app through the user interface and app functions are protected as PII, including the locations visited by these participants and routes taken to reach their destinations [GPS]. The use of customer activity and trace data in performance measures will be delineated in this protocol. These data will be stored, managed, and protected on the secure server in accordance with the research server protocol.	Approved Research Server Setup and Operation Protocol
November 2022	IRB Approval Letter to be provided to USDOT and included within the HUAS Appendix	**Targeted App Customer Survey Data** - All customer data are protected as PII, including any responses to survey questions implemented through the app that are used to identify trip purpose and collect customer experience data. The use of customer survey data in performance measures will be delineated in this protocol. Survey protocols must include the research design and sampling plan, human-computer interactions, final design of the survey instrument, and the specific questions that will be asked. These data will be stored, managed, and protected on the secure server in accordance with the research server protocol.	Approved Research Server Setup and Operation Protocol

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | 33

Appendix A. IRB Documentation

Dr. Guensler and Dr. Guin from Georgia Tech will be responsible for development of all ST-CTN IRB protocols, in collaboration with the entire ST-CTN project team and will shepherd these protocols through the Georgia Tech IRB. The Georgia Tech Office of Research Integrity Assurance is fully apprised that a series of protocols will be forthcoming for this project. During initial discussions, the IRB reiterated that they do not pre-approve protocols and that the deployment team may not start any Phase 2 activities that involve human subjects or collection of PII until relevant protocols are submitted, deemed complete, and approved.

As discussed in **Section 5** of the HUAS, the IRB does not pre-approve research projects. The team will be required to submit the entire set of Phase 1 documents to provide the basis for the overall Phase 2 (2022-2023) design / test and Phase 3 (2024-2025) operate / evaluate activities. The team will then need to apply for individual protocols for each ST-CTN system or module that involves the collection or handling of PII as outlined in **Section 5**. Upon IRB protocol approval, the ST-CTN project team will provide an update and approval letter to USDOT for their continued monitoring and information. In addition, the HUAS document will be updated to reflect the IRB protocol status, the content submitted to the IRB, the approval letter, and IRB-stamped consent/assent forms will be included within the Appendix.

U.S. Department of Transportation
Office of the Assistant Secretary for Research and Technology
Intelligent Transportation Systems Joint Program Office

Phase 1 Human Use Approval Summary - ARC | 35

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