Phase 2 Human Use Approval Summary

Georgia Department of Transportation: Safe Trips in a Connected Transportation Network ITS4US Deployment Project

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Final As-Built — August 8, 2025
FHWA-JPO-21-895

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U.S. Department of Transportation

Produced by the Georgia Department of Transportation (GDOT)
U.S. Department of Transportation
Intelligent Transportation Systems (ITS) Joint Program Office (JPO)
Federal Highway Administration
Office of the Assistant Secretary for Research and Technology
Federal Transit Administration

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Technical Report Documentation Page

1. Report No.	2. Government Accession No.	3. Recipient's Catalog No.
FHWA-JPO-21-895		

4. Title and Subtitle	5. Report Date
Phase 2 Human Use Approval Summary Safe Trips in a Connected Transportation Network ITS4US Deployment Project	August 8, 2025
	6. Performing Organization Code

7. Author(s)	8. Performing Organization Report No.
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9. Performing Organization Name and Address	10. Work Unit No. (TRAIS)
Georgia Department of Transportation – One Georgia Center 600 West Peachtree NW, Atlanta, GA 30308	11. Contract or Grant No. 693JJ32250011

12. Sponsoring Agency Name and Address	13. Type of Report and Period Covered
U.S. Department of Transportation ITS Joint Program Office 1200 New Jersey Avenue, SE Washington, DC 20590	Phase 2 Final As-Built Report
	14. Sponsoring Agency Code HOIT-1

15. Supplementary Notes

The following USDOT partners are supporting this document development: Elina Zlotchenko (Program Manager), Sarah Tarpgaard (Agreement Officer), and Norah Ocel (Agreement Officer Representative)

16. Abstract

The Georgia Department of Transportation 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, and reliability. 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 efficient and cost-effective transportation options for all.

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.

17. Keywords	18. Distribution Statement
Human Use Approval Summary, ITS4US; Complete Trip; Deployment; ITS; Intelligent Transportation Systems	

19. Security Classif. (of this report)	20. Security Classif. (of this page)	21. No. of Pages	22. Price
Unclassified	Unclassified	49	

Form DOT F 1700.7 (8-72) **Reproduction of completed page authorized**

Revision History

Name	Date	Version	Summary of Changes	Approver
EMT / Subsystem Developers	2021, November 17	0.1	Initial Draft	Randall Guensler
EMT / Subsystem Developers	2021, November 19	0.2	Initial Draft	Maria Roell
EMT	2022, January 3	1.0	Final	Randall Guensler
GDOT Team	2023, October 23	1.1	Draft Phase 2	Bennett Foster
GDOT Team	2025, June 6	2.0	Final As-Built	Natalie Smusz-Mengelkoch
GDOT Team	2025, July 25	2.1	Final As-Built	Natalie Smusz-Mengelkoch
GDOT Team	2025, August 8	2.2	Final As-Built	Natalie Smusz-Mengelkoch

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1 Introduction

The Georgia Department of Transportation (GDOT) and Atlanta Regional Commission's (ARC) Safe Trips in a Connected Transportation Network (ST-CTN) project was selected by the U.S. Department of Transportation (USDOT) as a part of the ITS4US Deployment Program. The project seeks to enhance the traveler's complete trip travel experience by enhancing mobility, reliability, and safety for system users. This is done by leveraging innovative solutions, existing deployments and team collaboration such as integrating connected vehicle (CV) data with an open-source software-based trip planner that is used to provision web-based and mobile application user access. The trip planner will provide users with the ability to create a personalized trip plan with information regarding the navigation of physical infrastructure, the ability to resolve unexpected obstacles, and ensure users' visibility throughout the trip. The proposed deployment will provide users with the ability to dynamically plan and navigate trips.

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) that will be used in research. 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 Phase 2 Concept of Operations (ConOps) and Phase 1 Safety Management Plan (SMP) as well as the Phase 2 Data Management Plan (DMP) and Phase 2 Performance Measurements and Evaluation Support Plan (PMESP). The HUAS also served as input into the development of the following documents: 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 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 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 enhance transportation availability across American communities. This multimodal initiative leverages innovative technology to improve transportation efficiency while creating strong public-private partnerships, implementing cutting-edge solutions, and delivering cost-saving, scalable results that other communities can replicate. The ITS4US Deployment Program aims to address mobility challenges for all travelers. The Program builds upon the USDOT's previous and ongoing foundational research, along with emerging technologies, practices, and other critical inputs gathered from various sources. The ITS4US Program is designed to bring publicly and privately

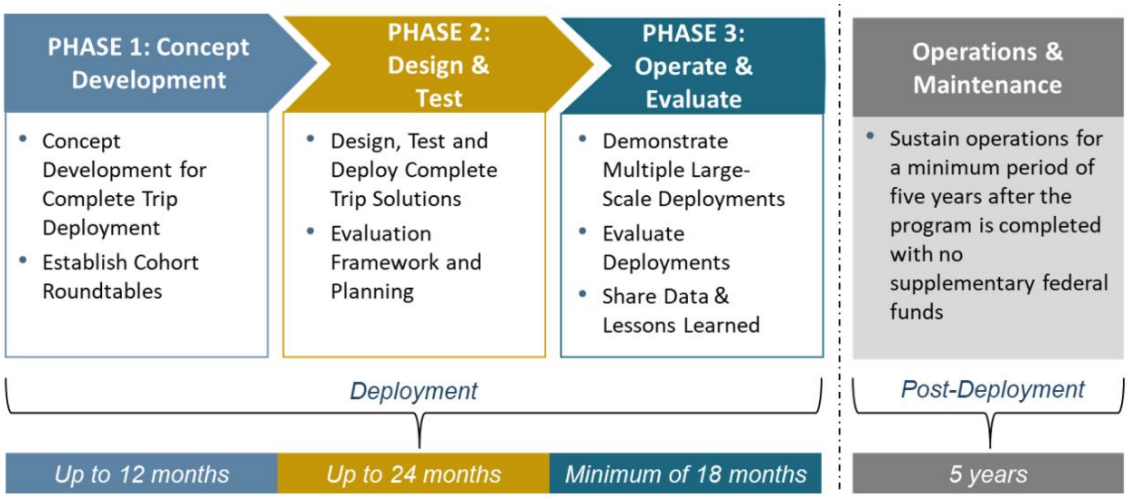
sponsored research together to create large-scale, replicable deployments to address the challenges of planning and executing all segments of a trip.

The program aims to solve safety and mobility challenges for Americans who find transportation options unavailable or difficult to access. The ITS4US program aims to solve these challenges through technology solutions; providing options and connecting different modes of transportation so individuals can travel from origin to destination without gaps in their travel plan.

The 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

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

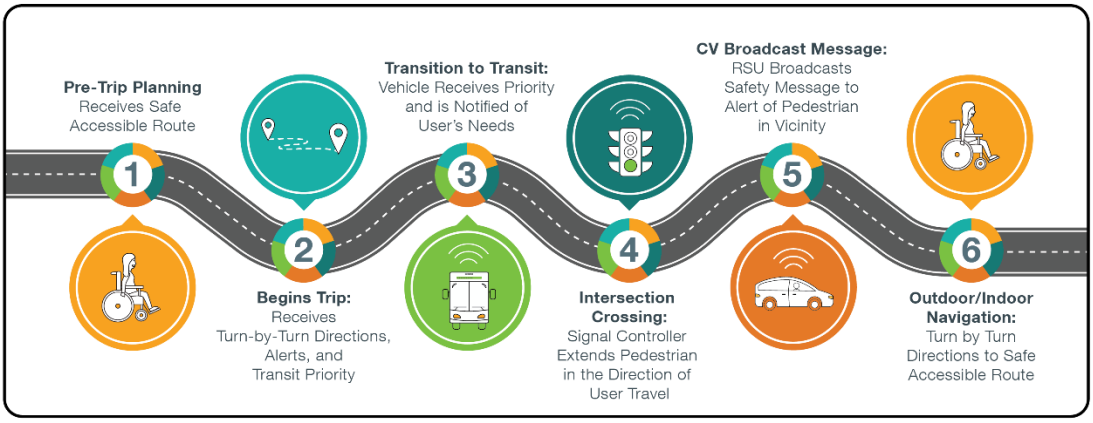


Source: USDOT, 2021

Figure 1. Phases of the ITS4US Deployment Program

1.2.2 Project Scope

The ST-CTN project aims to upgrade and integrate existing technologies and services so that all travelers can accomplish their complete trip successfully, safely, and reliably. The vision of the project is to provide users with directions, conditions, and status on the links between trip legs that are personalized based on the user's profile, while connecting the user to Connected Vehicle (CV) infrastructure to provide safer trips and more transportation network awareness. As an illustration of how the ST-CTN system will be used, transit-based trips were delineated into six segments (as depicted in **Figure 2**) to allow for easier understanding and a greater breakdown of priorities and goals.



Source: ARC, 2020

Figure 2. Traveler's Complete Trip

The delineated trip segments include the following steps and project components:

- **Step 1 Pre-Trip Planning.** The traveler plans for and receives a safe accessible route.
  - The ability to customize trip preferences based on the user's needs.
- **Step 2 Begins Trip.** The traveler begins their trip and receives turn by turn directions, alerts, remote pedestrian activation, and can trigger transit signal priority (TSP).
  - Turn by turn, shortest path, directions along pathways that meet user defined preferences.
  - Provides support services for users if they become disoriented or have issues accessing defined paths.
  - Activates TSP if the user's trip includes fixed route transit service that is behind schedule.
- **Step 3 Transition to Transit.** The traveler transitions to transit and the transit vehicle receives priority and is notified of users' needs. TSP can be triggered if the bus is running behind schedule due to a longer boarding time needed by a user.
  - Provides users with transit trips that meet user defined preferences.
  - Sends alerts to transit vehicles when users need additional time to board, navigate internally, or alight the transit vehicle.
  - Remotely requests service from transit vehicles while waiting to board or alight.
  - Triggers TSP if the bus is running behind schedule greater than one minute.
- **Step 4 Intersection Crossing.** When crossing a signalized intersection, the traveler indirectly interacts with the signal controller in that an authorized system call is made to the controller which extends the pedestrian phase in the direction of user travel.
  - Allows the user to communicate with connected intersections if they are unable to reach or press the crosswalk button.
  - Provides the user with information about the intersection crossing and adds time to the crossing if needed.
- **Step 5 CV Broadcast Message.** Roadside units (RSUs) broadcast safety message to alert CVs of pedestrians in the intersection.

- Provides communications to enabled CVs from pedestrian crossing signal systems (via RSUs) to make them aware of pedestrians crossing a roadway.

- **Step 6 Outdoor/Indoor Navigation.** The traveler is provided with turn by turn directions to a safe accessible route.
  - Hands-free navigation via mobile apps and/or wearables and multiple channels (haptic, voice, text).
  - Alerts and dynamic rerouting in response to changes in path conditions.
  - Provides the user with efficient routes into and through two facilities within the project area.
  - Provides users with updates on the operating status of indoor infrastructure such as elevators and escalators.

There is an additional **Step 7** that is not part of the traveler's complete trip but is part of the ST-CTN system: **Reporting**. This step provides summaries of the data collected during the Complete Trip process.

System development and system integrations completed within the scope of this project will enable travelers to program and safely complete single mode or multimodal trips that are based on their needs; improve the transition between modes by providing additional details to users and transit service operators; suggest dynamic routing changes based on infrastructure condition and calculated delay.

The existing initiatives that are being leveraged to support the proposed ST-CTN system are defined in more detail below as well as those components that will be developed specifically to support ST-CTN project evaluation. The icons and colors depicted below are used throughout the SDD to clearly identify the critical components of ST-CTN. In some cases, partner agencies are upgrading the services within their current systems to create a more robust data set or toolset for the ST-CTN program.



OTP for G-MAP. Atlanta Rider Information and Data Evaluation System (ATL RIDES) includes an Open Source Software (OSS) multi-modal trip planning and mobile application, integrated mobile fare payment options, and a Connected Data Platform (CDP) using regional General Transit Feed Specification (GTFS) transit service data. The tool supports multi-agency context, multilingual support, and mobile app turn by turn directions. The OpenTripPlanner (OTP) architecture facilitates integration with additional OSS tools including a data analytics engine, call center module with application programming interfaces (APIs), and account management system. The existing ATL RIDES application was modified and enhanced based on ST-CTN project needs and leveraged to create a new, independent application which is differentiated as the *OTP for G-MAP* subsystem (hereafter referred to as Georgia Mobility and Access Planner [G-MAP]).



SIDEWALKSIM. SidewalkSim is an asset management system and shortest path (lowest impedance) routing tool for pedestrian pathways. Site inspections provide more detailed design and condition data for use in pathway efficiency analysis. SidewalkSim identifies the best path between any two points in the pedestrian network, given the set of pathway characteristics and any user-specified needs and route penalties.

CV1K. The Atlanta region is home to one of the largest CV deployments in the United States – Regional Connected Vehicle Infrastructure Deployment Program (CV1K). CV1K is deploying interoperable CV technologies at signalized intersections throughout the Atlanta region using both Dedicated Short-Range Communications (DSRC) and Cellular Vehicle to Everything (C-V2X) technologies to deliver safety and mobility-based applications. The program provides support to configure, operate, and maintain CV infrastructure and applications, including TSP. Gwinnett County is one of the largest recipients of the first phase of this deployment.

CVTMP. Gwinnett County's Connected Vehicle Technology Master Plan (CVTMP) sets out to develop and improve economic viability and quality of life, address the needs and challenges to motorized and non-motorized modes, establish guidelines for deploying technology, and have broad applicability to Gwinnett, other local jurisdictions, and across the state—to set the standard for implementing CVs. Among the high priorities is establishing a mobile safety program and alternative strategies for TSP in Gwinnett County.

STM. The Space Time Memory (STM) platform processes traffic volume and speed data from multiple monitoring and modeling sources, tracks network performance measures, and predicts evolving route conditions using traditional and machine learning techniques. The STM projects trip trajectories through the transportation network, as network conditions change in space and time. This tool will be applied to analyze and predict performance through the multi-modal transportation network. The shortest path analysis will be applied to the combined roadway, transit, sidewalk, and shared-use path networks, allowing routing decisions to incorporate travel time, safety, and other impedances into path selection.

In addition, the ST-CTN system will include the development of a Performance Measurement Dashboard (PMD) that is not currently in use.

PMD. The PMD is a data storage and distribution tool that archives operational, survey and performance metrics of the system. The PMD intends to ingest, quality check, and curate all types of data – static and dynamic, structured and unstructured, open and private datasets. The PMD stores the datasets so that they can be viewed and accessed based on user roles. And the PMD includes a public PMD for the public to access open data presented on an interactive dashboard to the public.

1.3 System Overview

The ST-CTN 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 the context diagram of the proposed system – indicating the system of interest and added subsystem connectivity. Critical ST-CTN data exchanges are identified by number and color in the context diagram and correspond to the exchanges described in **Table 1**. These descriptions are focused only on the scope of work required to implement the new system and information that is necessary to provide context to that work. There are a number of existing and on-going efforts that are being performed outside the scope of this project that are critical to the success of ST-CTN. The Phase 2 System Architecture Design Document (SAD) provides more information about each subsystem component and interfaces. The legend below describes the objects displayed in the diagrams.

- SideBold dashed boxes outline the system/subsystem of interest,
- Major subsystem components presented by the ST-CTN project are depicted by rectangular boxes with black bold outlines,
- Major subsystem components that are existing are depicted by rectangular boxes with transparent outlines,
- External system components are depicted by light grey rectangular boxes,
- People are designated with a silhouette inside of a rectangular box,
- Each subsystem is indicated by color and icon, as shown on the right.

Sidewalk Inventory Collection Tools is burnt orange

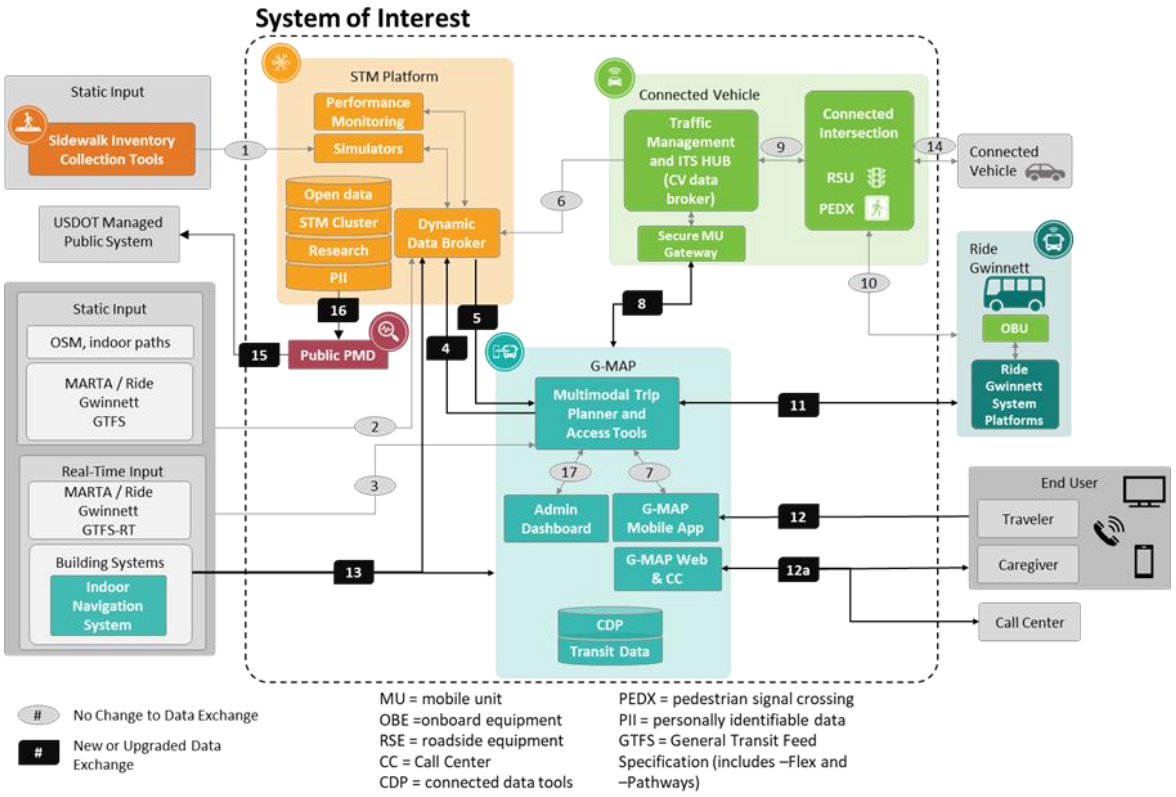
STM is peach

CV is green

OTP for G-MAP is turquoise

Gwinnett County Transit is teal

PMD is **red**



Source: GDOT, 2024

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

The system information flows are identified by number in the functional 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. The information flow identifiers (column 1) in the table are used in every functional diagram in this section.

Table 1. Critical ST-CTN Information Flow Descriptions

Information Flow ID	Description	Source	Destination
1	Sidewalk inventory data, including accessibility features to the STM Platform simulators	External	STM
2	Static data from various existing sources to the STM Platform dynamic data broker	External	STM
3	Static and dynamic data from various existing sources to the G-MAP multimodal trip planner	External	G-MAP
4	G-MAP Mobile App logs and trip feedback	G-MAP	STM
5	STM Network Impedance API	STM	G-MAP
6	CV and Traffic Operations Messages: signal phasing and timing NaviGAtor ITS, road characteristics, traffic data	CV	STM
7	OTP APIs and G-MAP APIs	G-MAP (trip planner)	G-MAP (channel access)
8	Mobile Accessible Pedestrian Signal System (PED-SIG)	G-MAP	CV (Secure Mobile Unit (MU) gateway)
9	CV messages	CV (CV data broker)	CV (Connected Intersection)
10	TSP and other CV application messages	GCT On-board Unit (OBU)	CV (Connected Intersection)
11	Ride Request messages	G-MAP Mobile App via G-MAP	Ride Gwinnett
12	G-MAP Mobile App APIs and Traveler exchange – profile, trip plan, settings, notifications, feedback, etc.	End user G-MAP mobile app	G-MAP Mobile App
12a	Similar data flows to Data Exchange ID 12 with restrictions on viewing and changing certain data.	End user G-MAP mobile app	Website, Call Center, Trusted Companion device
13	Dynamic information from building facilities, (including beacon signals to the G-MAP Mobile App) and INS vendor cloud SDK	Building System (external)	G-MAP
14	CV data	CV OBU	CV RSU
15	Project data for USDOT-managed Public System	Public PMD	USDOT Managed Public System

Information Flow ID	Description	Source	Destination
16	Public facing data and visualizations for reporting on system operations and performance	Private PMD (STM)	Public PMD
17	G-MAP Web Services and Traveler exchange – profile, trip plan, settings, notifications, feedback, etc. Access to functions and information depends on user role. Interface available to traveler (registered person), trusted companion, or call taker in call center.	G-MAP (trip planner)	G-MAP Admin Dashboard

Dataset storage systems and their access levels (personally identifiable information (PII) confidential, operational, open or research) embedded in the G-MAP and STM subsystems are described in **Table 2.** These dataset storage systems as well as the datasets stored in each system are detailed in the DMP.

Table 2 provides a summary of dataset storage systems, shown as cylinders in the figure above.

Table 2. ST-CTN Network Dataset Storage Systems

Subsystem	Dataset Storage System Name	Access Level
G-MAP	G-MAP CDP Module	PII Confidential
External	External (not stored in project data stores including Intelligent Transportation Systems (ITS) Data Hub in CV subsystem)	Operational
STM	Open Data Server (Open data)	Open
STM	PII Server (PII)	PII Confidential
STM	Research Server (Research)	Research
STM	STM Server Cluster (STM Cluster)	Open and Research
G-MAP	TRANSIT-data-tools (Transit Data)	Open

1.3.1 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 through Phase 2 and 3.

- **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 7** identifies the IRB protocols proposed for this project.

1.3.2 Related Tasks

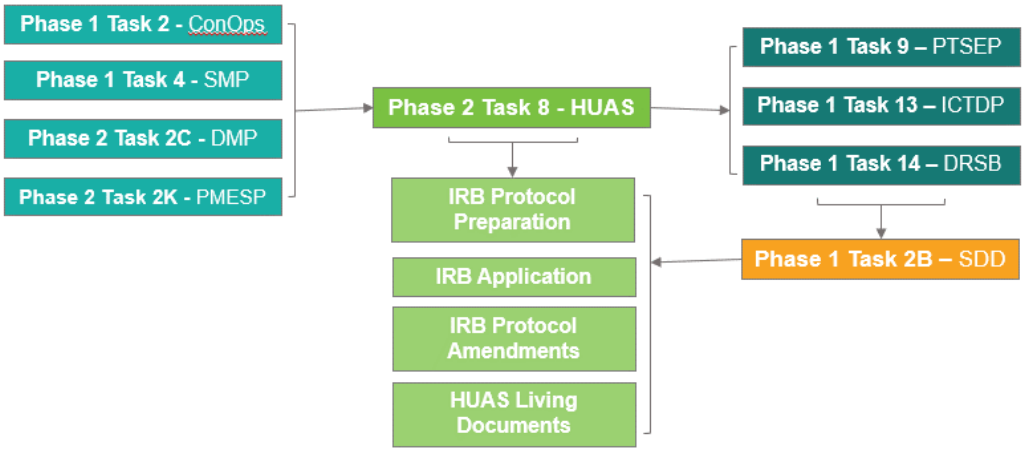
The ST-CTN project team is required to follow the IRB application and review process due to the nature of the project and the interactions with human subjects. **Table 3** provides a summary of the interactions with participants in other project tasks and key task areas that provide supporting information to (or will be guided by) the HUAS.

Table 3. HUA Related Project Tasks

Related Task	Summary
Phase 1 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 Error! Reference source not found., ST-CTN users will interact with the system through exchange 12 which includes user profiles, routing information, access to the call center, etc.
Phase 1 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.
Phase 1 Task 9 – Participant Training and Stakeholder Education Plan (PTSEP)	The PTSEP is an output of the Phase 1 HUAS. The PTSEP outlines the recruitment and training of all travelers and potential trusted companions. The interactions defined in the HUAS were used to develop the PTSEP.
Phase 1 Task 13 – Integrated Complete Trip Deployment Plan (ICTDP)	The ICTDP is an output of the Phase 1 HUAS. The HUAS was used to refine the deployment concept and guide any potential changes in the deployment costs or risks.

Related Task	Summary
Phase 1 Task 14 – Deployment Readiness Summary Briefing (DRSB)	The DRSB is an output of the Phase 1 HUAS. Information from the HUAS was used to assess the project's readiness for deployment in order to begin the Design/Build/Test Phase.
Phase 2 Task 2C – 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.
Phase 2 Task 2C – Data Privacy Plan (DPP)	The DPP is an input for the HUAS. The DPP highlights the data privacy controls and measures used by the project team to mitigate risk of harming individuals as a result in the improper handing or disclosure of the Personally Identifiable Information (PII) or Sensitive Personally Identifiable Information (SPII) collected from individuals in connection with the ST-CTN Project. The document reviews the access requirements for data entering and exiting the system with a specific focus on specifically personally identifiable information (PII). The document describes the data assessments used to ensure traveler privacy. These assessments consider the potential risks and mitigation strategies as well as security controls developed to maintain a secure and private environment for all end users.
Phase 2 Task 2K – 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.

Figure 4 illustrates the key elements and interactions between the HUAS and related project tasks. The HUAS provides information that supported the development of the following Phase 1 documents: PTSEP, ICTDP, and DRSB. These Phase 1 tasks 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: GDOT, 2023

Figure 4. HUAS Related Tasks

1.4 Acronyms and Glossary

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

1.4.1 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

G-MAP – Georgia Mobility and Access Planner

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

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

1.4.2 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]

1.5 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 4. References

ID	Referenced Documents
[ConOps]	Atlanta Regional Commission. Deliverable Task 2 Concept of Operations. Atlanta: U.S Department of Transportation. (2021).
[DMP]	Georgia Department of Transportation. Deliverable Task 2C Phase 2 Data Management Plan. GDOT: U.S Department of Transportation. (2023).
[DPP]	Georgia Department of Transportation. Deliverable Task 2C Phase 2 Data Privacy Plan. GDOT: U.S Department of Transportation. (2023).
[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).

ID	Referenced Documents
[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
[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).

ID	Referenced Documents
[GDPR]	Wolford, Ben. What is the GDPR, the EU's new data protection law?. Geneva: Proton Technologies. (2021).

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 designed 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' trusted companion through the ST-CTN application enhance your experience?

Survey instruments designed to answer these research questions were designed in Phase 2. Survey questions were 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 3** summarizes the related Phase 1 and Phase 2 tasks that provide supporting information or will be guided by the HUAS and IRB process. A Configuration Manager (CM) is 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 is 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 Systems Engineering Management Plan (SEMP).

In addition, beyond documentation configuration management, the individual IRB protocols implemented for this project were refined and updated as necessary based on key design and

Agile development activities during Phase 2. These design and development decisions are 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 sought IRB protocol approval to include all participants legally capable of providing informed consent. This did not include those persons with a severe mental disability or children under 18.

The ST-CTN project team did 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 exception is that the project will only recruit individuals 18 years of age or above who are able to provide consent per the guidance from the IRB. 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 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 trusted companion assent) are required for the participation of children and individuals with such impaired decision-making capabilities. Trusted companions will also participate directly with this program.

The ST-CTN project will be deployed without the participation of children or individuals that cannot consent for themselves, however trusted companions will be included. Hence, all protocols 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 team specifically asks whether a participant is located in the EU and exclude these individuals from participation in any data collection processes. Participants must 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. The informed consent documents are comprehensive in nature and tailored as necessary for different use cases or user groups which was determined during Phase 2. As noted in **Section 2.3**, children and individuals with impaired decision-making capacity are 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 trusted companion. 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. This will require users to confirm re-approval of the user agreement presented during application use or survey responses. 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 G-MAP app and application. 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 G-MAP 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).

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 2 DMP and DPP. Hence, the team has ensured that each protocol reflects the content of the DMP, DPP, and that any changes to data handling required by the IRB are reflected in an update to the DMP and/or DPP.

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. The DPP highlights the data privacy controls and measures used by the project team to mitigate risk of harming individuals as a result in the improper handing or disclosure of the PII or SPII collected from individuals in connection with the ST-CTN Project.

Each dataset will be assigned a data owner and data steward, as described in Section 2.1 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 2 of the DPP. Data shared with GA Tech researchers is not anonymized and is for academic and research purposes only. This data will not be sold to third parties.

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, specifically GA Tech researchers. 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, trusted companions 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 trusted companions. The majority of this information will be collected through surveys that will be available through the G-MAP 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.

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 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 trusted companions of the system. Training will be developed to support end users of all target populations, including people with physical 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 G-MAP application resources.
  -
- Infrastructure Owner/Operator (IOO):
  - ST-CTN Transit Signal Priority (TSP) and Ride Request – In-person or live virtual trainings conducted for Ride Gwinnett Transit Operators.
  - ST-CTN Call Center Interface – In-person or live virtual trainings conducted for Ride Gwinnett Call Center Operators.

2.7 Team Human Subjects Research Training

Those 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. Certificates of completion will be maintained by certificate holders and will be available to the sponsor at any time.

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 were developed during Phase 2, once research protocols and human use interface designs were finalized for review. For each protocol, the team is also required to upload an annotated bibliography and all relevant ST-CTN project documents: Concept of Operations (ConOps), Data

Management Plan (DMP), DPP, 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 ST-CTN project 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 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 2 Data Management Plan
- Phase 2 Data Privacy Plan
- Phase 1 Safety Management Plan
- Phase 2 Performance Measurement and Evaluation Support Plan
- Phase 2 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 were 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.

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 ST-CTN project 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 5**, 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.

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. During Phase 2, three protocols were submitted and either determined by the IRB to be exempt from human subject approval as non-research activities, or were approved by the IRB (see Section 5 and Table 6). The determination letters are included in Appendix A. These IRB protocols support the full ST-CTN system deployment, evaluation, and use of human subject data in research.

4.1 Type of Review

The ST-CTN project team will be submitting IRB protocols for specific data collection methods and data types. The Human Use Approval confirmation materials are outlined below and provided in full detail in **Table 7**.

- ITS4US-Georgia G-MAP App Beta Tester Data Collection Protocol
- G-MAP Quarterly User Experience and Demographics Survey Protocol
- ITS4US-Georgia G-MAP App Data Transfer and Use in Impedance Calibration

Any protocols for the ST-CTN project that require Full Board Review generally takes two to three months to process. 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 ST-CTN planning documentation, but also the development of all final sampling plans, recruitment plans, recruitment documents, survey instruments, human-computer interaction details, consent and assent forms, and data handling protocols. Hence, the team prepared and submitted all of the protocols outlined in **Section 5** (**Table 7**) during the last nine months of Phase 2 of the ST-CTN project when the development of the architecture is fully designed and understood. Formal approval status of each protocol has been obtained. In addition, the HUAS has been 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

During Phase 1, the team shared the proposal and discussed the project with OIRA staff members. 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. During Phase 2, the ST-CTN project team received formal feedback from the Central IRB after each protocol was submitted. On complex studies such as the ST-CTN, multiple interactions with the IRB were required and the team had to respond to comments during the application process. The project team received feedback on IRB approval stating that the protocols should ensure that the project team is not knowingly allowing restricted groups to participate, specifically children and those unable to give informed consent. Protocols should also state that users will have the opportunity to re-approve any changes made to the user agreement. In addition, protocols should state that data is shared with GA Tech researchers that is not anonymized but that the data will only be used for research purposes, and that location data will not be sold to third parties. This research disclosure must be received by users when prompted to take the in-app survey, quarterly email surveys, and a final email survey. Because the team had 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 did not encounter any significant problems with obtaining approval for all project-related protocols during Phase 2.

4.4 Conditions

As noted earlier, once an IRB protocol is approved, the research team may not deviate from the protocol. Whenever any change to the ST-CTN system that would materially affect approved human subject research is proposed over the course of the project, the team is required to revisit the HUAS and relevant IRB protocols. When the team identifies that proposed changes to the system could affect human subject data integrity or the disclosed use of human subject data in IRB-approved human subject research, the team will submit a proposed amendment to relevant IRB protocols to the IRB for approval. 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.

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 was required to submit the entire set of ST-CTN planning 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 then applied for individual IRB protocols for each ST-CTN subsystem or module that involves the collection of data and handling of PII, as outlined in Error! Reference source not found.**Table 7.** The ST-CTN team has already obtained approval for 16 prior protocols (identified in the **Table 5**) that have collectively included the data collection of all data types that may be employed in the ST-CTN evaluation. This data may be used to consider confounding factors or assess broader trends. As such, the ST-CTN team will be generating new protocols for the ST-CTN project that are based upon elements within these previously approved protocols.

Table 5. 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
Sidewalk Accessibility Stakeholder Interviews (2016)	Survey instrument and implementation (pre-approved questions)	H16116

IRB-Approved Protocol	Relevance to ST-CTN	Protocol ID
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

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 submitted individual protocols for each data collection and analysis element of the project as outlined in Error! Reference source not found.**Table 7**. 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 were reviewed and approved by the IRB prior to recruitment and participation of any members of the public in system testing or deployment. The team prepared and submitted all of the protocols during the last nine months of Phase 2 when the architecture and design of the G-MAP application was understood and could be accurately defined. The ST-CTN project team received final decisions for each protocol within three months of submission (with interactions and modifications during that period). IRB approval status for each protocol was shared with USDOT in the team's progress reports.

Protocols may need to evolve during the Agile process to reflect any needed changes in data collection interfaces, data management protocols, data use protocols for research, and to expressly account for any potential change participant risk or burden. Once a participant has been recruited, and executes the informed consent in the app user agreement, the protocol cannot be changed for that recruit without renewing their recruitment, under a new/modified IRB protocol and with potential changes to the disclosure in the app-user agreement. Hence, protocol versioning will be tracked with new IRB-assigned protocol IDs, whenever a substantive change needs to be made by the team.

Table 6 provides those ST-CTN data streams that include PII that would require specific IRB protocols if such data were used in human subject research. More specific information about each data set can be found in the DMP and DPP. The initial storage date in the table is the date that data will be available in each data storage system. During Phase 3, any proposed changes to research activity or procedures that have been approved by IRB as human subject research will require the submission of proposed updates for IRB approval prior to implementation.

Table 6. 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
51	Mobile App Logs	PII Server Processed Data on Research Server G-MAP Connected Data Platform Module	STM; Operational	4	April 2024 when beta testing begins (Phase 2)
52	Traverse Data	PII Server Processed Data in Research Server and STM Server	STM; Operational	4	April 2024 (Phase 2)
53	Trip Feedback Reports	PII Server Processed Data on Research Server G-MAP Connected Data Platform Module	STM; Operational	4	April 2024 (Phase 2)
58	ST-CTN Performance Measures Data	PII Server Processed Data in Research Server and STM Server	STM; Operational Research Server	-	April 2024 (Phase 2)

DMP Data ID	Dataset Name	Data Storage System Name	Data Storage System Subsystem and Status	Data Exchange ID	Initial Storage Date
59	STM Communication Logs (does not contain PII)	PII Server Processed Data in Research Server and STM Server	STM; Operational	-	April 2024 (Phase 2)
60	STM Impedance Calculation Logs (does not contain PII)	PII Server Processed Data in Research Server and STM Server	STM; Operational	-	April 2024 (Phase 2)
65	Ride Gwinnett Complaint Log	External	External		April 2024 (Phase 2)

5.2 Phase 2/3 Human Use Approval Confirmation Materials

During the last nine months of Phase 2, the research team prepared and submitted three IRB protocols for the ST-CTN project. The IRB reviewed the materials and focused on the human interaction for research. It was determined that allowing pedestrians to interact with signals is a service, rather than research. Fewer research protocols than originally identified in Phase 1 were required to be submitted, as many did not constitute human subject research. Data transfer elements were integrated into the final G-MAP protocol, given that only one major research protocol would be required. As described in **Section 4.1**, IRB protocols are submitted online via ORIA's IRBWISE portal. The HUAS was updated to document the approval status of each protocol and IRB approval letters, which are provided in the Appendix for reference. These protocols and status are summarized below in **Table 7**.

Table 7.

Table 7. Human Use Approval Confirmation Materials Summary

Final IRB Decision	Confirmation Material	Description	Protocol Dependencies
Exempt	The IRB exemption decision is included in the HUAS Appendix	**ITS4US-Georgia G-MAP App Beta Tester Data Collection Protocol (Protocol Number H2338)** – A full research protocol was submitted the IRB to govern the collection of data by project staff and stakeholder volunteers for G-MAP beta testing in Phase 2. The protocol defined that the following testing requirements will be maintained: • All beta testers must be official partner employees/advisors and providing input from the perspective of their company/agency/organization. • No beta testing data shared outside of development team. • Data will only be used internally for improving the app and backend • Research results using the data shall not be published; however, summarizing generalities in reports and presentations is acceptable. • Beta testing data will not be maintained past the end of the project (scrubbed from system). The IRB determined that beta tester data collection did not constitute human subjects research and was exempt from IRB jurisdiction. No approval was required.	None

Final IRB Decision	Confirmation Material	Description	Protocol Dependencies
Exempt	The IRB exemption decision is included in the HUAS Appendix	**G-MAP Quarterly User Experience and Demographics Survey Protocol (Protocol Number H24340).** The use of customer demographic and preference data for app improvement was delineated in a full research protocol submitted to IRB. However, the IRB determined that the use of the customer survey data to improve the G-MAP app did not constitute human subjects research and was exempt from IRB jurisdiction. No approval was required. These data will be stored, managed, and protected on the secure server in accordance with data privacy standards.	None

Final IRB Decision	Confirmation Material	Description	Protocol Dependencies
Approved	The IRB Protocol Approval Decision is included in the HUAS Appendix	**ITS4US-Georgia G-MAP App Data Transfer and Use in Impedance Calibration (Protocol Number IRB2025-491).** This protocol establishes the procedures that will be used in the project to collect user activity data (route decisions made by users) and how these data would be used in research to refine the impedance values used for providing routes to users. The procedures employed in customer activity data collection via the G-MAP app, transmission of the data to the ST-CTN research systems, management of the data, and use of the data for research purposes were provided in this research protocol (collection of user settings, generation of recommended routes, capturing trace data for routes selected, etc. The protocol protects all customer data transmitted by the app to the research server 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 for impedance improvement was delineated in this protocol and is disclosed to the user in the app user agreement. The protocol also covers transmission of weekly in-app user queries about why the user chose a different route than was recommended by the system, so improvements to that the researchers can identify specific impedance factors can be improved.	None

Appendix A. IRB Documentation

Dr. Guensler and Dr. Guin from Georgia Tech were 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. The ST-CTN project team has provided to USDOT two IRB exemption letters (beta collector data collection and quarterly survey data collection), and the final research protocol approval letter for transmission and use of PII in impedance factor research. This HUAS document was updated to reflect the IRB protocol status, the content submitted to the IRB, and exemption and approval letters within the Appendix. The protocols for research use of data collected by the G-MAP app are now in place and user data collection and transmission can commence in Phase 3.

The current IRB confirmation material is summarized in **Table 8**.

Table 8. Human Use Approval Documentation Summary

Description	Confirmation Material	Received
ITS4US-Georgia G-MAP App Beta Tester Data Collection Protocol (Protocol Number H2338)	IRB letter stating that G-MAP Beta Testing is exempt from Human Subjects Research status.	September 28, 2023
G-MAP Quarterly User Experience and Demographics Survey Protocol (Protocol Number H24340)	IRB letter stating that G-MAP Beta Testing is exempt from Human Subjects Research status.	October 14, 2024
ITS4US-Georgia G-MAP App Data Transfer and Use in Impedance Calibration (Protocol Number IRB2025-491)	Final Protocol Approval letter.	April 16, 2025

Georgia Tech
Office of Research
Integrity Assurance

Protocol Number: H23389
Funding Agency: Georgia Department of Transportation (Doc ID: 150622)
Review Type: Not Research
Title: ITS4US-Georgia G-MAP App Beta Tester Data Collection Protocol

September 28, 2023
Randall Guensler
Civil Engineering
randall.guensler@ce.gatech.edu

Dear Dr. Guensler:

The Institutional Review Board (IRB) has carefully considered your proposal referenced above. The IRB determined that this proposal does not constitute research involving human subjects at this time. This was determined as the data/results from this study will be used for product development and will only be disseminated back to program for further product development.

As defined in 45 CFR 46, research is a *systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*

Your care in ensuring compliance with the regulations and policies governing human subjects' research is greatly appreciated.

If you have any questions concerning this approval or regulations governing human subject activities, please contact me at 404.385.5208.

Sincerely,

Scott Katz, MS, CIP
Research Associate
Compliance and Regulatory Affairs
Office of Research Integrity Assurance
Georgia Institute of Technology

cc: Barbara Henry, IRB Chair

Office of Research Integrity Assurance
Georgia Institute of Technology
Atlanta, Georgia 30332-0700 U.S.A.

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Georgia Tech
Office of Research
Integrity Assurance

Protocol Number: H24340
Funding Agency: GDOT (Doc ID: 150622)
Review Type: Exempt Category 2iii
Title: G-MAP Quarterly User Experience and Demographics Survey

October 14, 2024
Randall L Guensler
Civil Engr
randall.guensler@ce.gatech.edu

Dear Dr. Guensler:

The Institutional Review Board (IRB) has carefully considered the referenced protocol. Your determination is effective as of **10/14/2024**. The proposed procedures and affiliated documents are exempt from further review by the Georgia Tech Institutional Review Board.

Minimal risk research qualified for exemption status under 45 CFR 46 104d.2iii.

Thank you for allowing us the opportunity to review your plans. If any complaints or other evidence of risk should occur, or if there is a significant change in the plans, the IRB must be notified.

For your reference, detailed PI responsibilities are included following this letter. If you have any questions concerning this determination or regulations governing human subject activities, please contact me at 678.372.7739.

Thank you,

Brook Cabrera

Brook Cabrera, BA
Research Associate I
Email: brook.cabrera@gatech.edu
Phone: 678-372-7739
Office of Research Integrity Assurance
Georgia Institute of Technology

cc: Barbara Henry, IRB Chair

Office of Research Integrity Assurance
Georgia Institute of Technology
Atlanta, Georgia 30332-0700 U.S.A.

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Georgia Tech
Office of Research
Integrity Assurance

Date: April 16, 2025
PI: Randall Guensler
Re: IRB2025-491 - Initial
Protocol for Transfer and Use of Impedance Calibration Research Data from the ITS4US-Georgia G-MAP App to Georgia Tech

The Georgia Institute of Technology Institutional Review Board has reviewed the above-referenced submission and rendered the decision below.

Decision: Approved
Decision Date: April 16, 2025
Study Expiration Date: --
Review Type: All reviewed research activities fall under 45 CFR 46.110.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Findings:
Research Notes:

All approval letters and study documents are located in the tabs on the Submission Details page. This approval is contingent upon your agreement to abide by the Georgia Institute of Technology Assurance of Compliance for the Protection of Human Subjects, follow the submitted study protocol, and maintain appropriate records concerning your subjects. For your reference, a letter with the detailed PI responsibilities has been sent to you.

If there are any adverse events, unanticipated problems, complaints, other evidence of risk, or significant changes in the plans, the IRB must be notified.

If you have any questions concerning this decision or regulations governing human subject activities, please contact the Georgia Institute of Technology Institutional Review Board at IRB@gatech.edu. Please include the IRB number in all correspondence with the IRB.

Sincerely,

Georgia Institute of Technology Institutional Review Board

U.S. Department of Transportation
ITS Joint Program Office-HOIT
1200 New Jersey Avenue, SE
Washington, DC 20590

Toll-Free “Help Line” 866-367-7487
www.its.dot.gov

FHWA-JPO-21-895



U.S. Department of Transportation