Phase 1 Human Use Approval Summary

UW ITS4US Deployment Project

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COMPLETE TRIP
ITS4US

U.S. Department of Transportation

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16. Abstract

This report presents a summary of the University of Washington (UW) ITS4US Team's human subject's application to the UW's Institutional Review Board (IRB) for the Team's ITS4US Project, the Transportation Data Equity Initiative (TDEI.)

IRB approval of the research protocol is necessary before human subjects can participate in the federally - funded ITS research experiments. This Human Use Summary document describes the information used in the TDEI IRB application. Information used in developing the IRB application was derived from tasks either previously completed or that are currently being written as part of Phase 1 of the ITS4US project. These related documents include the Concept of Operations (Task 2), Data Management Plan (Task 3), Safety Management Plan (Task 4), Performance Measurement and Evaluation Support Plan (Task 5), Participant Training and Stakeholder Education Plan (Task 9) and Outreach Plan (Task 11). This information was integrated into the tasks associated with each participant's recruitment, selection, registration, obtaining of informed consent, training, safety needs and personal identification security requirements.

The TDEI project is currently in Phase 1, planning and systems engineering development, in which the preliminary idea is developed into a structured concept that is suitable for further design, building, testing, and operation. Phase 2 consists of project engineering, concept development, testing and deployment. Phase 3 consists of operation and evaluation of the concept.

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Table of Contents

List of Tables

List of Figures

1 Introduction

This document presents the Human Use Approval Summary (HUAS) for the University of Washington's (UW) ITS4US Deployment Project, the Transportation Data Equity Initiative (TDEI). The TDEI is being performed as part of the U.S. Department of Transportation's (USDOT's) Complete Trip—ITS4US Deployment Program https://www.its.dot.gov/its4us/index.htm.

This HUAS is informed by work documented previously in a number of project documents[1] including: 1) Concept of Operations (ConOps) for the proposed system, which bridges the user needs that motivated the project and the specific technical requirements from which the project is built, 2) the Data Management Plan (DMP), which discusses how the data that is expected to be acquired or generated during the course of the ITS4US project will be managed, analyzed, protected, stored, and shared, 3) the Safety Management Plan (SMP) which assesses the safety needs and risks in how travelers and others interact with the planned deployment, 4) the Performance Measurement and Evaluation Support Plan which describes the evaluation activities that will be performed as part of the project, 5), Participant Training and Stakeholder Education Plan which describes the interactions with project participants planned to ensure that they can interact with deployed system efficiently and effectively, and 6) the Outreach Plan for increasing public awareness of the deployed system during Phases 2 and 3 of the project.

1.1 Document Purpose

This document is an overview of material and process used to obtain the human use approval required for the UW's ITS4US technology deployment project. This report:

- documents the University of Washington's IRB's authority to conduct an IRB review,
- summarizes the content of the initial IRB application,
- includes the UW IRB's feedback from their review of the initial IRB application and the UW team's responses to those review comments,
- provides the IRB's Notice of Approval for the pilot deployment,
- describes the coordination between this activity and other project tasks, and
- reviews next steps with respect to the IRB review and approval process.

This summary also describes the project's human subject review process, how the UW team will obtain participants' consent, and how the team will secure the IRB approval for phases 2 and 3,

[1] ITS4US project documents available at: https://www.its.dot.gov/its4us/htm/publications.htm

as well as the process for amending and renewing the IRB application and approval throughout the project period.

The UW IRB efforts reflect the fact that the UW team has been working on projects that led up to the UW team's ITS4US proposal for over four years. During that time, we have been working with the UW IRB to ensure the safe participation of all participants in an ethical and responsible fashion. This USDOT sponsored ITS4US project is a direct extension of that previous work.

Consequently, team discussions regarding IRB topics and issues have been ongoing for over four years and include both regularly scheduled meetings among all relevant team members, and ad hoc meetings to address specific topics. These discussions have included open and honest dialogue regarding participants' rights, the team's responsibilities towards participants, the contractual and legal obligations to the human use process, as well as practical constraints and trade-offs. Importantly, the UW IRB has been included in this process from the beginning of our pre-cursor projects. The UW team has consistently consulted with IRB staff on both general procedures and specific IRB questions and topics; these interactions have helped guide the approach to the human use approval process.

This report also reflects careful coordination across project tasks to ensure compliance with the IRB review and approval process, consistency between planned activities and human use protections, and uniformity in the representation of IRB-related topics and plans across task reports to the United States Department of Transportation (U.S. DOT).

Because the deployment is currently in its concept phase, this report should be considered a preliminary IRB summary. Revisions to the IRB application and continued IRB reviews will be performed whenever appropriate as the program evolves through the design and deployment phases.

1.2 Project Overview

The UW ITS4US Deployment Project is one of five Phase 1 Complete Trip – ITS4US Deployment Program projects selected to showcase innovative business partnerships, technologies, and practices that promote independent mobility for all travelers regardless of location, income, or disability. It aims to create the foundational data tools necessary for both public and private entities to collect, share, manage, and use transportation data that provide equitable outcomes to all travelers. At its core, the project is about creating the foundational requirements for interoperable transportation data sharing that fulfills the informational needs of all travelers. This requires a specific focus on the unmet needs of people with mobility disabilities and other historically travel-disadvantaged communities that are the focus of this project. Without implementing this type of project, the needs of these communities will continue to remain unmet or underserved, limiting the ability of citizens in these communities to access destinations, explore opportunities, and be aware of all services available to them.

The project consists of five major parts. The performance of each of these parts will be the subject of project evaluation activities described in this document.

The first part of the project includes working with existing standards committees to extend and update three existing, early-stage international data standards: OpenSidewalks, GTFS-Flex, and GTFS-Pathways. These three data standards enable the consistent collection and reporting of

data that provide the underlying information needed by the currently underserved target populations—people with disabilities, older adults, and individuals with low income—to efficiently travel.

The second part of the project is to develop a series of tools that help agencies, jurisdictions, and other stakeholders collect the data that can be stored with these refined data standards. These tools are needed to lower the cost and improve the quality and consistency of those data collection efforts to increase the availability of the data.

The third portion of the project is to develop tools, policies, and procedures that allow sharing and governance of the collected data. The tasks performed will enable effective and efficient vetting, aggregation, management, and fusion of the data that participating agencies, jurisdictions, and other stakeholders collect. This portion of the project also includes tasks required to enable and manage the sharing of those data with application developers that write software to deliver requested travel information.

The fourth portion of this project is the development of a data repository to contain the data to be shared within the six counties that represent the geographic boundaries for this ITS4US project. The data repository will be developed to illustrate how these data can be collected, stored, governed, updated, and maintained over time and then served upon request to application developers.

Finally, the fifth portion of this project is the development of three example applications that use the collected data. The three applications are intended to demonstrate three very different uses of the data that are collected, maintained, and made available to application developers as a result of the other four aspects of this project. Those data can be used to fulfill a variety of information needs, and those needs can be met through an almost infinite number of applications. The three applications deployed as part of this project are meant to show other application developers how the newly available data can be obtained and delivered.

Figure 1 illustrates the overall “new mobility” ecosystem to which the UW’s ITS4US project is contributing. The outer circle consists of the variety of public transportation services that exist. Many of these services already generate data that can be readily obtained by applications via internet connections – the act which results in the discovery of “new mobility” options. These include fixed route transit services, micro-mobility services, and taxi services. The UW ITS4US Deployment project will help add the data sources that are particularly important to people with mobility disabilities, shown in purple at the bottom of the image. These are data that describe pedestrian pathways, transit station infrastructure, on-demand paratransit and community transit services, and other on-demand shared ride modes. The UW ITS4US Deployment project is also building the interoperable integrated transportation data sharing layer and Application Programming Interfaces (APIs) shown in the green inner circle. This is the functionality needed to collect, fuse, and aggregate the data from disparate transportation services. Finally, the UW ITS4US project will demonstrate a small number of applications used by the travelers shown in the center of the diagram. The applications take requests for information from the travelers, extract the required data from the data sharing layer (green circle), perform any required tasks—such as computing navigation directions—and deliver information to users in formats (audio, text, tactile displays) designed to meet their needs.

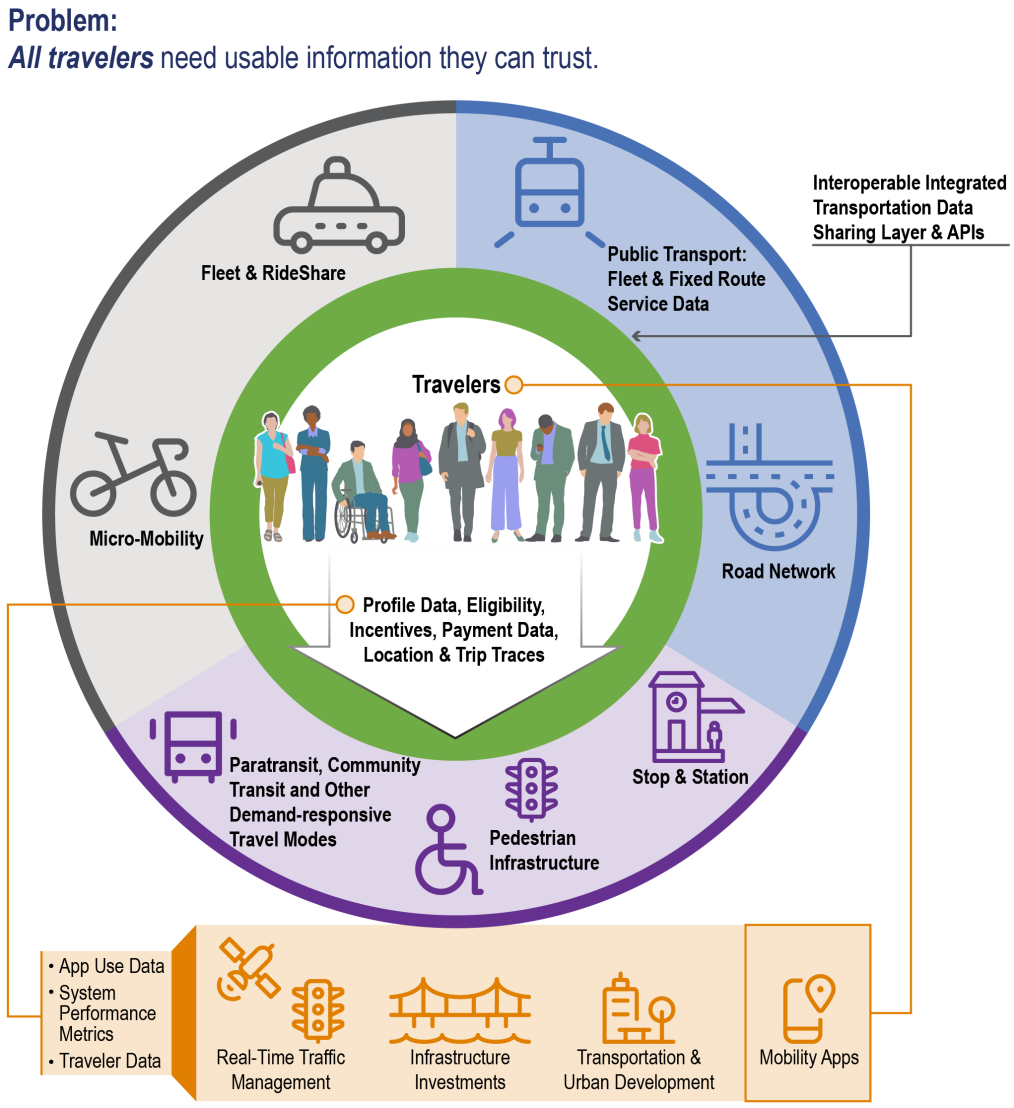

Figure 1. Diagram. UW ITS4US Deployment Project's ecosystem.

Source: University of Washington.

The project ConOps[2] describes a set of 62 user needs that drive the design of the system. The user needs statements were developed from extensive interaction with project stakeholders. Project stakeholders have been categorized based on the following five groups:

[2] Phase 1 Concept of Operations (ConOps)—University of Washington ITS4US Deployment Project, by the University of Washington and Cambridge Systematics, Inc., June 2021, Report Number FHWA-JPO-21-861. Available at: https://its.dot.gov/its4us/htm/publications.htm

- Data generators (e.g., municipal infrastructure –owner/operators, private sector pedestrian-built-environment owner/operators, crowdsourced sidewalk reporters, elevation data providers),
- Transportation service providers (e.g., transit agencies and the companies that support the delivery of transit services operated by or for those transit agencies),
- Data service providers (e.g., mapping services, weather data providers),
- Application developers (e.g., AccessMap developers, Soundscape developers, Digital Twin developers, third-party application developers), and
- Digital device end users (e.g., travelers with sidewalk preferences, blind, vision disabled, or deafblind travelers, sighted older adults, multilingual or multicultural travelers, low-income transit users, rural transit users).

The needs described by these groups describe the basic functionality of a successful system deployment. The needs are presented in detail in Chapter 4 of the ConOps.

The project is currently in Phase 1, which focuses on the planning elements of the systems engineering process, in which the initial project idea is decomposed into a structured concept that serves as the foundation for more detailed design, building, testing, and operation. The structured concept includes identifying specific performance measures, targets, and capabilities associated with performance monitoring and performance measurement. The next phase, Phase 2, focuses on the design, testing, and deployment of the proposed system, while in Phase 3, the system will be operational and evaluated for its effectiveness.

This Human Use Approval Summary is designed to document the steps taken to obtain the approvals needed to proceed to Phases 2 and 3 of the project.

2 Human Subjects Research Plan

The TDEI is designed to expand the ability of individuals to travel efficiently and effectively regardless of their physical abilities. By the end of the project, the technologies being developed and deployed as part of the TDEI are designed to be useful to the U.S. population as a whole, with a clear path identified for expanding the TDEI infrastructure and systems to cover the entire U.S.

While much of the research and development work being performed as part of the TDEI (e.g., the data collection technology, and database and data service technology, and the business and partnership models) do not pose human subjects concerns, there are aspects of the project, which require human subjects review and approval.

The Human Subjects aspects of the TDEI project are described in the remainder of this chapter.

2.1 Research Questions

The Project Overview section in Chapter 1 provides a useful description of the TDEI project. The research questions being answered for the larger project include:

1. What data are required to describe pedestrian paths so that all individuals can determine if a given path is accessible to them?
2. What data are required to describe pedestrian paths through multi-level or indoor transit stations so that all individuals can determine if paths through a station are accessible to them?
3. What data are required to describe on-demand transit services so that all individuals can determine what services are available and accessible to them, and allow them to reach a desired destination?
4. What technologies and processes can be used to cost effectively collect the data described in bullets1 through 3?
5. How should those data be stored and served to 3rd party applications in ways that support the development and deployment of applications which meet the information needs of travelers with mobility disabilities?
6. What business plans support the operation of the system described in the previous two bullets?
7. Can the system described in bullets 5 and 6 be successfully demonstrated, allowing travelers with mobility disabilities identify and execute multi-modal trip plans?
8. Can the above system be successfully demonstrated, allowing third party applications to successfully incorporate the collected data into their applications?

To answer these research questions, the TDEI project will help refine and update three data standards (OpenSidewalks, GTFS-Flex, and GTFS-Pathways) so that they can store the data

needed by users. The project will then develop and refine technologies needed for cost-effectively collecting the objective, quantitative data needed to describe transportation infrastructure and transit services. The project will build a data system which collects and serves those data via modern Internet services. The data will then be used to plan trips, and navigate the travel activities (walking along paths, taking transit rides) required to make those trips.

To conduct this research, interaction with research subjects occurs in three areas.

1. We will interview a variety of travelers (Digital device end users) with disabilities to determine the types of information they require for selecting accessible routes and paths, and then successfully navigate the paths they select in order to identify needed improvements in data standards, which describe transportation infrastructure and services.
2. We will interview a variety of application developers and transportation professionals (Data generators, Transportation and Data service providers, and Application developers) to help identify and test the effective mechanisms for collecting, storing, and publishing the data required to improve travel opportunities for people with disabilities.
3. We will work with travelers with mobility disabilities (Digital device end users) to design and demonstrate applications which deliver these data to demonstrate that improved travel outcomes can be obtained from the developed system.

2.2 Interactions with Other Tasks and Consistency

This section discusses how the Human Subjects requirements of this project are reflected in other project tasks, and how consistency is maintained within those tasks and the human subjects requirements.

The human subjects requirements are informed by, and influence, work in six other Phase 1 project tasks. These are

1. Task 2, the Concept of Operations (ConOps)
2. Task 3, the Data Management Plan (DMP),
3. Task 4, the Safety Management Plan (SMP)
4. Task 5, the Performance Measurement and Evaluation Support Plan
5. Task 9, the Participant Training and Stakeholder Education Plan, and
6. Task 11, the Outreach Plan.

Each of these interactions are discussed below.

2.2.1 Concept of Operations (ConOps)

The ConOps bridges the user needs that motivated the project and the specific technical requirements from which the project is built. The ConOps describes the user needs which are being addressed by the project and the technology deployment being performed to meet those needs. The operational concepts, technology deployments, data flows, and project scenarios described in the ConOps serve as the basis for determining the interactions the project will have

with human subjects and thus the expected benefits and potential risks. These outcomes produce the primary material included in the IRB application for the project.

2.2.2 Data Management Plan (DMP)

The DMP discusses the data that is expected to be acquired, generated, and shared during the course of the UW ITS4US project. This includes how the data on routing requests will be handled to protect the privacy of participants, as well as what data will be collected, stored and analyzed in support of the project evaluation. Safe and secure data management is one of the key tasks for ensuring the privacy and security of project participants who will be demonstrating and helping evaluate the AccessMap Smartphone application. Any unexpected outcomes in terms of data use from Phase 2 or Phase 3 of the project will result in review of the DMP with changes made to the document as required.

2.2.3 Safety Management Plan (SMP)

The SMP assesses the safety needs and risks in how travelers and others interact with the planned deployment. The vast majority of the UW ITS4US team's SMP discusses how data will be handled to maintain the safety and security of project participant's data. Other than when assisting in the collection or vetting of data for use by others – project participants are not being asked to perform tasks they would not otherwise be performing. Thus, relatively little participant risk is expected in this project. One subset of participants will be performing travel activities. These activities are entirely at the discretion of the participant. They will be using data delivered to them via a new, project developed, Smartphone application. The SMP does discuss how there may be errors in these data, and the mitigation taken within the smartphone application to address those errors. Those mitigation steps will be updated as appropriate based on feedback from project participants in Phase 3 of the project.

2.2.4 Performance Measurement and Evaluation Support Plan (PMESP)

The PMESP describes the evaluation activities that will be performed as part of the project, several of which involve the collection of data about trip making activity of individuals demonstrating the Multi-Modal AccessMap smartphone application. As a result, the PMESP discusses the collection, analysis, and sharing of data which involves project participants. These data collection plans are described in the UW team's IRB application. The PMESP includes discussions of how potential adverse impacts will be identified, reported, and handled in the field. The PMESP also discusses data security and privacy protection, as well what data will be shared with the Independent Evaluator and how that data sharing will take place.

2.2.5 Participant Training and Stakeholder Education Plan (PTSEP)

The PTSEP describes the interactions with project participants planned to ensure that they can interact with deployed system efficiently and effectively. The PTSEP involves both classes of project participants, those that work for agencies/jurisdictions/firms that are responsible for operating, regulating, and providing transportation infrastructure and services, and those that will be using the project's Multi-Modal AccessMap smartphone applications for routing and navigation assistance. The training material for these two groups is different.

Training for the data provisioning group does not entail risk and is therefore exempt from human subjects review. The training of individuals that use the smartphone application does entail risk, although those risks are modest. However, training on the use of the application is part of the on-boarding process for those project participants. That training includes identifying invalid data, use of the "help system" built into the smartphone application if the participant needs help pre- or mid-trip, and the existence of multiple feedback opportunities and mechanisms that allow project participants to highlight areas where improvements in 1) the data being used, 2) the smartphone application's operational performance, and 3) the on-boarding training activities need to be improved. Training material and communications performed with participants will include language and disability accommodations as needed to meet the needs of those who are deaf, have vision impairments, or do not have English as their primary language. Other accommodations will be provided as needed.

Training and training material will be modified as appropriate based on feedback obtained during the co-design process in Phase 2 of the project, as well as based on feedback received during the Phase 3 operational tests.

2.2.6 Outreach Plan (OP)

The Outreach Plan has direct connections to both classes of participants in this project. The first and larger class of participants are individuals that work for agencies/jurisdictions/firms that are responsible for operating, regulating, and providing transportation infrastructure and services. These individuals will support both the collection and vetting of the data that describe their services and infrastructure. The outreach plan is designed to help recruit these individuals, their agencies and firms, and describe both ways to maximize the benefits they can obtain through participating in the project and the ways in which the system being developed and deployed can minimize the risks individuals face when using their infrastructure or services.

The second class of project participants are the individuals that will use smartphone applications that take advantage of the data being collected and published. This group represents the key end users who are the focus of the travel benefits of the UW ITS4US project. During Phase 2, the outreach effort in this area will focus on recruiting individuals that will demonstrate the Multi-Modal AccessMap smartphone application and the Internet-based GTFS-Pathways routing application during Phase 3. Recruitment of these participants includes the need to identify both the tremendous improvement in mobility that they can achieve with the technology being deployed, but also pass along the limitations in that technology, and the care that must continue to be taken by individuals when traveling, because of the limitations in data accuracy that are part of collecting and publishing data on large amounts of physical infrastructure, and the changing condition of that infrastructure over time.

For both classes of project participants, communications and materials provided will include language and disability accommodations as needed to meet the needs of those who are deaf, have vision impairments, or do not have English as their primary language. Other accommodations will be provided as needed.

To reflect what these classes of individuals tell the project team as a result of their participation, outreach material will be updated periodically based on the work in Phase 2 of this project, as well as the findings of Phase 3.

2.3 Considerations for Vulnerable Populations

The TDEI is not recruiting or using vulnerable populations as part of this project. No minors will be used as participants in this project. Participants must be at least 18 years of age. Individuals with an intellectual disability, while not specifically excluded, will not be recruited as participants in the study. Inclusion of individuals with cognitive disabilities would create significant additional complexity in the IRB application and delay approval because of the difficulty in ensuring the informed consent of those individuals, as well as the need to have user interfaces specifically designed for this population as part of the application demonstration and testing process. Individuals with cognitive disabilities may participate if they are able to provide verifiable informed consent, but none of the demonstration applications are specifically designed for this group of individuals.

The project will not use incarcerated persons. Neither will the project specifically recruit Native American or non-U.S. populations, although members of these demographic groups may participate if they respond to the general recruitment material.

2.4 Informed Consent

2.4.1 Participant Groups

Informed consent will be obtained from all participants in the project.

There are two classes of participants. The first, and far larger class of participants interact with the UW research team entirely via electronic surveys and interviews. The role of these participants is to help inform the refinement of the data standards, participate in the generation and vetting of data that describe transportation infrastructure and/or the IT systems which obtain, store, and serve those data to applications. These individuals come from all five stakeholder groups, since all five groups have different insights into what data are needed, how they can be collected and vetted, and how they can be shared and effectively delivered to end users. This set of participants are discussed further in subsection 2.4.1.1.

The second class of project participants will actually demonstrate a smartphone application in the field. The individuals are all from the Digital device end users group of stakeholders. This set of participants are discussed further in subsection 2.4.1.2.

2.4.1.1 Participants Involved with Data Standards and Data Collection

For the first class of participants, all interaction will be in the form of surveys and interviews. The information being requested by these individuals is data or information they use to describe transportation infrastructure and transportation services, and how that data and information is used in order to determine whether that infrastructure or those services are accessible and usable by them for accomplishing a travel activity.

The data collected using these methods has limited potential to harm the individual supplying that information, and the information being requested from participants (the data/information they use when making travel decisions) is readily understood by a reasonable member of the subject population. The data being obtained is intended to inform the types of data being collected, the

methods with which it is collected, the quality of the information that has been collected, or the general functionality of data systems and applications being examined in a laboratory setting.

To obtain informed consent, these participants will be given access to an information sheet in a format appropriate for their participation (e.g., an electronic format included within, or linked from, an online survey, an electronic format made available before an in-person session, an online form available for viewing during an in-person session). This form will also include contact information for asking questions about the research.

Before participants in this class start taking a survey or participating in an individual or group interview session, and before the project data collection system starts recording data, each individual will be shown the consent form. All participants will be asked to read through the form and then agree before continuing in the study. The text being read, and the researcher leading any live survey, will emphasize that a participant can skip any question, skip any task, or end participation at any point. In addition, for meetings or surveys performed online, the information sheet will be made available as part of accessing the online materials. Participants may print the consent information provided in electronic forms at their discretion. They may also request paper copies from the research team.

During video meetings that are being recorded, the video recording software informs the user that recording is taking place via a text message on the screen. This message is also played audibly if the user is using a text reader. The researcher leading each on-line session will indicate that questions can be asked verbally, or via a public or private chat message.

For video meetings, an individual who does not wish to be recorded can watch the video after the conclusion of the meeting, without having access to the on-line consent methodology, but they cannot participate in the live meeting.

Contact information will be provided in all recruitment and correspondence to allow participants to ask questions about the research. Study information will be delivered in a manner that accommodates assistive technology needs (e.g., accessible PDFs formatted for screen readers, offering to read documents aloud before a study).

Participants will be provided an appropriate information sheet at each stage of participation. As with new participants, continuing participants will be able to ask questions and decide whether they want to continue participation. Participants have the ability to ask the research team for additional copies of all consent material at any time during the project by either calling or emailing the project team.

Participants will be separately and explicitly prompted to give or deny permission to use anonymized versions of their quotes or their artifacts in research publications. They will also be separately and explicitly prompted to give or deny permission for their contact information and characteristics to be used in recruitment for future relevant research studies.

While no potential harm is expected to come from participation in this project, as it is primarily about the collection of insight into the participants use of data, if additional information needs to be sent to participants, the project team retains contact information for all participants. This contact information will be used transmit that additional information, with confirmation of receipt of that information requested and receipt of consent to continue to participate in the study required if the new information requires that step due to changing conditions.

2.4.1.2 Participants Demonstrating the Smartphone Application

The second class of participants will demonstrate the smartphone application. This class of participants will be drawn from a convenience sample of individuals that express interest in participating in the study by responding to email and social media recruiting efforts. Those recruiting materials will include information about the purpose of the study, the data that will be collected, how that data will be used, the tasks to be performed by participants and the risks associated with those tasks – which involve performing their normal trip making, with the smartphone application making suggestions on paths that can be taken to perform those trips, with the participant choosing to accept or decline to use the suggested paths identified by the smartphone applications, and then recording the outcome of those travel decisions and reporting on their satisfaction levels concerning those outcomes.

When using the smartphone application, the application will collect information about uses of the application and the phone. This will include the requests made concerning potential trips to be taken (i.e., requests for routing assistance), the use of the application for navigation instructions for trips being made, and the collection of trace data associated with those trips (current time, phone location at that time (~10 m accuracy), phone ID), screen status, battery status, network status, notification information, and call and SMS events which are logged only when help requests are made.

The phone-application will continuously collect time-stamped GPS location information (including the precision metric associated by the sensor with its reading), and, for every 30 second period, aggregated average and standard deviation of gyroscope and accelerometer sensor data.

The phone application will detect when a participant has stopped moving for over five minutes and consider that to be the end of a trip. The phone application will then pop up a survey for users to respond to about their recent trip. Participants have the option of responding or opting out of any pop-up survey. Participants who choose to respond to the in-app survey will answer closed-ended questions about the trip they took recently.

These data will be saved onto the phone until the phone is within range of a wireless internet connection, at which point the app will automatically upload the data to our secure servers using the participant's assigned UUID (a hash tagged ID that is randomly assigned by our login server). Once uploaded, the phone application will empty its cache. In addition, the phone application will be the vehicle for collecting in-app responses to survey questions about trip segments. The responses will be directly entered and saved on our servers. The responses will be linked with the same UUID for the participant. No names or addresses or other identifiable information will be transmitted from the phone to our servers at any time.

The in-app surveys will consist of closed-ended contextual questions served to participants in a mobile phone application pertaining to the context of a recent trip they took. The surveying is triggered by the participant ending their trip. By obtaining this data we will have trip information with (a) accurate duration of trip and all its segments (including portion spent in different modalities of transportation) (b) accurate information about delays incurred during travel and where they occurred, (c) participants' overall satisfaction and difficulty with the trip and the infrastructure they used or passed during their trip.

The participants will have time to complete each questionnaire. We will specifically instruct the participants not to compromise their safety while completing study procedures. We will remind the participants to follow responsible phone practices by refraining from using their phones for study

procedures in situations where the participants normally would not use their phone (i.e., driving or actively walking).

While none of the questions we will ask are expected to present risk, discomfort, or embarrassment to subjects, the research team does acknowledge that some participants might feel an invasion of privacy because the study design involves the collection of sensor data that could be potentially private, such as location. Participants can opt out of sensor and trace data collection. Participants will never be asked in person about any of the sensor data. This minimizes the risk of in-person embarrassment. Participants can opt-out of any of the in-app surveys as well. Participants will be made aware that they do not have to answer any question that they find too personal and can also end their participation in the study at any point.

At the end of the data collection period, researchers will survey the participants. The survey will consist of closed-ended questions about their travel experiences. The researchers will then have an informal on-line conversation with participants to better understand their experience with the application and explain how to uninstall the smartphone application from their mobile device. Participants will be advised again as to how their trace data will be used to identify travel preferences and obstacles and whether the data now being collected and delivered via the smartphone application are reducing those obstacles. Again, none of the questions being asked are expected to present risk, discomfort or embarrassment to subjects.

If selected as a potential participant for this aspect of the study, the participant will meet with a research team leader for an on-boarding session. During this session, the research team leader will explain the purpose of the study, the data that will be collected, how that data will be used, the tasks to be performed by participants and the risks associated with those tasks. Written versions of this material will also be provided to the potential participants. The potential participant will then be given the opportunity to ask questions of the research team leader. At this point, if the potential participant still wishes to participate, written consent will be obtained from them.

After consent is obtained, the research team leader will help users install the smartphone application, explain how to use the application and how to respond to the in-app surveys, show participants how to open an anonymous channel of communication with the researchers and collect demographic and mobility profile information (specifically, whether they use any assistive devices or experience any trouble walking or standing during commutes) as well as demographic information about them. This information, but not names or direct identifiers, will be linked to the data being collected from the smartphone application.

As with the individuals participating in the data standards and data collection activities for this project, the name and contact information for participants in the smartphone application demonstration, would be considered a level 2 risk. Name and contact information will therefore be stripped from all analysis datasets but retained in a contact information dataset that will not be accessible outside of the core research group. All data in the contact information dataset will be protected by best-practices protocols: access will be mediated by OAuth-2.0 authorization methods via University of Washington or equivalent accounts following the requirements outlined in HSG guidance. All data in the analysis dataset will fall under the same protocols until a decision to share information outside of the core research group is made, at which point access would be restricted to clean copies of the data.

All data collected via participant smartphones will be identified through the device ID only and not by participant name.

2.4.2 Participant Questionnaires / Evaluation

This section describes the types of surveys and questionnaires to be performed during Phase 2 and Phase 3 of the project.

A variety of surveys, questionnaires and on-line interviews will be performed during the project. Some of these are designed to assist with the design and development of the systems and services being deployed in the project, and others are designed to evaluate the outcomes of those deployed systems.

2.4.2.1 Participants Involved with Data Standards and Data Collection

All surveys taken by individuals participating in the refinement of data collection standards, development and testing of data collection techniques, and vetting of data will be electronic surveys submitted via on-line web form. None of the survey or interview questions to this group of participants relates to the individual participant's travel, travel behavior, personal characteristics, or other sensitive or private information, with the exception that demographic information will be collected to ensure that insights into the information needs of all segments of the population are incorporated into the refined data standards.

For each survey and/or interview, participants in that data collection effort will be given electronic consent forms. Prior to the conduct of the data collection effort, each participant will be given material that that describes the type of information being requested, and how that information will be used. The participant will then be informed that by continuing in taking the survey, they are consenting to their responses being included in research.

For participants in on-line meetings which include interview question responses from participants, the researcher leading the meeting will go through this information verbally at the start of the meeting, in addition to having this information provided to participants electronically prior to the meeting.

For all survey work, participants will be free to skip any question or stop the survey at any time. They may also stop participating in the ITS4US project completely at any time without penalty.

All survey and interview procedures will take place at the UW, remotely via videoconferencing or phone, or at a mutually convenient local location.

2.4.2.2 Participants Demonstrating the Smartphone Application

This class of participants will use the Multi-Modal AccessMap application. They will take both short in-app surveys during their use of the application, and a longer close-out survey describing their overall experiences with the application at the end of their participation in the application demonstration/evaluation.

As part of their recruitment and selection for this aspect of the project, each subject will be given written material describing the application, their role in the project, the data that will be collected as part of their participation, a description of how that data will be used, and their ability to opt out of any and all aspects of the data collection activities. This includes being able to stop participating in the project at any time, and the ability to remove the application from their smartphone at any time. Prospective participants will be given the opportunity to ask questions of

the research team about their role in the project, the tasks they will perform, and the data that will be collected prior to offering to be part of the project.

After their selection for participation in the project, each participant will take part in an "on-boarding" meeting, either in-person, or via a video-meeting. At that meeting, this same information will be presented verbally, and an opportunity will be given for participants to ask any questions they have.

If after their questions have been answered, they wish to participate in the project, the researcher leading the on-boarding session, will lead them through the steps which place the project's Multi-Modal AccessMap application on their smartphone. And inform them that use of the application will constitute their consent to participate in the project. However, even after giving that consent, participants will be free to skip any question or task or stop the study completely at any time.

2.4.3 Participant Data

The data to be collected from participants during the project falls into two categories. Data to be collected from those participating in the data standards and data collection tasks only describes physical infrastructure, transportation services, or the effectiveness and accuracy of specific data collection techniques or collected data.

Data collected from individuals participating in the demonstration of the Multi-Modal AccessMap smartphone application will be providing detailed trace data (stored without a direct identifier to their personal information), and descriptions of the outcomes of their routine travel activities performed using the application.

2.4.3.1 Data Standards and Data Collection Participants

In general, privacy is less of a concern for the data being collected from this group of project participants, as no data being collected describes the behavior of an individual or could result in harm to that individual.

We will collect demographic information (age, gender, ethnicity) and mobility profile information (any assistive devices or support participants require during trips) from all individuals that are participating in the refinement of the data standard. The insight we will gather from participants include the types of data they are looking to obtain in order to identify safe travel paths or options, such as sidewalk width, the presence of curb ramps, the availability of a traffic signal to cross a road, the location of transit stops, the time when transit vehicles are expected to arrive at that location, the features on that transit vehicle (e.g., do they have wheelchair tie-downs), and the destination of that vehicle. We will not collect demographic data on the transportation and computer science professionals participating in the project.

All data in the analysis dataset can be considered level 1 risk level per the HSD guidance protocols. The most sensitive data are name and contact information, which could be considered a level 2 risk. Name and contact information will be stripped from the analysis dataset but retained in a contact information dataset that will not be accessible outside of the core research group. All data in the contact information dataset will be protected by best-practices protocols: access will be mediated by OAuth-2.0 authorization methods via University of Washington or equivalent accounts following the requirements outlined in HSD guidance. All data in the analysis

dataset will fall under the same protocols until a decision to share information outside of the core research group is made, at which point access would be restricted to clean copies of the data.

We will gather qualitative information from interviews via transcripts, notes, and recordings. Participants will be sharing information about their experience with travel data, transportation data, data discovery, and data exploration about transportation infrastructure and services.

The answers to surveys being used will include multiple choices responses, checkboxes, and short text. We will also make audio and video recordings (with transcripts) of interviews and on-line meetings, in order to both maintain an accurate record of the insights participants provide us into what data they use and how they use it to make travel decisions, and to allow participants who cannot attend these meetings live, or do not wish to be recorded, to listen to those meetings in order to hear what other participants say.

We will obtain participants' names and contact information when we recruit them. We will also have their names during interviews and user testing. However, these names will not be stored with the data they provide to the project team describing their insights offered on revised data standards.

If the participant's consent, identifiers of name and contact information may be shared for future recruiting for similar studies. Data may be shared in the form of quotations in publications. This data will not be identifiable or connected to the participant.

2.4.3.2 Smartphone Application Participants

This group of project participant will provide some data which has privacy concerns, in that they will be providing the project team with data on their actual travel behavior as they use the demonstration smartphone application, Multi-Modal AccessMap.

This group will supply three sets of data. The first set of data consists of the demographic and mobility profile of the user. This information, along with their contact information, and phone MAC address will be stored separately from all other information and will be used to generate an indirect identifier that will be associated with travel trace data collected from that individual. No protected health information will be collected. Neither will genome data.

The second set of data consists of the trip routing and navigation requests they make using the application. When they then perform one of those trips and use the navigation function of the application, the application will collect trace data (time and location information at 30 second intervals) during those trips, along with the planned trip navigation directions. These will be compared to determine if the traveler is able to follow the planned trip.

At the end of these trips, the app will ask the user to fill out a short "trip completion survey" which will ask questions about their experiences during the trip, and their satisfaction with the navigation instructions they received. These surveys are part of the third set of data collected for this group of study participants. The last is that an "end of demonstration" survey will be given to each participant when their participation in the project ends. This survey will collect the user's "summary thoughts and perceptions" about the use of the application and the value of the new data being collected on paths and on-demand transit services.

As noted above, none of these data will be stored with direct identifiers associated with the user. Instead, they will be stored with indirect identifiers that only indicate the demographic and mobility disabilities associated with that traveler. This includes all interview and survey responses. In addition, all personal identifiers associated with travel activity traces will be deleted from datasets that must be shared publicly.

2.5 Recruitment Design

2.5.1 Recruitment

We will recruit only adult participants (i.e., at least of age 18). Researchers will identify interested participants with disabilities, participants who work on access to mobility and transportation (including therapy professionals like Physical Therapists, Orientation & Mobility professionals, Occupational Therapists), professionals managing sidewalk data and GIS systems, and other public employees interacting with sidewalk and transit data.

Minors under the age of 18 will be excluded. Those who do not have a direct connection to transit and sidewalk data collection, use, or management or who are not interested in the research will also be excluded from the interview recruitment process. Prisoners will not be used. Pregnant women will not be recruited, although the team will not specifically ask if a woman is pregnant. Neither will the project specifically recruit Native American or non-U.S. populations, although members of these demographic groups may participate if they respond to the general recruitment material.

The research will NOT collect private identifiable information about other individuals from the study subjects. That is, we will not collect medical history information or contact information about family members, friends, co-workers.

For the data standards refinement and data collection technology tasks, recruitment will occur working directly with interested public agencies, city and county staff, and firms working in this field. Surveys and interviews will also be conducted with people with various mobility disabilities (e.g., use a wheelchair, a walker, or have low- or no vision) or who work with those individuals, to learn from them the types of information (data) they require in order to travel more safely and efficiently and how that data can be best provided to them.

Finally, some individuals with disabilities will be recruited to demonstrate a smartphone application that assists with planning and executing multi-modal trip making. Individuals selected for participation must be capable of providing informed consent. We will recruit through email, social media (including online communities), announcements at public events including webinars, word-of-mouth, and through community partners and organization who extend our recruiting using these same methods (e.g., sharing a social media post, forwarding an email to their membership). We will also reach out to specific individuals working for organizations that own or regulate transportation infrastructure or that operate transportation services via phone and email who are likely to have information useful to our study. Similarly, we will reach out to organizations that advocate for improved mobility for people with disabilities and for active transportation, in that these organizations may play a role in obtaining or vetting data.

UW researchers have previously created a participatory design community called Open The Paths comprised of people with disabilities, people concerned with bicycle and pedestrian

access, people committed to active transportation options, as well as a community of GIS and urban planning professionals, transportation professionals. This group is included in the above recruitment process.

The expectation is that 40 individuals will be recruited to demonstrate the Multi-Modal AccessMap smartphone application.

2.5.2 Payment to Participants with Disabilities

To help ensure sufficient participation from individuals with mobility disabilities, participants with disabilities will be compensated via cash card or gift card. Professionals working in transportation or software design will not be compensated for their time. For each engagement (survey tool or interview), an assessment of the time commitment required by the participant will be made, and compensation will be offered at the rate equivalent to $20 per hour. Any participation that will be equivalent to 2 hours or less will be offered a gift card of choice, any longer time commitment will require the participant sharing their social security number (due to UW rules on compensation), and compensation will be in the form of a cash card purchased online in accordance with UW purchasing regulations.

2.6 Training of Participants

Participant training is discussed more completely in the Participant Training and Stakeholder Education Plan. Relevant to Human Subjects approval are two training efforts. The first is for individuals helping with data collection and data vetting. The second is for individuals participating in the Multi-Modal Access Map application demonstration.

Training will be provided for all individuals that work with the UW ITS4US project team to generate or vet data that will be included in the data published for use as part of the project. These data generation activities do not carry significant human risk, as they are mostly carried out in an office setting and involve the manipulation of images and databases using a variety of computer software applications.

Training exists – or will be developed during Phase 2 of the UW ITS4US project for

- mapping sidewalk, path, and crossing data,
- generating on-demand transit service description data
- generating transit center pathway data.

Training will also be provided for how to vet these data, and how to submit corrections for those data when errors are identified. Finally, training will be provided to agencies for managing these tasks, as collecting and vetting sidewalk data requires effective management and oversight. Examples of current training material for sidewalk data collection and vetting can be found on-line at this URL: https://tasks.opensidewalks.com/learn

Three training modules currently exist:

- Learn to Map - which includes three documents (a Quick Start Guide, a Tasking Manager User Manual, and Learn OpenStreetMap Step by Step), and 3 videos (Signing Up on Tasking Manager, Select a Task & Mapping Buildings, and Mapping Roads),

- Learn to Validate - which includes three documents (Identify if becoming a validator is right for you, Build your skills, and Collaborate as part of the community) and two videos (How to Validate, and Validation Training)
- Learn to Manage – which contains four documents (Become part of a community or organization, Create a project and be loud about it, Use the data, and an Administration Guide.)

Training for participants in the demonstration of the Multi-Modal AccessMap smartphone application will occur during the on-boarding session for each of those individuals. Training includes identifying invalid data the user encounters, use of the “help system” built into the smartphone application if the participant needs help pre- or mid-trip, and the existence of multiple feedback opportunities and mechanisms that allow project participants to highlight areas where improvements in 1) the data being used, 2) the smartphone application’s operational performance, and 3) the on-boarding training activities need to be improved.

Training during the on-boarding session will also emphasize the need for safety, and the ability to not answer any question or survey the participant wishes to not answer, for any reason. The participants will also be trained to use their own judgement when following navigation instructions, given the potential for errors in reported conditions that can exist either because conditions have changed since data were submitted and vetted (e.g., a construction project has removed or made a curb ramp inaccessible) or because specific features have not been accurately reports (e.g., a sidewalk is narrower than reported.)

2.7 Team Human Subjects Research Training

The University of Washington requires all researchers that are working with human subjects to have undergone and passed Human Subjects training. UW Human subjects training is available on-line starting at these two URLs:

- https://www.washington.edu/research/hsd/training/
- https://www.washington.edu/research/hsd/training/required-training/

The UW has also partnered with the Collaborative Institutional Training Initiative (CITI) to provide free online training for those who are affiliated with UW or collaborating with someone who is affiliated with UW. This training consists of courses on Human Subjects Protections, Good Clinical Practice, and Responsible Conduct of Research. Th CITI training can be found at: https://www.washington.edu/research/hsd/training/required-training/web-based-citi-training/

Finally, the UW provides assistance in the documentation of human subjects training, so that research teams can ensure that all team members have received the appropriate training. This training can be found at: (https://www.washington.edu/research/hsd/training/required-training/documenting-and-tracking-training/)

Researchers and their departments are responsible for maintaining their own documentation of training in order to provide to funders or other organizations if requested. Researchers are also responsible for monitoring whether or not they need to complete refresher trainings.

3 Protocol / Application Summary

3.1 Institutional Review Board

The UW ITS4US project will use the University of Washington's Institutional Review Board for the human subjects review for the Transportation Data Equity Initiative. The UW IRB is managed by the University's Human Subjects Division (HSD), https://www.washington.edu/research/hsd/, which is a service and compliance unit within the Office of Research. It is the core of the UW's Human Research Protection Program (HRPP), and in order to manage the volume of IRB requests, the HRPP manages four Institutional Review Boards (IRBs) that review and oversee UW human subjects research. HSD has about 40 staff and about 80 IRB members.

HSD and the IRBs perform the federally-required review of human subjects research that is conducted by UW faculty, staff and students and a few local institutions. There are about 6000 human research studies at the UW, distributed across almost every department and academic unit, including the Seattle, Bothell and Tacoma campuses. The research may occur anywhere in the world. A significant percentage of UW research occurs outside of the U.S. UW human subjects research is remarkably diverse ranging from clinical trials of investigational devices such as the Wearable Kidney, to ethnography of the blues music culture in Angola prison, to "think aloud" studies of new mobile technology, and more.

3.1.1 Federal-wide Assurance

The UW Federal-wide Assurance Number is 00006878.

3.2 IRB Review Process

The following material describes the University of Washington's IRB review process. It is taken from material published by the University's Human Subjects Division (HSD.) HSD maintains a complete on-line support system with directions, training, and support services. The primary page for HSD can be found at the following URL: https://www.washington.edu/research/hsd/

All UW IRB documentation is submitted via the UW's Zipline electronic document submittal system. All UW Principal Investigators must take and pass mandatory Human Subjects training before being able to lead research involving human subjects. IRB review and approval is required for all non-exempt human subjects research activities in which the UW is engaged, except when necessary to eliminate apparent immediate hazards to the human subjects. Review is required:

- Before beginning a project (initial review);
- Before making any modifications to the project;
- At least once each calendar year (continuing review), except as allowed under the Flexibility Policy;

- For any problems or relevant new information that develops during the research (e.g., adverse events).

Review and approval must be obtained before implementing the activities, except for activities that are necessary to eliminate apparent immediate hazards to the subjects. Approval cannot be granted retrospectively, after a research activity has begun. This applies to all activities, including modifications that may appear to investigators to be largely administrative in nature.

Investigators are expected to use the forms and guidance provided by the Human Subjects Division (HSD) to provide sufficient information to HSD and the IRB to make specific required determinations and to decide whether the criteria for IRB approval have been met.

When the research is conducted by a team of two or more individuals, the IRB requires the name and identifying information for only those individuals who will fulfill certain roles, as described in the Standard Operating Procedures (SOP) document for Research Teams ("SOP Research Team")[3], which describes policies and procedures about research teams conducting human subjects research, and on the IRB application forms. The IRB also must be provided with information about the qualifications required for individuals who will perform research procedures involving risks to subjects.

Federal regulations and Washington State law give the UW IRBs the authority to take specific actions. UW policy grants additional authority to the UW IRB, and to the Director of HSD, for some specific additional actions. The IRBs are not authorized to take actions not specified in federal regulations, state law, or UW policy.

With each review of an entire project (i.e., at initial and continuing review), the IRB is required to specify the duration of the approval period. This determines the date of the next continuing review (i.e., Status Report).

Outcomes of IRB review are communicated in writing using standardized templates to the investigator, the UW, any other UW components or external bodies (as required or appropriate), and the IRB.

Investigators are expected to respond to IRB reviews by the deadline described in the written reviews. Failure to respond by the specified deadline may result in the administrative closure of the item. When the investigator fails to respond to the review of an initial application or a Status Report, the entire project may be administratively closed, unless there is an unresolved issue related to compliance or subject safety and rights. When this occurs, human subjects research activities must cease immediately (except as necessary to protect the safety of the subjects) and cannot resume until the investigator has fulfilled the requirements of the IRB.

The IRB review is preceded by a pre-review process performed by HSD staff. This ensures that applicable regulatory requirements and determinations have been identified, and that the

[3] Note that in this section, documents of UW standard operating procedures available on-line through the UW website. These documents are referenced in quotes, and a URL link is provided to the document being referenced.

provided materials and information are complete. The IRB reviews the materials provided by the investigator, the HSD staff, and any other sources. As needed, the IRB asks the investigator for additional information, materials, or clarification. Consultants may also be obtained at any point during the review process.

After IRB approval has been granted, the complete IRB file is always available at any full convened IRB meeting when any item is reviewed for the study. The completed IRB file is also always available for any reviewer performing expedited review. The review may be conducted by the full convened IRB or by the expedited process. (The expedited process is often called "Minimal Risk review" at the UW.)

- These two types of review differ only with respect to who performs the review. Both types of review: (1) require the same materials for review; (2) apply the same criteria for approval; and (3) have authority to take the same actions (with some exceptions).
- Full IRB review occurs at a convened meeting of the full IRB, following the procedures described in this document.
- Expedited review follows the procedures described in this document. Eligibility for expedited review is determined by experienced senior HSD staff during the pre-review process, applying the criteria described in the WORKSHEET: Expedited Review Eligibility.

The criteria for IRB approval are described in the CHECKLIST: As indicated, some of these criteria apply to all research. Other criteria are specific to certain types of research. The pre-review process identifies for the IRB which criteria of approval are applicable to an item being reviewed.

- The IRB may require changes, actions, and/or information in order to determine that the criteria for approval have been met.
- The CHECKLIST is used by the IRB: (1) to ensure that it considers all applicable criteria for approval; and (2) to document that an approved study has met the applicable criteria for approval.

The IRB is required by federal regulations or UW policy to make the following determinations for each initial review and continuing review. These determinations are noted in the IRB meeting minutes, except where noted.

- The approval period granted by the IRB, thus establishing the frequency of continuing review. The approval period can be no longer than a year, based on the federal requirement that a study be re-reviewed at least once each year. In determining the frequency of review (i.e., the duration of the approval period), the IRB considers:
  - The nature of the study;
  - The nature, probability, and magnitude of risks to subjects;
  - The vulnerability of the subject populations;
  - The experience of the investigators in conducting research;
  - The IRB's previous experience with the investigator (e.g., compliance history, previous problems with the investigator obtaining informed consent, or prior complaints from subjects about the investigator);
  - The projected rate of enrollment.

- For reviews conducted by the full convened IRB, the IRB decides:
  - Whether the study meets the Expedited Category criteria for conducting the next continuing review by the expedited review process. Those criteria are:
    - The remaining research activities involve no more than minimal risk to subjects;
    - No additional risks have been identified;
    - The research does not involve an IND[4] or investigational device exemption (IDE); and
    - The remaining research activities do not fall into the expedited categories 2 through 8.
  - Which individual(s) who will assess the investigator's response to the Conditional Approval review letter from the IRB.
  - Which IRB members (if any; and any consultants) will participate in the preparation of the IRB review letter to the investigator.

The IRB communicates its actions and determinations, as required by federal regulations and as appropriate to the situation. Communication is in writing, using standardized templates. As appropriate, phone calls may communicate the outcomes in advance of a written communication.

- To the investigator. A review letter is prepared by the expedited reviewer (for expedited reviews) or by an IRB member (usually HSD staff for full convened IRB review). For full convened IRB reviews, the draft letter is reviewed and revised as needed by the IRB Chair and/or the primary reviewer, and any other IRB members as indicated at during the review process. Final approval of review letters by the IRB chair or primary reviewer may be made by signature or by email; a copy of the email should be placed in the file. Courtesy copies of the final letter are provided to the investigator's contact person (if applicable).
- To the institution (UW). The outcomes are reported to the UW with the meeting minutes, by providing them to the Institutional Official listed on the UW Federal Wide Assurance.
- To the IRB. The IRB members are advised of research proposals which have been approved by the expedited review process, by providing them with regular Subcommittee reports which are attached to meeting minutes.
- To the sponsor (if applicable). The sponsor receives a copy of the review letter sent to the investigator.
- To other UW components or external entities (if applicable). A copy of the review letter sent to the investigator is provided.

Examples of IRB-required actions, changes and information include the following (which is not a complete list):

- Require additional information from the researcher.

[4] An application submitted to the Food and Drug Administration (FDA) whereby a drug sponsor requests authorization from the FDA that will allow the interstate transport of investigational agents for administration to humans

- Require additional information or consultation from others.
- Change the frequency of continuing review.
- Require reports from the investigator after specific milestones (for example, after the first five subjects have completed the study intervention).
- Obtain verification from sources other than the investigator that no material changes have occurred since the last IRB review.
- Observe or have a third party observe the consent process and/or the research.
- Require changes to parts of the research. Examples: add or drop procedures; changes in eligibility criteria; changes in recruitment approaches; changes in subject populations; enhanced confidentiality protections for data; etc.
- Require changes to parts of the research. Examples: add or drop procedures; changes in eligibility criteria; changes in recruitment approaches; changes in subject populations; enhanced confidentiality protections for data; etc.
- Addition of safety monitoring procedures, such as additional lab tests for subjects or the additional of a medical monitor.
- Enhanced confidentiality protections for data, such as data encryption on laptops.
- Provision of a subject advocate.
- Require re-consenting and/or re-authorization of subjects.
- Require information to be provided to subjects (for example, new information about the risks of the study).
- Require information to be provided to others – such as other entities involved in the research; subjects' physicians; etc.
- Require HSD and/or the researcher to report a problem or concern to funding agencies, sponsors, other UW offices, co-investigators, collaborators, and/or collaborating institutions.
- Require training and education for the investigator or other individuals involved in the research.
- Require the investigator to obtain permission from a site, to conduct the research.
- Require that subject identifiers (or the link between data and identifiers) to be destroyed if those identifiers were collected (or relevant research procedures were performed) without prior IRB approval.
- Require the investigator to submit a new (i.e., replacement) application for the study (especially if the existing file has become exceedingly large and complex).
- Require the investigator to separate the existing study/application into two separate IRB applications, to facilitate IRB review and oversight. For example, a repository might be spun off of the main study.
- Require the HSD Director to forward to the appropriate institutional office (as determined by the Director) a request to consider the following actions (for which the IRB itself does not have the authority):
    - Require that data not be published or presented
    - Require that data not be used for a thesis or dissertation
    - Require that data be destroyed

- Restrict the number of active studies for an investigator
- Prohibit an investigator from engaging as the lead responsible party in human subjects research

3.3 Ensuring IRB Understanding of Project

The UW ITS4US team provided the following material to the UW IRB to describe the project. The UW team believes that the potential impacts and risks associated with this project are easily understandable by individuals not familiar with the planned technology improvements.

> There is substantive evidence that both a lack of data and the inability of many people with disabilities to access data that does exist about transportation infrastructure and services results in many travel destinations inaccessible to people with disabilities and makes their reaching other destinations very inefficient. The inability of people with disabilities to discover accessible travel options in many built environments and for many transit services reduces the quality of life of those individuals. This research will both explore the specific problems causing a lack of transportation accessibility data as well as how data that are collected can be made accessible and discoverable to people with a wide variety of disabilities. The project includes the development and testing of new technologies for mitigate these problems.
>
> The Taskar Center for Accessible Technology has produced and translated, for the use of populations at large, several technology products to help address the lack of data about the accessibility of transportation infrastructure and services, as well as improving the discoverability of transportation services and locations which are accessible to individuals with disabilities. The most prominent of these products are AccessMap.io (800 monthly users, supported by the center since 2017) and sidewalkscore.accessmap.io (a dashboard for municipal Seattle that can use to evaluate accessibility and compare neighborhood access information.)
>
> This research will collect and publish objective, quantitative and qualitative data about the existing transportation infrastructure and transit services. Those data will then be used to allow users to plan trips, analyze alternative trip plans, and examine the travel activities (walking along paths, taking transit rides) required to make those trips. These data will be available to everyone, but they are specifically intended to fill in information gaps experienced by individuals with disabilities, who lack personalized accessibility information about what travel paths are accessible to them. In addition to collecting a wide variety of data (e.g., sidewalk and path locations and attributes, transit schedules and vehicle configurations), we will build and test software tools to help individuals with mobility disabilities use these data to discover travel options that are accessible to them, so that they can travel more easily and successfully.
>
> As part of this project, we will interview a variety of users, developers and transportation professionals to identify needed improvements in data standards, that are required to adequately describe transportation infrastructure and services, as well as the computer science tasks associated with collecting, storing, quality assurance testing, and publish the data required to improve travel opportunities for people with disabilities.

Our project's objectives are focused on improving available information about sidewalk and other pathways systems, as well as on-demand (e.g., paratransit) transit services, and data systems that facilitate accessibility assessments for transportation planners and travel forecasting for people with disabilities.

3.4 Relevant IRB Procedures

The formal UW IRB submittal occurred on January 4, 2022.

The UW maintains four separate IRB committees. Each meets every two weeks in closed door session.

The UW ITS4US team expects to have formal IRB approval prior to the submittal of the UW team's proposal in response to the ITS4US NOFO, which is due March 11, 2022.

4 Human Use Approval

4.1 Type of Review

The UW ITS4US project was granted Exempt status for Phase 1 at the time of the Phase 1 proposal submittal, as all human subject interaction was interview based and contained the collection of no information which placed participants at risk.

The UW team's application for phases 2 and 3 is being submitted for Full Review. The team believes that the project places participants at very limited risk, as participants are performing no activities that are not already part of their daily activities. However, because the project is providing test subjects with data that, if invalid, could lead to invalid decisions on the part of the participants, a Full Review of the team's plans has been requested.

4.2 Approval Status

The IRB application for phases 2 and 3 is currently in pre-review and has been submitted for full review on January 4, 2022.

4.3 Feedback from IRB Review

The UW ITS4US team has not received feedback on their pre-review. The UW team does not expect to receive significant feedback, in that the team has already completed similar work – the original AccessMap testing – under the review of the UW IRB, and the UW ITS4US IRB application for phases 2 and 3 is similar to that earlier application.

4.4 Conditions

The UW team must apply for continuing IRB approval each year .If an adverse event occurs, or if significant changes to the planned activities need to occur for some unanticipated reason, the UW team would likely need to submit a change request to the approved IRB application. This change would occur prior to the annual renewal, and any changes required by IRB would be incorporated into that renewal.

5 Future Steps and Schedule

5.1 IRB-Required Future Actions

The UW team must apply for continuing IRB approval each year. Each yearly approval will require the submittal of reports which describe any adverse impacts which have occurred up to that point, and revisions made to the study protocols in response to those events or other programmatic activities.

5.2 Phase 2/3 Human Use Approval Confirmation Materials

Table 1: Human Use Approval Confirmation Materials Summary

Planned Timing	Confirmation Material	Description	Dependencies
Jan 2022	A copy of the email / screenshot of web service confirming receipt will be provided to USDOT	Initial IRB application	
Feb 2022	A copy of response will be provided to USDOT	IRB response expected	IRB application
Feb 2022	A copy of the email / screenshot of web service confirming receipt will be provided to USDOT	Final IRB application	IRB feedback received
March 2022	A copy of the formal IRB approval will be provided to USDOT along with a transmittal email from the UW ITS4US team.	IRB Approval expected	Satisfactory response to IRB feedback

Planned Timing	Confirmation Material	Description	Dependencies
March 2023	Summary memo will be provided to USDOT, with details of any changes required by IRB, and proof of confirmation by UW IRB.	Annual IRB update application	2022 IRB approval Submission of adverse impacts report
March 2024	Summary memo will be provided to USDOT, with details of any changes required by IRB, and proof of confirmation by UW IRB.	Annual IRB update application	2023 IRB approval Submission of adverse impacts report
March 2025	Summary memo will be provided to USDOT, with details of any changes required by IRB, and proof of confirmation by UW IRB.	Annual IRB update application	2024 IRB approval Submission of adverse impacts report
March 2026	Summary memo will be provided to USDOT, with details of any changes required by IRB, and proof of confirmation by UW IRB.	Annual IRB update application	2025 IRB approval Submission of adverse impacts report

Appendix A. Definitions, Acronyms, and Abbreviations

This appendix includes a list of acronyms and a glossary of key terms used in the document.

Acronym	Definition
AD	Application developer
ADA	Americans with Disabilities Act
AI	Artificial intelligence
API	Application program interface
ATTRI	Accessible Transportation Technologies Research Initiative
BAA	Broad Area announcement
ConOps	Concept of Operations
COVID	Coronavirus disease
DG	Data generator
DMP	Data Management Plan
DOT	Department of transportation
DRSB	Deployment Readiness Summary Briefing
DS	Data service provider
DU	Digital device end user experiencing travel barriers
ETRA	Enabling Technology Readiness Assessment
FHWA	Federal Highway Administration
FTA	Federal Transit Administration
GIS	Geographic information systems
GOFS	General On-Demand Transit Feed Specification
GTFS	General Transit Feed Specification
GTFS-Flex	The Flex route extension to the General Transit Feed Specification, designed to describe demand-responsive or paratransit service
GTFS-Pathways	The Pathways extension to the General Transit Feed Specification which defines pathways linking together locations within stations
HSD	Human Subjects Division
HUA	Human Use Approval
ICTDP	Integrated Complete Trip Deployment Plan
IDE	Investigational Device Exemption
IE	Independent Evaluation
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IND	An application submitted to the Food and Drug Administration (FDA) whereby a drug sponsor requests authorization from the FDA that

Acronym	Definition
	will allow the interstate transport of investigational agents for administration to humans
IRB	Internal Review Board
ISO	International Organization for Standardization
IT	Information technology
ITS	Intelligent transportation system
ITS JPO	Intelligent Transportation Systems Joint Programs Office
ITS4US	The name of a USDOT program to enable communities to showcase innovative business partnerships, technologies, and practices that promote independent mobility for all that is led by the Intelligent Transportation Systems Joint Program Office with support from the Office of the Secretary of Transportation, Federal Transit Administration, and Federal Highway Administration.
LEP	Limited English proficiency
LiDAR	Light detection and ranging
MARC	Mid-Atlantic Regional Council
MOOVEL	A software services provider to transit agencies
MVP	Minimum viable product
OGC	Open Geospatial Consortium
OSM	OpenStreetMap
OST	Office of the Secretary
OSW	OpenSidewalks
PII	Personally Identifiable Information
PMESP	Performance Measurement and Evaluation Support Plan
PMP	Project Management Plan
PPNA	Personalized pedestrian network analysis
PTSEP	Participant Training and Stakeholder Education Plan
REST API	Representational State Transfer Application Program Interface
ROI	Return on investment
SEMP	Systems Engineering Management Plan
SMP	Safety Management Plan
SOP	Standard Operating Procedures
SyRS	System Requirements Plan
Taskar Center or TCAT	Taskar Center for Accessible Technology at the University of Washington
TCRP	Transportation Cooperative Research Program
TDEI	Transportation Data Equity Initiative
TRAC	Washington State Transportation Center at the University of Washington
TSP	Transportation service provider
U.S.	United States
U.S. DOT	United State Department of Transportation

Acronym	Definition
USGS	United States Geological Survey
UW	University of Washington
VA	Veterans Affairs
W3C	World Wide Web Consortium

Appendix B. References

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Appendix C. IRB Documentation

An IRB approval letter will be added to this appendix when it is received.

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