Phase 2 Human Use Approval Summary (HUAS)

Buffalo, NY ITS4US Deployment Project

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Report — June 24, 2024

FHWA-JPO-21-898

ITS4US

IT'S TRANSPORTATION FOR ALL OF US

U.S. Department of Transportation

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Intelligent Transportation Systems Joint Program Office
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Notice

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15. Supplementary Notes

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16. Abstract

The Buffalo NY ITS4US Deployment Project seeks to improve mobility to, from and within the Buffalo Niagara Medical Campus by deploying new and advanced technologies with a focus on addressing existing mobility and accessibility challenges. Examples of the technologies to be deployed are electric and self-driving shuttles, a trip planning app that is customized for accessible travel, intersections that use tactile and mobile technologies to enable travelers with disabilities navigate intersections, and Smart Infrastructure to support outdoor and indoor wayfinding. The deployment geography includes the 120-acre Medical Campus and surrounding neighborhoods with a focus on three nearby neighborhoods (Fruit Belt, Masten Park, and Allentown) with underserved populations (low income, vision impaired, deaf, or hard of hearing, wheeled mobility device users and older adults).

This document describes the Human Use Approval Plan (HUAP) for Phase 2 of the Buffalo All Access Deployment in Buffalo, NY. It identifies this project's Institutional Review Board (IRB) as the University of Buffalo (UB) IRB, summarizes the content of a modified and updated Phase 2 IRB application.

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Revision History

Name	Date	Version	Summary of Changes
NFTA	February 3, 2022	1	Phase 1 HUAS
RSG	April 19, 2024	1	Phase 2 HUAS
RSG	May 15, 2024	2	Revised Phase 2 HUAS
RSG	June 24, 2024	2.1	Updated Phase 2 HUAS

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1 Introduction

Buffalo, New York (NY) is one of five sites selected for U.S. Department of Transportation (USDOT) Buffalo All Access - ITS4US Deployment Program, which seeks to integrate innovative technologies to improve mobility and accessibility for underserved populations. The Buffalo, NY project plans to deploy an integrated set of travel support services and systems within neighborhoods surrounding Buffalo Niagara Medical Campus (BNMC) to meet these goals. The project team is not only developing the technologies, but also conducting performance measurement and evaluation research for the Buffalo NY ITS4US Deployment Project. The project is now in Phase 2: System Design and Test, having successfully completed Phase 1: System Concept Development. Phase 2 is focused on establishing working end-to-end data collection and processing capabilities and on the collection and processing of baseline data to support performance measurement activities.

1.1 Document Purpose

This document summarizes the updated content of a modified Phase 2 Institutional Review Board (IRB) application to conduct the performance measurement and evaluation research. This modified IRB application was submitted to University of Buffalo Institutional Review Board (UBIRB), and it was approved on March 26, 2024 (see Appendix A). This technical report also presents in Appendices other approved human subjects-facing materials, including consent form, study flyer, pre-deployment questionnaire, and post-deployment questionnaire.

Team discussions regarding IRB topics have included open 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. 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 USDOT.

1.2 Project Overview

The Buffalo All Access ITS4US project will deploy technologies aimed to enhance the mobility accessibility and inclusion of underserved travelers, as well as individuals who need access to the jobs and health care services at the BNMC. To provide a seamless complete trip, the Buffalo, NY ITS4US technologies include:

- The *Buffalo All Access* App, a trip planning app that is accessible for registered users, including people with vision, hearing, and mobility disabilities.

- Community Shuttle Service (both human-operated and self-driving shuttles) that will be used only by registered users of the *Buffalo All Access* App and provides circulation in BNMC campus and Fruit Belt/Masten Park/Allentown neighborhoods near the campus.

- Smart Infrastructure improvements within and around BNMC, such as adding communication, connectivity and traveler information technologies to the sidewalks, loading/parking areas, bus shelters, intersections, and wayfinding technologies in indoor and outdoor venues. This technology is accessed only through the *Buffalo All Access* App.

The technologies will be used by study participants, defined as those who have registered to use the *Buffalo All Access* App and have agreed to participate in the performance measurement and evaluation research. However, people can elect to use the app in "Guest Mode" if they do not wish to register to participate in the research. In Guest Mode, people can get a preview of how the app can be used to plan trips but cannot use any other app capabilities. Any data entered into the app by those using Guest Mode will not be saved or used for project analysis, so they will not be active research participants.

The research involving human subjects will assess whether the technologies deployed in the Buffalo ITS4US project improve accessibility to the BNMC for persons who are older (age 65+); low-income; have vision, hearing, or mild cognitive impairments; are wheelchair users or have mobility impairments and those to travel there for employment or health services purposes. It will explore travelers' current travel experiences including challenges and determine the degree to which the deployed technologies mitigate these issues. Caregivers are also considered in this project given their role assisting and/or accompanying the participants of interest in their travel. As such, all matters described in this document would apply to them as well. The ICF/UB team will investigate NY ITS4US technology users' levels of satisfaction with using the deployed technologies and whether trip planning and execution is enhanced.

This research will use before and after user surveys, in combination with data collected in the app itself recording planned and executed trips, to assess whether the deployed technologies were effective in improving the mobility of underserved populations. Researchers will be collecting data using app-based, telephone, and web-based surveys as well as operations data drawn from usage of the *Buffalo All Access* app and the community shuttles to draw conclusions and answer research questions. The research results will help enable others to understand and build upon the investments made in this project to facilitate incorporating ITS4US strategies such as Buffalo All Access more effectively in other future deployments.

1.3 Definitions, Acronyms, and Abbreviations

Table 1 lists the acronyms used in the document.

Table 1. List of acronyms

Acronym	Description
BNMC	Buffalo Niagara Medical Campus
FHWA	Federal Highway Administration
IRB	Institutional Review Board
NY	New York
PMESP	Performance Measurement and Evaluation Support Plan
U.S.	United States
UB	University at Buffalo
USDOT	U.S. Department of Transportation
UBIRB	University at Buffalo Institutional Review Board
VIA	Visually Impaired Advancement Center
WNY	Western NY

2 Human Subjects Research Plan

This section summarizes the project elements that involve or relate to human subject research. Content for this section was largely drawn from the revised Phase 2 IRB application.

2.1 Research Questions

The research involving human subjects will evaluate whether the deployed technologies enhance the mobility of underserved persons and others (i.e., workers and visitors) traveling to/from the BNMC and within their neighborhoods. Several hypotheses will be explored:

- The deployed technologies will be perceived as useful in improving mobility by the study participants.
- The deployed technologies will be perceived as enabling affordable mobility.
- The deployed technologies will make traveling to/from the BNMC and other locations more efficient.
- The deployed technologies will make traveling to/from the BNMC and other locations more reliable.
- The deployed technologies will make traveling to/from the BNMC and other locations safer.

2.2 Interactions with Other Tasks and Consistency

This revised document reflects the ongoing coordination among the research team 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 USDOT. In particular, much of the material included in the Phase 1 IRB application was produced in other tasks and incorporated (either directly or in some summary form) into the initial IRB application. The updated content for the Phase 2 IRB application reflected continuing interaction and information sharing among the entire project team. Few substantive changes were made relative to the Phase 1 application. These were:

- The Phase 1 IRB application listed a more restricted set of screening criteria for who would be invited to participate in the research. Although the recruitment process will still focus on those with disabilities, advanced age, low incomes, and BNMC employees, the only restrictions on participation stated in the revised application are that participants have to be age 18 or older and have traveled to or from the BNMC in the last year. This change was made to be more inclusive (“all access”), and to better reflect non-experimental deployments where such an app will be available to a wider population.
- The revised 2024 application stated that some of the app capabilities will be available to people who do not consent to participate in the research. This is the case, although “Guest Mode” will only allow a preview of the trip planning function, and data from such

people will not be used in the research. The revised IRB submittal and consent form in the revised appendices clarify this.
- The “detailed risk” sections of the IRB submittal and consent form were updated to add more information on the possible risk of using the self-driving shuttle. Although we still consider the risk to be minimal, extra information was provided.
- In Phase 1, it was thought that all who completed surveys would receive direct cash incentives. It is now planned that those who complete surveys will be enrolled in prize drawings for up to $500 for each survey phase. This change is noted in the revised IRB application.

2.3 Considerations for Vulnerable Populations

The USDOT’s Buffalo All Access ITS4US program aims to mitigate mobility challenges for underserved travelers through the funding of pilot deployment of innovative and emerging mobility technologies, services, and vehicles. As such, this research involving human subjects focuses on underserved travelers, but not exclusively. Underserved travelers are defined as those who are age 65+, low income (below $25,000 in total annual income), and persons who have a disability (i.e., vision impairment, hearing loss, mobility impairment, mild cognitive impairment).

We expect that the caregivers that participate in the study will be caretakers of older persons or persons with impairments who regularly travel with the care recipient to/from the BNMC. The caregiver will answer the evaluation questions based their point of view as to how the system helped them in their travel assistance duties. It may be that both the care recipient and a caregiver participate in the study; however, the priority will be on facilitating the participation of care recipients who represent the underserved groups.

Study participants can include persons other than underserved travelers. These persons include BNMC workers and those who visit the BNMC for healthcare services. It also includes residents of the Fruit Belt and Masten Park neighborhoods near the BNMC and caregivers for underserved travelers. Other study participants will not only provide useful information about the performance of the deployed technologies, but also will serve as a quasi-experimental control group for the underserved travelers. The priority will be on recruiting underserved travelers as study participants. To the extent necessary so that underserved travelers receive proper attention during the research, the number of other study participants may be capped so as not to overwhelm the sample and obscure the findings among underserved travelers.

All participants will be English speaking. English, however, need not be the participant’s primary language. All participants must also be 18 years of age or older, and they must be able to independently understand the consent form and give consent to participate in the study.

The research team is offering an incentive to participate in the research that may constitute an inducement to participate in a study in which they otherwise would not participate. The incentives are the same for all recruited participants who complete four surveys over an 18-month period (i.e., inclusion in a drawing to win $500).

As discussed in the IRB application, this research does not involve prisoners or children. It is possible that a participant may be pregnant during her participation in the research. In such cases, no portions of the protocol pose any risk to the woman or fetus and do not involve interventions/invasive procedures to the participant.

2.4 Informed Consent

Subjects' eligibility to participate in the study will be screened during the *Buffalo All Access* App download and registration process. Potential participants (or caregivers) will be asked to review a consent form upon downloading the *Buffalo All Access* app and beginning the registration process. Upon downloading the app, potential study participants will encounter both the 'Terms & Use' and 'Consent Form,' where they will be prompted to review the content, verify their eligibility, and either agree or disagree with the provided statements. Potential participants will have as much time as needed to review the consent notice and provide their consent prior to completing the app registration process. Study participants will have to approve the terms of use and consent form prior to participating in any performance measurement or evaluation activities.

Individuals who choose not to consent to register to participate in the study will be given the option of using the app in "Guest Mode", which allows only a preview of the trip planning capabilities, but none of the other app features. No data from Guest Mode will be analyzed as part of the research... Upon agreement to the terms and conditions, participants will proceed to create a profile for registration and login to the app for usage. During the registration process, participants will be asked to provide a respondent ID (e.g., email address). The e-mail address is then encrypted to provide a confidential ID that can be used to link data files.

Individuals (or their caregivers) must have the cognitive capacity to read and understand the consent document. The research does not focus on cognitively impaired individuals. Those that cannot independently understand the consent form and give consent will be excluded from the study; however, caregivers of such individuals could be eligible if they can independently understand the consent form and give consent.

A revised consent form was submitted with the modified Phase 2 IRB application. It was approved by the UB IRB on March 26, 2024. It is presented in Appendix B.

2.5 Participant Questionnaires/Evaluation

Performance measurement and evaluation research data collection will take place at four points in time: 1) prior to the pilot field deployment of the technologies to serve as a baseline, 2) about 3 months after the start of the pilot field deployment, 3) about 9 months after the start of the pilot field deployment, and 4) about 18 months after the start of the pilot field deployment and prior to the end of the pilot deployment.

The survey link will be disseminated via email to individuals who have provided consent to participate in the study. Surveys will be administered via the research team's custom web-based survey platform and also by telephone. The pre-deployment (baseline) questionnaire will be distinct from the post-deployment questionnaire. The questionnaires are included as Appendices C and D. Upon completion of all four surveys, participants will be eligible for inclusion in a raffle to receive up to $500. Data from the survey iterations will be linked via a respondent ID number.

Data collected from the surveys will include demographic information, trip-making to/from the BNMC, challenges to trip-making, perceptions of the utility, ease, and safety of travel using the deployed technologies, and satisfaction with the deployed technologies.

In addition to the web-based surveys, a single prompted question will be presented on the *Buffalo All Access* app after each trip to assess trip satisfaction.

In addition to the survey data, passive data will also be captured in the same general time frame in which the surveys are being administered to reduce burden on respondents. Passive data are from the *Buffalo All Access* app and the community shuttle operations

center. Such data will include registration and app usage information such as frequency, time of day, etc., as well as trip information such as trip planning, trip booking, and trip execution (e.g., mode, location). Such data will be tied to the survey data via the respondent ID of study participants to protect personally identifiable information and will be collected and stored only for those persons who have consented to be a part of the study. While possible, specific geolocations will not be captured also to protect personally identifiable information.

Aggregate summaries of all data will be available to study participants, the general public, and research team members through a Performance Measurement Dashboard that has its own data management plan. The type of aggregate information displayed will include:

- *Buffalo All Access* app overall satisfaction summary
- *Buffalo All Access* app registrations
- Use of *Buffalo All Access* app preferences, trip planning, and booking functionalities
- Use of the community shuttles.

2.6 Participant Data

Because this evaluation research will track specific respondents over time, it is necessary to ask recruited participants for their name, zip code, email, and contact number. The personally identifiable information collected during recruitment will then be stored in separate, password protected files within a secured database. This information will not be linked to any survey data and will be under the stewardship of the University at Buffalo. A registered user's email address is collected only at the time of registration and one-way (non-reverable) encryption is used to create a respondent ID based on the email address. The email address is used only to send survey invitations. All data files other than that from the initial registration will only list the encrypted respondent ID for the purpose of matching participants between surveys and app data. (Those using the app in Guest Mode will not be asked to provide email address or any other personal information.) Access to the survey data will be limited to users who must meet IRB requirements. According to the UB IRB guidelines, all personnel with access to the raw data need to complete the required CITI training courses. All courses must be the University at Buffalo prescribed CITI courses. The independent evaluation team (IE) for this pilot deployment could have access aggregated performance data processed by persons with access to the raw data and forwarded to the IE team.

2.7 Recruitment Design

We will recruit participants via three non-probability sampling strategies. This is because the underserved populations are difficult to sample in adequate numbers using probability sampling strategies such as address-based sampling (ABS) or random digit dialing (RDD). Three types of sampling approaches, covering multiple strategies, will be used to ensure that enough participants are recruited to participate in the study. The sampling strategies are:

- **Convenience sampling**: We will station interviewers at various locations at the BNMC campus to describe the research opportunity and the incentive structure and then to invite them to participate in the evaluation study.
- **Voluntary response sampling**: We will place flyers (see Appendix E) in neighborhoods near to the BNMC, and on the campus, which describe the research opportunity and the incentive

structure and invite people to volunteer themselves for the evaluation study. A toll-free phone number and a web link will be offered for people to contact the research team.

- **Targeted outreach**: Recruitment will be done via community-based organizations in the neighborhoods surrounding the BNMC, particularly the Fruit Belt neighborhood. We would also recruit through community services organizations such as ASPIRE of WNY, WNY Independent Living Center, Inc., or the New York State offices of vocational rehabilitation. Community-based or community services organizations that will assist with recruitment are formally contracted under the grant. Any community member who assists participants with completing the consent form will first go through IRB training. The flyer will be emailed to the organization contact for distribution. The project team also expects to sample NFTA paratransit (PAL) subscribers through the service's database. Since NFTA will be the lead agency for Phases 2 and 3 of this project, we assume that NFTA will send out the study opportunity to PAL subscribers. The project team will provide NFTA with the recruitment flyer, which will then be passed along to their subscribers.

Recruitment will continue until a minimum of 100 participants are obtained by the end of Phase 2, with this number being expanded to 500 participants as the study advances into Phase 3.

2.8 Training of Participants

Users of the system will need to take training to clearly understand how the system works and its capabilities (i.e., what it can and cannot do). The details of the training are available in the Phase 1 Participant Training and Stakeholder Education Plan (FHWA-JPO-21-903). The training plan details the different education and training modules available and links them to the several user groups that would need to take them. Furthermore, the training procedure and materials are governed by the IRB, which the latest round was approved on March 26, 2024—see Section 3 for more details.

Note that users are not the only ones that will need training. People involved with the operation of the system may also need some level of training. For instance, call center operators will need to be trained on how to use the system to support users when making a reservation. Their training is also detailed in the training plan.

2.9 Team Human Subjects Research Training

Relevant members of the ICF-UB research team who will access participant data for quality assurance, processing, or analysis, already have completed the University at Buffalo prescribed Collaborative Institutional Training Initiative (CITI Program) courses (https://about.citiprogram.org/). This is required for anyone who has or wants access to the data, regardless of whether they use that data or not, or the frequency with which they access the data.

3 Protocol/Application Summary

This section summarizes the formal Institutional Review Board application process and documentation.

3.1 Institutional Review Board

The Institutional Review Board (IRB) being used by the project is the University at Buffalo (UB). UB's Human Research Protection Program protects the rights of research volunteers, guided by a 1964 World Medical Organization declaration: "In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject." UB researchers are integral members of the project team.

3.1.1 Federal-wide Assurance

The Federal-wide Assurance Number assigned to the UB IRB by the US Department of Health & Human Services is ID#: FWA00008824.

3.2 IRB Review Process

IRB application templates provided by UB (for the protocol and informed consent) were used for the initial IRB submission in Phase 1 and also for the updated and modified Phase 2 IRB application. The results of the Phase 1 IRB review were that the UB IRB granted the project exempt status due to minimal risks posed to participants Exempt status means that minor changes in research design do not need to be submitted to the IRB, although the study team chose to do so in this project, and then to do so once again to address US DOT suggestions. In addition to the IRB application, other materials submitted and reviewed for the Phase 2 modifications included: the IRB consent notice, the pre- and post-deployments survey questionnaires, and the project flyer. (The relevant documents are attached as Appendices A-E.) Collectively, they presented all the necessary information to be provided for the review process. Jordana Maisel, a member of the research team and assistant professor in UB's department of urban and regional planning and director of research at UB's IDEA Center, submitted the updated and modified Phase 2 IRB application for this project to the UB IRB on February 23, 2024. Approval was received on March 26, 2024. A revised IRB application was submitted on June 6, 2024 and approval was received on June 12, 2024. Appendices A and B reflect this latest submittal. Ensuring IRB Understanding of the Project

The IRB application protocol template provided by UB required very detailed information on project plans, research participants, recruitment and screening, and project procedures covering the deployed technologies. The information submitted in response to these requirements was sufficiently detailed such that the IRB reviewers were able to understand the planned technologies. The updated Phase 2 IRB text on study design is presented in the following paragraphs.

This is evaluation research conducted as part of the US Department of Transportation's Buffalo All Access - ITS4US Deployment Program, which aims to solve mobility challenges for all travelers with a specific focus on underserved communities through technology deployment. Buffalo is one of four selected demonstration sites. The Buffalo ITS4US project will be completed in three phases: Phase 1 – Technology Concept Development; Phase 2 – Technology Design and Test; and Phase 3 – Technology Deployment and Evaluation. Human subjects data collection will occur in Phase 2 and Phase 3.

This research will use an experimental design to assess whether the deployed technologies were effective in improving the mobility of underserved populations. Researchers will be collecting data using app-based, telephone, and web-based surveys as well as operations data drawn from usage of the Buffalo All Access app and the community shuttles to draw conclusions and answer research questions

Use of the Buffalo All Access app is by registered users. Use of the community shuttle service will be registered users of the app only. The indoor and outdoor navigation and smart infrastructure technologies are accessed only through the app. However, not ALL registered users are also study participants.

In Phase 2, survey questions for both the baseline and post-deployment surveys will be reviewed by organizations serving persons with disabilities and older adults to ensure question clarity, appropriate response categories, and the use of appropriate language regarding the disabilities of focus. VIA, for instance, provides review and consulting services for research involving blind and low vision persons and we will seek similar assistance from organizations serving persons with mobility disabilities, hearing loss, and persons 65 and older.

We will pilot test the survey questions with members of VIA so these are evaluated for accessibility. Such testing typically involves the use of widely used screen reading technology, typically NVDA and JAWS. The survey will also be evaluated for compatibility with screen magnification technologies like Zoom Text. The research team, as necessary, will iteratively modify the deployed survey based on feedback from these organizations until reaching a satisfactory level of accessibility.

Participant Recruitment

This research is an evaluation of the deployed technologies. We will recruit participants using the strategies outlined in Section 11.1.

Recruitment will initially involve the aforementioned strategies (i.e., convenience, targeted, and voluntary). Subsequently, flyers will be distributed to residences in nearby neighborhoods, and the PAL database will be utilized. Additionally, outreach efforts will target various community-based and community serving organizations to attain the

desired numbers of participants. Recruitment will continue until a minimum of 100 participants are obtained by the end of Phase 2, with this number being expanded to 500 participants as the study advances into Phase 3.

Interventions & Consent Process

Participants will be required to utilize one of the deployed technologies, namely the *Buffalo All Access* app, which incorporates state-of-the-art accessibility features. They will be prompted to download the app from the app store. Upon downloading, users will encounter both the 'Terms & Use' and 'Consent Form,' where they will be prompted to review the content, verify their eligibility, and either agree or disagree with the provided statements. Individuals who choose not to consent to participate in the study will still retain access to the app and other deployed technologies. Upon agreement to the terms and conditions, participants will proceed to create a profile for registration and login to the app for usage. During the registration process, participants will be asked to provide a respondent ID (e.g., email address).

Data Collection

The evaluation surveys will take place at four points in time: 1) prior to the pilot field deployment of the technologies to serve as a baseline, 2) about 3-6 months after the start of the pilot field deployment, 3) about 9 months after the start of the pilot field deployment, and 4) about 18 months after the start of the pilot field deployment and prior to the end of the pilot deployment. The survey link will be disseminated via email to individuals who have provided consent to participate in the study. Surveys will be administered via research team's custom web-based survey platform and also by telephone. The baseline questionnaire will be distinct from the post-deployment questionnaire. The questionnaires are included. Upon completion of all four surveys, participants will be eligible for a raffle to receive up to $500. Data from the survey iterations will be linked via a respondent ID number.

In addition to the web-based survey, a single prompted question will be presented on the app after each trip to assess trip satisfaction.

In addition to the survey data, passive data will also be captured in the same general time frame in which the surveys are being administered to reduce burden on respondents. Passive data are from the *Buffalo All Access* app and the community shuttle operations center. Such data will include registration and app usage information such as frequency, time of day, etc., as well as trip information such as trip planning, trip booking, and trip execution (e.g., mode, location). Such data will be tied to the survey data via the respondent ID of study participants to protect personally identifiable information and will be collected and stored only for those persons who have consented to be a part of the study. While

possible, specific geolocations will not be captured also to protect personally identifiable information.

3.3 Relevant IRB Procedures

The SUNY University at Buffalo IRB (UBIRB) approved the updated and modified application on March 26, 2024. The modification materials for the project referenced above were reviewed and approved by Non-Committee Review. The UBIRB has determined that the materials submitted as part of this modification do not change the Exempt status of the research study, according to 45 CFR Part 46.104. There is no expiration date. This UB IRB determination was given with the understanding that the proposed study design will be followed. If modifications are needed that significantly alter the purpose, design, or data collected, then those changes should be submitted to the IRB to determine if the modifications alter the research such that the criteria for an exempt determination are no longer met.

A revised IRB application was submitted on June 6, 2024 and approval was received on June 12, 2024. Appendices A and B reflect this latest submittal.

4 Human Use Approval

The study team has received IRB approval on its Phase 2 application and on a revised Phase 2 application. The approval letter from the IRB is included at the end of Appendix A.

4.1 Type of Review

The project involves non-clinical behavioral research. The type of review conducted by the IRB was a non-committee review, meaning that an IRB was not convened to review the application. The review was conducted by a single individual that has been designated as a qualified IRB reviewer. No other reviews were required by the IRB in its approval letter.

4.2 Approval Status

The study team has received IRB approval on its Phase 2 application submitted in February 2024, and then received approval of an updated application submitted in June 2024. The research was deemed exempt according to 45 CFR Part 46.104, meaning that the research qualifies as no risk or minimal risk to subjects and is exempt from the requirements of the Federal Policy for the Protection of Human Subjects.

4.3 Feedback from IRB Review

The team received no feedback from the IRB other than the notice at the end of Appendix A.

4.4 Conditions

This UB IRB determination was given with the understanding that the proposed study design will be followed. If modifications are needed that significantly alter the purpose, design, or data collected, then those changes should be submitted to the IRB to determineif the modifications alter the research such that the criteria for an exempt determination are no longer met.

5 Future Steps and Schedule

This section presents currently known future steps relating to Human Use Approval and serves as a plan for future supporting activities in later Phases.

IRB approval has been obtained (see Appendix A). The UB IRB determined on March 26, 2024 and again on June 12, 2024, that the research is Exempt according to 45 CFR Part 46.104. There is no expiration date to this approval. However, if the research design differs significantly, the modifications need to be submitted to the UB IRB.

Appendix A. IRB Submittal

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Complete Research Protocol (HRP-503)

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Template Instructions

Sections that do not apply:

In several sections, the addition of checkboxes for ***Not Applicable*** *have been added to the template as responses.*

If an N/A checkbox is present, select the appropriate justification from the list.

If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.

In addition:

For research where the only study procedures are records/chart review: Sections 6, 21, 22, 24, 25, 26 and 27 do not apply.

For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.

Studies with multiple participant groups:

If this study involves multiple participant groups (e.g., parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:

Response Example
Intervention Group:
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- *Update the version date or number* ***on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response:

Evaluation Research for the Buffalo NY ITS4US Deployment Project

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

Jordana Maisel

Associate Professor; Director of Research, Center for Inclusive Design and Environmental Access

(716) 829-5902

jlmaisel@buffalo.edu

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response:

Version 4.0

June 6, 2024

REVISION HISTORY

Revision	Version Date	Summary of Changes	Consent Change?
Version 2.0	December 6, 2021	Responded to comments of IRB reviewer	
Version 3.0	February 23, 2024	Updated protocol details	yes
Version 4.0	June 6, 2024	Funding agency requested us to elaborate on minimal risk associated with riding the community (self-driving) shuttle (particularly in the consent documents), as well as eliminate	yes

Revision	Version Date	Summary of Changes	Consent Change?
		mention of CTP and refer to app as Buffalo All Access app	

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response:

This protocol is being funded by the USDOT through its Buffalo All Access - ITS4US Deployment Program

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g., NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response:

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

Location: 309 Hayes Hall (secured computer and locker)

Address: 3435 Main Street, Buffalo, NY 14214

Department: Architecture/IDEA Center

1. Study Summary

Study Title	***Evaluation Research for the Buffalo NY ITS4US Deployment Project***
Study Design	Individuals in and around the Buffalo Niagara Medical Campus, will be invited to download the *Buffalo All Access* app for trip planning, as well as use of a community shuttle (human-operated and self-driving) and smart crosswalk technology.

	A Pre-Post-Post-Post Design will be utilized. Data collection occurs (1) Pre-deployment as a Baseline to serve as a control group (2) Initial post-deployment after 3 months of deployment, (3) Mid-term deployment about half-way between start and end of deployment, and (4) Final deployment at end of deployment. In all, about 18 months. Data sources are: (1) survey (trip planning app or online), and (2) non-survey (performance metrics from the trip planning app, information from the performance management dashboard, and data from the shuttle operations center).
Primary Objective	The purpose of this research is to evaluate whether the technologies deployed in the Buffalo NY ITS4US project (i.e., a transit planning application platform (*Buffalo All Access*), human-driven and self-driving community shuttle services, indoor and outdoor guidance, and smart intersection crossing technologies) improve accessibility to the Buffalo Niagara Medical Campus (BNMC) as well as around their neighborhoods for travelers with disabilities, older adults and low-income travelers (especially those without access to personal automobiles).
Secondary Objective(s)	None
Research Intervention(s)/ Investigational Agent(s)	The intervention is the deployed technologies: a transit planning application platform (*Buffalo All Access*), human-driven and self-driving community shuttle services, indoor and outdoor navigation, and smart intersection crossing technology.
IND/IDE #	
Study Population	Study participants must be age 18 or over and work and/or travel to the Buffalo Niagara Medical Center.
Sample Size	100 individuals recruited to begin, increased to up to 500 individuals during the technology deployment.
Study Duration for individual participants	The surveys should take 15-20 minutes to complete.
Study Specific Abbreviations/ Definitions	Human driven shuttle (HDS) Self-driving shuttle (SDS)

2. Objectives*

Describe the purpose, specific aims, or objectives of this research.

Response: Buffalo, New York (NY) is one of five demonstration sites selected for the U.S. Department of Transportation (USDOT) Buffalo All Access – ITS4US Deployment Program, which seeks to deploy innovative technologies to improve mobility and

accessibility for underserved populations. This research will assess whether the technologies deployed in the Buffalo ITS4US project improve accessibility to the BNMC (and other desired destinations) for all travelers (for employment or health services purposes), including individuals who are older (age 65+), low-income, have vision, hearing, or mild cognitive impairments, are wheelchair users or have severe mobility impairments. It will explore travelers' current travel experiences including challenges and determine the degree to which the deployed technologies mitigate these issues. We will investigate their levels of satisfaction with using the deployed technologies and whether trip planning and execution is enhanced. The research results will help enable others to understand and build upon the investments made in this project to facilitate incorporating Buffalo All Access – ITS4US strategies more effectively in other future deployments.

State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response:

The deployed technologies will be perceived as useful in improving mobility by the participants.

The deployed technologies will be perceived as enabling affordable mobility.

The deployed technologies will make traveling to/from the BNMC and other locations more efficient.

The deployed technologies will make traveling to/from the BNMC and other locations more reliable.

The deployed technologies will make traveling to/from the BNMC and other locations safer.

3. Scientific Endpoints*

Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response: The primary endpoint is the end of deployment when mobility of participants has been improved through the deployed technologies.

4. Background*

Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

The USDOT's Buffalo All Access – ITS4US Deployment Program aims to mitigate mobility challenges for underserved travelers with a specific focus on people with disabilities, older adults, low-income individuals, through the funding of pilot deployment of innovative and emerging mobility technologies, services, and vehicles. An aspirational benefit of new mobility services for example is that they may provide transportation for those who are underserved and disadvantaged either by not being able to drive because of disability, age, or car access (Zmud and Reed, 2018). But adequate empirical research is not available to ascertain whether this is indeed the case and also whether programs like the USDOT's Buffalo All Access ITS4US is meeting its objectives.

For example, people with disabilities, a specific focus of the USDOT activities, experience a broad range of travel limitations and associated needs. Overall, people aged 18 to 64 with disabilities make fewer trips per day on average than people without disabilities (2.6 v. 3.6 trips) (Brumbaugh, 2018). People aged 65 and older with disabilities make significantly fewer trips than those without disabilities (Zmud, et al., 2017). In the US, they make an average of 2.1 trips per day versus 3.5 trips for people without disabilities (Brumbaugh, 2018). According to the National Household Travel Survey (2017) people with disabilities simply travel less often:

- Reducing day-to-day travel (70.6 percent)
- Giving up driving (21.6 percent)
- Using public transit less often (14.4 percent).

Technology may help people with disability-related transportation limitations in three ways: 1. Technology can connect people to paratransit and ride-hailing services which can accommodate their special needs. 2. Technology can help people navigate through unfamiliar places or unsafe infrastructure conditions 3. Autonomous vehicles (AV) and other assistive technologies may decrease the cost of travel as well as help people who previously could not drive. The NHTS (2017) does not ask about using technology to compensate for transportation issues. It does, however, have data showing that people with disabilities use related technologies less often than people without disabilities. But there is little research to understand why this is the case.

Likewise low-income persons are a demographic that require reliable and affordable transportation. They are less likely to own a private vehicle, thus, increase the importance of having easy access to public transportation (Agrawal, et al., 2011). In addition to cost, challenges

include fare systems that require credit cards and limited transit service in off-peak times (Sener et al, 2021). In low-density cities with sparse public transport services, a private car can be a critical factor in finding (and keeping) paid employment – creating a structural barrier for low-income households. A study by a USC student (Junken, 2015) visualized public transit data from 43 U.S. metropolitan regions (Levinson 2013; Owen and Levinson, 2014) to compare the accessibility of work by car compared to transit. For Los Angeles, 92 percent of jobs required a public transit commute of greater than one hour as a result of multiple transfers, whereas only 7 percent of jobs required a car commute of greater than one hour, with other U.S. urban regions having a similar ratio.

The Buffalo All Access ITS4US program funds research to develop, test, and deploy technologies that mitigate challenges for underserved populations such as above. A complete trip starts at the trip planning stage and ends when the traveler successfully completes the trip to their final destination (Federal Transit Administration, 2020).

Despite the proliferation of scientific research on mobility technologies, and widespread media attention claiming these services will improve community mobility for underserved populations, there is a dearth of research on how well these new mobility technologies and vehicle designs address the needs of these populations. Since their implementation will be difficult to change once in use, it is imperative that these technologies and vehicles are accessible and usable from the start so that people with disabilities will benefit from their deployment.

Mobility inclusion is not an impact, but a goal, and the role of government (like the USDOT) is to promote and facilitate the adoption of technology solutions in ways that meet the needs and aspirations of all people in a community. The technologies and vehicle designs used, the markets addressed, and the regulations imposed are all factors that may exert a strong influence over how mobility improvement are distributed. This study will gather and analyze information to inform how technologies can lead to more accessible and more inclusive mobility services.

While the overall goal of this work is to address the needs of underserved communities, the focus of this research is to gather feedback and data from all users of the deployed technologies.

Include complete citations or references.

Response:

Agrawal, A. W., Blumenberg, E., Abel, S., Pierce, G., & Dannah, C. (2011). *Getting around when you're just getting by: The travel behavior and transportation expenditures of low-income adults* (No. 10–02). Mineta Transportation Institute. https://rosap.ntl.bts.gov/view/dot/18612

Brumbaugh, S. *Travel Patterns of American Adults with Disabilities.* (2018) U.S. Department of Transportation. https://travel-patterns-american-adults-disabilities-11-26-19.pdf (bts.gov)

Federal Highway Administration. (2018). Summary of Travel Trends. 2017 National Household Travel Survey. https://2017_nhts_summary_travel_trends.pdf (ornl.gov)

Federal Transit Administration. (2020). *Mobility Performance Metrics (MPM) for Integrated Mobility and Beyond.* Mobility Performance Metrics (MPM) for Integrated Mobility and Beyond (dot.gov)

Junken, R. (2015). Job Accessibility: Cars vs Transit. Online. https://transportationist.files.wordpress.com/2015/09/job-accessibility-revised1.png.

Levinson, D. M. (2013). "Access Across America: Auto 2013 Data." Center for Transportation Studies. Minneapolis, MN: University of Minnesota.

Owen, A., and Levinson, D. M. (2014). "Access Across America: Transit 2014 Data." Online. Retrieved May 2018 from https://conservancy.umn.edu/handle/11299/168064.

Sener, I., J. Zmud, C. Viggiano, A. Blair, A. Pulido, D. Kaiser (2021). *Impacts of Transformational Technologies on Underserved Populations: 6Technical Memorandum on Survey Data Analysis to Investigate Travel Behavior and Transportation System Impacts.* Research in Process. https://apps.trb.org/cmsfeed/TRBNetProjectDisplay.asp?ProjectID=4686.

Zmud, J., and Reed, N. (2018). Synthesis of the Socio-Economic Impacts of Connected and Automated Vehicles and Shared Mobility. Proceedings of the 6th EU-US Transportation Research Symposium "Socio-Economic Impacts of Connected and Automated Vehicles." Washington, DC: Transportation Research Board.

Zmud, J., L. Green, T. Kuhnimhof, S. Le Vine, J. Pollack, P. Phleps. (2017). *Still Going…and Going: The Emerging Travel Patterns of Older Adults.* Institute for Mobility Research. A Research Institute of the BMW Group. https://2017_ifmo_senior_generation_mobility_en.pdf

5. Study Design*

Describe and explain the study design (e.g., case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response:

This is evaluation research conducted as part of the US Department of Transportation's Buffalo All Access – ITS4US Deployment Program, which aims to solve mobility challenges for all travelers with a specific focus on underserved communities through technology deployment. Buffalo is one of five selected

demonstration sites. The Buffalo ITS4US project will be completed in three phases: Phase 1 – Technology Concept Development; Phase 2 – Technology Design and Test; and Phase 3 – Technology Deployment and Evaluation. Human subjects data collection will occur in Phase 2 and Phase 3.

This research will use an experimental design to assess whether the deployed technologies were effective in improving the mobility of underserved populations. Researchers will be collecting data using app-based, telephone, and web-based surveys as well as operations data drawn from usage of the *Buffalo All Access* app and the community shuttles to draw conclusions and answer research questions.

6. Study Intervention/Investigational Agent

Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

Response: This research is an evaluation of the deployed technologies. The technologies will also be available to people who do not participate in this study.

Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.

Response: Use of the *Buffalo All Access* app is by registered users. Use of the community shuttle service will be registered users of the app only. The indoor and outdoor navigation and smart infrastructure technologies are accessed only through the app. However, not ALL registered users are also study participants.

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

Identify the holder of the IND/IDE/Abbreviated IDE.
Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response: N/A

7. Local Number of Subjects

Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: We aim to recruit 100 persons in Phase 2 of the study and will attempt to increase that to 500 persons in Phase 3. Evaluation data collection will continue into Phase 3. Alpha and Beta testing of the deployed technologies will be outside of this IRB application.

If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e., your screen failure rate).

Response: While we expect it will be difficult to recruit as many as 500 participants, we believe we can achieve this through non-probability sampling strategies that will be employed as well as the incentive structure.

Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: These individuals will be recruited to participate in the evaluation study using non-probability sampling strategies. This is because these sub-populations are difficult to sample in adequate numbers using probability sampling strategies such as address-based sampling (ABS) or random digit dialing (RDD). Three types of sampling approaches, covering multiple strategies, will be used to ensure that enough participants are recruited to participate in the study.

- **Convenience sampling**: We will station researchers at various locations at the BNMC campus to describe the research opportunity and the incentive structure, and then to invite them to participate in the evaluation study.

- **Targeted outreach**: Recruitment will also be done via community-based organizations in the neighborhoods surrounding the BNMC, particularly the Fruit Belt and Masten Park neighborhoods. We will also recruit through regional community services organizations such as ASPIRE of WNY, WNY Independent Living Center, Inc., or the New York State offices of vocational rehabilitation. Contacting people through trusted community leaders boosts participation levels. The project team also expects to sample Niagara Frontier Transportation Authority (NFTA) paratransit (PAL) subscribers through the service's database. In addition, designated research staff may access the IDEA Center's database of participant contact information from past studies in order to recruit participants for the study.
- **Voluntary response sampling**: We will also place flyers in the neighborhoods near to the BNMC, as well as on the campus, that describe the research opportunity and the incentive structure and invite people to volunteer themselves for the evaluation study. A toll-free phone number and a web link will be offered for people to contact the research team.
- All three strategies may include some level of "snowball" sampling. (Any researcher who assists participants with completing the consent form will first go through IRB/CITI training.)

8. Inclusion and Exclusion Criteria*

*Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

- All participants must be at least 18 years of age to participate.
- Participants can be persons who have traveled to/from the BNMC campus in the past year either for work or for health services.
- Although not required, we will particularly seek participants who are older adults (age 65+), individuals with low income (below $25,000 in total annual income), persons with disabilities (e.g., vision impairment, hearing impairment, severe mobility impairment/wheelchair users), or caregivers of individuals who meet these criteria.

*Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: Those that cannot independently understand the consent form and give consent will be excluded from the study; however, caregivers of such individuals could be eligible if they can independently understand the consent form and give consent.

Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☐ Individuals who are not yet adults (infants, children, teenagers)

☒ Pregnant women

☐ Prisoners

Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may ***not*** *be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response: All participants will be English speaking. English, however, need not be the participant's primary language.

9. Vulnerable Populations*

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response: It is possible that a participant may be pregnant during her participation in the study. No portions of the protocol pose any risk to the woman or fetus and do not involve interventions/invasive procedures to the subject.

☐ **N/A**: This research does not involve pregnant women.

*For research that involves **neonates of uncertain viability or non-viable neonates,** safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

*For research that involves **prisoners**, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

*For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*For research that involves **cognitively impaired adults**, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. ***Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response: Participants with disabilities and older adults will be enrolled in this study. Participation in this research does not involve more than minimal risk to any participants that they would experience in their normal daily lives and does

not involve interventions/invasive procedures to the participants. Participants will be eligible to withdraw their participation at any time during the study without penalty. No identifying information will be collected and responses will not be linked to the participants.

10. Eligibility Screening*

*Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g., screening protocol, script, questionnaire).

Response: Subjects' eligibility will be screened during the app download and registration process. Participants (or caregivers) will be asked to review a consent form upon downloading the *Buffalo All Access* app and completing the registration process, which outlines the eligibility criteria, and verifies that they meet the eligibility requirements. They will have to approve the terms of use and consent form prior to receiving the surveys.

☐ **N/A:** There is no screening as part of this protocol.

11. Recruitment Methods

☐ **N/A:** This is records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g., searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.)

Response: We will recruit participants via three non-probability sampling strategies. All three strategies may include some level of "snowball" sampling.

- **Convenience sampling**: We will station researchers at various locations at the BNMC campus to describe the research opportunity and the incentive structure and then to invite them to participate in the evaluation study.
- **Voluntary response sampling**: We will place flyers in neighborhoods near to the BNMC, and on the campus, that describe the research opportunity and the incentive structure and invite people to volunteer themselves for the evaluation study. A toll-free phone number and a web link will be offered for people to contact the research team.
- **Targeted outreach**: Recruitment will be done via community-based organizations in the neighborhoods surrounding the BNMC, particularly the Fruit Belt neighborhood.

We would also recruit through community services organizations such as ASPIRE of WNY, WNY Independent Living Center, Inc., or the New York State offices of vocational rehabilitation. It is assumed that the research team will provide these organizations with the door hanger text, which will be passed along to known eligible persons. The project team also expects to sample NFTA paratransit (PAL) subscribers through the service's database. Since NFTA will be the lead agency for Phases 2 and 3 of this project, we assume that NFTA will send out the study opportunity to PAL subscribers. We will provide NFTA with the recruitment flyer, which will then be passed along to their subscribers.

Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

- Response: Because this evaluation research will track specific respondents over time, it is necessary to ask recruited participants for their name, zip code, email, and contact number. The personally identifiable information collected during recruitment will then be stored in separate, password protected files within a secured database. This information will not be linked to any survey data and will be under the stewardship of the University at Buffalo. Only the email address will serve as the respondent ID and will be stored in the survey databases for the purpose of matching participants between surveys and app data. Access to the survey data will be limited to users who must meet IRB requirements.

Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response: Materials that will be used to recruit subjects include (1) A flyer that will be posted around the BNMC neighborhoods. (2) Community-based or community services organizations that will assist with recruitment are formally contracted under the grant. Any community member who assists participants with completing the consent form will first go through IRB training. The flyer will be emailed to the organization contact for distribution.

12. Procedures Involved*

*Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response:

Study Preparation

In Phase 2, survey questions for both the baseline and post-deployment surveys will be reviewed by organizations serving persons with disabilities and older adults to ensure question clarity, appropriate response categories, and the use of appropriate language regarding the disabilities of focus. VIA, for instance, provides review and consulting services for research involving blind and low vision persons and we will seek similar assistance from organizations serving persons with mobility disabilities, hearing loss, and persons 65 and older.

We will pilot test the survey questions with members of VIA so these are evaluated for accessibility. Such testing typically involves the use of widely used screen reading technology, typically NVDA and JAWS. The survey will also be evaluated for compatibility with screen magnification technologies like Zoom Text. The research team, as necessary, will iteratively modify the deployed survey based on feedback from these organizations until reaching a satisfactory level of accessibility.

Participant Recruitment

This research is an evaluation of the deployed technologies. We will recruit participants using the strategies outlined in Section 11.1.

Recruitment will initially involve the aforementioned strategies (i.e., convenience, targeted, and voluntary). Subsequently, flyers will be distributed to residences in nearby neighborhoods, and the PAL database will be utilized. Additionally, outreach efforts will target various community-based and community serving organizations to attain the desired numbers of participants. Recruitment will continue until a minimum of 100 participants are obtained by the end of Phase 2, with this number being expanded to 500 participants as the study advances into Phase 3.

Interventions & Consent Process

Participants will be required to utilize one of the deployed technologies, namely the *Buffalo All Access* app, which incorporates state-of-the-art accessibility features. They will be prompted to download the app from the app store. Upon downloading, users will encounter both the 'Terms &

Use' and 'Consent Form,' where they will be prompted to review the content, verify their eligibility, and either agree or disagree with the provided statements. Individuals who choose not to consent to participate in the study will still retain access to the app and other deployed technologies. Upon agreement to the terms and conditions, participants will proceed to create a profile for registration and login to the app for usage. During the registration process, participants will be asked to provide a respondent ID (e.g., email address).

Data Collection

The evaluation surveys will take place at four points in time: 1) prior to the pilot field deployment of the technologies to serve as a baseline, 2) about 3-6 months after the start of the pilot field deployment, 3) about 9 months after the start of the pilot field deployment, and 4) about 18 months after the start of the pilot field deployment and prior to the end of the pilot deployment. The survey link will be disseminated via email to individuals who have provided consent to participate in the study. Surveys will be administered via research team's custom web-based survey platform and also by telephone. The baseline questionnaire will be distinct from the post-deployment questionnaire. The questionnaires are included. Upon completion of all four surveys, participants will be eligible for a raffle to receive up to $500. Data from the survey iterations will be linked via a respondent ID number.

In addition to the web-based survey, a single prompted question will be presented on the app after each trip to assess trip satisfaction.

In addition to the survey data, passive data will also be captured in the same general time frame in which the surveys are being administered to reduce burden on respondents. Passive data are from the *Buffalo All Access* app and the community shuttle operations center. Such data will include registration and app usage information such as frequency, time of day, etc., as well as trip information such as trip planning, trip booking, and trip execution (e.g., mode, location). Such data will be tied to the survey data via the respondent ID of study participants to protect personally identifiable information and will be collected and stored only for those persons who have consented to be a part of the study. While possible, specific geolocations will not be captured also to protect personally identifiable information.

Aggregate summaries of all data will be available to study participants, the general public, and research team members through a Performance Measurement Dashboard that has its own data management plan. The type of aggregate information displayed will include:

- *Buffalo All Access* app overall satisfaction summary
- *Buffalo All Access* app registrations

- Use of *Buffalo All Access* app preferences, trip planning, and booking functionalities
- Use of the community shuttles (both human-operated and self-driven)

Data Analysis

Data will be organized and analyzed using inferential statistics to answer the proposed research questions.

Findings will be summarized and described in a manner that will directly address the study's *research hypotheses*. The expected outcomes from the Buffalo ITS4US pilot are:
More efficient trips for disabled travelers to/from BNMC
Wayfinding capability indoors/ outdoors near BNMC
Enhanced PAL access and support for non-PAL trips
Safer intersection crossing
Improved destination accessibility through shuttle service

Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response: Data collected from the surveys will include demographic information, trip-making before and after the deployment, challenges to trip-making, perceptions of the utility, ease, and safety of travel using the deployed technologies, satisfaction with the deployed technologies, and changes in trip-making with use of the deployed technologies. Identifiers (stored separately from the survey data) will include name, address, contact information (telephone and email). The *Buffalo All Access* app data include information on traveler characteristics and preference provided during the registration process, as well as data from each trip that is planned, booked, and/or carried out using the app. The data can also include frequency of using the app, time using the app, and fidelity of using trip plans while traveling. Data will also be available on each trip made by the Community Shuttle (and PAL-spontaneous) systems. These data include the actual pick-up and drop-off times and locations for all passengers (identified by app user ID), which can be compared against the reservations data to assess on-time performance. Data will also record the start and end time and distance traveled on each vehicle-trip, and identify and classify any vehicle malfunctions, driver or steward interventions, accidents, near-accidents or other problems encountered during each trip. Smart Infrastructure Operations Data: These data include the operating functionality over time of the smart infrastructure (including outdoor and indoor wayfinding infrastructure and smart intersection controls).

List any instruments or measurement tools used to collect data (e.g., questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response: see attached

Describe any source records that will be used to collect data about subjects (e.g., school records, electronic medical records).

Response: *Buffalo All Access* app and community shuttle operations center.

*Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response: N/A

*Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: N/A

13. Study Timelines*

Describe the anticipated duration needed to enroll all study subjects.

Response: This project is completed in three phases over a 44-month schedule (Phase 1=12 months, Phase 2=24 months, Phase 3=18 months. Phase 1 was Concept Development. Phase 2 is to Design and Test the deployed technologies. Phase 2 will follow an agile development approach in terms of technology development and Alpha and Beta testing as well as initial study participant recruitment. It is expected that 100 participants will be recruited late in Phase 2 so that the baseline survey can be administered early in Phase 3. Recruitment will continue throughout Phase 3 to reach up to 500 participants. After the successful completion of Phase 2, the primary risk in Phase 3 is ensuing that the 100 initial participants are maintained in the study and that the number of study participants can be increased up to 500 persons.

Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: It is estimated that participants will require 10 minutes to read the consent notice. After that each of the four subsequent surveys will take about 15-20 minutes to complete.

Describe the estimated duration for the investigators to complete this study (i.e., all data is collected, and all analyses have been completed).

Response: The estimated duration to complete the full study and analyses is 60 months.

14. Setting

Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g., locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response: The surveys will all be conducted using the *Buffalo All Access* app, online using the research team's online survey system, or by telephone to a call center.

For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e., research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

15. Community-Based Participatory Research

Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

16. Resources and Qualifications

*Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response: One of the PIs works at the IDEA Center at UB. The co-PIs of the study have experience on several other related and un-related research studies, and have tremendous experience conducting research with vulnerable populations. The research staff includes full-time research staff and graduate students who may assist with the protocol. All research staff have completed CITI training.

Describe other resources available to conduct the research.

Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response:

Effort in Months (%) Distribution Chart

	Year 1			Year 2			Year 3		
	CY	AY	SU	CY	AY	SU	CY	AY	SU
Maisel		.2	.3		.2	.3		.2	.3
Paquet		.2	.3		.2.	.3		.2	.3
Graduate Asst.		6.0			12.0			6.0	

**Notes: CY = Calendar Year (12 months), AY = Academic Year (9 months), SU = Summer (3 months).*

Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response: N/A

Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: The research staff includes full-time research staff and graduate students who may assist with the protocol. All staff will be trained on recruitment procedures, consent procedures, and administration of study tools.

17. Other Approvals

Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

18. Provisions to Protect the Privacy Interests of Subjects

Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: The research will involve no observation or intrusion in situations where the subjects have a reasonable expectation of privacy. Subjects are free to disregard recruitment attempts, flyers, and emails and phone calls if they wish (i.e., privacy during recruitment). Data collection will occur in a private setting at participants' convenience.

Every effort will be made not to infringe on the research subjects' right to control the extent, timing, and circumstances under which they share any aspect of themselves with others. Prospective subjects have the right to decline participation.

Potential participant personal information will be kept in a separate computer file, only accessible by members of the project team, who have completed IRB training. All computer files will be password protected. Identities of all participants on data collection forms will be noted as a respondent ID (i.e., email address), including during the data collection.

Safety, privacy, and confidentiality procedures will be monitored by the project PI. Any breaches or deviations will be corrected immediately. The Principal Investigators will monitor and report any serious events or problems to the IRB.

Indicate how the research team is permitted to access any sources of information about the subjects.

NOTE: Examples of appropriate responses include school permission for review of records, consent of the subject, HIPAA waiver. This question ***does apply*** *to records reviews.*

Response:

19. Data Management and Analysis*

Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response:

The quantitative data from the app-based and/or online/telephone surveys will be analyzed in one of several ways, depending on the nature of the questions. Descriptive statistics will be provided for all survey items and relevant respondent

groupings. The relationships between categorical responses will be examined and quantified using loglinear analysis. Loglinear analysis extends the traditional two-way contingency table method of testing for dependencies by allowing any number of categorical (non-ordinal) responses. This technique does not distinguish between independent and dependent variables; it only pertains to associations amongst them. Those questions involving ordinal responses (i.e., those that use Likert scales) will be analyzed using ordinal logistic regressions. One such model will be developed for each ordinal item on the questionnaire. All statistically significant relationships, and notable statistically insignificant relationships, will then be discussed and visualized.

Data from the passive data sources will be used to validate the survey responses and also to provide contextual detail to support understanding of the study results.

If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response: This will be a convenience sample to answer exploratory questions. A power analysis is not necessary.

Describe any procedures that will be used for quality control of collected data.

Response: The Principal Investigator and designated research staff will remain the same throughout the course of the study to maintain consistency of procedures and analysis.

20. Confidentiality*

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*A. Where and how will all data and records be stored? Include information about password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g., paper) **and** electronic files.*

Response: All survey and *Buffalo All Access* app data will be stored in a password protected electronic files on the secured University at Buffalo server and only be accessible to members of the research team. The personally identifiable information that was collected during recruitment (i.e., name, address, telephone and email contact) will be stored in a separate, password protected file within the secure database. This information will not be linked to any survey data, except for the email address, which will be used to connect participants across different survey waves.

A. How long will the data be stored?

Response: Data, and identifiers will be stored for a period of not less than three and no more than six years following the completion of the study.

A. Who will have access to the data?

Response: Only project personnel who were involved in assisting with consent will know the participants' identities. The personally identifiable information collected during recruitment will be stored on a server with restricted, password-protected access at the University at Buffalo.

A. Who is responsible for receipt or transmission of the data?

Response: Designated research staff and/or the Principal Investigator will be responsible for receipt and/or transmission of the data.

A. How will the data be transported?

Response: Survey data will be collected through the internet and stored immediately as stated above. Telephone survey data will be entered in the online survey platform so it too will be internet-based. When necessary, data will be transported using a UB owned, password protected laptop.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 21.0)*

B. Where and how will all specimens be stored? Include information about physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

B. How long will the specimens be stored?

Response:

B. Who will have access to the specimens?

Response:

B. Who is responsible for receipt or transmission of the specimens?

Response:

B. How will the specimens be transported?

Response:

21. Provisions to Monitor the Data to Ensure the Safety of Subjects*

☐ **N/A:** This study is not enrolling subjects or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response Monitoring of privacy and confidentiality procedures will be ongoing throughout the conduct of the study. The Principal Investigator will be responsible

for evaluating data regarding harms and benefits annually, prior to renewal or closure of the IRB approval.

Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: Safety, privacy and confidentiality will be monitored by the PI. Any breaches or deviations will be corrected immediately. The Principal Investigator will monitor and report any serious events or problems to the UB IRB.

Describe any safety endpoints.

Response: Safety information will be monitored by key personnel during the data collection period.

Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: If there is a safety event or concern during the data collection period, it will be reported to the PI as a written communication immediately after the event.

Describe the frequency of safety data collection.

Response: Any/all safety concerns will be documented in real-time throughout the data collection period.

Describe who will review the safety data.

Response: The PI will review any safety incidents and determine the appropriate corrective action. All incidents and corrective actions will be reported to the UB IRB.

Describe the frequency or periodicity of review of cumulative safety data.

Response: The PI will review incidents within 48 hours of the report.

Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: No statistical tests will be used to evaluate whether or not harm is occurring. Every breach in data security and privacy will be considered an incident that should be addressed with corrective action.

Describe any conditions that trigger an immediate suspension of the research.

Response: Data collection will be suspended until a corrective action is made in response to a data security incident or a retention rate drops below 80%. The effects of the corrective actions for incidents will be re-evaluated immediately after data collection resumes, and at regular intervals thereafter.

22. Withdrawal of Subjects*

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: N/A. Subjects will not be withdrawn from the research without their consent.

Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: N/A

Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: Should research participants choose to withdraw from the study, the data collected prior to withdrawal may be used in the analysis unless they explicitly request it not to be used.

23. Risks to Subjects*

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: The risks for participating in this study are minimal, and are no greater than those which are present in everyday life.

These minimal risks are primarily associated with use of the self-driving shuttle. While the likelihood of these risks occurring is small, we need to mention them here. With the self-driving shuttle, there may be sudden stops due to the way the technology perceives its surrounding environment as well as the potential for the self-driving shuttle to travel beyond the operating environment for which it is designed.

An experienced steward/operator will be on board the self-driving shuttle throughout the entire study. The vehicle will be operated at a low speed to eliminate the risks associated with sharp accelerations or decelerations.

We do not expect the protocol will be overly taxing- physically, cognitively, or emotionally. Shuttle riders may take breaks as they would in their daily lives using transportation; this study does not impose or discourage any particular behaviors.

Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: The self-driving community shuttle (i.e., Adastec) has been used successfully in automated mode at other locations (e.g., Michigan, Norway) without incident and at much higher rates of speed than what research participants will experience in this study. In addition, a steward will be on board at all times.

*If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response: Some participants may feel uncomfortable sharing their thoughts and perspectives, even with an app-based or online survey.

If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: N/A. No risks to an embryo or fetus are involved.

If applicable, describe risks to others who are not subjects.

Response: N/A. No risk to others.

24. Potential Benefits to Subjects*

Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: There is no direct benefit from participating in this study. The study may provide valuable lessons learned to the USDOT and future technology deployers as to effective and easily used technologies for improved mobility.

25. Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g., survey studies, records review studies). This section does not apply.

If the research procedures carry a risk of research related injury, *describe the available compensation to subjects in the event that such injury should occur.*

Response:

Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

26. Economic Burden to Subjects

Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response:

☐ **N/A:** This study is not enrolling subjects or is limited to records review procedures only. This section does not apply.

27. Compensation for Participation

27.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response: Participants will be eligible for a drawing to receive up to $500 as noted in Section 12.0.

☐ **N/A:** This study is not enrolling subjects or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

28. Consent Process

Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 29.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*

☐ ***No*** *(If no, Skip to Section 29.0)*

Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response: Participants will encounter a consent notice upon downloading the *Buffalo All Access* application/before registration and will provide consent by agreeing to participate in the study. A summary of the consent process will occur once more online prior to commencing the online survey. Consent to the study is given by agreeing to participate in the survey.

Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response: Participants will have as much time as needed to review the consent notice prior to registering the *Buffalo All Access* app.

Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response: N/A. Each survey questionnaire will contain the consent statement in the introduction to verify that participants continue to voluntarily consent to participate in the study.

Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

The role of the individuals listed in the application who are involved in the consent process

The time that will be devoted to the consent discussion

Steps that will be taken to minimize the possibility of coercion or undue influence

Steps that will be taken to ensure the subjects' understanding

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects. *(Skip to Section 28.8)*

Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 8.4 of this protocol.

Response:

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults. *(Skip to Section 28.9)*

Describe the process to determine whether an individual is capable of consent.

Response: Individuals (or their caregivers) must have the cognitive capacity to read and understand the consent document. The research does not focus on cognitively impaired individuals.

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent. (*Skip to Section 28.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 28.11 and 28.12).*

Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

***For research conducted outside of New York State**, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

*Describe the process for **assent of the adults**:*

*Indicate whether assent will be obtained from all, some, or none of the subjects. **If some, indicate which adults will be required to assent and which will not.***

Response:

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Response:

*Describe whether **assent of the adult** subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 29.0)*

*Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)"*

to be aware of which individuals in the state meet the definition of "children."

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response:

***For research conducted outside of New York State**, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

Describe whether parental permission will be obtained from:

Response:

- ☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
- ☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- ☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

*Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

When assent of children is obtained, describe how it will be documented.

Response:

29. Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☐ **N/A:** A waiver or alteration of consent is not being requested.

If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response: I believe that this protocol is eligible for exemption of the written informed consent requirement because the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Those participating in the online survey will be provided information regarding the purpose of the study, and their responsibilities and expectations. Participants must choose to agree to the terms and conditions prior to starting the survey. See attached.

If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

30. Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 31.0)

Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how

consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e., consent script or Information Sheet).

Response: A signed consent will not be obtained and completing the survey will serve as 'deemed consent'.

☐ We will be following "SOP: Written Documentation of Consent" (HRP-091).

31. Multi-Site Research (Multisite/Multicenter Only)*

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

*If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following.*

All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.

All required approvals have been obtained at each site (including approval by the site's IRB of record).

All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented.

All engaged participating sites will safeguard data as required by local information security policies.

All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.

All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

Response:

Describe the method for communicating to engaged participating sites.

Problems (inclusive of reportable events)

Interim results

Study closure

Response:

*If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality.*

Where and how data or specimens will be stored locally?

How long the data or specimens will be stored locally?

Who will have access to the data or specimens locally?

Who is responsible for receipt or transmission of the data or specimens locally?

How data and specimens will be transported locally?

Response:

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.

Describe when, where, and how potential subjects will be recruited.

Describe the methods that will be used to identify potential subjects.

Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Response: N/A

32. Banking Data or Specimens for Future Use*

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response:

List the data to be stored or associated with each specimen.

Response:

Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response:

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Research Institute on Addictions
1021 Main St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

APPROVAL OF SUBMISSION: MODIFICATION TO EXEMPT RESEARCH

June 12, 2024

Dear JORDANA MAISEL,

On 6/12/2024**,** the University at Buffalo IRB reviewed the following submission:

Type of Review:	Modification / Update
Title of Study:	Performance Measurement and Evaluation Research for the Buffalo NY ITS4US Deployment Project
Investigator:	JORDANA MAISEL
IRB ID:	MOD00014154
Funding:	Name: , Funding Source ID: pass through from U.S. DOT
Grant ID:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• Flyer, Category: Recruitment Materials; • Proposal, Category: Sponsor Attachment; • Protocol, Category: IRB Protocol;• Survey Questions (post), Category: Surveys/Questionnaires; • Survey Questions (pre), Category: Surveys/Questionnaires;
Personnel Changes:	NA

The IRB approved this modification on **6/12/2024.** The modification materials for the project referenced above were reviewed and approved by the SUNY University at Buffalo IRB (UBIRB) by Non-Committee Review. The UBIRB has determined that the materials submitted as part of this modification do not change the Exempt status of the research study, according to 45 CFR Part 46.104. There is no expiration date.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the Click system.

This UBIRB determination is given with the understanding that the proposed study design will be followed. If modifications are needed that significantly alter the purpose, design, or data collected, then those changes should be submitted to the IRB to determine if the modifications alter the research such that the criteria for an exempt determination are no longer met. You can create a modification by navigating to the active study in Click IRB and selecting 'Create Modification / CR'. Otherwise, this study no longer needs to be reviewed by the IRB.

For more information on exemption criteria and categories, see the IRB Toolkit Worksheet: Exempt Determination (HRP-312). If you have any questions about this determination, please contact the IRB.

As principal investigator for this study involving human participants, you have responsibilities to the SUNY University at Buffalo IRB (UBIRB) as follows:

1. Ensuring that no subjects are enrolled prior to the IRB approval date.

2. Ensuring that the UBIRB is notified of all reportable information in accordance with the New Information SOP (HRP-024).

3. Ensuring that the protocol is followed as approved by UBIRB including minor changes which can be made if they do not impact the exempt determination.

4. Ensuring that the study is conducted in compliance with all UBIRB decisions, conditions, and requirements.

5. Bearing responsibility for all actions of the staff and sub-investigators with regard to the protocol.

6. Bearing responsibility for securing any other required approvals before research begins.

If you have any questions, please contact the UBIRB at 716-888-4888 or ubirb@buffalo.edu. Please include the project title and number in all correspondence with the UBIRB.

Appendix B. Consent Form

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

Title of research study: Evaluation Research for the Buffalo NY ITS4US Deployment Project

Version Date: June 6, 2024

Investigator: Jordana Maisel, PhD

Key Information: The following is a short summary of this study to help you decide whether or not you would like to participate. More detailed information is provided below.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you match one or more of the following categories: work and/or travel to the Buffalo Niagara Medical Center; and, at least 18 years of age.

What should I know about a research study?

- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to determine the usefulness of three new technologies for improving people's ability to travel to or from the Buffalo Niagara Medical Center or around their neighborhoods. The four technologies are a trip planning app (*Buffalo All*

Access), a community shuttle service (both human-operated and self-driving), outdoor and indoor route guidance, and safe intersection crossing technology.

How long will the research last and what will I need to do?

The research will last about 18 months. You will be asked to complete an introductory survey about your current travel behaviors, followed by three surveys on any changes in your travel behavior and your perceptions of the new technologies. More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

The risks to joining this study are minimal. More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There may not be a direct benefit to you personally for participating in this study. We cannot promise any benefits to others from your taking part in this research. However, the information you provide will enable further development of these technologies, and others like them, to offer improved travel experiences for people like you.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (716) 829-5902 or email jlmaisel@buffalo.edu**.** You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

You have questions about your rights as a participant in this research

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

- You want to get information or provide input about this research.

How many people will be studied?

We expect about 500 people will be in this research study; an initial 100 persons, increasing up to 500 persons as the study progresses.

What happens if I say yes, I want to be in this research?

If you choose to participate, you will use the trip planning app (***Buffalo All Access***), a community shuttle service (both human-operated and self-driving), outdoor and indoor route guidance, and safe intersection crossing technology.

In addition to using the four technologies, you will be asked to participate in a series of surveys. Each survey will take approximately 15-20 minutes to complete. The surveys will be conducted about every three-six months. You may complete the survey on your mobile device, laptop, desktop computer, or by telephone. The survey consists of questions about (1) your travel behavior, (2) challenges in traveling to or from the BNMC or your neighborhood, (3) use of the deployed technologies, (4) your perceptions of the technologies, and (5) demographic information. Demographic information includes your zip code, name, and contact information. A single question will also be prompted on the app to assess your satisfaction [with the app or the service] after each usage.

In addition to completing surveys, when you use the trip planning app or the community shuttle service as a participant in the study, passive data will also be captured. Such data will include registration and app usage (e.g., frequency, time of day) as well as trip (e.g., trip planning, trip booking, trip travel mode, shuttle pick-up/drop-off location). Such data will be tied to the survey data via the respondent ID of study participants to protect personally identifiable information and will be collected and stored only for those persons who have consented to be a part of the study. While possible, specific geolocations will not be captured also to protect personally identifiable information.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you decide to leave the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me? (Detailed Risks)

We are not anticipating any ways in which this study can harm you. The risks for participating in this study are minimal and are no greater than those which are present in everyday life.

These minimal risks are primarily associated with use of the self-driving shuttle. While the potential is small, we need to mention them here. With the self-driving shuttle, there could be sudden stops due to the way the technology perceives its surrounding environment as well as the potential for the self-driving shuttle to travel beyond the operating environment for which it is designed. An experienced steward/operator will be

on board the self-driving shuttle at all times to ensure safety and assist with any situations that may arise. The self-driving vehicle has been successfully deployed in other locations and tested for safety.

What happens to the information collected for the research?

The data collected will be stored in secured servers at the University at Buffalo and will only be accessible to members of the research team and will be password protected. Identities of subjects will be kept confidential. This information will be securely stored in separate password protected files in secured servers.

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The results of this study may be published in scientific journals, professional publications, or educational presentations. Your name will only be connected to your survey responses through a study ID number and will not be used in any report. The de-identified information collected during the study could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participants.

Can I be removed from the research without my OK?

You cannot be removed from the research study without your OK.

What else do I need to know?

Who is paying for this research?

This research is being funded by the U.S. Department of Transportation.

Will I get paid for my participation in this research?

If you agree to take part in this research study, and complete all four surveys, you will be eligible to enter a drawing to receive up to $500. You should plan to complete four surveys over an 18-month period. Payments that you receive for your participation in this research are considered taxable income.

PARTICIPANT'S STATEMENT OF INFORMED CONSENT:

"I am at least 18 years of age, have read and understand the explanation provided to me and voluntarily agree to participate in this study." (Clicking "Next" assumes consent.)

Appendix C. Pre-Deployment Survey

Buffalo NY ITS4US PMESP Baseline Questionnaire (Pre-Deployment)

Thank you for agreeing to participate in the Buffalo NY ITS4US Deployment Project. This project seeks to improve mobility to, from, and within the Buffalo Niagara Medical Campus using new technologies. The project is funded by a grant from the US Department of Transportation (grant number 693JJ321C000005).

The survey will take about 10 minutes to complete. After you complete the survey, you will be eligible to be entered into a prize drawing to receive a $500 cash prize.

To begin the survey, please continue by clicking the "Next" button below.

BNMCFREQ

The first set of questions asks about your travel to, from, and within the Buffalo Niagara Medical Campus (BNMC). For the purposes of this survey, the BNMC includes the buildings listed below, as well as adjacent medical offices and pathways.

- Buffalo General Medical Center
- Oishei Children's Hospital
- Gates Vascular Institute
- Roswell Park Comprehensive Cancer Center
- Buffalo Hearing & Speech Center
- VIA (Olmsted Center for Sight / Ross Eye Institute)
- Center for Hospice and Palliative Care
- Jacobs School of Medicine
- Innovation Center-BNMC
- Institute for Myelin and Glia Exploration

In general, the boundaries of the BNMC are between Main St. and Michigan Ave. from West to East, and between Tupper St. and North St. from South to North (and we are also including VIA on Main St.).

BNMCFREQ How often do you typically travel to the BNMC?

- o Every day or almost every day
- o At least once a week
- o At least once a month
- o About every two months
- o Multiple times in the last 12 months
- o Only once in the last 12 months
- o Have traveled there, but not in the last 12 months
- o Have never traveled there [**SKIP TO WHYNOBNMC**]

PURPOSE What is the primary purpose of your trip(s) to the BNMC?

- ○ Work
- ○ Healthcare services (i.e., in or outpatient treatment)
- ○ School
- ○ Visit family/friend(s) receiving healthcare services
- ○ Accompany a patient to a medical visit
- ○ Other (please specify) _____

USUALMODE Which best describe(s) how you most often travel to and from the BNMC (the single method of transportation used for the longest distance)?

- ○ Driver in a personal vehicle
- ○ Passenger in a personal vehicle
- ○ NFTA-Metro paratransit (PAL) service
- ○ Other shuttle service for persons with disabilities
- ○ NFTA bus or light rail service
- ○ Taxi, Uber, or Lyft
- ○ Walk / wheelchair
- ○ Bicycle
- ○ Other (please specify) _____

PLANHELP For your most recent trip to the BNMC, did anyone assist you in planning your trip?

- ○ No
- ○ Yes, a family member or friend
- ○ Yes, a professional caregiver or assistant
- ○ Other (please specify) _____

TRAVELHELP For your most recent trip to the BNMC, did anyone other than a shuttle driver or taxi driver travel with you to assist you in making the trip?

- ○ No
- ○ Yes, a family member or friend
- ○ Yes, a professional caregiver or assistant
- ○ Other (please specify) _____

Please tell us how much you agree or disagree with the following statements based on your experience **traveling to, from, and within** the Buffalo Niagara Medical Campus (BNMC).

SUFFINFO There is sufficient information available (e.g., transportation options, schedules, routes, etc.) for me to plan my trip(s) to/from the BNMC.

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree

USEFULINFO The information available for planning my trip(s) to/from the BNMC is useful.

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree

EASEACCESS Once I begin a trip to/from the BNMC, it is easy for me to get to my destination.

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree

SAFEPATHS The pedestrian pathways near or within the BNMC are safe for me to walk/roll.

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree

EASETRANSIT It is easy to travel to/from the BNMC using public transportation.

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree
6. I have not used public transportation to travel to/from the BNMC [**SKIP TO BESTMAIN**]

ONTIMETRANSIT I will likely reach my BNMC destination on time using public transportation.

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree

[SKIP TO BESTMAIN]

WHYNOTBNMC What are reasons why you've never traveled to the BNMC? (Select all that apply)

1. Unaware of the medical services available there
2. No need to visit (e.g., no medical needs or lack of events/activities)
3. Travel elsewhere for medical needs (due to limited medical services, personal preference, or cost)
4. Lack of suitable transportation options
5. Insufficient information on transportation options
6. Other (please specify) _____

BESTMAIN Do you ever cross the street as a pedestrian at the intersection of Best St. and Main St.?

1. Yes, quite often
2. Yes, but not very often
3. No, not at all [**SKIP TO PALUSER**]

Please tell us how much you agree or disagree with the following statement.
SAFECROSS I feel safe crossing the intersection of Best St. and Main St. as a pedestrian.

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree

PALUSER Are you registered to use the NFTA-Metro paratransit (PAL) service?

1. Yes
2. No [**SKIP TO NFTAFREQ**]

PALFREQ How frequently do you use the PAL service for any trips?

1. Every day or almost every day
2. At least once a week
3. At least once a month
4. 5 to 10 times in the past 12 months
5. 1 to 4 times in the past 12 months
6. Not at all in the past 12 months

NFTAFREQ How frequently do you use NFTA bus or light rail services (not including PAL) for any trips?

1. Every day or almost every day
2. At least once a week
3. At least once a month
4. to 10 times in the past 12 months
5. 1 to 4 times in the past 12 months
6. Not at all in the past 12 months

OWNVEH Do you own or have access to a personal vehicle?

1. Yes
2. No [**SKIP TO HEARINGDIS**]

VEHFREQ How often do you drive a personal vehicle or ride as a passenger?

1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Multiple times in the past 12 months
5. Never

HEARINGDIS. Are you a person who is deaf or has serious difficulty hearing?

1. Yes
2. No

VISUALDIS Are you a person who is blind or has serious difficulty seeing, even when wearing corrective glasses or contact lenses?

1. Yes
2. No

MOBILITYDIS Are you a person who uses a wheelchair, walker/cane, or has serious difficulty walking?

1. Yes
2. No

MOBILDEVICE What mobility or assistive device(s) or equipment do you use? (Select all that apply)

- Manual wheelchair
- Power wheelchair
- Scooter
- Support cane, walker, or crutches
- Mobility cane (white cane) for vision impairment needs
- Service animal
- Oxygen tank
- Hearing aids
- Augmentative communication device
- I do not use any mobility equipment or assistive devices
- Prefer not to answer
- Other (please specify)

AGEGROUP What year were you born?

_____

ZIPCODE What is the 5-digit zip code of your home address?

_____

GROUPHOUSE Do you live in a group care or assisted living facility?

1. Yes [**SKIP TO EDUC**]
2. No

HHSIZE How many people live in your household, including yourself?

1. 1 person (only yourself)
2. 2 people
3. 3 people
4. 4 people
5. 5 or more people

EDUC What is the highest level of formal education that you have completed?

1. Less than high school, high school diploma or GED
2. Some college
3. Associate's degree
4. Bachelor's degree
5. Graduate degree or higher
6. Prefer not to answer
7. Other (please specify) _____

EMPL What is your current employment status?

1. Employed, working full time
2. Employed, working part time
3. Not employed, looking for work
4. Retired
5. Prefer not to answer
6. Other (please describe)_____

RACE What would you consider yourself as?

1. American Indian or Alaska Native
2. Asian
3. Black or African American
4. Native Hawaiian or Other Pacific Islander
5. White
6. Prefer not to answer
7. Two or more races (please describe) _____

HISP Are you of Hispanic, Latin, or Spanish origin?

1. Yes
2. No
3. Prefer not to answer

HHINC What is your total household income?

1. Less than $10,000
2. $10,000 to $24,999
3. $25,000 to $49,999
4. $50,000 to $74,999
5. $75,000 to $99,999
6. $100,000 to $149,999
7. $150,000 or more
8. Prefer not to answer

CLOSING If you have any final remarks or comments about your travel experience or about this survey that you would like to share with the research team, please add below.

_____

DRAWING Thank you for participating! Would you like to enter a random drawing for a chance to win up to a $500 cash prize?

1. Yes
2. No

Appendix D. Post-Deployment Survey

Buffalo NY ITS4US PMESP Post-Deployment Questionnaire (s)

Administrative Items:

- **Respondents are study participants. All have given consent to participate and have registered to use the *Buffalo All Access* app.**
- **Language (English or Spanish) same as Baseline Questionnaire.**
- **Same questionnaire used for the three post deployment surveys.**
  People will be identified by their respondent ID (based on e-mail address) assigned during recruitment so deleted demographic questions will carry through from Baseline survey.

You have agreed to participate in the Buffalo NY ITS4US Deployment Project. This project, funded by the US Department of Transportation, seeks to improve mobility to, from and within the Buffalo Niagara Medical Campus (BNMC) using new technologies.

This survey collects information on your use of the new technologies developed for this study (i.e., a transit planning application platform [*Buffalo All Access*]), your level of satisfaction with any that you have used, and your opinions regarding your recent travel situation to, from, or within the BNMC.

You may have answered some of these questions in earlier surveys you completed regarding this project. If that is the case, please complete the questions again thinking about your most recent travel over the last few months.

The survey will take 20 minutes to complete. After you complete this survey, you will be eligible to be entered into a prize drawing to receive up to a $500 cash prize. (A new prize drawing is done for each survey you are asked to complete.)

To begin the survey, please continue by clicking the "Next" button below.

USEDCTP Have you used the *Buffalo All Access* app to plan and/or make any trips since registering?

- o Yes
- o No [**GO TO WHYNOT]**

TOBNMC Did any of those trips involve traveling to, from, or within the Buffalo-Niagara Medical Center (BNMC)?

- o Yes
- o No [**GO TO WHYNOT]**

BNMCPURP What was the primary purpose of those trips to, from, or within the BNMC?

- o Work
- o Healthcare services (i.e., in or outpatient treatment)
- o School
- o Visit family/friend(s) receiving healthcare services
- o Accompany a patient to a medical visit

- Other (please specify) _____

SUFFINFO2 [PMESP Metric 1.3]
Please tell us how much you *agree or disagree* with the following statements based on your experience **traveling to, from, and within** the Buffalo Niagara Medical Campus (BNMC) since you registered to use the *Buffalo All Access* app.

There is *sufficient* information available for me to plan my trip(s) to/from the BNMC.

6. Strongly agree
7. Somewhat agree
8. Neither agree or disagree
9. Somewhat disagree
10. Strongly disagree

USEFULINFO2 [PMESP Metric 1.3]
This information available for planning my trip(s) to/from the BNMC is *useful*.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

EASEACCESS2 [PMESP Metric 1.1]
Once I begin a trip to/from the BNMC, it is *easy* for me to get to my destination.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

SAFEPATHS2 [PMESP Metric 1.2]
The pedestrian pathways near or within the BNMC are *safe* for me to walk/roll.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

EASETRANSIT2 [PMESP Metric 1.4]
It is *easy* to travel to/from the BNMC using public transportation, including the new Community Shuttle.

7. Strongly agree
8. Somewhat agree
9. Neither agree or disagree
10. Somewhat disagree
11. Strongly disagree
12. I have not used public transportation to travel to/from the BNMC [**SKIP TO REGEASE**]

ONTIMETRANSIT2 [PMESP Metric 1.5]
I will likely *reach* my BNMC destination *on time* using public transportation.

1. Strongly agree

2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

REGEASE [PMESP Metric 2.1]
The *Buffalo All Access* app includes several specialized features. The remaining questions are about these features.

The next questions are about when you first registered to use the *Buffalo All Access* app and provided your user profile and preferences.

How *easy or difficult* was it to register and input your preferences?
1. Very easy
2. Easy
3. Neutral
4. Difficult
5. Very difficult

REGUSEFUL[PMESP Metric 2.2]
How *useful* were the customized trip options in satisfying your preferences?
1. Very useful
2. Useful
3. Neutral
4. Not very useful
5. Not useful at all

PLANNINGUSED [PMESP Metric 3.1]
The *Buffalo All Access* app includes a **trip planning feature** that allows you to plan a route from your origin to your destination in advance, including the transportation modes used.

Have you ever used this feature and saved those trip plans?
1. Yes
2. No [**GO TO BOOKINGUSED]**

PLANNINGFREQ [PMESP Metric 3.1]
Approximately how *often* have you used this feature during the past three months?
1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

PLANNINGEASE [PMESP Metric 3.1]
How *easy or difficult* was it to use this feature to plan a door-to-door trip?
1. Very easy
2. Easy
3. Neutral
4. Difficult
5. Very difficult

PLANNINGSAT [PMESP Metric 3.2]
In general, how *satisfied* were you with the route/path options provided by the *Buffalo All Access* app?

1. Very satisfied
2. Satisfied
3. Neutral
4. Unsatisfied
5. Very unsatisfied

BOOKINGUSED [PMESP Metric 3.3]
The *Buffalo All Access* app includes a **Shuttle trip reservation feature** that allows you to reserve a trip on the new Shuttle services (i.e., door-to-door human-driven Community Shuttle and fixed-route self-driving Shuttle) from your origin to your destination at a specific time.

Have you used this feature, regardless of whether you made the reserved trip? (We will ask additional questions later about making actual trips using the Community Shuttle.)

1. Yes
2. No [**GO TO REPORTUSED]**

BOOKINGFREQ [PMESP Metric 3.3]
Approximately how *often* have you used this feature during the past three months?

1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

BOOKINGEASE [PMESP Metric 3.4]
How *easy or difficult* was it to reserve new Shuttle trips using this feature?

1. Very Easy
2. Easy
3. Neutral
4. Difficult
5. Very difficult

BOOKINGUSEFUL [PMESP Metric 3.4]
How *useful* was it to reserve new Shuttle trips in advance (rather than at the last minute)?

1. Very useful
2. Useful
3. Neutral
4. Not very useful
5. Not useful at all

REPORTUSED [PMESP Metric 3.5]
The *Buffalo All Access* app includes a **feature to report incidents or conditions** encountered during travel.

Have you ever used this feature?

1. Yes
2. No [**GO TO REVIEWEUSED]**

REPORTFREQ [PMESP Metric 3.5]
Approximately how *often* have you used this feature during the past three months?
1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

REPORTEASE [PMESP Metric 3.6]
How *easy or difficult* was it to use this feature?
1. Very Easy
2. Easy
3. Neutral
4. Difficult
5. Very difficult

REVIEWUSED [PMESP Metric 3.7]
The *Buffalo All Access* app includes a **trip history feature** that allows you to review your past trips made using the *Buffalo All Access* app.

Have you ever used this feature?
1. Yes
2. No [**GO TO OUTDOORUSED]**

REVIEWFREQ [PMESP Metric 3.7]
Approximately how *often* have you used this feature during the past three months?
1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

REVIEWUSEFUL [PMESP Metric 3.8]
How *useful* was this feature?
1. Very useful
2. Useful
3. Neutral
4. Not very useful
5. Not useful at all

OUTDOORUSED [PMESP Metric 4.1]
The *Buffalo All Access* app provides an enhanced **navigation feature of outdoor routes** within the BNMC, including all pedestrian paths and building entrances.

Have you ever used this feature?
1. Yes
2. No [**GO TO INDOORUSED]**

OUTDOORFREQ [PMESP Metric 4.2]
How *frequently* have you used this feature when traveling to or in the BNMC in the past three months?
1. Every day or almost every day

2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

OUTDOORUSEFUL [PMESP Metric 4.5]
How *useful* was this feature in helping you get to your BNMC destination on-time?
1. Very useful
2. Useful
3. Neutral
4. Not very useful
5. Not useful at all

OUTDOORRAPUUD [PMESP Metric 4.7]
Please indicate how much you *agree or disagree* with the following statements about using this feature.

This feature is easy to use.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

For me, using this feature poses a personal safety risk.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

I often need assistance to use this feature.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

When using this feature, I make mistakes that require me to do over some steps.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using this feature takes more time than it should.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using this feature requires minimal mental effort.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using this feature draws unwanted attention to me.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

INDOORUSED [PMESP Metric 4.3]
The *Buffalo All Access* app provides an enhanced **indoor navigation feature** to help find destinations inside some of the buildings in the BNMC.

Have you ever used this feature?
1. Yes
2. No [**GO TO CROSSINGUSED]**

INDOORFREQ [PMESP Metric 4.4]
How *frequently* have you used this feature in the past three months?
1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

INDOORUSEFUL [PMESP Metric 4.6]
How *useful* was this feature in helping you get to your BNMC destination on-time?
1. Very useful
2. Useful
3. Neutral
4. Not very useful
5. Not useful at all

RAPUUDINDOOR [PMESP Metric 4.8]
Please indicate how much you *agree or disagree* with the following statements about using this feature.

This feature is easy to use.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

For me, using this feature poses a personal safety risk.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

I often need assistance to use this feature.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

When using this feature, I make mistakes that require me to do over some steps.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using this feature takes more time than it should.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using this feature requires minimal mental effort.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using this feature draws unwanted attention to me.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

CROSSINGUSED [PMESP Metric 5.2]
The *Buffalo All Access* app has a feature that allows you to **remotely activate the Walk signal** at the Best and Main Street intersection.

Have you ever used this feature?
1. Yes
2. No, I haven't crossed at that intersection [**GO TO HDSUSED**]
3. No, I have crossed there but haven't needed to use the remote signal activation **[GO TO HDSUSED]**

CROSSINGFREQ [PMESP Metric 5.4]
How *frequently* have you used this feature in the past three months?
1. Every day or almost every day

2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

CROSSINGEASE [PMESP Metric 5.3]
How *easy or difficult* was it to use this feature?
1. Very easy
2. Easy
3. Neutral
4. Difficult
5. Very difficult

CROSSINGTIME **[PMESP Metric 5.3]**
How *satisfied* were you with the response time when you activated the signal using this feature?
1. Very satisfied
2. Satisfied
3. Neutral
4. Dissatisfied
5. Very dissatisfied

SAFECROSSING [**PMESP Metric 5.5]**
How did using this feature impact your ability to cross the intersection *safely*?
1. Extremely
2. Moderately
3. Somewhat
4. Slightly
5. Not at all

HDSUSED [PMESP Metric 6.4]
The *Buffalo All Access* app allows you to reserve or request trips on the **new human-driven Community Shuttle** that provides **door-to-door service**.

Have you ever taken trips on the door-to-door Community Shuttle requested through the *Buffalo All Access* app?
1. Yes
2. No [**GO TO SDSUSED**]

HDSFREQ [PMESP Metric 6.4]
How *often* have you used the door-to-door Community Shuttle service in the past three months?
1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

HDSRELIABLE [PMESP Metric 6.3]
How *reliable* was the door-to-door Community Shuttle service in terms of being able to reach your destination on time?
1. Very reliable
2. Somewhat reliable
3. Neutral
4. Somewhat unreliable
5. Very unreliable

HDSRAPUUD [PMESP Metric 6.5]
Please indicate how much you *agree or disagree* with the following statements about using the door-to-door Community Shuttle service.

The door-to-door Community Shuttle service is easy to use.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

For me, using the door-to-door Community Shuttle service poses a personal safety risk.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

I often need assistance to use the door-to-door Community Shuttle service.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

When using the door-to-door Community Shuttle service, I make mistakes that require me to do over some steps.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using the door-to-door Community Shuttle service takes more time than it should.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using the door-to-door Community Shuttle service requires little physical effort.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using the door-to-door Community Shuttle service requires minimal mental effort.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using the door-to-door Community Shuttle service draws unwanted attention to me.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

SDSUSED [PMESP Metric 6.4]
NOTE: SKIP TO QUESTION PALUSER2 IF THE SDS IS NOT IN SERVICE YET
The *Buffalo All Access* app also allows you to request trips on the **new self-driving Shuttle** that provides **fixed route service** within the BNMC and north to VIA on Main St.

Have you taken trips on the self-driving Shuttle requested through the *Buffalo All Access* app?
1. Yes
2. No [**GO TO PALUSER2**]

SDSFREQ [PMESP Metric 6.4]
How *often* have you used the self-driving Shuttle service in the past three months?
1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

SDSRELIABLE [PMESP Metric 6.3]
How *reliable* was the self-driving Shuttle service in terms of being able to reach your destination on time?
1. Very reliable
2. Somewhat reliable
3. Neutral
4. Somewhat unreliable
5. Very unreliable

SDSRAPUUD [PMESP Metric 6.5]
Please indicate how much you *agree or disagree* with the following statements about using the self-driving Shuttle service.

The self-driving Shuttle service is easy to use.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

For me, using the self-driving Shuttle service poses a personal safety risk.
1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

I often need assistance to use the Self-driving shuttle service.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

When using the self-driving Shuttle service, I make mistakes that require me to do over some steps.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using the self-driving Shuttle service takes more time than it should.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using the self-driving Shuttle service requires little physical effort.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using the self-driving Shuttle service requires minimal mental effort.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

Using the self-driving Shuttle service draws unwanted attention to me.

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

PALUSER2 [PMESP Metric 6.5]
Are you registered to use the NFTA-Metro paratransit (PAL) service?

1. Yes
2. No [**SKIP TO NFTAFREQ2**]

PALFREQ2 [PMESP Metric 6.5]
How *frequently* have you used the PAL service for any trips in the past three months (not including any trips reserved via the *Buffalo All Access* app)?

1. Every day or almost every day

2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

NFTAFREQ2 [PMESP Metric 6.4]
How frequently have you used NFTA bus or light rail services in the past three months (not including PAL or the new Shuttle services)?

1. Every day or almost every day
2. At least once a week
3. At least once a month
4. Only once or twice
5. Not at all

[GO TO DRAWING2]

WHYNOT
What is the main reason why you haven't used the *Buffalo All Access* app for any trips?

1. I haven't made any trips to the BNMC
2. I haven't made any trips where I needed the *Buffalo All Access* app features
3. I do not know how to use the *Buffalo All Access* app
4. I do not like to use smartphone apps that know my location
5. Other (please specify) _____

DRAWING2 Thank you for participating! Would you like to enter a random drawing for a chance to win up to a $500 cash prize? (Only those who have completed this survey will be included in the drawing.)

3. Yes
4. No

CLOSING2 If you have any final remarks or comments about your travel experience or about this survey that you would like to share with the research team, please add below.

_____

Appendix E. Recruitment Flyer

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-21-898

U.S. Department of Transportation