Phase 1 Human Use Approval Summary

California Association for Coordinated Transportation ITS4US Deployment Project

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Final Report — January 6, 2021
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COMPLETE TRIP
ITS4US

U.S. Department of Transportation

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Peggy Wang (California PATH), Thomas Craig (CALACT), Taylor Bailey (Garnet Consulting, LLC)	(Delete and insert information here or leave blank)

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Robert Sheehan, COR

16. Abstract

This report provides an overview of all project plans that involve the use of human subjects and the scope of those plans. It details this project's work with the Institutional Review Board (IRB) that will review and approve all human subject use and lists the specific vulnerable populations that may be engaged in the research. The goal purpose of this report is to ensure that the project has adequate plans for ethically engaging human subjects in a way that will be both ethical and useful to the project's goals.

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Peggy Wang, CA PATH	24 March 2022	1.0	Final Draft	Thomas Craig, CALACT

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1 Introduction

1.1 Document Purpose

The purpose of the Human Use Approval Summary (HUAS) is to describe the planned extent and nature of research involving human subject participants and how that research will be approved. The project will involve coordination with an Institutional Review Board (IRB) to review and approve each research element. The project will work with the IRB at University of California at Berkeley (UCB) Committee for Protection of Human Subjects (CPHS).

Section 1 of this document gives a document summary and overview of the project as a whole. Section 2 details the planned research involving human subjects. Sections 3 and 4 describe plans for coordination with the IRB, the IRB review process, and feedback received from the IRB. Finally, Section 5 addresses the future steps required based on the IRB feedback and how these steps will be accomplished.

1.2 Project Overview

The CALACT project addresses the clear need for riders who use demand-responsive services, including riders with disabilities, to have equal access to the real-time trip planning technology that is already available for urban fixed-route transit. Nearly 300 of the over 500 transit operators in California, Oregon, and Washington deliver a form of demand-responsive service. Rider characteristics of these services likely differ substantially from those on fixed-route services as rural residents and people with disabilities are more likely to be low-income, unable to use fixed-route services due to disability, and/or are living in a physically isolated environment.

The demand-response systems themselves offer a lower quality of rider experience, where would-be passengers must find a transit provider that will serve their needs, call a dispatch system to plan and reserve their trip, requiring a long lead time (typically at least a day in advance), and allowing little room for flexibility. The trip planning experience of demand-response systems is further and uniquely burdened by a complex web of determining operator coverage area, for what qualifications that operator or specific service within that operator's service menu they qualify, if the operator has availability, if they need to pay and how. Unlike fixed route services, which have a well-established data standard and a stable industry of third-party trip planning services, and private Transportation Network Companies (TNCs), which produce their own seamless and instantaneous booking and payments flows, demand-responsive transit lacks the technical solutions which could ease these burdens for their riders. There's no comparable desktop or smartphone experience and no other innovations which exist to untangle these webs of availability, reservations, or payments.

Most fixed route users in the three-state region have access to real-time information about transit services through any mobile device. However, very few users have that information about public demand-responsive transit, and none have that information except through custom proprietary systems implemented at a few local agencies. Further, users of fixed-route services who would

like more access to details regarding the transit system accessibility features and other amenities often cannot easily find that information.

The particular underserved communities the project focuses on are people with mobility disabilities, people with vision disabilities, people with cognitive and developmental disabilities, people with hearing disabilities, older adults, low-income populations, rural residents, veterans, and people with limited English proficiency.

This project is one of five deployments of the Complete Trip - ITS4US Deployment Program, led by the ITS JPO and supported by Office of the Secretary (OST), Federal Highway Administration (FHWA), and Federal Transit Administration (FTA). These deployments were selected to showcase innovative business partnerships, technologies, and practices that promote independent mobility for all travelers regardless of location, income, or disability. The Complete Trip - ITS4US Deployment Program is carried out in three phases over five years: Concept Development (current phase), Design and Testing, and lastly Operations and Evaluation. There is a post-deployment operations and maintenance phase for an additional five years. The intended outcomes for the CALACT deployment are to improve the user experience and cost efficiency of demand responsive transit for riders at agencies throughout the Washington, Oregon, and California.

Project partner (subcontractor) organizations include:

- California Partners for Advanced Transportation Technology at UC Berkeley: Project evaluation and stakeholder safety and human use leads. Alex Kurzhanskiy of CA PATH will be the PI for the project and lead the human use approval process.
- Oregon Department of Transportation (ODOT): Agency outreach in Oregon, member of PMT, transit directory product manager
- Washington Department of Transportation (WSDOT): Agency outreach in Washington, member of PMT, transit analysis product manager
- California Department of Transportation (Caltrans): Agency outreach in California, member of PMT, payments product manager
- Washington State Transit Association (WSTA): Support agency outreach in WA and assist with event coordination
- Trillium, an Oregon small business: Concept design, report writing and product management support
- Compiler LA, a California small business: Software systems requirements and data management lead
- Tamika L. Butler Consulting, a California small business: Internal evaluation and stakeholder engagement
- Mark Wall Associates, a California small business: Agency outreach and support for reporting and project administration

- Estolano Advisors, a California small business: Agency and stakeholder outreach support
- MobilityData IO, a Canadian nonprofit: Data specification development and technology readiness assessment lead
- Transit, a Canadian private corporation registered for business in the US: Technical advice on customer interface needs and development
- Navilens, a Spanish private corporation registered for business in the US: Digital accessible signage and text to speech product leads
- Google, an American public corporation (unfunded): Participation in an advisory and user testing coordination role

1.3 Definitions, Acronyms, and Abbreviations

Accessibility – Accessibility is used in this document to indicate the ability all riders—especially people with disabilities, Limited English Proficiency, or who faces other barriers to access transit—to use transit and transit technologies in a way that best supports those users' individual experiences with transit. A service or technology may be "accessible" as defined by the ADA, but may also present "accessibility barriers" which this project seeks to help riders manage, in order to make the service or technology "more accessible".

ADA - Americans with Disabilities Act

API - Application Programming Interface

B2C - Business to consumer

B2G - Business to government

BAA - Broad Agency Announcement

CA - State of California

CA PATH - California Partners for Advanced Transit and Highways

CAD/AVL – Computer-Aided Dispatch/Automatic Vehicle Location

CALACT - California Association for Coordinated Transportation

Caltrans - California Department of Transportation

CCPA - California Consumer Protection Act

CDL - Concept Development Lead

ConOps - Concept of Operations

Deep link – a deep link is a link within a mobile application which directs the user to another mobile application, rather than to a website.

Demand-responsive transit – Transit services which provide trips at a location and/or time that is requested by a rider. Generally, any transit service that is not Fixed-route is considered a type of Demand-responsive transit for the purposes of this document, including general public DAR, ADA paratransit, and other transit models.

DOT - Department of Transportation

Fixed-route transit – Transit services that provide service to the general public through vehicles which stop at designated locations (stops and stations) at designated times.

GPS – Global Positioning System

GTFS - General Transit Feed Specification

IEEE - Institute of Electrical and Electronics Engineers

IRB - Institutional Review Board

NEMT – Non-Emergency Medical Transportation

NIST 800-53 - National Institute of Standards and Technology

PII – Personally Identifiable Information

PLC - Project Leadership Committee

PML - Project Management Lead

PMO - Project Management Organization

PMP - Project Management Plan

PMT - Project Management Team

ODOT - Oregon Department of Transportation

OR - State of Oregon

OS - Operating System

SMP – Safety Management Plan

SCC - System Coordination Committee

SDL - System Development Lead

SEMP - Systems Engineering Management Plan

SyRS - System Requirements Specification Document

TBD - To Be Determined

TTS – Text-to-Speech

TNC - Transportation Network Company

UI - User Interface

WA - State of Washington

WBS - Work Breakdown Structure

WSDOT - Washington State Department of Transportation

WSTA - Washington State Transportation Association

1.4 References

CALACT, Phase 1 Concept of Operations (ConOps) (2021) **FHWA-JPO-21-858**

CALACT User Needs Identification and Requirements Planning report, USDOT (2021)

CALACT Needs Summary, USDOT (2021)

CALACT, Phase 1 Safety Management Plan (SMP) (2021) **FHWA-JPO-21-871**

CALACT, Phase 1 Performance Measurement and Evaluation Support Plan (PMESP) (2021) **FHWA-JPO-21-876**

CALACT Stakeholder Registry and ConOps Review Panel Roster, USDOT (2021)

GTFS, gtfs.org, Github (2021).

GTFS-Flex, https://github.com/MobilityData/gtfs-flex/blob/master/spec/reference.md, Github (2021)

Fares v2, bit.ly/gtfs-fares, Google Documents (2021).

GOFS: Working group documents, MobilityData (https://mobilitydata.org/the-gofs-project-first-phase-is-in-the-book-whats-next/)

IEEE Std 1362TM-1998 (R2007), IEEE Guide for Information Technology—System Definition—Concept of Operations (ConOps) Document, IEEE (2007)

2 Human Subjects Research Plan

This section gives an overview of the planned research questions that will require feedback from human subjects as well as detailing how those subjects will be protected. This includes special considerations for vulnerable populations as well as practices for getting informed consent and protecting confidentiality and participant data.

Other project participants which do not require Human Use Approval will be referenced but not investigated. These project participants will use the system in ways that are exempt from the IRB subcommittee or full committee review process, as has been determined in discussion with the UC Berkeley OPHS and is further described in Section 3.2.

2.1 Research Questions

In the ConOps and Performance Measurement and Evaluation Support Plan, CALACT identified the following deployment goals and research objectives:

- Is there more GTFS data published that is in compliance with the accessibility-focused enhancements encouraged and facilitated by this project?
    - More specifically, will the promotion of Data and Procurement Guidelines, supported by the project through technology coordination teams, lead to more GTFS data published include more accessibility-focused information?
- Are general public and underserved users able to successfully answer their questions regarding transit services by using the tools and resources provided by the project?
    - More specifically, will the development of a support desk, data APIs, and directory lead to riders more successfully answering their questions and planning trips?
- Do third-party application developers implement the accessibility features suggested by the project?
    - More specifically, will the directory and engineers' guide to inclusive transit encourage third-party application developers to implement new accessibility-focused features?

More specific formulations of and processes for investigating these research questions have been developed through the design of the Performance Measurement and Evaluation Support Plan, and can be reviewed within that report. Those relevant to human subjects research will be identified in Section 2.4.2 below.

2.2 Interactions with Other Tasks and Consistency

This report may need to be updated after the completion of the Stakeholder Participant Training report, which is being finalized slightly later than the Human Use Approval Summary. The task team will review that report upon completion and identify whether any changes are needed to this report.

This report includes a future timeline of activities in Section 5 which will identify any specific actions which are known that must be taken in the future related to Human Use Approval. This report may be updated in response to some of those actions.

Early in Phase 2, the Performance Measurement and Evaluation Support Plan requires that the Evaluation support team detail more precisely the methodologies to be used to collect and publish all performance metric reporting. The Human Use Approval report may be updated at that time based on those changes.

2.3 Considerations for Vulnerable Populations

This project will include surveys and interviews with subjects from vulnerable populations.

Table 1. Vulnerable Subjects Checklist

Yes	No	Group
	N	Children/Minors
	N	Prisoners
	N	Pregnant Women
	N	Fetuses
	N	Neonates
Y		Educationally Disadvantaged
Y		Economically Disadvantaged
Y		Intellectual/Developmental Disabilities
Y		Mobility/Hearing/Vision Disabilities

The separate list below, which is required by University of California at Berkeley (UCB) Committee for Protection of Human Subjects (CPHS), provides more details regarding the research project potential impact on vulnerable populations.

Table 2. General Checklist

Yes	No	Group
Y		Is the research receiving any federal funding (e.g., NIH, NSF, DOD, etc.)?
	N	Is another institution relying on UC Berkeley for IRB review by means of an Inter-institutional IRB Authorization Agreement?
	N	Will subjects be compensated for participation?
	N	Will any type of deception or incomplete disclosure be used? If yes, submit a non-exempt application.
	N	Do investigators have a Conflict of Interest (COI)? If yes, submit a non-exempt application.

2.4 Informed Consent

The overall goal of this project is to implement changes to improve access to public transportation for riders. As such, it is necessary to the success of the project to frequently incorporate rider feedback to ensure riders are actually benefitting from these changes. Multiple performance measures (PMs) are based on rider surveys and measuring rider satisfaction. In order for the project to receive accurate feedback and act ethically, it is vitally important that all participants are treated respectfully and participate voluntarily after giving informed consent. This section details the expected study procedures as well as anticipated risks and discomforts and how those will be addressed.

2.4.1 Participant Questionnaires / Evaluation

This study will require providing detailed information to the IRB during Phase 2. The information provided below gives a summary of the anticipated study procedure information which will be required by the IRB, but the procedure descriptions will be developed and refined in Phase 2 (see Section 5.2 for IRB process timeline). Outlines of planned responses are represented in bold text.

Study Procedures

This section will describe in chronological order of events how the planned research will be conducted, providing information about all study procedures and who will conduct each (e.g., how participants are identified, the consent process, interventions/interactions with subjects, data collection), including follow-up procedures. For the surveys that will be conducted in the study, we will explain and attach copies of all study instruments (standard and/or non-standard) in the Attachments section. We will indicate frequency and duration of visits/sessions, as well as total time commitment for participants in the study and an estimated time frame for when the study will be completed. If the proposed research involves secondary use of data/specimens, we will describe how data/specimens will be acquired.

The survey will be developed by the performance evaluation team, and include a small number of Likert-scale questions similar to "How was your trip planning experience today? [select value from 1 to 5]".

The survey will ask whether the person identifies as a person with a disability, and will save the language the client device is set to (and in which the survey is presented), but will not maintain any identifier associated with any Personally Identifiable Information.

The performance evaluation team will analyze the survey responses per a process to be specified during the first year of Phase 2.

The baseline survey will be performed one year into Phase 2, and time series surveys with the same questions will be performed annually through Phase 2 and 3. The survey will be distributed through multiple channels including in app, email, and social media.

This section will state if photographing, audio, or video recording will occur and for what purpose (e.g. transcription, coding facial expressions).

No such activities will occur.

Alternatives to Participation: This section will describe appropriate alternative resources, procedures, courses of treatment, if any, that are available to prospective subjects. If there are no appropriate alternatives to study participation, this should be stated. If the study does not involve treatment/intervention, enter "N/A" here.

There are no alternatives to standard participation.

Risks and Discomforts

This section will describe all known risks and discomforts associated with study procedures, including physical, psychological, economic, or social (e.g., pain, stress, invasion of privacy, breach of confidentiality), noting probability and magnitude of potential harm.

There are no known risks or discomforts associated with the study procedures.

If conducting educational tests, survey procedures, interview procedures, or observation of public behavior, AND linking to subjects' identifying information, this section will explain why inadvertent release of the data would not have detrimental consequences (i.e. place subjects at risk of civil or criminal liability, or cause damage to their financial standing, employability or reputation).

N/A

2.4.2 Deployment sites and performance measures

The project is deployed through four distinct deployment sites, with distinct performance measures (PMs). More information on the PMs can be found in the Performance Measurement

and Evaluation Support Plan. The following is a high-level description of each deployment site, and more information regarding the participants and training plans at each deployment site can be found in the Participant Training and Stakeholder Evaluation Plan.

The following subsections will review the study procedures of each deployment site for their potential risks or discomforts. These subsections overall find that there are no known risks with the planned study procedures. This finding will be reviewed after the study procedures are further defined in Phase 2. Additionally, there may be safety risks associated with the use of the system by users, outside the study procedures but related to those procedures. These risks are related to the use of public transit generally, even when supported by electronic information (apps, websites, etc. that are based on the proposed system), and are evaluated for their impact on the project in the Safety Management Plan Section 6.

Deployment Site 1: Region-wide
This deployment site encompasses the three states of Washington, Oregon, and California and can include any operator with service in that region. The focus of Deployment Site 1 is to provide GTFS and various GTFS extension data from as many operators as possible to establish as much data coverage as possible. The Deployment Site is also characterized by the coordinated effort between the three state DOTs to establish agreed-upon data guidelines for regional transit, and the publication of standardized data through the Data APIs.

Deployment Site 2: Coordinated, community transportation region
This deployment site encompasses the Puget Sound area of Washington State. A local operator will serve as the lead agency in this deployment site and provide a connected One-Call One-Click system. This third-party One-Call One-Click system will be built on top of the Data APIs among other software dependencies. This One-Call One-Click system will integrate transit services in the area, including non-emergency medical transportation and community transit.

Deployment Site 3: Rural area with connecting services and small urban communities
This deployment site encompasses three counties in Oregon including multiple small urban communities and rural areas. Deployment Site 3 has various overlapping demand-response and fixed route services and thus will serve as a good location to pilot the 1st Tier Support Desk and the integration of a microtransit service into a frontend interface through the use of an open data specification.

Deployment Site 4: Large urban and suburban region with diverse service offerings including rail
This deployment site encompasses the San Bernardino County area in California with a focus on the city of San Bernardino around the regional transit center. This area has frequent intercity bus and rail connections which present complex wayfinding accessibility challenges. The project intends to provide better pathway information, digital infrastructure and wayfinding signage, and fares data showing inter-agency discounts to improve the rider experience in the deployment area.

2.4.2.1 Deployment Site 1: Region-Wide

Deployment site 1 does not have any associated PMs that will require human use. Participants in this deployment site include only organizations (transit agencies, regulators, software vendors). For a discussion of the training these organizations will received, see the Participant Training and Stakeholder Evaluation Plan.

2.4.2.2 Deployment Site 2: Puget Sound Deployment Site

Deployment site 2 will have the following PMs associated that require human use:

- PM 2.1: Increased rider satisfaction with regard to station and stop wayfinding as reported in rider surveys
- PM 2.2: % of riders reporting satisfaction with the trip planning process

These PMs will require a rider survey collecting feedback from human subjects. The Study Procedures and Risks and Discomforts are expected to be the following:

Table 3. Deployment Site 2 Anticipated PM Study Procedure, Risks, and Discomforts

PM	Procedure	Photos/ recording	Alternatives	Risks/Discomforts	Collection of PII
PM 2.1	• Survey of trip planning experience • Collection of disability status and device language • Analysis of survey results • Baseline and time series data collection	No	N/A	Minimal time commitment (1-2 minutes), and no known risks or discomforts associated with research process.	N/A
PM 2.2	• Survey of trip planning experience • Collection of disability status and device language • Analysis of survey results • Baseline and time series data collection	No	N/A	Minimal time commitment (1-2 minutes), and no known risks or discomforts associated with research process.	N/A

2.4.2.3 Deployment Site 3: SW Oregon Deployment Site

Deployment site 3 does not have any associated PMs that will require human use. Participants in this deployment site include only organizations (transit agencies and software vendors). For a discussion of the training these organizations will receive, see the Participant Training and Stakeholder Evaluation Plan.

2.4.2.4 Deployment Site 4: San Bernardino Deployment Site

Deployment site 4 will have the following PMs associated that require human use:

- PM 4.1: Increased rider satisfaction with regard to station and stop wayfinding as reported in rider surveys
- PM 4.2: % of riders reporting satisfaction with the trip planning process

These PMs will require a rider survey collecting feedback from human subjects. The Study Procedures and Risks and Discomforts are expected to be the following:

Table 4. Deployment Site 4 Anticipated PM Study Procedure, Risks, and Discomforts

PM	Procedure	Photos/ recording	Alternatives	Risks/Discomforts	Collection of PII
PM 4.1	• Survey of trip planning experience • Collection of disability status and device language • Analysis of survey results • Baseline and time series data collection	No	N/A	Minimal time commitment (1-2 minutes), and no known risks or discomforts associated with research process.	N/A

PM	Procedure	Photos/ recording	Alternatives	Risks/Discomforts	Collection of PII
PM 4.2	• Survey of trip planning experience • Collection of disability status and device language • Analysis of survey results • Baseline and time series data collection	No	N/A	Minimal time commitment (1-2 minutes), and no known risks or discomforts associated with research process.	N/A

2.4.3 Participant Data

This study will require providing detailed information to the IRB regarding confidentiality during Phase 2. The information provided below gives a cursory summary of the anticipated needs and approach, but these procedures will be further developed and refined in Phase 2. Anticipated responses to these needs are represented in bold text.

Confidentiality

Will data be collected anonymously (i.e., no identifying information from subjects will be collected/recorded that can be linked to the study data)? If no, please list all identifiable and/or coded data elements to be collected. Data is not anonymous if there is a code linking it to personally identifiable information. Also, audio and video recordings are generally not considered anonymous unless distinguishing features can be successfully masked.

Data will be collected anonymously.

Explain how data, audiotapes, videotapes and photographs, etc. will be secured (e.g., password-protected computer, encrypted files, locked cabinet), stored and who will have access to them. Indicate at what point they will be transcribed and/or destroyed (if ever).

N/A

2.4.3.1 Deployment Site 1: Region-Wide

No personally identifiable data will be collected.

2.4.3.2 Deployment Site 2: Puget Sound Deployment Site

All potentially personally identifiable data will be collected anonymously through an online survey. No code will connect data to other PII.

2.4.3.3 Deployment Site 3: SW Oregon Deployment Site

No personally identifiable data will be collected.

2.4.3.4 Deployment Site 4: San Bernardino Deployment Site

All potentially personally identifiable data will be fully collected anonymously through an online survey. No code will connect data to other PII.

2.5 Recruitment Design

This study will require providing detailed information to the IRB during Phase 2. The information provided below gives a summary of the anticipated study procedure information which will be required by the IRB, but the procedure descriptions will be developed and refined in Phase 2 (see Section 5.2 for IRB process timeline).

Subject Population

> *Describe proposed subject population, including criteria for study inclusion and exclusion (e.g., age, health status, language, gender, race, ethnicity). State the maximum number of subjects planned for the study. This number should account for all subjects to be recruited, including those who may drop out or be found ineligible.*

2.5.1.1 Deployment Site 1: Region-Wide

There will not be any human subject recruitment in Site 1. Research participants consist only of transit agencies and technology vendors.

2.5.1.2 Deployment Site 2: Puget Sound Deployment Site

Recruitment in Site 2 will focus on users of the Transit app (all users in region will receive banner notification of survey) and additional outreach through email and social networks. There will not be a maximum set on recruitment because the survey methodology is scalable and participation is low-impact for participants. The research protocol will specify that all users who click on the survey link are participants in the research project.

2.5.1.3 Deployment Site 3: SW Oregon Deployment Site

There will not be any human subject recruitment in Site 3. No users will participate in research. Organizations (agencies and software vendors) will be research participants, from which aggregate statistics will be collected.

2.5.1.4 Deployment Site 4: San Bernardino Deployment Site

Recruitment in Site 4 will focus on users of the Transit app (all users in region will receive banner notification of survey) and additional outreach through email and social networks. There will not be a maximum set on recruitment because the survey methodology is scalable and participation is low-impact for participants. The research protocol will specify that all users who click on the survey link are participants in the research project.

2.6 Training of Participants

There is no training needed for direct participants within the survey research which is relevant to the Human Use Approval process.

2.7 Team Human Subjects Research Training

CALACT, Transit, and Garnet Consulting will be collaboratively engaged in research. Transit will provide consulting regarding the survey approach and technology for survey distribution and analysis. CALACT and Garnet Consulting will assist by providing administrative support to the research team. All parties will receive relevant training from UCB prior to engaging in research. The exact nature of the training will be known after the development of the detailed performance measurement processes during Phase 2, but is expected to include a short class on specific human subject engagement best practices.

3 Protocol / Application Summary

This section summarizes the involvement of the IRB, including the application process, review process, and relevant policies and procedures.

3.1 Institutional Review Board

UCB's Committee for Protection of Human Subjects (CPHS) is comprised of two groups (CPHS-1 and CPHS-2) that serve as Institutional Review Boards (IRBs) for the University of California, Berkeley[1]. The primary mission of the IRB is to ensure the protection of the rights and welfare of all human participants in research conducted by university faculty, staff and students. The IRB review process is guided by federal and state regulations, university policy, and the Belmont Report. IRB members include faculty, staff and community members, scientists and non-scientists, who, in the aggregate, possess a broad range of interests and expertise that correspond with the areas of research reviewed.

The Office for Protection of Human Subjects (OPHS) is the administrative office that supports the Committee for Protection of Human Subjects by coordinating the review of research, keeping abreast of the changing policies, rules and regulations, and working with CPHS and researchers to address research protocol and compliance issues.

3.1.1 Federal-wide Assurance

Federal-wide Assurance (FWA) #: FWA00006252[2]

Institutional Review Board (IRB) Name (on file with OHRP): U of California Berkeley IRB #1 - CPHS-I

IRB Identification/Registration #: IRB00000455

Institutional Review Board (IRB) Name (on file with OHRP): U of California Berkeley IRB #2 - CPHS-II

IRB Identification/Registration #: IRB00005610

[1] https://cphs.berkeley.edu/about.html

[2] https://cphs.berkeley.edu/fwa.html

3.2 IRB Review Process

The project will apply for Exempt Review Process to be determined by OPHS staff.[3] The following are the UCB guidelines describing research activities that may be exempt from full committee review. It is anticipated that the project meets the second exempt category listed below (bolded), because the planned research procedure is a survey in which data collection is anonymous. The IRB approval process cannot proceed until all final research procedures including precise survey questions are drafted, which is anticipated during Phase 2 five months before the baseline surveys are planned.

Additional review has been performed related to other interventions with human participants performed by the project, but which are not related directly to the performance metrics defined in the PMESP. In conversation with the CALACT project Human Use Lead at CA PATH, the UC Berkeley OPHS confirmed on February 17, 2022 that rider apps released to the public and outreach events performed by the project would not "meet the threshold for human subjects research". The reason for this determination is that any written or verbal feedback from participants will only be used for internal Quality Assurance of the app or system component.

> *Federal Policy for the Protection of Human Subjects (45 CFR 46) identifies categories of research activities involving human subjects that may be exempt from some of the requirements of subcommittee (expedited) or full committee review. In addition, UCB utilizes flexibility within the regulations to allow certain non-federally regulated activities to be exempted under UCB-defined category #70 (formerly #7).*
>
> *Select one or more of the following exempt categories. If research activities do not fit into one or more exempt categories, complete a non-exempt application.*
>
> *NOTE: Certain research activities are not eligible for exempt status because additional protection has been required by federal regulations for vulnerable populations. Specifically, the following do not qualify for exempt status: (1) survey or interview of children; (2) observation of the public behavior of children when investigators interact with the children; (3) interactions with children; and (4) research involving prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners.*
>
> *EDUCATIONAL PRACTICES: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact student's opportunity to learn required educational content or the assessment of educators who provide instruction.*
>
> ***EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF***

[3] See more information about the Exempt Research policies of OPHS at https://cphs.berkeley.edu/exempt.pdf

PUBLIC BEHAVIOR (INCLUDING VISUAL OR AUDITORY RECORDING):Research involving these procedures is exempt, IF one of the following is correct:

- ***Any information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects;***

- *Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation;*

- *Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects CAN readily be identified, directly or through identifiers linked to the subjects, AND an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).*

  RESEARCH INVOLVING BENIGN BEHAVIORAL INTERVENTIONS in conjunction with the collection of information from adult subjects through verbal or written response (including data entry) or audiovisual recording, if the subject prospectively agrees to the intervention and information collection, is exempt,

  Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens,

  Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

  TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES:

RESEARCH THAT INVOLVES NO GREATER THAN MINIMAL RISK TO SUBJECTS, BUT DOES NOT CONFORM TO A SPECIFIC EXEMPT CATEGORY UNDER 45 CFR 46.104(d) (exempt categories 1 through 6).[4]

Exempt determinations must be made by OPHS Staff and the research must not begin until you have received notification that the research was determined to be exempt.

The process of exempt review is as follows:

The investigator submits to the IRB an application for determination of exempt status and any additional required information/documentation (e.g., copy of survey instrument). An IRB administrative staff member reviews the application to determine if the investigator has submitted all of the necessary documentation and supporting materials for exempt review and ensures that all required elements are complete and in proper format. The staff member, in consultation with the OPHS Director or her/his designee as appropriate, evaluates the exemption request for (1) level of risk; (2) category of activity; and (3) other relevant considerations. If the research qualifies as exempt, the staff member provides the investigator with a letter confirming exempt status. If the research does not qualify for exemption, the staff member contacts the investigator to request a non-exempt application for expedited or full committee review. Investigators are not permitted to make the determination of exempt status on their own. Exemption can only be granted by the OPHS staff.

3.3 Ensuring IRB Understanding of Project

In UCB's eProtocol system (https://eprotocol.berkeley.edu/), the research team will communicate all necessary information about the project plans so that the reviewers are able to understand the planned interactions with the project subjects. Beside information listed in section 2, the following information of the study will also be provided during Phase 2. Information regarding planned responses is provided in bold text.

Purpose of the study

Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

The purpose of the study will be described based on the content above in section 2.1 above, as well as additional project overview information from section 1.2.

Background

[4] This UCB Exemption #70 cannot be applied to federally funded projects, including the CALACT ITS4US project, and is included in this list only for completeness. More information at https://cphs.berkeley.edu/guide/exemptcategory70.html

Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations (with attached bibliography) if applicable.

An updated literature review of related research will be performed during Phase 2 by the performance evaluation team but it is not anticipated that there are other research projects would be required or necessary background for the understanding of the proposed research process.

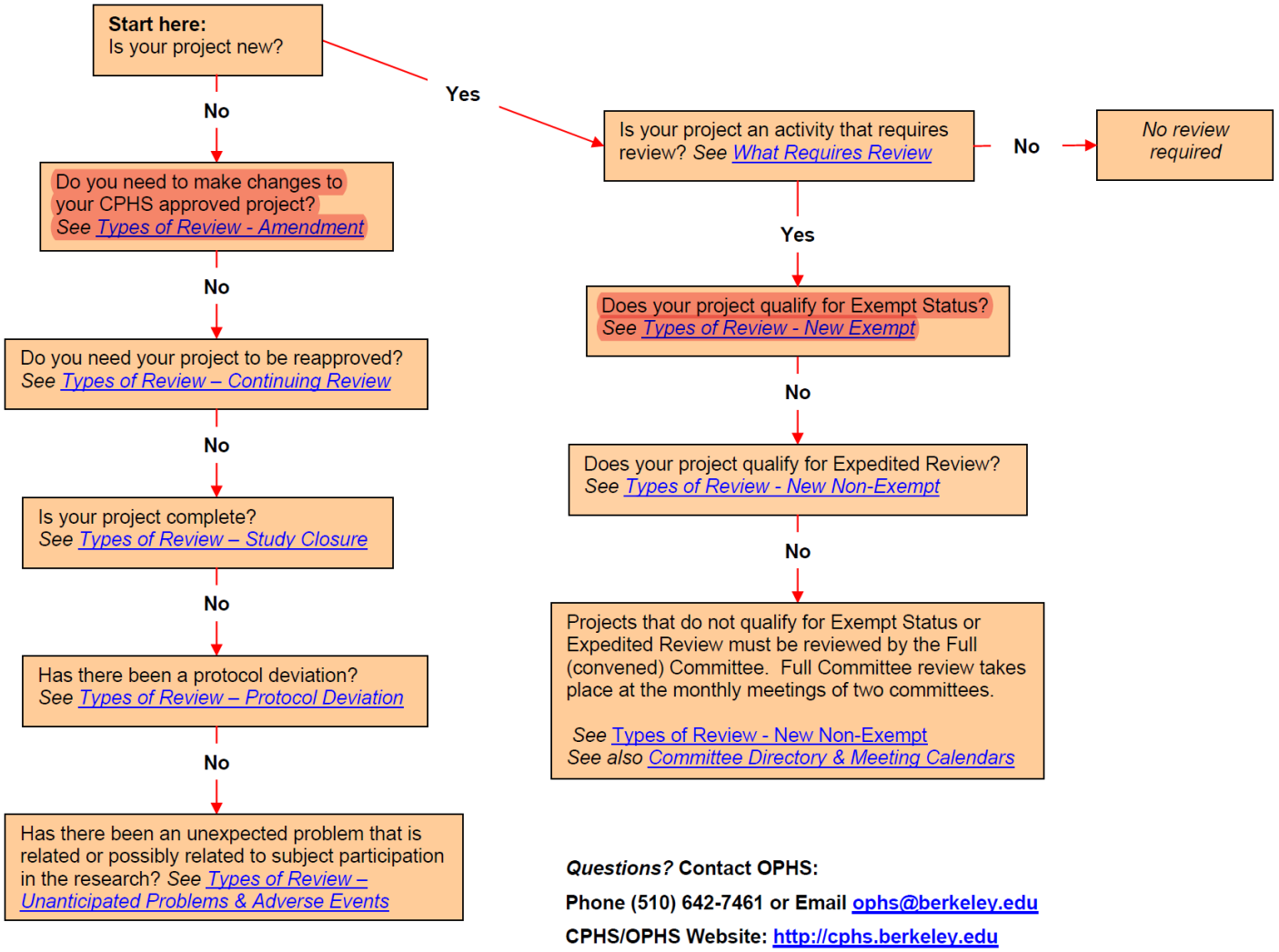
This information will be provided to the IRB at the time of application for exempt status. If any information that is missing or incomplete, the reviewers will contact the research team through the eProtocol system to request further information about the research activities.

3.4 Relevant IRB Procedures

Below is a decision tree about UCB's relevant IRB procedures[5]. In particular, two procedures are relevant to this project. One is the exempt review process, which is specified in section 3.2. Another procedure is the amendment, for making changes to the protocol after it is approved. These two branches are highlighted in the decision tree.

[5] https://cphs.berkeley.edu/DecisionTree.pdf

Figure 1. UCB IRB Decision Tree (Source: UCB)



4 Human Use Approval

This section documents the formal approval, conditions, and feedback expected from the IRB application process. No application for human use approval can be made until Phase 2 of the project, thus this report documents exactly what that process will look like when the project applies.

4.1 Type of Review

This project anticipates having the protocol as an exempt review. However, the exempt determinations must be made by OPHS Staff. Further defense of why this determination is expected can be found in section 3.2.

4.2 Approval Status

Formal approval status for research will be sought during Phase 2 of the project, according to the schedule in Section 5.1, and this section will be updated based on that process.

4.3 Feedback from IRB Review

Feedback will be added to this section during the approval process with the UCB IRB.

The project team participated in IRB submission, review, feedback, and successful approval for exemption related to Phase 1 research. Additionally, the Human Use lead for the CALACT ITS4US project has consulting CPHS and OPHS staff regarding the anticipated exempt status of planned research.

4.4 Conditions

Amendment procedure is described in section 5.1. In order to maintain approval status all changes to the research process must be managed through the IRB amendment procedure.

5 Future Steps and Schedule

This section provides an explanation of all currently known future steps relating to Human Use Approval.

5.1 Phase 2/3 Human Use Approval Confirmation Materials

The following filings must be made in order to achieve Human Use Approval for this project in Phase 2 and 3. They are planned relative to the timing of the “baseline surveys” in deployment sites 2 and 4, which are tentatively scheduled for 12 months after the beginning of Phase 2. The Evaluation Contractor, CA PATH, will be the team in charge of filing all reports related to human use with the IRB, led by Alex Kurzhanskiy, Principal Investigator for the project.

Table 5: Human Use Approval Confirmation Materials Summary

Planned Timing	*Confirmation Material*	*Description*	*Dependencies*
5 months before baseline survey	Form submitted to IRB	Full description of survey information and other details identified in section 2.4.	Detailed survey developed during Phase 2 by the Evaluation Contractor as specified by the Performance Measurement and Evaluation Support Plan.
3 months before baseline survey	Responses to IRB questions submitted to IRB	Any details provided on follow up after initial IRB review.	May be optional if all details are provided at initial filing. Dependent on receipt of questions received from IRB.
2 months before baseline survey	Approval from IRB	IRB sends official approval of research processes	Dependent on original applications and successful follow up to IRB questions.

5.2 IRB-Required Future Actions

The following text in this section is a description of the UCB IRB amendment process, which will be followed in the case of any future modification of the research process.

Amendment (Modification)

Amendment applications must be submitted for all proposed modifications/changes to exempt and currently approved protocols.

Amendment applications for minor changes to Non-Exempt research can receive Expedited Review. Minor changes are defined as changes that (if considered independently from the overall research) involve no significant alteration in research design or fall into one or more of the exempt or expedited review categories, and involve no more than minimal risk to participants. Amendment applications that do not qualify for Expedited Review must be reviewed by the Full Committee. The level of review is determined by OPHS staff in consultation with the IRB Chair as needed.

Policies and Procedures: Amendment Review[6]

Protocol Deviation

Any deviation from an approved Non-Exempt protocol or Exempt protocol must be reported to CPHS/OPHS promptly. The IRB will review the report to determine whether the incident was a serious or a minor noncompliance and assess whether any corrective actions or substantive changes are needed in order to protect the safety, welfare, and rights of subjects or others.

Policies and Procedures: Noncompliance[7]

Unanticipated Problem/ Adverse Event

Unanticipated problems or adverse events must be reported to CPHS/OPHS if they are: 1) unexpected; 2) related or possibly related to participation in the study; and 3) suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized. The IRB will review the report to assess whether any corrective actions or substantive changes are needed in order to protect the safety, welfare, and rights of subjects or others.

An initial report should be made by mail/delivery, phone, or email to the Director, Research Subject Protection as soon as possible, but within no more than one week (7 calendar days) of the Principal Investigator learning of the incident. The initial report must be followed by a formal written report within no more than two weeks (14 calendar days) of the Principal Investigator learning of the incident.

[6] https://cphs.berkeley.edu/policies_procedures/rr404.pdf

[7] https://cphs.berkeley.edu/policies_procedures/rr410.pdf

Policies and Procedures: Unanticipated Problems and Adverse Events[8]

[8] https://cphs.berkeley.edu/policies_procedures/rr408.pdf

Appendix A. IRB Documentation

IRB documentation has not been submitted officially at this time, for reasons described in Section 3.2 of this report. Certain pre-application communications have confirmed the viabilitiy of the research plan described in section 2 and the IRB approval process described in section 4:

- Review of research plan by Human Use lead Dr. Peggy Wang of CA PATH
- Email communication with CPHS by Dr. Wang on February 17, 2022 to confirm understanding of relationship of some research to IRB process.

Further content to be added upon submission of application and receipt of approval status.

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

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