Phase 1 Human Use Approval Summary

Heart of Iowa Regional Transit Agency ITS4US Deployment Project

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Final Report — March 10, 2022
FHWA-JPO-21-897

COMPLETE TRIP
ITS4US

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16. Abstract

The Heart of Iowa Regional Transit Agency (HIRTA) is one of the 5 awardees for Phase 1 of the Complete Trip – ITS4US contract for its proposed concept "Health Connector for the Most Vulnerable: An Inclusive Mobility Experience from Beginning to End" (Health Connector) by the United States Department of Transportation (USDOT). Building on the Concept of Operations (ConOps), Data Management Plan (DMP) and Performance Management and Evaluation Support Plan (PMESP) developed earlier in Phase 1, the Human Use Approval Summary (HUAS) describes the planned extent and nature of the Health Connector project relating to research involving human subject participants, including the process for seeking and securing Institutional Review Board (IRB) approval for the research to be conducted in Phases 2 and 3 of this project.

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1 Introduction

The Heart of Iowa Regional Transit Agency (HIRTA) is one of the 5 awardees for Phase 1 of the Complete Trip – ITS4US contract for its proposed concept "***Health Connector for the Most Vulnerable: An Inclusive Mobility Experience from Beginning to End***" (Health Connector) by the United States Department of Transportation (USDOT). The Health Connector solution will offer a collection of electronic applications and interfaces designed to improve the experience of Dallas County residents looking for transportation services for their medical appointments.

The Human Use Approval Summary Plan (HUAS) builds on the user scenarios and performance measurement framework as established in the ConOps report. The primary purpose of this summary is to explain the need for Human Use Approval in Phases 2 and 3 of this project and to document the solicitation of Institutional Review Board (IRB) review and approval for activities that involve human subjects. In this project, the only such activities will be the annual surveying of some Health Connector participants to gather information used in conducting internal evaluations of the Connector and its outcomes.

In addition to discussing human use approval, this HUAS document provides an overview of the Health Connector project, and presents an overview of the research plan that the project partners at Iowa State University's Institute for Transportation (InTrans) will refine and follow as they develop and conduct the above-mentioned evaluations, discussing how the measures established in the project's Performance Measurement and Evaluation Support Plan (PMESP) will inform the data collection and evaluation process. Considerations of engaging "vulnerable" populations in this project, which is an essential issue in assuring Human Use Approval, are presented, and linkages between this research plan and other aspects of the project's Phase 2 and 3 activities are discussed in brief.

1.1 Document Purpose

This Human Use Approval Summary describes the planned extent and nature of the project relating to research involving human subject participants (i.e., a summary of the Iowa State University's Institutional Review Board (IRB) application) and documents the IRB application / process covering the project and Phase 1 outcome.

1.2 Project Overview

The Health Connector solution intends to demonstrate an innovative concept that will address various bottlenecks associated with healthcare access for HIRTA communities. Some of these challenges are the key reason behind missed appointments or unacceptable level of preventive or as-needed healthcare in HIRTA service area. For this deployment, the HIRTA team plans to implement a scalable and replicable solution that enables inclusive access to non-emergency medical transportation for all underserved populations and their caregivers by resolving access barriers with the use of advanced technologies. This solution will allow Dallas County residents

without access to transportation who may be seeking a medical appointment to explore their transportation alternatives and book both medical and transportation appointments at the same time. Further, this solution will include information and wayfinding services to guide them at every step of their trip. Figure 1 provides an overview of the Health Connector concept.

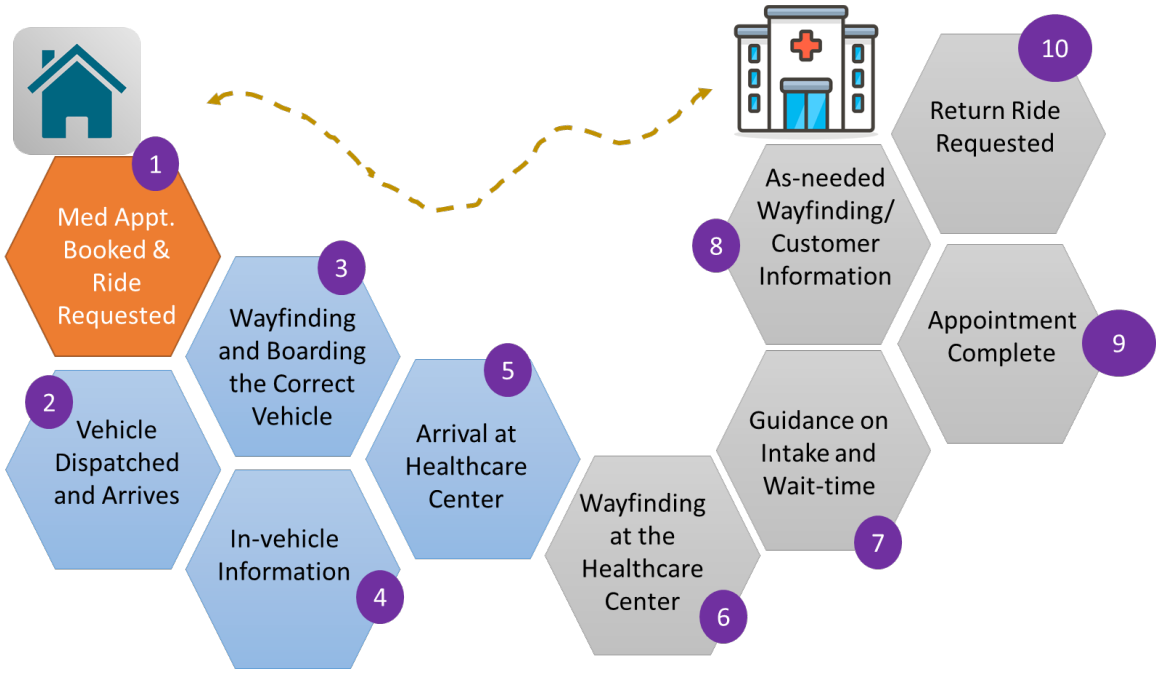

Figure 1. Health Connector Overview (Source: HIRTA Team)

Key capabilities of the proposed technology solution are as follows:

- Enable the customer to use a smart device (e.g., smartphone, smartwatch) application or equally effective alternate methods to schedule and manage medical appointments and transportation services, all in one location (Unified Health Connector App).
- Provide customers options to choose from available providers. Provide same day response if needed by customers.
- Send customers alert before arrival and again when the vehicle is approaching.
- Keep customers informed on trip progress at every step of their complete trip (see Figure 1).
- Provide directions (audible and visual) on where to meet the vehicle/driver. On arrival, drivers should have the ability to automatically confirm customer identity and assist with boarding as needed.
- Provide drivers the capability to request turn-by-turn navigation to a desired destination.

- The Health Connector App will enable the customer to utilize advanced wayfinding solutions with the help of indoor and outdoor navigation technologies to provide personal concierge-style travel from origin to destination. This will include:
    - Locating the vehicle outside origin and destination locations
    - Locating healthcare facility when dropped off by vehicles
    - Locating desired floor/room when inside the healthcare facility
- Customers will be able to use the Health Connector solution for any contactless payment needs at any point for transportation-related payments.
- Customers can initiate return trip when the appointment is complete and follow the similar process as the inbound trip to medical facility to locate and board the vehicle for the return trip.
- If customers or their caregivers desire to book and pay for another local trip as an additional leg along with the medical trip they will be able to do that using Health Connector solution.

The systems and interfaces involved in the context of Health Connector can be defined as follows:

- **Traveler-end Subsystem:** this subsystem includes the tools and technologies to be used by travelers or patients seeking transportation services for their medical appointments as part of pre-trip, en-route trip, on arrival and return trip activities.
- **Transportation Management Subsystem (TMS):** this subsystem includes the tools and technologies used to assist customer care and operations staff with reservations, scheduling, dispatching and administration activities. This includes the existing Routematch software and planned upgrades to deploy a combined Routematch/Uber back-end, and new development to deploy additional functionalities, as required for Health Connector.
- **Vehicle Subsystem:** this subsystem refers to the technologies deployed on vehicles to support Driver-end functions for manifest management, on-board customer information and customer payments.
- **Wayfinding Subsystem:** this subsystem refers to the technologies and infrastructure to be used for providing indoor positioning, orientation and step-by-step guidance on request to travelers.
- **Integration:**
    - **Access2Care:** this subsystem refers to State of Iowa Medicaid Brooker's system used for booking and managing Medicaid trips. HIRTA is one of the providers used by Access2Care.

- **Health Navigator-end Subsystem:** this subsystem refers to the information and referral system used by Dallas County Health Department. This subsystem will be used to obtain medical and transportation appointment details or availability for a Dallas County resident health navigation/social care services.

- **EHR/Medical Record Subsystem:** this subsystem refers to the systems used by partner hospitals and clinics for booking medical appointments and maintaining their appointments, including discharge and any subsequent referral activities.

Figure 2 provides a generic system context diagram for HIRTA Health Connector.

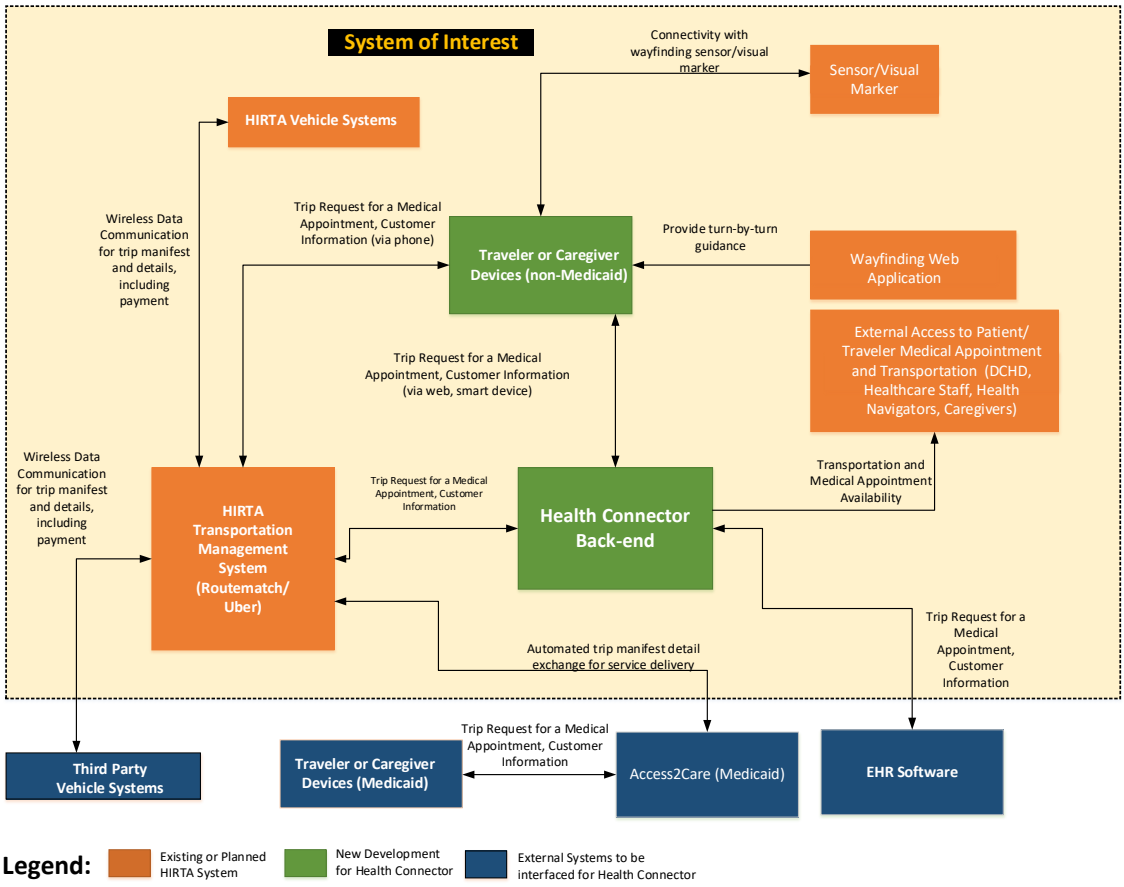

Figure 2. High-level System Context Diagram for Health Connector (Source: HIRTA Team)

1.3 Definitions, Acronyms, and Abbreviations

Access2Care

A transportation broker for State of Iowa Medicaid program that performs booking and scheduling and works with service providers such as HIRTA for successful delivery of Medicaid-eligible trips.

ADA – Americans with Disabilities Act

Refers to the civil rights legislation passed and signed into law in 1990 to prevent discrimination against people with disabilities.

Billing

Refers to the process of invoicing third-party funding sources (e.g., Medicaid) after a successful delivery of a trip. Billing is typically done on a monthly basis.

CHNA – Community Health Needs Assessment

Refers to the Community Health Needs Assessment Report developed by Dallas County in 2019.

CO – Contract Officer

The CO will serve as the USDOT point of contact for any concerns related to the contracts.

COR – Contract Office Representative

The Contract Office Representative will serve as the USDOT representative for this project and is responsible for coordination and review of the proposer's work.

Cost Allocation

Refers to the process of associating a funding source that should be billed for a trip in a shared ride scenario when riders covered by separate funding sources share the vehicle for their trips and trip purposes at the same time.

CTAA – Community Transportation Association of America

One of the project Partners who will lead stakeholder engagement on this project.

DCHD – Dallas County Health Department

One of the project Partners who will lead integration with health care services.

DR – Demand Response

Refers to a service that is not run on a fixed route or a schedule (e.g., dial-a-ride, vanpool etc). This requires making trip booking by contacting the service provider (e.g., HIRTA). However, DR is different than an ADA Paratransit service which is provided as a complement to a fixed route and is governed by specific requirements provided in 49 CFR- Part F. HIRTA operates only DR Service in Dallas County and all discussion in this document is related to DR Service.

Dispatching

Refers to an operations management function which involves assigning vehicle, tracking fleet location, managing schedule adherence, managing trip manifests and other operational functions.

DMP – Data Management Plan

The Data Management Plan is Task 3 of Phase 1 and will describe the approach for data collection, processing, storage and utilization.

DOT – Department of Transportation

The government department responsible for transportation. In this report, this generally refers to either the State of Iowa's DOT or the United States DOT referred to as Iowa DOT and USDOT, respectively.

EDI – Electronic Data Interchange

In this context, refers to the electronic data interchange (EDI) format messages developed by HIPAA following American National Standards Institute (ANSI) X12 standard for electronic data exchange and are used to communicate with third-party health care provider systems (e.g., Medicaid).

EHR – Electronic Healthcare Record

Refers to the healthcare information management system used by hospitals for patients' healthcare-related appointments, transactions, and records management.

GTFS – General Transit Feeds Specification

GTFS is a standard to provide static public transportation schedule information. The standard has been expanded to include real-time passenger information (GTFS-real-time), flexible services (GTFS-flex) and accessible routing within stations (GTFS-pathways).

HIPAA – Health Insurance Portability and Accountability Act of 1996

Provides guidelines for data protection of sensitive patient health information.

HIRTA – Heart of Iowa Regional Transit Agency

Rural, regional public transit agency in central Iowa. HIRTA will serve as Proposer/Applicant for the Complete Trip - ITS4US project.

HL7 – Health Level Seven International

A not-for-profit, standards developing organization focused on electronic health information.

HN – Health Navigator

Refers to services provided by Dallas County Health Department to Dallas County residents in identifying resources as necessary for improving social determinants of health.

ICTDP – Integrated Complete Trip Deployment Plan

The Integrated Complete Trip Deployment Plan is a deliverable of Task 13 under Phase 1.

Information and Referral

Refers to public and private entities that help their customers in identifying resources for health and human services and other needs.

IPFP – Institution, Partnership, and Financial Plan

The Institution, Partnership and Financial Plan is a deliverable of Task 10 under Phase 1.

ISU – Iowa State University

Iowa State University is a public research university with multiple campuses in the State of Iowa and will be engaged as the research and evaluation partner in Phases 2 and 3.

KPI – Key Performance Indicators

Represents primary metrics used to assess the success of a project or operations.

LEP – Limited English Proficiency

Refers to individuals who have a limited ability to read, speak, write, or understand English.

NDSP – Non-Dedicated Service Provider

NDSP refers to operators providing service under contract (e.g., taxis) to an agency (e.g., HIRTA).

NEMT – Non-emergency Medical Transportation

The provision of transportation to patients for medical appointments, lab visits, and other routine care. Generally, used in the context of Medicaid service only.

PII – Personally Identifiable Information

Refers to any data that can distinguish an individual, either alone or when linked with other available data.

Provider

Provider in this context mainly refers to an entity performing service delivery for requested trips, sometimes also referred as service provider. We have also used healthcare partners as providers in some cases but referred as ‘healthcare providers.’

Reservation

Refers to the act of booking a trip based on a request from a customer. Reservation is available to only registered customers.

RWP – Requirements Working Group

Is subset of identified stakeholders that will guide the requirements development process.

Scheduling

Refers to the process of identifying driver and vehicle resources and their runs/shifts for a given work day. Scheduling is typically performed for all requests received until 24 hours in advance. Booking within 24 hour notice and on-demand is offered but not encouraged due to limited system capacity and resources.

SEMP – System Engineering Management Plan

A System Engineering Management Plan describes how systems engineering process of planning, design, and deployment is applied to a project.

SMP – Safety Management Plan

A Safety Management Plan describes the steps to be taken to ensure the safety of the project stakeholders and beneficiaries.

Smart Device

Refers to smartphone, smartwatch and similar personal devices that may be internet enabled and are equipped with sensors.

TAG – Transportation Advisory Group

The TAG is a diverse group of community stakeholders and business representatives interested in the advancement and improvement of public transportation in the HIRTA service area.

TNC – Transportation Network Company

Encompasses a group of companies that provide on-demand Ridehailing services.

Wayfinding

Refers to the tools and technologies that assist in orientation, locating objects, and step-by-step navigation to destinations in outdoor and indoor environments using visual markers, sensors or physical signage.

2 Human Subjects Research Plan

Per the requirements of the Phase 2 and 3 of the Complete Trip- ITS4US Deployment project, the HIRTA Project team will be conducting an evaluation of the Health Connector system deployment. The evaluation will be conducted per the PMESP to measure the outcomes on riders, HIRTA system, Dallas County and broader HIRTA service area. These evaluations will be performed during Phases 3 by the Institute for Transportation (InTrans) at Iowa State University (ISU).

It is determined by the Iowa State University (ISU) Institutional Review Board (IRB) in its initial review of the proposed plan for carrying out this project, including surveys of its participants, the Health Connector project is determined by the IRB to be "research that does not involve human subjects according to federal regulations." The IRB submission and determination process is detailed later in this document, and the IRB letter of determination is included as an appendix to this document (see Appendix A).

Regardless the current determination by the IRB, InTrans will follow up with the IRB in the initial period of Phase 2 with specific details concerning research techniques and methodology and will not commence any survey work or other use of individuals' data without either IRB approval or a reaffirmed determination from the IRB that this project continues to be exempted from the need for IRB approval. Furthermore, InTrans will solicit review and approval from the ISU IRB in the first quarter of every project year during the performance of Phases 2 and 3 of the Health Connector project.

The current determination by the ISU IRB was based on an initial estimate of what would be included in Phases 2 and 3. Several details, such as specific data to be collected were not available. As a result, it will be necessary to submit an updated IRB plan which provides in-depth details of what data will be collected, how data will be stored, how PII will be handled (if gathered), who will have access to the data, and how data will be analyzed. The IRB will be updated in Phase II and the IRB determination and a plan for following IRB protocols will be provided to USDOT. The updated IRB will be necessary before ISU is able to begin collection or analysis of data. The IRB will also need to be updated at the beginning of Phase III since some details may have changed. Any new determinations or protocols will also be provided to USDOT. At any point in the project, if data collection, data storage, or analysis methods change, it will also be necessary to update the IRB. A plan for how ISU will address all IRB protocols will also be provided and updated as needed.

2.1 Research Questions

In determining the apparent results and outcomes associated with the Health Connector, four primary research questions will be explored. They are:

1. How did the Health Connector improve mobility for Dallas County residents in terms of their access to medical care?

2. Which deployed strategies, services, and/or components of the Health Connector contributed most significantly to the Health Connector's positive outcomes?

3. In general, what was the degree to which the benefits of the Health Connector accrued to Dallas County's (a) residents over the age of 60, (b) residents of households with income below the federal poverty line, (c) veterans receiving health care services or benefits from the U.S. Department of Veterans Affairs, (d) residents for whom English is not their primary language, (e) residents with disabilities, and (f) residents who live outside the Census-defined Des Moines urbanized area?

4. More specifically, to what extent did use of the Health Connector reduce the number of missed medical appointments for Dallas County's (a) residents over the age of 60, (b) residents of households with income below the federal poverty line, (c) veterans receiving health care services or benefits from the U.S. Department of Veterans Affairs, (d) residents for whom English is not their primary language, (e) residents with disabilities, and (f) residents who live outside the Census-defined Des Moines urbanized area?

2.2 Interactions with Other Tasks and Consistency

The goals, objectives, metrics and overall methodology for determining and evaluating the outcomes of this project are specified in the Performance Measurement and Evaluation Support Plan (PMSEP). That plan calls for analysis of system performance to be examined on two tracks: (1) Quantitative analysis of data collected during routine operation of the Health Connector, which is kept anonymous in this evaluation, and which uses only those data provided or generated during the routine daily operations of the Connector, and (2) Surveys of Health Connector users, and of a control group of HIRTA passengers not using the Connector, that will confirm the quantitative information gathered through data analysis, and also will provide qualitative responses not able to be collected in the system's ongoing use of data. Some data will be based on information supplied by third-party stakeholders (primarily, healthcare providers), but those data will summarize operations and outcomes reported by these third parties, and will not involve the collection or examination of any individualized data, nor will these third parties have any need to conduct research on human subjects as part of their involvement with the Health Connector. Because there will be some direct interaction with individual persons using the Health Connector and other HIRTA transportation services, Human Use Approval needs to be considered in this project.

In addition to being guided by the details of the PMESP, this Human Use Approval Summary is informed by the details of the Data Management Plan and elements of the Safety Management Plan. All these plans, of course, are developed from the underlying Concept of Operations.

Human Use Approval is an essential issue to be considered not only in the system evaluation aspect of the PMESP, but also in how the tasks of Outreach and of Participant Training and Stakeholder Education are planned. In particular, linkage to the Participant Training and Stakeholder Education Plan (PTSEP) is discussed in sections 2.6 and 2.7, below, and Human Use Approval considerations are to be cited in some detail in both the Outreach Plan and PTSEP documents.

Within the PMESP, there are 24 specific performance measures as shown in Table 1 below. Most of these measures are examined with no participant input, but a couple are derived through a

combination of system-generated data and user surveys, some are derived exclusively from the results of surveying Health Connector users and other HIRTA passengers, and the remaining measures are determined through information supplied by third parties.

More specifically, here's the breakdown of data sources for the performance measures that are used in determining and evaluating the Health Connector's outcomes:

- Data derived solely through the regular operations of the Health Connector – 14 performance measures (PMs 1, 2, 3, 4, 5, 6, 7, 15, 16, 17, 18, 19, 21, 24)
- Data derived through a combination of system data and user surveys – 2 performance measures (PMs 10 and 14)
- Data derived solely from user surveys – 5 performance measures (PMs 8, 9, 11, 12, 13)
- Data derived from information supplied by third parties – 3 performance measures (PMs 20, 22, 23)

Table 1. Performance Measures, Evaluation Questions, and Nature of Input

Performance Measure	Evaluation Question	Primary Data Source	Nature of Human Subject Input
PM 1 - Ability to Dynamically Reassign Vehicles to Address Service Disruption	Will Health Connector enhance service reliability by reassigning disrupted healthcare trips in an efficient manner?	Data supplied by system operations	None
PM 2 - Availability of Transportation Alternatives	Will Health Connector promote self-reliance for underserved groups by providing reliable access to preferred alternatives for healthcare transportation?	Data supplied by system operations	None
PM 3 - Trips Unfulfilled Due to System Unreliability	Will Health Connector help reduce the number of unfulfilled trips by improving system reliability through improved transportation management capabilities?	Data supplied by system operations	None

Performance Measure	Evaluation Question	Primary Data Source	Nature of Human Subject Input
PM 4 - ETA Prediction Accuracy	Will Health Connector help in delivering reliable services by calculating ETA predictions accurately and reliably?	Data supplied by system operations	None
PM 5 - On-time Performance	Will Health Connector help in delivering services on-time in a reliable manner?	Data supplied by system operations	None
PM 6 - Travel Time Prediction Accuracy	Will Health Connector help in calculating on-board (in-vehicle) travel time for a trip accurately and reliably at the time of scheduling?	Data supplied by system operations	None
PM 7 - Spontaneity Time	Will Health Connector improve self-reliance and spontaneity by making travel alternatives available per Traveler preferences within a reasonable time window when requested?	Data supplied by system operations	None
PM 8 - Reliability of the system in Assisting with non-vehicle component of a complete trip	Will Health Connector provide wayfinding tools to increase self-reliance in Travelers so they are able to navigate to/from a pick-up or a drop-off location?	Data derived from survey input	Health Connector users and control group of other HIRTA passengers are surveyed
PM 9 - Privacy Protection	Do Travelers feel confident that their information is protected when using Health Connector?	Data derived from survey input	Health Connector users and control group of other HIRTA passengers are surveyed

Performance Measure	Evaluation Question	Primary Data Source	Nature of Human Subject Input
PM 10 - Traveler Safety in Healthcare Transportation	Will Health Connector help ensure safety of Travelers during all Complete Trip segments of healthcare transportation?	Data derived through combination of system-generated information and survey input	Health Connector users and control group of other HIRTA passengers are surveyed, with results compared to system data
PM 11 - System ability to meet accessibility needs of Travelers	Do Travelers feel confident that the system and services are accessible?	Data derived from survey input	Health Connector users and control group of other HIRTA passengers are surveyed
PM 12 - Self-reliance/ dignity index	Will Health Connector provide Travelers freedom of movement with dignity while accommodating their needs and preferences so they can become self-reliant?	Data derived from survey input	Health Connector users and control group of other HIRTA passengers are surveyed
PM 13 - Reduced anxiety/ stress	Will the system help in reducing stress related to medical transportation?	Data derived from survey input	Health Connector users and control group of other HIRTA passengers are surveyed

Performance Measure	Evaluation Question	Primary Data Source	Nature of Human Subject Input
PM 14 - Complaints and Customer Satisfaction	Will the system help in reducing complaints related to a medical trip and increase Traveler satisfaction with delivery of service for healthcare trips?	Data derived through combination of system-generated information and survey input	Health Connector users and control group of other HIRTA passengers are surveyed, with results compared to system data, such as to substantiate or quantify service attributes related to specific complaints (e.g., if a user complains about lateness of service, length of trip, driver no-show, etc., what do actual system data reveal around these reports)
PM 15 - System Productivity	Will the system enhance productivity as evidenced by increasing number of medical trips per hour each month?	Data supplied by system operations	None
PM 16 - Ability to Assign Trips to Third-Party Providers	Will Health Connector demonstrate efficient transportation management capabilities to provide as needed capacity by assigning trips to third-party providers when needed?	Data supplied by system operations	None
PM 17 - Deadhead miles and hours	Will the system help improve efficiency by minimizing deadhead miles and hours for healthcare trips?	Data supplied by system operations	None

Performance Measure	Evaluation Question	Primary Data Source	Nature of Human Subject Input
PM 18 - WAV reliability	Will the system help demonstrate efficiency by assigning vehicles with operational wheelchair lifts as needed on a consistent basis?	Data supplied by system operations	None
PM 19 - Increased Cost Efficiency	Will system demonstrate efficient transportation management by reducing the cost of medical transportation?	Data supplied by system operations	None
PM 20 - Improved coordination among HIRTA, healthcare providers, health navigators	Will the system demonstrate efficiency by coordinating trips among HIRTA and its partners in a short period of time?	Data supplied by third parties	Human subjects are not surveyed for this measure.
PM 21 - Delivery of Safe Healthcare Transportation	Will Health Connector help provide safe transportation?	Data supplied by system operations	None
PM 22 - Reduction in Medical Appointment Deferment Due to Lack of Transportation	Will capabilities available through Health Connector encourage Dallas County Residents to not miss their medical appointments due to convenient access to transportation services available through HIRTA?	Data supplied by third parties, supplemented by survey input	Health Connector users and control group of other HIRTA passengers are surveyed, with results compared to healthcare provider data, so as to substantiate or quantify any changes in medical appointment schedule changes, deferments or cancellations attributed to transportation.

Performance Measure	Evaluation Question	Primary Data Source	Nature of Human Subject Input
PM 23 - Savings due to reduction in the number of missed medical appointments	Will the system result in financial savings for healthcare partners with reduction in the missed number of medical appointments?	Data supplied by third parties	Human subjects are not surveyed for this measure.
PM 24 - Safe Transportation Access to Healthcare Facilities	Will the system help provide safe transportation access to healthcare facilities?	Data supplied by system operations	None

As mentioned earlier, the details behind these measures, including their definitions and how their underlying data are collected, can be found in the PMESP, and more about methodology will be presented in the PTSEP.

2.3 Considerations for Vulnerable Populations

In as much as this project is focused primarily on improving transportation access to healthcare for a variety of “vulnerable” populations, the human use considerations for any research involving these populations are of paramount importance. The population cohorts being examined in this project include some of those that are considered vulnerable populations under federal research guidelines and requirements, plus other at-risk populations not considered as vulnerable where federal research on human subjects is concerned. The specific populations being examined in this project are:

(a) residents over the age of 60 (“older adults”),

(b) residents of households with income below the federal poverty line (“low- or no-income households”),

(c) veterans receiving health care services or benefits from the U.S. Department of Veterans Affairs (“veterans”),

(d) residents for whom English is not their primary language (“Limited English Proficiency [LEP] populations”),

(e) residents with disabilities, and

(f) residents who live outside the Census-defined Des Moines urbanized area (“rural residents”)

In advance of Phase 3 of this project, individuals will be recruited to participate in the Health Connector. A comparable cohort of current HIRTA customers in Dallas County will be recruited for

participate as a “control group” for helping evaluate Health Connector outcomes. Trusted third parties in Dallas County will assist in the recruitment of participants, and may participate as project stakeholders, but those third parties will not have any role in operating the Health Connector nor in handling, reviewing or analyzing any personally identifiable information arising from Health Connector activities or assessments. These trusted third parties will be identified and engaged in Phase 2 of the project, and are likely to include public sector or nonprofit entities serving older adults, public sector or nonprofit entities providing services or assistance to low-income families, local veterans service organizations, entities providing services to Spanish-speaking populations, immigrants, and refugees, public sector or nonprofit entities providing advocacy and services for adults with disabilities in Dallas County.

Both HIRTA – who will oversee operation of the Health Connector, in addition to continuing to provide its ongoing public transit services in Dallas County - and the area healthcare providers already are maintaining personally identifiable information (PII) for these individuals with the full degree of appropriate and required protection and confidentiality; any data collected from individuals as part of their use of the Connector will be limited only to what is operationally necessary to arrange and provide transportation and associated wayfinding information, arrange for fare collection or third-party payments, maintain currently required records, and prepare reports and grant-related accounting under current terms and conditions of federal or state grants and contracts already in place.

As mentioned above in Section 2.2, and discussed in somewhat greater detail below in Sections 2.4.1 and 2.4.2, a randomly selected cohort of Health Connector participants (and a randomly selected control group of other HIRTA passengers) will be given opportunities to respond to surveys about using the Health Connector. Participation in any such survey will be, and will be presented as, entirely voluntary. Surveys will be developed by InTrans, with methodological consultation provided by the ISU Center for Survey Statistics and Methodology (CSSM), and will not be conducted without a permissive determination by the ISU IRB. To ensure meaningful levels of participation, while also assuring accessibility to survey respondents regardless of disability, income, language or other factors, surveys are likely to be conducted through a variety of media, which could include online or in-app surveys, telephone interviews or paper-based surveys. In any case, none of these survey media will be used in ways that present or imply any pressure or mandate for survey participation.

- All survey respondents will be given the option of remaining anonymous in their responses, in which case they will be assigned unique identifiers that prevent duplication or corruption of survey response data, while preserving anonymity and protecting anonymous respondents’ personally identifiable information.

- All respondents will be asked to voluntarily indicate if they identify themselves with one or more of the six targeted population cohorts listed above, but will not be asked to verify or validate those affiliations, nor will they be asked anything more about their indicated population cohort affiliation(s). Information about these affiliations is used simply to illustrate the extent to which the Health Connector is used by target populations, and not for any detailed or comparative analysis. Demographically, it’s expected that the majority of Health Connector users, like the majority of HIRTA passengers, identify with two or more target populations (e.g. Spanish-speaking older adults living in rural Dallas County, low-income veterans with disabilities, etc.).

- Survey respondents may be asked if they were using HIRTA or the Health Connector for medical transportation; however, under no circumstances will any survey respondent or be asked anything at all about their medical condition or treatment, their reason(s) for seeking medical transportation, the name or nature of the healthcare provider, nor even the addresses or specific locations of their Health Connector origins and destinations.

- Survey respondents may be asked very general questions about their perceptions of health and safety while using HIRTA or the Health Connector, but will not be asked to provide any specific information about health outcomes or changes in their health status during their period of HIRTA or Health Connector utilization.

- Surveys will not be administered to anyone under the age of 18.

2.4 Informed Consent

Each participant in the Health Connector will be required to register as a Health Connector user. As part of this registration process, all participants will be asked to provide Informed Consent. In addition, the "control group" of other HIRTA users whose experiences will be measured in comparison to the Connector also will be required to provide Informed Consent. Statements of Informed Consent will include the appropriate language as outlined by the ISU IRB process. Precise wording will be based on ISU IRB guidance, but will include the following elements, with some possible elements of suggested text as illustrated below:

- Title of the study

- Principal investigators

- Purpose of the study

- Invitation to participate

  Possible text, to be refined by principal investigator, and to be reviewed and approved by IRB before use: "You are invited to participate in a research study. This form has information to help you decide whether or not you wish to participate—please review it carefully. Research studies include only people who choose to take part—your participation is completely voluntary, and you can stop at any time.

  "Please ask the project staff any questions you have about the study or about this form before deciding to participate."

- Eligibility to participate

  Possible text, to be refined by principal investigator, and to be reviewed and approved by IRB before use: "You are eligible to participate in this study if you are a resident of Dallas County and are 18 years or older.

  "You should not participate if you are not a Dallas County resident age 18 years or older."

- Expected duration

  Possible text, to be refined by principal investigator, and to be reviewed and approved by IRB before use: "You will be welcome to continue using the Health Connector as long as you wish, for as long as HIRTA continues to operate it. We will ask you to affirm your consent once a year."

- Risks or discomforts that may be experienced

  Possible text, to be refined by principal investigator, and to be reviewed and approved by IRB before use: "You should not experience any risks or discomforts as a result of participating in the Health Connector. If you or any responsible party feel participation in this study is causing you risk or discomfort, it is encouraged, but not required, that you discuss this with the principal investigator. Any discussion concerning possible risk or discomfort this study is causing for you will be kept in complete confidence. If you decide to withdraw from the study, you may do so, without penalty or prejudice."

- Benefits to participants or others

- Costs or compensations

  Possible text, to be refined by principal investigator, and to be reviewed and approved by IRB before use: "You will not receive any reimbursement, compensation or other monetary gifts or awards in connection with your participation in this study."

- Rights as a research participant:

  Possible text, to be refined by principal investigator, and to be reviewed and approved by IRB before use: "You have the right to withdraw from this study at any time, for any reason. You are requested to notify the principal investigator prior to withdrawing from the study, but such notification is not a requirement."

- Confidentiality

  Possible text, to be refined by principal investigator, and to be reviewed and approved by IRB before use: "You will not be required to share or disclose any confidential information as part of your participation in this study, nor are the study researchers to receive any confidential information about you from third parties. If you believe confidential information about you has been collected as part of this study without your approval and in violation of this statement, please notify the principal investigator as promptly as you can."

- Consent statement

2.4.1 Participant Questionnaires / Evaluation

As cited above, and as mentioned in the PMESP and other project documents, some information to gauge the outcomes and effectiveness of the Health Connector will be gathered via surveys of willing and informed participants, as well as comparable surveys of some HIRTA passengers who

are not using the Connector. Anticipated data to be collected are discussed below in Section 2.4.2. Survey work will be performed by the Institute for Transportation at Iowa State University (InTrans) and will be conducted in full accordance with ISU practices, guidelines and requirements concerning surveys of human subjects. In Phase 2, InTrans will consult with its sibling institution with Iowa State University, the ISU Center for Survey Statistics and Methodology, to determine the most suitable array of methodologies to employ in surveying Health Connector participants and other HIRTA customers. The expectation is that surveys will be administered online, through telephone interviews, and possibly through paper surveys or other media. In any event, it will be important to ensure that all users groups of the Health Connector are able to be represented proportionately in this survey work, regardless of potential barriers that could be associated with income, language, disability or other factors.

Obviously, telephone-based surveys will mean the InTrans surveyor is likely to encounter some respondents' names and phone numbers and will be exposed to these respondents' answers to survey questions. The conduct of telephone surveys will be carefully scripted to assure that no information is collected from participants until they've been able to give informed and voluntary content to participate in the survey. The scripting will assure that InTrans interviewers do not ask any leading questions, do not pressure or influence responses to individual survey questions, accept "decline to answer" as a valid response to any and all survey questions without prejudice, and fully and immediately respect any requests from participants to keep their survey response information anonymous.

2.4.2 Participant Data

While the specific wording and sequencing of the questions asked of participants will be refined by the InTrans team in preparation of Phase 2, participant data being collected in this survey process is expected to include the following elements, in accordance with this project's PMESP (data elements are keyed to performance measures as indicated):

- Participant's name and phone number
- Is participant a resident of Dallas County (Y/N)? (If no, then survey terminates and individual is not included in survey pool)
- Does the participant live in either the city of Clive, Urbandale, Waukee or West Des Moines? (Y/N) (Residents of those municipalities are within the Des Moines urbanized area, while residents of all other portions of Dallas County are rural residents, according to Census Bureau determinations)
- Is participant over the age of 60 (Y/N)?
- Is the participant's annual household income (a) less than $13,000, (b) between $13,000 and $30,000, or (c) more than $30,000?
- How many persons, including both children and adults, live in the participant's household? (This and the previous question will help determine whether a participant is living in a household with income below the federal poverty line)
- Is the participant a veteran receiving healthcare from the Department of Veterans Affairs (Y/N)?

- Does the participant speak English as their primary language (Y/N)? (If not, the surveyor will ask if the participant prefers to conduct the survey in another language, and will have to provide the most seamlessly possible transition to continuing with the survey in the participant's non-English language of choice)

- Does the participant have a disability (Y/N)? (This survey asks only for self-reported disability status; since this survey is not used to ascertain whether reasonable accommodation is being provided to individuals on the basis of disability, the surveyors do not need, and should not be asking about, any information on persons' specific disability status or accommodation)

- Did the participant use the Health Connector for their transportation to or from a medical appointment or healthcare during [the date range being studied] (Y/N)?

- Did the participant use HIRTA for their transportation during [the date range being studied], whether for medical trips or other purposes (Y/N)? (The responses to this and the preceding question will be used to place survey responses into either the Health Connector survey data set or the HIRTA control group survey data set)

- Were you given reliable, appropriate choices for your transportation? (PM 2)

- How often were your trips on time? (PM 5)

- Were you given reasonable estimates for your travel times? (PM 6)

- How well were changes, delays or disruptions in your travel resolved? (PM 1)

- Did you miss any scheduled appointments or trips because of delays, vehicle no-shows, or other disruptions? (PM 3)

- How easily and reliably could you make same-day trip requests or changes to previously scheduled trips? (PM 7)

- If you asked for this, were you given useful information to find your way from the bus to your destination? (PM 8)

- How confident do you feel that HIRTA and the Health Connector are keeping your personal information protected and secure? (PM 9)

- How safe do you feel when taking these trips? (PM 10) (PM 21) (PM 24)

- Do you have less anxiety about completing your medical trips than you used to have? (PM 13)

- Do you feel your trips provide the kind of accessibility you need? (PM 11)

- Do you feel this transportation is helping you live an independent and self-reliant life? (PM 12)

- On a scale of 1 (none or nearly none) to 5 (a lot), how many complaints did you make to HIRTA about your transportation in 2022 or previous years?
- On a scale of 1 (none or nearly none) to 5 (a lot), how many complaints did you make to HIRTA about your transportation in 2023 or 2024?
- On a scale of 1 (very poor) to 5 (very good), how do you feel your complaints were handled in 2022 or previous years?
- On a scale of 1 (very poor) to 5 (very good), how do you feel your complaints were handled in 2023 or 2024? (This and the preceding questions address PM 14)
- Are you skipping, missing, or rescheduling fewer medical appointments or healthcare services now, compared to earlier? (PM 22)

As outlined in this project's Data Management Plan, all survey response data will be managed securely and kept separately at ISU. To launch and analyze survey responses, some data will be extracted from the Health Connector's software and associated data and applications in use at HIRTA, but these will be episodic, secure transfers of data from HIRTA to ISU. Neither the surveys nor the ISU survey team will have dynamic or real-time access to any other Health Connector data.

Upon completion of ISU's analysis and evaluation, all survey data will be archived and secured in accordance with ISU policies and practices. These survey data will not be available to external users or interested parties, except in unusual circumstances, such as audits, investigations or legal proceedings.

2.5 Recruitment Design

The details of Health Connector participant recruitment and selection are explained separately in this project's Outreach plan and Participant Training and Stakeholder Education Plan (PTSEP). As the PTSEP describes, individuals volunteer to participate in the Health Connector. When they agree to participate in the Connector, individuals acknowledge and give informed consent to a number of things, including participation in surveys and evaluations.

What is significant, from a human use approval perspective, is that some Health Connector participants, along with a comparable number of HIRTA users who are not Health Connector participants, will be selected for participation in the survey and evaluation work being conducted by ISU. The potential survey pool will be assembled by ISU through a random sampling of Health Connector participants, and through a random sampling of a comparable number of HIRTA-using Dallas County residents who are not Health Connector participants. Once identified in these samplings, prospective survey participants will be notified electronically through the on-line notification systems used by the Connector and by HIRTA; these notifications will say the individuals are being invited to participate in a survey, and invited participants will be given the opportunity to accept or reject the invitations, with electronic or telephone follow-up to any non-respondents.

For the purpose of developing a meaningful internal evaluation of the Health Connector, the desire is to successfully enlist a sufficiently large survey pool, based on positive responses to

electronic invitations from within the app(s) used by the Health Connector and from email invitations to users of the website(s) associated with the Health Connector. There is a risk of an insufficient number of volunteers to be recruited for the survey in this way, in which case, direct "cold call" contacts will be made to Health Connector users, by telephone or other means, to elicit willingness to participate in this survey work. This survey pool will be designed to include representative numbers from all the target user groups (i.e., older adults, individuals with disabilities, residents of low-income households, veterans, non-English speakers, and rural residents), but the research design will not anticipate meaningful analysis within and among these targeted user groups. If that appears to be the case, the ISU team will enlist the assistance from trusted third parties among the project's stakeholder registry to help with survey outreach, engagement and/or administration.

ISU's Center for Survey Statistics and Methodology will be engaged to advise this project on how best to assure sufficient meaningful responses to this survey work, taking into account that the potential survey pool is going to be small in numbers.

2.6 Training of Participants

Training of participants is detailed in the Participant Training and Stakeholder Education Plan (PTSEP). This training is modeled after, and coordinated with, the travel training and user orientation services provided to new and prospective users of HIRTA's other services. Participants will need to know about the Health Connector's core functions and features, which they will be accessing by smartphone app, website, telephone, or via third parties (such as Health Navigators, medical office personnel, and family caregivers). The Connector's features themselves should be designed to be as intuitively useful as possible, especially for the target user groups of older adults, individuals with disabilities, residents of low-income households, veterans, non-English speakers, and rural residents in Dallas County. While the Health Connector is grounded in technology, its users do not need to be literate in, nor dependent on, any particular user technology. Some users will access the Connector via their smartphones, tablets or computers, while others will rely on their telephones; in any of these or other situations, an underlying principle of the Connector is to be universally accessible and understandable to its users.

Training for Health Connector participants is entirely voluntary. Participants are not required to complete any training prior to use, and no records of training are maintained. This is consistent with all customer training that HIRTA makes available to its users.

Following their enrollment in the Heath Connector, as detailed above, all new users will be contacted by HIRTA's Mobility Outreach Coordinator, who will offer travel training or other orientation services, ask about any disability-related accommodations that may be advised in the provision of travel, will walk the user (along with family members or caregivers) through the basics of trip arrangement and travel, and will offer having the Mobility Outreach Coordinator to ride along on their first trip, or even their first few trips, to provide ad hoc training or trouble shooting to help ensure that users are able to successfully and independently navigate the system. Additional training will be through in-app and on-line help/tutorial sessions that will help users through key elements of the Connector's "complete trip" arranging and fulfilment, augmented by some freestanding video or other on-line information to help explain how to use the Health Connector and its features. Some of this training information will be included in outreach materials and sessions, designed and delivered as per the project's Outreach Plan.

In order for training to be offered and provided, HIRTA's Mobility Outreach Coordinator will need to have limited-term access to some personal information about new Health Connector participants, including participants' names, addresses and contact information. Additional personal information, such as disability status and accommodation, languages spoken other than English, and likely recurring destinations of their Health Connector trips, may be presented to the Mobility Outreach Coordinator in the course of arranging and providing initial orientation and travel training. Once new users have demonstrated their ability to use the Connector without HIRTA's ongoing assistance, this information is no longer needed by the Mobility Outreach Coordinator and is neither retained nor analyzed.

All other Health Connector training materials are kept online and available to any interested party, regardless of their Health Connector participation. Persons accessing these training materials do not have to identify themselves, and users' interactions with, or use of, online training materials are not tracked or assessed.

2.7 Team Human Subjects Research Training

Training for all team members, including the project's internal evaluation research team at the Iowa State University Institute for Transportation (InTrans), is addressed in the PTESP. In addition to noting how InTrans and other team members are trained on the specifics of the Health Connector, it's important to note that ISU requires IRB training is required for all team members who have access to the data or will participated in collection of survey data. All of the InTrans team have current IRB training from ISU. This includes completing the Collaborative Institutional Training Initiative (CITI) program training: https://about.citiprogram.org/.

3 Protocol / Application Summary

To ensure that this project is conducted in accordance with federal guidelines concerning the use of human subjects in research, and as a core component of developing this Human Use Approval Summary, the project team engaged with the Institutional Review Board (IRB) at Iowa State University (ISU) for consideration and approval of the research approach. The process for seeking formal IRB approval is discussed in this section, and the IRB response is discussed later in this document, at Section 4.

3.1 Institutional Review Board

The team includes the Institute for Transportation at Iowa State University (InTrans). Shauna Hallmark will lead the InTrans team and will be responsible for obtaining and ensuring compliance with IRB oversight.

IRB training is required for all team members who have access to the data or will participated in collection of survey data. All of the InTrans team have current IRB training from ISU. This includes completing the Collaborative Institutional Training Initiative (CITI) program training: https://about.citiprogram.org/

It is anticipated that IRB approval will be solicited for two main tasks. The first is an analysis of data to evaluate measures of effectiveness for the Health Connector. The second entails a survey of participants and non-participants. An application was submitted in Phase I and was based on an estimate of the work that would be accomplished in Phase II. An IRB application was submitted in October 2021 to the ISU- IRB. The team received a letter on November 11, 2021 indicating the research as stated did not require IRB oversight since no PII was involved.

Since the final methodology and survey will be updated in Phase II, it will be necessary to submit an IRB application which will include all of the updated details. It is anticipated both will be exempt since no Personally Identifiable Information (PII) will be collected for use in any of the evaluations. However, if needed the team has the capability of meeting IRB oversight.

Also, as stated earlier, the current determination by the ISU IRB was based on an initial estimate of what would be included in Phases 2 and 3. Several details, such as specific data to be collected were not available. As a result, it will be necessary to submit an updated IRB plan which provides in-depth details of what data will be collected, how data will be stored, how PII will be handled (if gathered), who will have access to the data, and how data will be analyzed. The IRB will be updated in Phase II and the IRB determination and a plan for following IRB protocols will be provided to USDOT. The updated IRB will be necessary before ISU is able to begin collection or analysis of data. The IRB will also need to be updated at the beginning of Phase III since some details may have changed. Any new determinations or protocols will also be provided to USDOT. At any point in the project, if data collection, data storage, or analysis methods change, it will also be necessary to update the IRB. A plan for how ISU will address all IRB protocols will also be provided and updated as needed.

3.1.1 ISU's IRB Process

Iowa State's Institutional Review Board (IRB) is a federally mandated committee whose purpose is to ensure that 1) the rights, well-being, and safety of human subjects in research are protected; and 2) that Iowa State University research is compliant with applicable federal and state regulations as well as Iowa State policies and guidelines. To achieve these objectives, the IRB advises principal investigators in designing research projects that minimize potential harm to subjects, reviews all research involving human subjects prior to initiation of the research, approves research that meets established criteria for the protection of human subjects, and monitors approved research to confirm that subjects are being protected.

In accordance with federal regulations and Iowa State policy, human subjects research conducted by employees, students, or other agents of Iowa State University must receive IRB approval or determination of exemption prior to initiation of any human subjects research activities. Research must remain under IRB oversight until all human subjects research activities are complete.

Iowa State human subjects research and the activities of the IRB are guided by the ethical principles outlined in the Belmont Report, and by applicable regulations governing human subjects research. Principal investigators (PIs) and supervising investigators (SIs) are ultimately responsible for protecting the rights, well-being, and safety of human research subjects as well as assuring compliance with all applicable regulations and requirements.

Research involving human subjects must receive IRB approval in accordance with federal regulations set forth by the U.S. Department of Health and Human Services (HHS) (known as the "Common Rule"— 45 CF$ 46.102(1)) and the U.S. Food and Drug Administration (FDA). A project may be subject to one or both sets of regulations depending on whether the project meets the definition for Human Subjects Research (HHS) and/or Clinical Investigation (FDA). Human subjects are defined under 45 CF 46.102(e).

Additional details about the ISU/IRB process can be found at:
https://www.compliance.iastate.edu/

3.1.2 Federal-wide Assurance

The current assigned number for ISU's Office of Research Ethics' federal-wide assurance of compliance with federal regulations for the protection of human subjects in research is FWA00002678.

3.2 IRB Review Process

As noted, an updated application(s) will be submitted in Phase 2. The following describes the process used to obtain IRB approval for Phase I and is the same method that will be used to obtain final approval in Phase 2. Two types of data will be collected which may be subject to IRB oversight. The first type includes data that will be downloaded from the Health Connector app. Data from the Health Connector app will include data such as trip information (i.e., number of trips, dead-head, trip length), information about what populations are using the Health Connector app (i.e., age, gender, participation by under-represented groups), and fleet information (i.e. number of vehicles deployed). Any information from the Health Connector app that has PII is expected to be removed before this information is provided for use in evaluation of performance

metrics. If any changes are noted in how the data are provided and PII are included, the IRB application will need to be updated and resubmitted.

The second type of data are those gathered through the surveys. An electronic survey sent via email is the main survey method. Telephone or in-person surveys may also be used if needed. Demographic data about the participant will be collected and includes information such as age, gender, race, economic status, disabilities, number of medical appointments per week/month, etc. Information about their use of the app will also be include such as how many times they utilize the Health Connector app, whether they have any safety concerns, whether they use the wayfinding feature, number of appointments missed due to lack of transportation options, etc. In addition to the main survey, short participant surveys may be collected through the Health Connector app. For instance, a participant may be asked if they used the wayfinding information for their most recent trip. Currently, we do not anticipate requesting any PII such as name or address. However, if app based and electronic surveys are both administered, there may be some value in being able to link responses for a participant. In this case, the IRB application will specify how these data will stored, handled, and used.

A survey will also be conducted for a control group. They will be asked similar questions as the participant group. No in-app survey will be collected from this group. As a result, there is no anticipated need for any PII data to be collected.

Several different methods will be used to gather the various data needed for the performance measures as noted above. Additionally, some data will be collected regularly (i.e. downloads from the Health Connector App/trip information from HIRTA) while the surveys will be conducted at discrete intervals. Since each of the above data gathering methods and reporting times differ, an IRB application will likely be submitted for each type of data collected.

The IRB process includes the following steps.

First, an application is submitted to determine whether IRB oversight is needed. The IRB includes the following primary sections. As noted above, separate IRB applications may be submitted for each different data gathering method. In this case, only the information pertinent to that method would be included.

- *A summary of the proposed research (including funding source)*: This is a paragraph summary of the overall Health Connector project. It will briefly describe the project objectives. This summary simply provides an overall big picture perspective of the project for the IRB reviewers. The funding source is also requested. In this case, the USDOT project number will be noted.

- *What data will be collected and from whom*: This section will describe the type of data to be collected and the source. For instance, for the data gathered from the Health Connector app this will include a list and description of each variable that will be provided to the ISU team (i.e., trip length, number of trips by age/gender, number of no-shows.

  For the surveys, this will describe the data that will be gathered from the questions. This includes participant demographics (i.e., age, gender, race, economic status, disabilities, number of medical appointments per week/month, etc.). Information about their use of the app will include data such as how many times they utilize the

Health Connector app, whether they have any safety concerns, whether they use the wayfinding feature, number of appointments missed due to lack of transportation options, etc.

- *Collection of PII:* Any type of PII that will be collected such as name, address, social security number is noted. Data to evaluate the Health Connector app will be provided in an aggregated formation (i.e., total number of trips by age group) and is not expected to contain any PII.

  The survey(s) will include Dallas County Residents who have used the app as well as those who have not. Questions will be specific to their experience in using the app to access to medical care (or information about how they access transportation for those who have not used the app). An ID will be assigned to each survey respondent. Information such as age, gender, income category, etc. will be collected.

  As noted, the initial project plan does not include any collection of PII (i.e., name, address). At any time, if PII is expected to be included, the IRB application will be updated and additional approval or changes in oversight will be obtained. For instance, if the process for data download from the Health Connector app is determined to include the participant starting point (address), the IRB would be updated and resubmitted with this information. Or as noted above, there may be some value in linking survey responses across participants. If it was determined participant name was needed for this, an IRB application would be included.

- *Inclusion of vulnerable populations such as the elderly, pregnant women, children, prisoners, low income, etc*.: It is anticipated children and prison populations will not be included in the evaluations. All other vulnerable users will be included. No differential impact is expected for any population.

- *Benefits and any negative impacts to participants*: Benefits to participants (i.e., better access to health measures) are listed along with any drawbacks. Drawbacks include anything that would adversely impact a study participant. For instance, in a driving simulator study the participants would be advised that they could experience motion sickness. In the proposed evaluations, no negative benefits are anticipated.

- *Description of survey instrument and questions*: A copy of survey questions will also be included with the IRB application. A description of how the survey will be conducted will also be included.

- *Description of how consent will be obtained:* This includes a description of how participant consent will be obtained as well as stating potential respondents are able to opt out of answering additional questions at any time.

- *Description of how sensitive data will be stored*: Although no PII is anticipated, it will still be necessary to state how data will be collected and stored. Data will be stored on CyBox which is a FERPA- and HIPAA-compliant file storage system. CyBox includes encryption of laptops and other devices that access the servers to minimize data breaches.

- *Team member names:* The names, titles, emails, and IRB certification for all ISU team members who can access the data are stated.

Once the application is submitted, the ISU IRB will review the information and make a determination of whether the study is exempt or requires IRB oversight. The team expects the proposed work to be exempt from IRB oversight. However, it will be necessary to ensure the steps outlined in the IRB application are followed since the designation of exempt only applies to the particular scenario for which IRB approval was obtained. If the parameters of the data collection or survey change during the study midway through a project year, it will be necessary to file a modification to the initial application to ensure the IRB remains exempt or needed oversight is followed.

The ISU IRB meets monthly which ensures IRB approval can be obtained in a timely manner.

Although unlikely, if oversight is required, that oversight will be managed by the ISU IRB committee. Oversight specifies reporting and updates that need to be made to the ISU IRB committee and the schedule for these.

ISU has language which can be utilized to inform survey participants about the study in order for them to make an informed decision about participating.

3.3 Ensuring IRB Understanding of Project

ISU IRB protocol requires applications provide sufficient detail so that the proper determination can be made and if required the appropriate IRB oversight can be conducted.

The major pieces of information required in the ISU IRB application are provided in Section 3.2. As noted, an initial application was submitted which described all of the data that would be collected, inclusion of and adverse impacts on disadvantaged groups, and how data would be managed.

Additional information that will need to be included in updated IRB application include the following:

- Description of how the survey will be conducted: This includes whether the survey will be conducted in person by the team, the survey will be sent electronically, or focus groups will be conducted.
- Draft questions that survey participants will be asked
- Sample size
- How vulnerable groups will be recruited and a plan to ensure no disadvantages or harm is borne by these groups: It is anticipated Dallas County's residents over the age of 60, residents of households with income below the federal poverty line, veterans, residents for whom English is not their primary language, and residents with disabilities will be included in the study.

3.4 Relevant IRB Procedures

A description of the IRB process was provided in Section 3.1. The following provides timelines for all phases of the project:

Phase 1

- October 2021: an initial application was submitted as part of Phase I
- November 11, 2021: a determination of no IRB oversight was received for the methodology as initially outlined

Phase 2:

- October 2022: An updated application will be submitted to the ISU IRB
- November 2022: Anticipated approval by the ISU IRB (a designation of “Exempt”) is anticipated
- October 2023: An annual update is required

Phase 3

- October 2023: An updated application will be submitted to the ISU IRB
- November 2023: Anticipated approval by the ISU IRB (a designation of “Exempt”) is anticipated
- October 2024: An annual update is required

4 Human Use Approval

Following the application and submission process described above in Section 3 of this Human Use Approval Summary, the ISU Institutional Review Board reported its decision in a letter to Dr. Shauna Hallmark, Director of the Institute for Transportation (InTrans) at ISU, in a letter dated November 11, 2021.

4.1 Type of Review

A full application for IRB was submitted. The steps required are outlined in Section 3.2. The IRB letter does not state what the review entailed, but follow-up conversation with the IRB indicated this was a staff review, since none of the information in the initial application discussed collecting PII. The IRB reviews in future phases this project may be more extensive, requiring consideration by the full panel.

4.2 Approval Status

An initial determination of no IRB approval needed was received on November 11, 2021 from the ISU IRB. The letter is provided in Appendix A. As stated in this letter, the IRB found that the planned project "is research that does not involve human subjects according to federal regulations." Although the IRB did not provide substantiation for how they arrived at this determination, InTrans' experience with IRB reviews on other projects suggests that the reason the IRB determined they did not need to approve Phase 1 activities in this project could be because no subjects' personally identifiable information is being collected in Phase 1.

4.3 Feedback from IRB Review

The initial applications were noted as not requiring IRB oversight. As a result, no formal feedback was provided. However, any changes to the methodology will require an update to be provided. Informally, the IRB staff was asked for an update on the application at the beginning of November 2021. At that time, the HIRTA project team asked whether the IRB panel needed any additional information. The team also explained that this IRB was preliminary and that another application would need to be submitted once all of the details were available in Phase 2. The IRB staff noted that no additional was information was needed at that time. They also agreed that their initial determination would be based on the information provided in the October 2021 IRB application and that the team would need to submit a new application once all of the details were available. Based on this discussion, they felt the initial application would be "Not IRB research."

4.4 Conditions

The primary condition that is applicable to the approval received for Phase I is an update to the IRB application which includes any additional information or changes to the protocol. An annual update is also required.

5 Future Steps and Schedule

The fundamental question of IRB review and Human Use Approval will be revisited at the beginning of Phase 2. Within the first 30 days of beginning Phase 2, InTrans will prepare and submit an updated application for IRB review. That application will be based on the HIRTA team's initial application from Phase 1, but will be revised and expanded as needed to include all details about the project's use of human subjects in carrying out project-related research, including any necessary adjustments to its planned approach for assuring voluntary participation, the protection of any HIPAA-protected medical information that may come into contact with the Health Connector, and the protection of personally identifiable information (PII) associated with project participants, especially where these participants are the "vulnerable" populations whose use as research subjects are to be protected under federal human use approval guidelines and requirements. Following the anticipated receipt of IRB approval, the team will make any necessary adjustments to its activities in Phase 2 as dictated by conditions associated with IRB approval. Follow-up applications for IRB review will be prepared and submitted each year thereafter in Phases 2 and 3 of this project.

5.1 IRB-Required Future Actions

A timeline for the planned future actions is provided in Section 3.4. A summary of future actions includes:

- Submit an IRB application with updates to the planned evaluation and survey as soon as Phase II commences
- Once IRB approval is received, a plan to meet any additional requirements will be developed and incorporated into the Phase II plan
- If IRB approval is required or the study is noted as "Exempt", an annual update is required
- Updates are required if any substantial modifications are made

5.2 Phase 2/3 Human Use Approval Confirmation Materials

The process to obtain current IRB approval and to apply for continuing approval were described in Sections 3 and 4. A summary is provided in Table 2 below.

Table 2. Human Use Approval Confirmation Materials Summary

The following information will be maintained and updated as the project team seeks IRB review in Phases 2 and 3 of this project.

Planned Timing	Confirmation Material	Description	Dependencies
Nov. 2021	Letter from IRB, included in Human Use Approval Summary document	An initial application was provided to the ISU IRB and a determination of no oversight required was obtained.	None expected.
1st quarter, 2022 project year	Memo to USDOT summarizing application to IRB and IRB response, including any conditions or considerations that may change how project is carried out.	An updated application will be submitted based on updates to the initial methodology.	None expected.
1st quarter, 2023 project year	Memo to USDOT summarizing application to IRB and IRB response, including any conditions or considerations that may change how project is carried out.	An annual update is required.	None expected.
1st quarter, 2024 project year	Memo to USDOT summarizing application to IRB and IRB response, including any conditions or considerations that may change how project is carried out.	An annual update is required.	None expected.

Appendix A. IRB Documentation

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office of Research Ethics
Vice President for Research
2420 Lincoln Way, Suite 202
Ames, Iowa 50014
515 294-4566

Date: 11/11/2021

To: Shauna Hallmark

From: Office of Research Ethics

Title: Heart of Iowa Regional Transit Agency ITS4US Deployment Project

IRB ID: 21-421

Submission Type: Initial Submission **Determination Date:** 11/11/2021

The project referenced above has been reviewed and the following determination has been made. The project:

Is research that does not involve human subjects according to federal regulations.

Accordingly, this project does not need IRB approval and you may proceed at any time. We do, however, urge you to protect the rights of your participants in the same ways you would if IRB approval were required. For example, best practices include informing participants that involvement in the project is voluntary and maintaining confidentiality as appropriate. Additionally, approval from other entities may be needed depending on your project. This IRB determination in no way implies or guarantees that permission from these other entities will be granted.

If you modify the project, we recommend communicating with the IRB staff to ensure that the modifications do not change this determination such that IRB approval is required.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.

IRB 07/2020

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-21-897

U.S. Department of Transportation