RESEARCHER INFORMATION

Principal Investigator Name	Ashley Whillans
Affiliation (check all that apply)	☒Faculty ☐Graduate Student ☐Post-Doc ☐Undergraduate ☐Extension School Student ☐Staff ☐Visiting Scholar ☐Other (specify):
Faculty Sponsor (if PI is not PI Eligible)	
Other Advisor Name (if applicable)	

STUDY INFORMATION

Study Title	Get There Commuting Field Study
ESTR Number	
Version Number	
Is this a re-submission of a previous Harvard IRB-approved study that has been closed?	☐Yes - Include previous IRB submission # here: ☒No

1. FUNDING INFORMATION

1.1 Is your study funded (either directly or through a sub-award) by a Federal Agency (i.e., HHS, NIH, NSF, DOD, DOE, DOJ, or EPA, etc.)?

☐Yes
☒No

1.2 Is your study funded (or will it be) by the National Institutes of Health (NIH)?

☐Yes
☒No

1.3 Does your study meet the definition of a "Clinical Trial"?

☐Yes
☒No

HHS and NIH define a **clinical trial** as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

If your study meets the definition of a **clinical trial**, there are additional requirements that you must follow. Ask your assigned IRB Reviewer or see the HUA IRB website for more information.

2. RESEARCH COLLABORATIONS AND LOCATIONS

LOCATIONS

Locations refer to the geographic location where the research will take place, not to the people or institutions that you may be collaborating with. Knowing the location helps the IRB determine the local context of the research as well as if there are additional laws, regulations, and policies researchers need to adhere to. If conducting online studies, please indicate the location of the researcher who is hosting.

2.1 Where will this study take place?

☐Harvard University
☐At another location in Massachusetts
☒In another US state ***(see below)***
☐Internationally ***(see below)***

If you chose "in another US state" or "Internationally" describe the laws that will need to be considered:

Participants will be located in Oregon.

Please ensure that what you have marked above matches what has been indicated in the ESTR SmartForm, section "Research Locations."

2.2 Are there any U.S. state laws, international laws, or other laws that the IRB will need to consider when reviewing this study?

☐Yes ***(see below)***
☒No

If "Yes" describe the laws that will need to be considered:

2.3 Thinking about the locations where this study will take place, are there any permissions that must be obtained from cooperating institutions, community leaders, government officials? *This may include a review by a local ethics board, school district, Ministry of Health, or other institutional approval process, whether domestic or international. A statement that formal review is not required along with your source of information that the proposed research is in accordance with local laws, regulations, and customs is also acceptable.*

☒Yes ***(see below)***
☐No

If "Yes" describe and if available, upload any permission documents to the ESTR SmartForm section "Local Site Documents."

The Oregon Department Transportation and Alta Planning has agreed to implement our experiment into their normal business practices and provide us with de-identified data. They have no other role in the research, and are not considered collaborators in this work.

2.4 Are there any community or cultural differences for the local population of participants that require consideration? *For example, cultural or gender dynamics or social structure considerations.*

☐Yes ***(see below)***

☒No

If "Yes" describe:

COLLABORATIONS/SITES

Collaborations, known as "sites" in ESTR, refer to people or institutions that are also taking part in the research study. An important part of knowing about these collaborations is knowing what each person/institution is doing in the research in order to determine the scope of IRB review.

2.5 Will you be collaborating with any researchers not affiliated with Harvard University Area to carry out this study? *HMS, HSPH, and HSDM are not part of Harvard University Area.*

☒Yes
☐No ***(skip to next section)***

2.6 Will the actions of these collaborators include any of the following: Have contact with human subjects; Have access to data that is identifiable; OR Are responsible for the design, conduct, or reporting of the research?

☒Yes
☐No ***(skip to next section)***

2.7 Will these collaborators receive their own IRB review?

☒Yes, all will receive their own IRB review (skip to next section)
☐No, none will receive their own IRB review
☐Some will receive their own IRB review and some will not

2.8 Is another institution and/or researcher requesting that the Harvard University Area IRB act as the IRB of record ("Reviewing IRB") for that institution's or that researcher's activities on the study?

☐Yes
☐No ***(see below)***

If you chose "No" describe the compliance/ethical oversight that this researcher will have in place:

2.9 If the Harvard University Area IRB will be providing review for the non-Harvard affiliated collaborating researchers, indicate which institutions they are affiliated with and their role and activities on this study (are they involved in recruitment, data collection, analyzing data, etc.) Add additional lines as necessary.

Name	Institution	Role on Study	Description of Activities that They will be Conducting

3. STUDY TEAM QUALIFICATIONS AND TRAINING

3.1 Describe the Principal Investigator's experience with the proposed research procedures, population, and local context.

Ashley Whillans has been conducting behavioral research for 6+ years.

3.2 Describe how the study staff are trained to ensure that they are adequately informed about this study and study-related duties.

Holly Dykstra has been conducting behavioral research for 4+ years.

3.3 Are there any other additional study staff whose role in this study requires special qualifications in addition to ethics training (e.g., licensed clinical psychologist, phlebotomist, etc.)?

☐Yes ***(see below)***
☒No

If "Yes" describe:

4. RESEARCH PURPOSE

4.1 Provide a brief, non-technical description of the purpose of the research, including the research questions that you hope to answer.

We're testing something that we're calling the "buy-in" effect, testing whether higher upfront effort leads to more sustained engagement with carpooling later on. Specifically, users of the old tool will be assigned to either (1) having an account in the new app pre-made for them or (2) having to recreate their account in the new app. What we're looking for is akin to the endowment effect - that making people feel invested will lead to higher follow through.

4.2 Describe the scientific background, rationale for the study, and importance of this research in adding to existing knowledge.

We want to investigate whether a "buy-in" effect exists. Research in behavioral economics has shown that automatically enrolling people into programs has tremendous effects on outcomes (e.g., Beshears, Choi, Laibson, & Madrian, 2010), but these are in settings where the outcome is a natural consequence of the policy: for example, in the automatic enrollment work on retirement savings, the outcome policymakers are looking for is larger retirement savings, which happens automatically when people are opted into these accounts (Madrian and Shea, 2001). In this case, however, we hope that participants are engaged with the program and will actively use the tool. We hypothesize that there might be a "buy-in" effect, where people are more engaged with the tool when they've made the active choice to opt in, even if they would have opted in anyway in the absence of automatic enrollment. This may mean that it would be more effective to actively recruit people to take up the tool rather than having them passively enrolled, and would have important consequences for nudges in similar contexts.

5. STUDY PROCEDURES

5.1 Provide a complete overview of the study:

- **Describe the procedures participants will be asked to complete or undergo.**
- **Explain step by step what participants will be asked to do**
- **Include how long the procedures will take.**

If your study includes multiple variations of the procedures, please make clear which procedures are included in the variations.

Alta Planning, in collaboration with the Oregon Department of Transportation, will be in charge of sending out the emails to participants (as per their standard business practice) as well as sending us a de-identified data file containing sign-up information and data about use of the app. RideAmigos is the company who developed, owns and runs the Get There rideshare app. The Oregon Department of Transportation subscribes to this software system and makes it available to the people of Oregon to promote carpooling and multimodal trips.

The research team will be in charge of designing the interventions (i.e., writing the wording of the two different emails), data analysis and presentation of results. We are simply creating two different versions of the email that Alta Planning will send out as their standard business practice (i.e., emailing current members with a request to sign up for the new platform) and analyzing the data that they provide to us.

The protocol is as follows:

First, participants will be randomly assigned to one of two conditions (the procedure for each and wording of the emails was designed by the research team):

1. Buy-In Condition: in this condition, participants will have their account already recreated for them in the new app.
2. Control condition: in this condition, participants must recreate their own account in the new app.

Second, participants will receive an email from Alta Planning with instructions for how to signup for the new app. This email and the procedure they must follow to sign up will differ depending on their assigned condition (see emails attached to this IRB protocol).

Finally, Alta Planning will send us de-identified data containing information as to (1) whether the user logs into the new tool at all, (2) whether the user looks for carpool matches and (3) whether the user logs trips in the new tool.

The below sections contain additional questions depending on the type of research that you are conducting and is meant to supplement the study overview. Please complete each section, as applicable.

SURVEYS/ QUESTIONNAIRES/PSYCHOMETRIC TESTING

Skip this section if not applicable.

5.2 List the names of all surveys/questionnaires/psychometric tests to be used in this study and a description of any that are not standard/formally named (such as study-specific questionnaires).

5.3 How often will participants be asked to complete the surveys/questionnaires/psychometric tests and how long will it take to complete?

5.4 Will you be using any survey software (such as Qualtrics)?

☐Yes (see question below)
☐No

If "Yes" which survey software will you be using? :

INTERVIEWS/ORAL HISTORY/FOCUS GROUPS

Skip this section if not applicable.

5.5 Explain where interviews/focus groups will take place (including possible online venues such as Skype, online chat rooms, etc.)

5.6 Describe any steps you will take to protect the participant's privacy during the interview/focus group.

5.7 Describe the number of interviews/focus group sessions you anticipate for each participant and approximately how long you expect each interview/focus group to last.

OBSERVATIONAL/ETHNOGRAPHIC RESEARCH

Skip this section if not applicable.

5.8 If you will be actively participating in the field (as in participant-observation), describe what this will entail.

5.9 Describe what and who will be observed and in what settings (such as public events, religious ceremonies, household activities, work meetings, internet chat-rooms and social media sites, etc.)

5.10 Will any observational data be considered private, according to the standards of that community?

☐Yes ***(see below)***
☐No

If "Yes" describe the information that would be private.

5.11 Will the data you collect contain any information that identifies specific individuals?

☐Yes
☐No

5.12 Do you plan to quote the remarks of participants in your study?

☐Yes
☐No

5.13 Will you notify participants that they are being observed?

☐Yes
☐No ***(see below)***

If "No" explain the circumstances why you would not be able to let participants know they are being observed.

5.14 If permission to observe participants is obtained, how will you ascertain whether there are individuals who do not want to participate, and how you will manage such a situation?

AUDIO-RECORDING/VIDEO-RECORDING/PHOTOGRAPHS

Skip this section if not applicable.

5.15 What type of recording will take place? (check all that apply)

☐Audio-Recording
☐Video-Recording

☐Photography
☐Other ***(see below)***

If "Other" describe:

5.16 Explain what types of data will be recorded or photographed.

5.17 If you will be collecting sensitive data, will you use any procedures to de-identify or anonymize the recordings or photographs?

5.18 Explain what will happen to the recordings/photographs at the end of the study.

DECEPTION AND INCOMPLETE DISCLOSURE

Skip this section if not applicable.

Deception is the intentional misleading of a subject about the nature of the study. While withholding of full information is known as incomplete disclosure.

5.19 Describe what information will be withheld from participants or what misinformation will be provided to participants.

Participants will not be aware that they are participating in a research study and will be unaware that they are randomly assigned to one of two different conditions.

5.20 Explain why this research involves no more than minimal risk to participants and why it would be impracticable to carry out the research without the use of deception or incomplete disclosure.

First, participants opted in to receive emails from Alta Planning when they signed up for the previous app, and this email request to sign-up for the new platform is a standard business practice. We are

simply changing the wording of this email and whether their account info is carried over to the new platform to allow us to test our research question. Further, the amount of risk involved does not differ depending on which email participants receive (both pose no risk to participants).

5.21 Describe the plans for debriefing participants after their participation. If you do not plan to debrief participants, explain why.

We will not debrief participants because participants have opted in to receive emails from Alta Planning, this email request to sign up for the new platform is standard business practice, and there is no foreseeable risk associated with participants not knowing that they were randomly assigned to condition. Further, sending them excessive emails likely poses a greater risk than this randomly assignment.

Please be sure to attach a copy of the debriefing script (if applicable) to the "Local Sites Documents" section in the ESTR SmartForm.

DATA FROM OTHER SOURCES

Please complete this section if you are receiving data that is coming from other sources, for example, from a repository, medical record, institutional data, etc. This section does not pertain to data that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.

5.22When was the data collected?

☐The data has already been collected to date (retrospective data).
☒The data will be collected (prospective data)
☐The data will include both types (retrospective and prospective)

5.23 Indicate the identifiability of the data:

☐Will not contain any direct or indirect identifiers; will be anonymous.
☒Will not be directly identifiable, but there will be a code held by the data source that links to the identities; will be coded.
☐Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.
☐Will contain direct identifiers; will be identifiable.

5.24 Describe which data sets you plan to analyze, who is providing the data to you, and whether the data are public use data sets, restricted access datasets, or another type of dataset.

Alta Planning will send us de-identified data containing information about (1) whether the user logs into the new tool at all, (2) whether the user looks for carpool matches, and (3) whether the user logs trips in the new tool. This data will be de-identified. There will be a code help by Alta Planning that links this data to identifiable information, but we will never receive or have access to this code.

5.25 Provide an overview of the types of variables that are contained in the dataset (for example, identifiable data such as names, dates of birth, addresses, or any data that are considered sensitive).
The de-identified data that Alta Planning will send to us will primarily contain the following types of variables:

- Participant code
- Whether they have logged into the new tool
- Whether the user looks for carpool matches
- Whether the use logs trips in the new tool
- Condition assignment

5.26 Was the data you plan to analyze collected in a previous research study?

☐Yes ***(see below)***
☒No

If "Yes" provide the title/name of the previous research study and which institution and researcher collected the data for the previous study. If the data were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.

5.27 Will any of your data be obtained from internet sites (including data mining and data scraping activities)?

☐Yes ***(see question below)***
☒No

If "Yes" what websites will you access to obtain the data?

Please know that it is your responsibility to check the terms of service of any websites from which you plan to collect data to determine whether your planned data collection is compatible with the terms of service.

5.28 Is the data publicly available on the internet (i.e., freely available without permission, sign-in, or other restrictions)?

☐Yes
☒No

5.29 Do you plan to access any data that is Protected Health Information (PHI) under the HIPAA law (for example, data held by a hospital or other healthcare provider or insurer)?

☐Yes ***(see question below)***
☒No

If "Yes", which organization will provide the HIPAA PHI to you?

How will permission to allow the use/disclosure of individual's protected health information (PHI) be obtained?

HRP-330 WORKSHEET: HIPAA, which may be found in the ESTR library, provides an overview of items pertaining to HIPAA that may be helpful to the study team.

5.30Do you plan to access any data that is FERPA protected (data that are held as education records by an educational institution)?

☐Yes
☒No

HRP-331 WORKSHEET: FERPA COMPLIANCE which may be found in the ESTR library provides an overview of items pertaining to FERPA that may be helpful to the study team.

5.31 Do you plan to obtain data that has been obtained under "Broad Consent" (as part of the 2018 Requirements)?

☐Yes
☒No
☐ Uncertain

BIOLOGICAL MATERIALS FROM OTHER SOURCES

Please complete this section if you are receiving biological material from other sources, for example, from a biorepository, pathology department, commercial provider, etc. This section does not pertain to biological material that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.

5.32When was the biological material collected?

☐The biological material has already been collected to date (retrospective).
☐The biological material will be collected (prospective)
☐The biological material will include both types (retrospective and prospective)

5.33Indicate the identifiability of the biological materials:

☐Will not contain any direct or indirect identifiers; will be anonymous.
☐Will not be identifiable, but there will be a code held by the data source that links to the identities; will be coded.
☐Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.
☐Will contain direct identifiers; will be identifiable.

5.34How will you obtain the material? (check all that apply)

☐Residual clinical material
☐Material obtained from a vendor
☐Material that was collected as part of another research study ***(please see below)***

☐Other – ***(see below)***

If you chose "another research study" provide the title/name of the previous research study and which institution and researcher collected the specimens for the previous study. If the specimens were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.

If "another research study" or "Other" please specify:

5.35 Will the material consist of any of the following? (check all that apply)

☐Embryonic tissue
☐Embryonic stem cells
☐Stem cells
☐Fresh human fetal tissue
☐None of the above

5.36 Provide an overview of the types of variables that will accompany the biological materials (for example, identifiable data such as names, date of birth, addresses, or any data that are considered sensitive).

DEVICES

Skip this section if not applicable.

5.37 List the device(s) that you plan to use in this study (add additional lines as necessary):

Device Brand Name	Generic/Common Name	Manufacturer	Purpose	Function/Operation

5.38 Is the device(s) that you plan to use FDA-approved/cleared?

☐Yes
☐No

5.39 If any of the devices that you plan to use require a certified professional to operate, please explain who is certified to operate this device and whether they are on your study team.

Please complete HRP-307 WORKSHEET: DEVICES which may be found in the ESTR library and attach to the "Local Site Documents" section in the ESTR SmartForm.

DRUGS

Skip this section if not applicable.

5.40 List the drug(s) or biologic(s) that you plan to use in this study (add additional lines as necessary):

Drug/Biologic Brand Name	Generic/Common Name	Manufacturer	Purpose	Function/Operation

5.41 Is the drug(s)/biologic(s) that you plan to use FDA-approved/cleared?

☐Yes
☐No

5.42 Please explain who is qualified to dispense this drug/biologic and whether they are on your study team.

Please complete HRP-306 WORKSHEET: DRUGS which may be found in the ESTR library and attach to the "Local Site Documents" section in the ESTR SmartForm.

6. RISK AND BENEFIT ASSESSMENT

6.1 Describe the foreseeable risks associated with your study. Please include discussion of any physical risks and non-physical risks, such as economic, psychological, social, and legal harms.

We do not foresee any risks associated with this study.

6.2 Describe the steps that you will take to minimize risks to your participants (for example, using pseudonyms or a coding system, etc.)

Participants will be provided with the contact information of Alta Planning. Any concerns will be directed to us and we will provide them with additional information as well as the contact information of our IRB.

6.3 Are provisions needed for medical and/or psychological support resources (for example, in the event of research-related distress or incidental findings)?

☐Yes
☒No

6.4 If applicable, what steps will you take if a participant becomes distressed during your study or reports intent to harm themselves or others?

N/A

6.5 Describe any potential direct benefits to participants in the study. If there are no individual benefits, indicate as such.

There are no individual benefits to participating in this study.

6.6 Describe any potential benefits to society.

Society could benefit from this research as we gain a better understanding of how to encourage active commuting.

7. CHARACTERISTICS OF THE STUDY POPULATION

7.1 Indicate the estimated number of participants, by subgroup if applicable. ***If it is not possible to estimate the number of participants (e.g., open online survey), please indicate that it is not possible and provide an explanation of why it is not possible.***

40,000 individuals will receive an email from Alta Planning.

7.2 Describe the criteria for enrollment – Will you be limiting your enrollment to a certain age range, gender, people with certain health conditions, etc.? Please also describe any criteria that will exclude people from enrollment.

Only participants who were previous users of the old app and have signed up to receive notifications from the Oregon Department of Transportation (via Alta Planning) will be contacted for this study. All of these participants will be 18+ years of age.

7.3 Are there any potential vulnerable populations or individuals proposed for involvement in the research? (check all that apply)

- ☐Children
- ☐Wards of the State
- ☐Prisoners/Detainees
- ☐Pregnant Women
- ☐Adults not Competent to Consent
- ☐Non-English Speaking
- ☐Employees of Harvard University (as a focus of the study)

☐Undergraduate Students of Harvard University (as a focus of the study)
☐Staff or students that are part of your lab or for whom you provide oversight
☐ Other – ***(see below):***

If "Other" please specify:

CHILDREN

Skip this section if not applicable.

7.4 What is the age range of children participating in your study?

7.5 Are there any special considerations that need to be taken into account? For example, do the children have a learning disability?

PRISONERS

Skip this section if not applicable.

7.6 Describe any advantages that prisoners may accrue through their participation in the research, especially in comparison to the general living conditions, medical care, quality of food, amenities, and earning opportunities in the prison.

7.7 Explain whether the risks of the research are commensurate with risks that would be accepted by non-prisoner research participants.

EMPLOYEES OR STUDENTS OF HARVARD UNIVERSITY

Skip this section if not applicable.

7.8 Explain how you will minimize the potential for employees and/or students of Harvard University to feel coerced or experience undue influence to participate in the research.

8. RECRUITMENT

8.1 Will potential participants be provided with information about the study?

☐Yes ***(see below)***
☒No ***(skip to next section)***

If "Yes" indicate how, when, where, and by whom participants will be recruited. If you are recruiting from a Harvard University Study Pool, describe how you meet their requirements.

8.2 Are there any materials that will be used to recruit participants (e.g., websites, emails, posters, oral scripts)?

☐Yes ***(see below)***
☐No

If yes, list the materials by document name here, and be sure to attach copies to the "Consent and Recruitment Materials" portion of the "Local Site Documents" section in the ESTR SmartForm.

HRP-315 WORKSHEET: ADVERTISEMENTS which may be found in the ESTR library provides an overview of items pertaining to advertisements that may be helpful to the study team.

9. SCREENING

9.1* Will you be screening participants for eligibility? *Note that If you are using inclusion or exclusion criteria, you will be "screening" individuals in order to determine who is eligible.

☒Yes
☐No ***(skip to next section)***

9.2 Explain what your screening criteria will be and how you will conduct the screening process.

The contact list for this study includes only participants who were users of the previous app and elected to receive notifications from the Oregon Department of Transportation (via Alta Planning. All participants who meet this criteria will be included.

9.3 Do you plan to destroy the data from people who participate in the screening process and do not qualify to be in the study as soon as the screening process is over?

☒Yes
☐No ***(see below)***

If "No" explain why you will keep the data collected in the screening process for people who are not eligible to participate in this study.

10. INFORMED CONSENT PROCESS

If you plan on having more than one consent process (such as signed, written consent for one population and use of an online "click" consent script for another population), please explain which variations of the study will use which types of consent process with each of these questions.

ADULT PARTICIPANTS

If you will not include adults in your study, please skip this section.

10.1 Will you be obtaining informed consent or an agreement to participate (for Exempt studies) from participants that take part in your study?

☐ Yes, I will be obtaining informed consent or an agreement to participate.
☒ No, I will not be obtaining consent or an agreement to participate **(skip to next section after answering below)**

If you will not be obtaining consent or an agreement to participate, please explain:

- ***why this research involves no more than minimal risk to participants and***
- ***why it would be impracticable to carry out the research with consent or an agreement to participate***

We are requesting a waiver of consent process because the participants in this study have consented and voluntarily signed up to receive these emails from Alta Planning. The research team is simply changing the content of these emails that Alta Planning would normally send out and the process by which participants are being transferred to the new app. We anticipate no risks associated with participation in this study – especially no risks above and beyond those that they would have experienced receiving this email and this transition from Alta Planning without our input. Finally, if participants were aware that we were conducting this research it may change their behavior and ultimately compromise the integrity of our data and results. Finally, notifying participants of this may negatively influence the relationship between the Oregon Department of Transportation/Alta Planning and their constituents, even though the organization would be sending out these emails and moving to this new platform anyways.

10.2 Will the consenting or an agreement to participate process involve obtaining a signature?

☐ Yes
☐ No ***(see below)***

If a signature is not obtained, explain why:

10.3 Where will the consent or an agreement to participate process take place?

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

If other, please describe:

10.4 Who will obtain consent or an agreement to participate from participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain consent?*

10.5 Describe the process that will be used to obtain consent or an agreement to participate.

10.6 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

CHILDREN PARTICIPANTS

If you will not include children in your study, please skip this section.

If you are including children in your research study, know that consenting or requesting an agreement to participate from a child is comprised of two parts: child assent and parent permission.

10.7 Will you be obtaining assent or an agreement to participate (for Exempt studies) from child participants that take part in your study?

☐ Yes, I will be obtaining assent or an agreement to participate.
☐ No, I will not be obtaining assent or an agreement to participate ***(skip to next section after answering below)***

If you will not be obtaining assent or an agreement to participate, please explain:

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with assent or an agreement to participate:***

10.8 Will the assenting or an agreement to participate process involve obtaining a signature?

☐ Yes
☐ No ***(see below)***

If a signature is not obtained, explain why:

10.9 Where will the assent or an agreement to participate process take place?

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

If other, please describe:

10.10 Who will obtain assent or an agreement to participate from child participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the assent?*

10.11 Describe the process that will be used to obtain assent or an agreement to participate from children.

10.12 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

PARENT PERMISSION

If you will not be including children in your research, please skip this section.

10.13 Will you be obtaining parent permission or an agreement to participate (for Exempt studies) from parents whose child takes part in your study?

☐ Yes, I will be obtaining parent permission or an agreement to participate.

☐ No, I will not be obtaining parent permission or an agreement to participate ***(skip to next section after answering below)***

If you will not be obtaining parent permission or an agreement to participate, please explain:

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with parent permission or an agreement to participate:***

10.14 Will the parent permission or an agreement to participate process involve obtaining a signature?

☐ Yes
☐ No (see below)

If a signature is not obtained, explain why:

10.15 Where will the parent permission or an agreement to participate process take place?

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

If other, please describe:

10.16 Who will obtain parent permission or an agreement to participate from the parents? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the permission?*

10.17 Describe the process that will be used to obtain parent permission or an agreement to participate from parents.

10.18 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

OTHER TYPES OF PARTICIPANTS

If this section is not applicable, skip to next section.

10.19 If you will be including Wards of the State, explain how consent of legal guardian(s) of ward(s) will be obtained. How will you ensure that the appropriate person granted permission for each ward to participate?

10.20 If you will be obtaining consent from special populations such as non-English speaking participants, illiterate participants, or adults not competent to consent, please explain how you will obtain consent from those individuals.

10.21 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

Please be sure to attach copies of all informed consent/parent permission/assent materials to the "Local Site Documents" section in the ESTR SmartForm.

11. PARTICIPANT COMPENSATION AND FINANCIAL OBLIGATION

11.1 Will your study offer any compensation/incentive to participants (including cash, gift cards, course credit, etc.)? *Please refer to the* Harvard University Financial Policy on Human Subject Payments.

☐Yes
☒No ***(skip to #11.6)***

11.2 What type of compensation will you provide to participants?

☐Cash
☐Check
☐Gift Card/Gift Certificate
☐Course Credit
☐Lottery/Raffle
☐Other ***(see below)***

If you chose "Other" please specify:

11.3 What amount will the compensation be worth?

11.4 Describe which participants will receive compensation and when the compensation will be given.

11.5 Will you provide partial compensation for participants who do not complete all the study procedures?

☐Yes **(see below)**
☐No

If "Yes" please explain how partial compensation will be managed:

HRP-316 WORKSHEET: PAYMENT which may be found in the ESTR library provides an overview of items pertaining to payment that may be helpful to the study team.

11.6Will participants incur any financial costs by taking part in this study?

☐Yes ***(see below)***
☒No

If "Yes" please explain.

DATA SECURITY AND MANAGEMENT

INITIAL COLLECTION

12.1 Describe the identifiability of the data when first obtained/collected:

☐Will not contain any direct or indirect identifiers (Anonymous)
☒Will not be directly identifiable but there will be a code held by the data source that links to the identities (Coded) – *i.e., if receiving data from another site*
☐Will contain direct identifiers (Identifiable)

12.2 In what format will the research data be collected?

☐Paper
☒Electronic
☐Other – ***(see below)***

If "Other" please specify:.

12.3 Do you plan to obtain data from individuals located in the European Economic Area (EEA)*?

☐Yes

☒No

If "YES" the data you obtain may be subject to the E.U. General Data Protection Regulation (GDPR). Click here for more information.

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway, and Switzerland. Note that this regulation may also apply to data obtained over the internet.***

12.4 Will data collected from individuals located in the EEA include any of the following? (mark all that apply)

☐Racial or Ethnic Origin
☐Political Opinions
☐Religious or Philosophical Beliefs
☐Trade Union Membership
☐Sexual Orientation
☐Data concerning a person's sex life
☐Biometric Data
☐Genetic Data
☒None

12.09 Will the study require the use of Mobile Apps?

☐ Yes, Harvard Developed – *Verify your device is configured per policy guidelines https://policy.security.harvard.edu/device-configuration-checklists*
☐ Yes, Non-Harvard Developed - *Please work with your Information Security team to review.*
☒ No

12.10 If you will be using a Mobile App, please list the names:

12.11 Select a web based survey tool if applicable.

☐ RedCAP Survey Tool (Up to level 4 data)
https://www.hsph.harvard.edu/ohra/resources-useful-links/redcap/
☐ Harvard Qualtrics Survey Tool (Up to level 3 data) Anonymizing Responses
https://www.qualtrics.com/support/survey-platform/survey-module/survey-options/survey-termination/

☐ Google Forms (Up to level 3 data) *Limit the questions to the results you need for the study. Consent forms should NOT be stored in the same account as the survey, storing this data in the same account loses confidentiality. Survey results should be coded or anonymously collected, collecting email addresses is not a best practice to securing data. Require a validation input for the survey to ensure data integrity. https://support.google.com/docs/answer/3378864?hl=en. Protect the data by using two-factor authentication on all participating google accounts. https://www.google.com/landing/2step/*
☐ Other- ***(see below)*** *Please work with your Information Security team to review.*

If "Other" please specify:.

12.12 If the use of audio recordings will be utilized, select the applicable storage method(s).

☐Encrypted Voice Recorder (Up to level 4)

☐ Voice Recorder (Up to level 3 data) *For recording devices that are not encrypted, physical protection is essential, treat the device like cash. Never leave the device unattended and off load recordings to encrypted USB or laptop ASAP.*

☐ Smartphone / Tablet (Up to level 3 data) *Confirm the device is passcode protected, software is up-to-date, etc. Disable device backup services, such as iCloud, as recordings might be copied there and you want to be careful to offload/delete all copies. https://policy.security.harvard.edu/device-configuration-checklists*

☐ Vendor Services (Up to level 3 data) *Written contracts must be executed with all vendors. https://policy.security.harvard.edu/v1-vendor-contracts*

☐ Other - ***(see below)*** *Please work with your Information Security team to review.*

☒ None

If "Other" please specify:.

12.13 Select any personal devices that will collect study data.

☐ Laptop (Up to level 3 data) *Follow Harvard's Personal Device Security Guidelines https://security.harvard.edu/personal-device-security-guides. If you should need assistance implementing these guidelines to bring your system in line with Data Security Level 3 contact https://harvard.service-now.com/ithelp?id=contact*

☐ Tablet & Smartphone (Up to level 3 data) *The device should be single use only – just for the purpose of the study, no email, web browsing, social media use, games, etc. Where applicable a physical privacy filter screen for the device, multiple options for purchase from places like Amazon. https://policy.security.harvard.edu/device-configuration-checklists*

☒ None

12.14 Select the devices if participants are using wearable technology as part of the study.

☐ FitBit (Up to level 3 data) *Wearable technology should not have identifiable information such as participant email addresses or DOB. De-identified, single use email addresses are recommend for the research study. Utilizing the default DOB is a common practice among researchers. If participants are to keep the devices, restore to factory settings. Provide a contact within the research team offering support of the devices to ensure confidential data is not intercepted by FitBit support.*

☐ Harvard Lab Managed Phillips (Up to level 3 data) *Wearable technology should not have identifiable information such as participant email addresses or DOB. Utilizing the default DOB is a common practice among researchers.*

☐ Other – ***(see below)*** *Please work with your Information Security team to review.*

☒ None

If "Other" please specify:.

DATA MANAGEMENT / STORAGE

12.15 Will the data be managed by Harvard researchers either remotely or housed at Harvard (e.g., physically or Harvard Cloud Storage)?

☒Yes

☐No

12.16 Describe the identifiability of the data when stored:

☐Will be directly labeled with personal identifying information (identifiable)

☐Will be labeled with a code that the research team can link to personal identifying information (Coded). *This refers to when the research team is using a crosswalk document to link identifiable data to research data and each dataset is kept separately.*

☒Will not be directly identifiable but there will be a code held by the data source that links to the identities (Coded) – *i.e., if receiving data from another site*

☐Will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information (Anonymous or De-identified)

☐Other – ***(see below)***

If "Other" please specify:.

12.17 In what format will the research data be stored?

☐Paper

☒Electronic

☐Other – ***(see below)***

If "Other" please specify:.

12.18 How will the consent forms be collected and stored?

☐ Paper- *Keep under lock and key away from collected data and samples. Shred when no longer needed.*

☐ Electronic - *Keep in separate systems from collected data and samples. Delete when no longer needed. Recommended Example: Use Qualtrics for consent forms and REDCap for survey data.*

12.19 Will subject contact information or other individually identifiable subject information be stored in the data set?

☒ No - *Paper consent form or key sheet only if applicable.*

☐ Yes – *Identifiable information combined in a data set could be identifiable information and should not be stored outside of the consent or key sheet.*

12.20 Explain where the research data will be stored while the study is active (e.g., personal laptop, thumb drive, departmental computer server, office file cabinet, etc.).

De-identified data that is shared with us by Alta Planning will be stored on secure HBS computers. This data will contain a code that Alta Planning can link to identifiable information, but we will never have access to this data.

12.21 Select the applicable storage and collaboration tools used for the study.

☐ Harvard Managed SharePoint for High Risk Confidential Data (Up to level 4 data) Available by request here: *https://harvard.service-now.com/ithelp?id=sc_cat_item&sys_id=6de6b5856ffcb100a54fa981be3ee4a8*

☐ Accellion/KiteWorks (Level 4 data) *Used for emailing high risk confidential Information to internal and external members of Harvard. Be careful of spelling typo's to email recipients to avoid accidental disclosure.*

☒ Harvard Managed SharePoint/OneDrive (Up to level 3 data) Ensure no High Risk Confidential Data is stored in this SharePoint site. For more information on file sharing options supported by Harvard visit *https://mso.harvard.edu/overview-file-sharing-options*

☐ Harvard Managed DropBox (Up to level 3 data) *Several researchers use Dropbox, especially to coordinate with outside collaborators at other institutions. There is solid guidance located here: https://www.howtogeek.com/129393/6-ways-to-secure-your-dropbox-account/ but to ignore the last step, 'Advanced Users: Encrypt Your Sensitive Dropbox Files'.*

☐ Harvard Managed Google (Up to level 3 data) *Limit the data you need for the study. Data should be coded or anonymously collected. Consent forms, email addresses and phone numbers should NOT be stored in the same account as the research data/analysis, storing this data in the same account loses confidentiality. Protect the data by using two-factor authentication on all participating google accounts. https://www.google.com/landing/2step/*

☐ External Storage Encrypted USB (Level 3 data) *Encrypt the device per instructions located here: Recommended USB device is Kingston Data Traveler found on Amazon. https://www.amazon.com/Kingston-8GB-Traveler-Encrypted-DTVP30/dp/B00G31OPB0 and disable cloud backup services.*

☐ Harvard Odyssey (Up to level 3 data) *Harvard Research Computing*

☐ None

12.22 If applicable, select the password manager used to maintain strong, unique passwords.

☐ Harvard Managed LastPass (Premium Edition) *Use strong, unique passwords and use Harvard's LastPass environment to secure them. https://security.harvard.edu/lastpass*

☐ Non-Harvard Managed LastPass (Personal Edition) *7 ways to make your LastPass account even more secure. https://blog.lastpass.com/2014/10/7-ways-to-make-your-lastpass-account-even-more-secure.html*

☐ Other – ***(see below)*** *Does not require additional security review*

☐ None

If "Other" please specify:.

12.23 Which Multi-factor authentication controls do you use to protect your account's access?

☐ Harvard Managed Office 365 - *Secure user sign-ins for cloud services beyond just a single password. https://mso.harvard.edu/multi-factor-autentication-office-365*

☒ Harvard's DUO MFA - *This step will greatly enhance our information security, and help to protect direct deposit information, research data, and intellectual property, as well as faculty, staff, and student personal information. https://huit.harvard.edu/twostep*

☐ Google MFA - Protect the data by MFA on all participating google accounts. https://www.google.com/landing/2step/

☐ Other – ***(see below)*** *Two Factor Auth List. Several organizations support multi-factor authentication to add security controls to your data. Verify if your service providers are offering this technology and enroll your account. https://twofactorauth.org/. Does not require additional security review.*

☐ None

If "Other" please specify:.

12.24 What will happen to the data at the conclusion of the study? (check all that apply)

☐Direct identifiers* and/or the key to the codes will be destroyed upon completion of the research (all data will be stripped of identifying information and/or the key to codes destroyed, identifiable paper documents shredded, identifiable electronic files purged, Identifiable electronic media securely erased).

☒Retained for study record keeping purposes per institutional policy.

☐Retained by the investigator for future research use.

☐Retained for future research use (create repository/bank).

☐Restricted use data will be destroyed or will be returned to the source.

☐No direct or indirect identifiers* are being collected. This anonymous data will be retained at the discretion of the investigator.

☐This research is a clinical trial conducted under FDA regulations. Direct identifiers* and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.

☐Other – ***(see below)***

If "Other" please specify:.

**** Direct identifiers.*** *These are variables that point explicitly to particular individuals or units. Examples include: names, addresses, including ZIP and other postal codes, telephone numbers, including area codes, Social Security numbers, other linkable numbers such as driver's license numbers, certification numbers, etc.*

Indirect identifiers. *These are variables that can be problematic as they may be used together or in conjunction with other information to identify individual respondents. Examples include: detailed geographic information (e.g., state, county, province, or census tract of residence), organizations to which the respondent belongs, educational institutions (from which the respondent graduated and year of graduation), detailed occupational titles, place where respondent grew up, exact dates of events (birth, death, marriage, divorce), detailed income, offices or posts held by respondent.*

12.25 How will the study data be disposed?

☐ Run Identity Finder- *Identity Finder is a tool which users on Harvard managed devices can run themselves to identify any Level 4 High Risk Confidential Information. https://policy.security.harvard.edu/faq/using-identity-finder*

☐ Use Data Shredder - *Shred papers, CDs, DVDs, etc. with confidential information using Harvard's approved shredding vendor (Data Shredder) or a crosscut shredder. https://policy.security.harvard.edu/faq/destroy-records-confidential-information*

☒ Comply with Information Security Policy – *For mobile devices secure delete by selecting reset to factory settings or by entering incorrect passwords until the device reformats itself. For computers, move local files to trash and empty. For more information visit:*

https://security.harvard.edu/information-security-policy-quick-reference-guide and https://policy.security.harvard.edu/faq/destroy-records-confidential-information

DATA TRANSFER

12.26 Do you anticipate that the research data will be transferred or transported from your possession to another at any time?

☐Yes

☒No ***(skip to question #12.28)***

12.27 Explain what methods you will use to transfer/transport the data and how you will minimize the risks of a data breach during the transmission process.

12.28 Will data be transferred from the EEA* to Harvard or another non-EEA location?

☐Yes

☒No

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway and Switzerland.***

DATA CONTROLS

12.29 Will (or has) a Certificate of Confidentiality (CoC) be (been) obtained for this study? ***If your study meets the definition of a clinical trial according to the NIH, a CoC will be automatically issued with your funding.***

☐Yes

☒No

12.30 Does your protocol have a Data Use Agreement?

☐ Yes

☒ No

12.31 How will confidentiality be achieved?

☐ De-identified- *Information that does not identify an individual. Coded data is not de-identified. The IRB recommends that researchers consult the OHRP/OCR Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule when seeking recommendations on methods for de-identification of research data. Standards can be found at https://nvl.pubs.nist.gov/nistpubs/ir/2015/nist.ir.8053.pdf*

☒ Coded-*Collected data and samples are unidentified by use of random code but the samples may still be linked to their source through the use of a key code by the investigator. Additionally, Harvard affiliates can participate in the Principles of Research Data Confidentiality course within the Harvard Training Portal for an overview of data confidentiality protection, the risk of re-de-identification of data, and data management strategies for minimizing the risk of inadvertent disclosure.*

13. SHARING DATA WITH OTHERS

13.1 Will the data be released to anyone who is not on the Harvard University Area research team?

☒Yes

☐No ***(skip to question #13.4)***

13.2 Other than the Harvard University Area research team, who will have access to the data?

☒Colleagues/Collaborators at other institutions

☐Transcribers/coders hired by the research team

☐Sponsor/Funding Agency

☐Other ***(see below)***

If "Other" please specify:.

We may share this de-identified data with collaborators, but not without receiving permission from Alta Planning.

13.3 How will the data be shared/disclosed beyond the Harvard University Area research team?

☐Without any identifiers
☒Coded
☐With Identifiers

13.4 Will you be sharing research findings with study participants?

☐Yes ***(see below)***
☒No

If "Yes" please describe which findings will be shared, when they will be shared, and how they will be shared with participants (in-person, over the telephone, etc.):

13.5 Does the study include establishing a repository for sharing data or specimens with other researchers?

☐Yes ***(If so, please know that a separate IRB submission will be needed if a data or specimen repository will be created)***
☒No

GENOMIC DATA SHARING

13.6 Will you be submitting data to a national data repository (dbGaP, GEO, etc.) or other type of repository for broad sharing of data?

☐Yes
☒No

13.7 Will you require a Genomic Data Sharing (GDS) Institutional Certification per NIH GDS policy?

☐Yes
☐No

13.8 Include a description of all fields to be submitted to the repository:

13.9 Describe the plan for de-identifying data for inclusion in the repository, including how the key linking the identity of participants will be maintained and who will have access:

If data will be prospectively collected, specific elements are required to be included in the informed consent form that you will be using in this study. Please see the NIH guidance document.

If data that will be submitted have already been collected under another IRB or other collection protocol, please be sure to attach a copy of the IRB approval and approved consent form(s) used to collect the underlying data/specimens to the "Local Site Documents" section in the ESTR SmartForm.