# Researcher information

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| --- | --- |
| Principal Investigator Name | Carole Turley Voulgaris |
| 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](https://cuhs.harvard.edu/am-I-PI-eligible)) |  |
| Other Advisor Name (if applicable) |  |
| Is this research activity being conducted under your responsibilities as a Harvard Faculty, Student, or other Harvard affiliation?  See [Statement on Outside Activities of Holders of Academic Appointments](https://provost.harvard.edu/statement-outside-activities-holders-academic-appointments) for more information. | Yes  No (explain below) |

# Study information

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| Study Title | Route Choice and Diversion for the Journey to School |
| ESTR Number  *Once a submission is created, ESTR will generate a number for your study.* |  |
| 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. **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 Specifically, 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**](https://grants.nih.gov/policy/clinical-trials/definition.htm)**” (see below)?**

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.”*

*The NIH also includes basic experimental studies involving humans (BESH) as clinical trials. BESH meet both the definition of basic research and the NIH definition of a clinical trial. BESH therefore are subject to NIH clinical trials policies such as registration and results reporting. All BESH meet the NIH definition of a clinical trial. But not all clinical trials are BESH. See the* [*NIH website*](https://grants.nih.gov/policy/clinical-trials/besh.htm) *for more information.*

*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*](https://cuhs.harvard.edu/requirements-all-nih-funded-human-subjects-research) *for more information.*

# 2. Research locations and collaborations

## 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)***

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| ***If you chose “in another US state” or “Internationally” describe the laws that will need to be considered:*** |
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*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

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| ***If “Yes” describe the laws that will need to be considered:*** |
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**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

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| ***If “Yes” describe and if available, upload any permission documents to the ESTR SmartForm section “Local Site Documents.”*** |
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**2.4 Will you be conducting the research in a setting where suspected child abuse/neglect or elder abuse/neglect may be witnessed? This may include school settings, elder care locations, or a private residence.**

Yes ***(see below)***

No

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| ***If “Yes” describe the location, if there is an existing process in place for reporting of abuse/neglect, and if not, what the study team will do should suspected abuse/neglect be witnessed.*** |
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**2.5 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

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| ***If “Yes” describe:*** |
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## 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 to determine the scope of IRB review.*

**2.6 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)***

**2.7 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)***

**2.8 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

**2.9** **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 *(Complete the HRP-220: Non-Harvard Personnel Form and attach to the ESTR SmartForm Section “Study Team Members” item 2. Note that those who are considered “volunteers” and are working under the auspice of Harvard University Area will also need to be included in HRP-220)*

No ***(see below)***

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| ***If you chose “No” describe the compliance/ethical oversight that this researcher will have in place:*** |
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# 3. study team qualifications and training

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

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| --- |
| I have published two journal articles on travel to school. I have led the development and deployment of a campus travel survey at California Polytechnic State University. The population being studied are families with school children at two schools in the Somerville public school system. I am the parent of a child at one of the study schools, so this is a community I am a member of. |

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

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| I am the only person who will have access to all raw survey data. Survey responses in non-English languages will be given to one of three student research assistants for translation. |

**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

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| ***If “Yes” describe:*** |
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**3.4 If you have a Faculty Sponsor, describe their role in your research including how they will oversee the implementation and conduct of this research study. If not applicable, skip to the next question.**

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# 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.**

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| The purpose of this study is to identify the types locations that children encounter on their journeys to school that they or their caregivers perceive to be unsafe or unpleasant. We hope to answer the question of which features of the built environment cause students to divert from the shortest path they could take on their journey to school. |

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

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| There is a large literature on interventions to create safe routes to school and the ways in which they might reduce pedestrian and cyclist injuries from vehicular crashes. Less is known about how such interventions might reduce the distance children must walk to school by reducing the need to take longer routes to avoid hazards. This research would contribute towards identifying locations where an intervention could reduce the distance children must travel to school. |

**4.3** **Is there any other way to do this research that would reduce risks to subjects and still answer the scientific question?**

Yes

No ***(see below)***

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| ***If ‘No’, describe your rationale for how your proposed study is being conducted in a way that does not increase/ensures reduced risks to participants:*** |
| Self-reported responses from a survey are the least invasive way to collect information about route choice on the journey to school. Alternative means of determining the routes students take to school (such as following them or tracking their locations) would place their privacy at greater risk. We are surveying caregivers rather than children to ensure that children do not participate in this survey without parental consent.  We will recruit survey participants through a flier that teachers will send home with students in their backpacks.  Sending papers home in students’ backpacks is a common way that both of these school communicate with parents, and it is the best way to reach as broad a sample of parents as possible. An alternative would be to disseminate information about the survey exclusively through online engagement. This would likely reduce both the overall response rate and the representativeness of the sample, since parents who spend a lot of time engaging with the student online (generally a higher-income and less racially diverse group than the general population) would be more likely to complete the survey. |

# 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.***

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| All students at two schools in Somerville (Winter Hill Community Innovation School and Benjamin G. Brown School) will receive a flier from their teachers inviting students’ caregivers to take the survey using a URL and QR code. They survey will include information in English, Spanish, Portuguese, and Haitian Creole.  Students will share these materials with their caregivers, who will complete the survey online using the provided URL or QR code.  Principals at each school will also include an invitation to take the survey, including a link to the online version of the survey, as part of a weekly newsletter they already routinely send to students’ families.  Sending papers home in students’ backpacks is a common way that both of these school communicate with parents, and it is the best way to reach as broad a sample of parents as possible. An alternative would be to disseminate information about the survey exclusively through online engagement. This would likely reduce both the overall response rate and the representativeness of the sample, since parents who spend a lot of time engaging with the student online (generally a higher-income and less racially diverse group than the general population) would be more likely to complete the survey.  We have attempted to write this survey, including the accompanying information about risks and benefits, in simple language that could be understood by a child, but the survey is intended to be taken by each student’s caregiver.  The survey will take less than ten minutes to complete. |

**5.2 Will your research study involve (or will be allied with) the provision of medical or clinical**  **services?** *“Clinical care” is defined health care services for the purpose of evaluating, diagnosing, or treating an illness, injury or disease.*

Yes ***(See [“Guidance: Provision of Clinical and Medical Services During Clinical](https://bpb-us-e1.wpmucdn.com/websites.harvard.edu/dist/6/18/files/2020/07/clinical_research_guidance_05_01_16.pdf)***

***[Research”](https://bpb-us-e1.wpmucdn.com/websites.harvard.edu/dist/6/18/files/2020/07/clinical_research_guidance_05_01_16.pdf)***

No

***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

**Check this box if this section is not applicable, then skip to next section.**

**5.3 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).**

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| We have developed a survey specifically for this study. The survey asks basic demographic data about the child in the caregiver’s care, including gender, grade level, and which school they attend. Respondents will indicate what mode of transportation their child uses to get to school on a typical day. Each respondent will also mark locations on a map to indicate the approximate locations of the child’s homes and places they stop on the way to school. They will be asked to identify locations along their route that are pleasant or unpleasant. If they indicated that their child does not take the shortest possible route to school, they will be asked about features of the shortest possible route that they find to be worse than the route the child actually takes. |

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

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| They will take the survey once, and it will take less than ten minutes. |

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

Yes **(see below)**

No

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| ***If “Yes” which survey software will you be using? :*** |
| Qualtrics. |

## interviews/oral history/focus groups

**Check this box if this section is not applicable, then skip to next section.**

**5.6 Explain where interviews/focus groups will take place (including possible online venues such as Zoom, Teams, online chat rooms, etc.)**

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**5.7 Describe any steps you will take to protect the participant’s privacy during the interview/focus group.**

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**5.8 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.**

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

☐ Yes *(You will need to include additional text in your informed consent form if doing so. Template language is included in the template informed consent forms in ESTR)*

☐ No

## observational/ethnographic research

**Check this box if this section is not applicable, then skip to next section.**

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

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

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

Yes ***(see below)***

No

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| ***If “Yes” describe the information that would be private.*** |
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**5.13**  **Will the data you collect contain any information that identifies specific individuals?**

Yes

No

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

Yes (*You will need to include additional text in your informed consent form if doing so. Template language is included in the template informed consent forms in ESTR)*

No

**5.15**  **Will you notify participants that they are being observed?**

Yes

No ***(see below)***

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| ***If “No” explain the circumstances why you would not be able to let participants know they are being observed.*** |
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**5.16**  **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?**

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## Audio-recording/video-recording/photographs

**Check this box if this section is not applicable, then skip to next section.**

*If you will be audio/video recording or photographing individuals, you must obtain permission from the individual to do so.*

**5.17**  **What type of recording will take place? (Check all that apply)**

Audio-Recording

Video-Recording

Photography

Other ***(see below)***

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| ***If “Other” describe:*** |
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**5.18**  **Explain what types of data will be recorded or photographed.**

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

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

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## deception and incomplete disclosure

**Check this box if this section is not applicable, then skip to next section.**

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

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

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**5.22**  **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.**

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

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*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

**Check this box if this section is not applicable, then skip to next section.**

*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.*

***Note the following terms when completing this section:***

***Direct identifiers.****These are variables that point explicitly to 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.*

**5.24 When 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)

**5.25**  **Indicate the identifiability of the data when you collect and/or receive it:**

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.

**5.26**  **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.**

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**5.27**  **Provide an overview of the types of variables that are contained in the dataset.**

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

Yes ***(see below)***

No

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| ***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.*** |
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**5.29**  **Will any of your data be obtained from internet sites (including data mining and data scraping activities)?**

Yes ***(see below)***

No

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| ***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.*** |

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**5.30 Is the data publicly available on the internet (see below definition)?**

Yes

No

*If an activity (textual, visual, auditory) is legally available to any Internet user without specific permission or authorization from the individual being observed, or from the entity controlling access to the information, the activity should be considered “public behavior.” Examples include “comment” postings on news sites; posting on publicly available hosting sites; postings on classified sites; and postings on unrestricted blog or wiki sites.*

**5.31 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 questions below)***

No

***If “Yes”, which organization will provide the HIPAA PHI to you?***

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

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*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.*

**5.32 Do 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.*

**5.33 Will you receive data that was collected from individuals located in the European Economic Area (EEA)/U.K.\*?**

Yes (***If “YES” the data you receive may be subject to the E.U. General Data Protection Regulation (GDPR). Click*** [***here***](https://gdpr.eu/) ***for more information.)***

No ***(skip to item 5.34)***

*\* The EEA/U.K. 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.*

**5.34 Will the data that were collected from individuals located in the EEA/U.K. include any of the following? (Mark all that apply)**

Information about a Subject’s Health

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 (i.e., which includes one or more factors specific to the genetic identity of that natural person, even without their name or other identifier.)

Criminal Activity

None

**5.35 Will you receive data from the Centers for Medicare & Medicaid Services (CMS)?** *Data from the Harvard Center for Healthcare Data Analytics/Center for the Study of Health System Performance is CMS data.*

Yes

No

**5.36**  **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

**Check this box if this section is not applicable, then skip to next section.**

*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.*

**5.37 When 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)

**5.38 Indicate the identifiability of the biological materials when you collect and/or receive it:**

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.

**5.39 How 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)***

***Use the text box below if you chose “another research study” or “other. 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.***

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**5.40 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

**5.41 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).**

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## Devices

**Check this box if this section is not applicable, then skip to next section.**

*If data from this study will be used to determine the safety or efficacy for the DEVICE under investigation, 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.*

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

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

**5.43 Does the use of the device in this research involve the following? (Check all that apply)**

To evaluate the safety or effectiveness of that device.

Data from its use in the research will be submitted to or held for inspection by FDA.

☐ Not applicable – not evaluating the safety or effectiveness or submitting or held for inspection by the FDA.

**5.44** **Is the device that you plan to use FDA-approved/cleared?**

Yes (if YES, got to item 5.44)

No (if NO, go to item 5.45)

Not applicable – not evaluating the safety or effectiveness or submitting or held for inspection by the FDA.

**5.45**  **Is the device that you plan to use being used in this research according to the FDA approval/clearance?**

Yes (if YES, go to item 5.46)

No (if NO, go to item 5.45)

Not applicable – not evaluating the safety or effectiveness or submitting or held for inspection by the FDA.

**5.46 Has the FDA determined whether the device is Significant Risk or Non-Significant Risk?**

Yes (indicate whether the FDA device determination is SR or NSR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

No

Not applicable – not evaluating the safety or effectiveness or submitting or held for inspection by the FDA.

**5.47**  **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.**

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## drugs

**Check this box if this section is not applicable, then skip to next section.**

*If data from this study will be used to determine the safety or efficacy for the DRUG/BIOLOGIC under investigation, 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.*

**5.48 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 |
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**5.49 Does the use of the drug or biological product (biologic) in this research involve the following? (Check all that apply)**

☐ To evaluate the safety or effectiveness of that drug or biological product (biologic).

☐ If an approved drug or biological product (biologic), it will be used in a way other than what it was approved for by the FDA.

☐ Data from its use in the research will be submitted to or held for inspection by FDA.

☐ Not applicable – not evaluating the safety or effectiveness or submitting or held for inspection by the FDA.

**5.50 Is the drug/biologic that you plan to use being used in this research according to the FDA approval/clearance?**

Yes

No

Not applicable – not evaluating the safety or effectiveness or submitting or held for inspection by the FDA.

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

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## Discontinue participation

**5.52 Is there any reason why you may discontinue the participation of an individual taking part in this research (For example, low performance, not passing attention checks)?**

Yes *(See below. Also, note that information pertaining to this should be included in the study consent form, if applicable)*

No

**If “YES”, describe the reasons that an individual would be discontinued from participating:**

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# 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.**

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| Survey respondents will be asked to describe unpleasant characteristics of their child’s journey to school and of alternative routes to school that children may go out of their way to avoid. If they feel anxiety about these places, these questions might make them feel anxious.  Survey respondents will indicate their approximate home locations on a map, which could present a risk of violating their privacy, but this risk is minimal because all locations they provide will be approximate. |

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

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| --- |
| No personally-identifiable information will be collected. We will gather email addresses in order to send respondents gift cards as an incentive, but these will be stored separately from survey responses. |

**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 **(if YES, describe these resources in item 6.4)**

No **(if NO, skip to item 6.5)**

**6.4 Describe medical and/or psychological resources here:**

|  |
| --- |
|  |

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

|  |
| --- |
| Participants will complete the survey on their own time. The survey instructions will indicate that participants do not have to answer any questions they do not want to. |

**6.6 For studies that involve higher levels of risk, a data and safety monitoring plan is needed. Note that this is also a requirement for NIH Clinical Trials. Please describe the data and safety monitoring plan for this study including 1) Identification and description of individuals responsible for monitoring the trial (e.g., PI, ISM, DSMB), their roles, qualifications, and the frequency of the monitoring activities, 2) description of any specific events that would preclude a participant from continuing the intervention, 3) description of the trial stopping rules for the study, if any (e.g., increased suicidal ideation, greater than expected morbidity or mortality rate), and 4) description of the plan for management of incidental findings.**

|  |
| --- |
| This study does not involve higher levels of risk, so no data and safety monitoring plan is necessary. |

**6.7 Describe any potential direct benefits to participants in the study. If there are no individual benefits, indicate as such.** *Payment for participation (in any form) is not considered a personal benefit.*

|  |
| --- |
| There are no benefits to participation. |

**6.8 Describe any potential benefits to society.**

|  |
| --- |
| The results of this research could inform decisions about prioritizing investments in pedestrian and cycling infrastructure to locations where improvements can reduce the distances students must walk to school. |

# 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.*

|  |
| --- |
| We will distribute the survey to all students in grades pre-K through 8 at two schools in Somerville: Winter Hill Community Innovation School and Benjamin G. Brown School.  In 2022, the total enrollment at Winter Hill Community Innovation School was 418 students (grades Pre-K through 8) and the total enrollment at Benjamin G. Brown School was 181 students (grades Kintergarten through 5). This results in a maximum of 599 total potential study participants. The actual number of total potential participants will be less than this since come caregivers have multiple children at the schools we are studying. |

**7.2 Describe the demographic characteristics of the proposed study sample (e.g. age, sex, race, ethnicity, SES)**

|  |
| --- |
| The Massachusetts Department of Elementary and Secondary Education characterizes 18.2 percent of students at Benjamin G. Brown School and 64.1 percent of students at Winter Hill School as low-income. 30.6 percent of students at Winter Hill School and 59.1 percent of students at Benjamin G. Brown School at White. 5.5 percent of students at Benjamin G. Brown School and 35.6 percent of students at Winter Hill School are English language learners. |

**7.3 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.**

|  |
| --- |
| We will be sending the survey home with all students, and we anticipate that all survey respondents will be caregivers of children at one of the two schools.  The online version of the survey will be available to anyone with a link, but we will not actively seek to disseminate the survey beyond those two schools, and the text of the survey clearly indicates that it is intended for caregivers of parents at the two study schools. |

**7.4 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 Person

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

**Check this box if this section is not applicable, then skip to next section.**

*If you will include children in your study, complete this section. By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally, the law considers any person under 18 years old to be a child however this may vary according to the U.S. state or country where the research will be taking place.*

***See Harvard University’s*** [***Policy for the Safety & Protection of Minors***](https://youthprotection.harvard.edu/policy)***,*** [***Harvard University Guidelines for Interacting with Minors***](https://youthprotection.harvard.edu/guidelines)***, and Harvard University’s*** [***Minors in Labs Policy***](https://youthprotection.harvard.edu/minors-labs-policy) ***before interacting with children.***

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

|  |
| --- |
|  |

**7.6 Will you be collecting private, identifiable information from children from an online website?**

Yes **(see important message below)**

No

*Important!* [*The Children’s Online Privacy Protection Act and Rule (COPPA)*](https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/childrens-online-privacy-protection-rule) *requires additional requirements including parental consent.*

**7.7 Are there any special circumstances that need to be considered? For example, do the children have a learning disability? Other?**

|  |
| --- |
|  |

## PRISONERS

**Check this box if this section is not applicable, then skip to next section.**

*If you will involve prisoners in your study, complete this section. The regulations define “prisoner” as follows:*

*“Prisoner” means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (45 CFR 46.303(c)).*

*Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons or may be untried persons who are detained pending judicial action, for example, arraignment or trial.*

**7.8 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.**

|  |
| --- |
|  |

**7.9 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

**Check this box if this section is not applicable, then skip to next section.**

*If you will include employees or students at Harvard University (whether a focus of your study or not), complete this section. If the Harvard employees or students will be the focus of your study, see guidance “*[*Recruiting Volunteers from the Harvard University Community*](https://cuhs.harvard.edu/recruiting-study-volunteers-harvard-university-community?admin_panel=1)*.”*

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

|  |
| --- |
|  |

# 8. recruitment

**8.1** **Describe the methods that will be used to identify potential participants. If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of recruiting.**

|  |
| --- |
| All students at two schools in Somerville (Winter Hill Community Innovation School and Benjamin G. Brown School) will receive a flier from their teachers inviting students’ caregivers to take the survey using a URL and QR code. They survey will include information in English, Spanish, Portuguese, and Haitian Creole.  Students will share these materials with their caregivers, who will complete the survey online using the provided URL or QR code.  Principals at each school will also include an invitation to take the survey, including a link to the online version of the survey, as part of a weekly newsletter they already routinely send to students’ families. |

**8.2 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.*** |

|  |
| --- |
| Yes. The first page of the survey includes information about the study. |

*Please be aware that the* [*Telephone Consumer Protection Act*](https://www.govinfo.gov/content/pkg/FR-2012-06-11/pdf/2012-13862.pdf) *prevents recruitment through auto-generated SMS/text messages as well as other restrictions.*

**8.3 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.*

**8.4 Are recruitment procedures taking into account approaches to engage underserved populations?**

Yes

No ***(see below)***

***If “No” explain why this is not necessary.***

|  |
| --- |
| Copies of the survey, including information about the study, will be provided in English, Protuguese, Spanish, and Haitian Creole. |

# 9. Screening

**9.1 Will you be screening participants for eligibility?** *If you are using inclusion or exclusion criteria, you will be “screening” individuals to determine who is eligible.*

Yes

No ***(skip to next section)***

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

|  |
| --- |
|  |

**9.3 Explain how you will conduct the screening process.** **If applicable, 1) describe any oral or written communication with the prospective participant for the purpose of screening/determining eligibility, or 2) describe procedures for accessing records or stored identifiable biospecimens for purposes of screening or determining eligibility.**

|  |
| --- |
|  |

**9.4 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

**Check this box if this section is not applicable (i.e., not enrolling adults in your study), then skip to next section.**

*Be sure to attach copies of all informed consent/parent permission/assent materials to the “Local Site Documents” section in the ESTR SmartForm.*

**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:***   1. ***Why this research involves no more than minimal risk to participants.*** 2. ***Why it would be impracticable to carry out the research with consent or an agreement to participate*** 3. ***If participants will be provided with additional pertinent information after participation, if appropriate. If not appropriate, explain why.*** |

|  |
| --- |
|  |

**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:*** |

|  |
| --- |
| We are not requiring survey respondents to provide any personally identifiable information, including a signature. Participants will check a box on the first page of the survey to indicate consent to participate. |

**10.3 What type of signature will you obtain?**

Inked

Electronic ***(Refer to the HUA Investigator Manual (HRP-103) for electronic signature requirements)***

Other ***(see below)***

|  |
| --- |
| ***If other, please describe:*** |

|  |
| --- |
|  |

**10.4 Where will the consent or agreement to participate process take place?**

In-person

Online

Over the telephone

Other ***(see below)***

|  |
| --- |
| ***If other, please describe:*** |

|  |
| --- |
| Respondents will answer a question affirming their consent to participate before proceeding to the survey. |

**10.5 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?***

|  |
| --- |
| Participants will give their consent by answering the first survey question, which asks whether the understand the provided information about the study and agree to participate. |

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

|  |
| --- |
| Respondents to the online version of the survey will answer a question affirming their consent to participate before proceeding to the survey. |

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

|  |
| --- |
| Survey respondents will be provided with a page explaining the research and the voluntary nature of participating, and will answer a multiple-choice question to indicate that they understand the provided information and agree to participate. |

## children participants

**Check this box if this section is not applicable (i.e., not enrolling children in your study), then skip to next 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.*

*Be sure to attach copies of all informed consent/parent permission/assent materials to the “Local Site Documents” section in the ESTR SmartForm.*

**10.8 Will the children taking part in this research be capable of understanding and providing assent, taking into consideration the ages, maturity, and psychological state.**

Yes

No ***(Skip to next section)***

**10.9 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:**

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

|  |
| --- |
| This research is a survey that involves minimal risk to participants. All data are self-reported and we will not be gathering personal-identifiable information. We expect that children will be in the care of their parents when they complete the survey.  Those who choose to provide an email address will be sent a summary of the survey results upon completion of the study. |

1. **If participants will be provided with additional pertinent information after participation, if appropriate. If not appropriate, explain why.**

**10.10 Will the assenting or agreement to participate process involve obtaining a signature?**

Yes

No ***(see below)***

***If a signature is not obtained, explain why:***

|  |
| --- |
|  |

**10.11 What type of signature will you obtain?**

Inked

Electronic *(Refer to the HUA Investigator Manual (HRP-103) for electronic signature requirements)*

Other ***(see below)***

|  |
| --- |
| ***If other, please describe:*** |

|  |
| --- |
|  |

**10.12 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:***

|  |
| --- |
|  |

**10.13 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?***

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**10.15 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

**Check this box if this section is not applicable (i.e., not enrolling children in your study), then skip to next 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.*

*Be sure to attach copies of all informed consent/parent permission/assent materials to the “Local Site Documents” section in the ESTR SmartForm.*

**10.16 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:***

1. ***Why this research involves no more than minimal risk to participants.***
2. ***Why it would be impracticable to carry out the research with consent or an agreement to participate.***
3. ***If participants will be provided with additional pertinent information after participation, if appropriate. If not appropriate, explain why.***

|  |
| --- |
|  |

**10.17 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:***

|  |
| --- |
|  |

**10.18 What type of signature will you obtain?**

Inked

Electronic ***(Refer to the HUA Investigator Manual (HRP-103) for electronic signature requirements)***

Other ***(see below)***

|  |
| --- |
| ***If other, please describe:*** |

|  |
| --- |
|  |

**10.19 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:***

|  |
| --- |
|  |

**10.20 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?***

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**10.22 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

**Check this box if this section is not applicable, then skip to next section.**

*Complete this section if you will be including Wards of the State, non-English speaking participants, illiterate participant, or adults not competent to consent.*

**10.23 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?**

|  |
| --- |
| Although some students may be Wards of the State, the survey participants are the caregivers of students, and not the students themselves. |

**10.24 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.**

|  |
| --- |
| Some students at the schools and/or their parents are non-English speakers. The survey and all associated information will be provided in English, Spanish, Portuguese, and Haitian Creole. |

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

|  |
| --- |
| We will be providing all materials in English, Spanish, Portuguese, and Haitian Creole.  Participants will give their consent by answering the first survey question, which asks (in each of those four languages) whether they understand the provided information about the study and agree to participate. |

# 11. participant compensation and financial obligation

*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****.***

**11.1 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*](https://policies.fad.harvard.edu/pages/human-subject-payments)*.*

Yes

No ***(skip to item 11.6)***

**11.2**  **What type of compensation will you provide to participants?**

Cash

Check

Gift Card/Gift Certificate

Course Credit

Lottery/Raffle ***(see below)***

Other ***(see below)***

***If you chose “Lottery/Raffle”:***

***What is the amount and total number of payments to be awarded?***

|  |
| --- |
|  |

***What are the odds of winning (if known)?***

|  |
| --- |
|  |

***What is the approximate timing of the drawing?***

|  |
| --- |
|  |

***How will participants who are awarded be notified?***

|  |
| --- |
|  |

***If you chose “Other” please specify:***

|  |
| --- |
|  |

**11.3**  **What amount will the compensation be worth?**

|  |
| --- |
| $10 |

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

|  |
| --- |
| All participants who fully or partially complete the survey. |

**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:***

|  |
| --- |
|  |

**11.6 Will participants be compensated for injuries caused by study procedures, if applicable?**

Yes ***(see below)***

No

***If “Yes” please explain.***

|  |
| --- |
|  |

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

Yes ***(see below)***

No

***If “Yes” please explain.***

|  |
| --- |
|  |

# 12. data collection

*Note the following terms when completing this section:*

***Direct identifiers.****These are variables that point explicitly to 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.*

## 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 or indirect identifiers (Identifiable) *If you will be collecting participant name, contact information, employee ID, MTurk worker ID, etc. this would be considered “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 target as a study population and obtain data from individuals located in the European Economic Area (EEA)/U.K.\*?**

Yes (*If “YES” the data you obtain may be subject to the E.U. General Data Protection Regulation (GDPR). Click* [*here*](https://gdpr.eu/) *for more information.)*

No ***(skip to item 12.6)***

*\* The EEA/U.K. 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/U.K. include any of the following? (mark all that apply)**

Information about a Subject’s Health

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 (i.e., which includes one or more factors specific to the genetic identity of that natural person, even without their name or other identifier.)

Criminal Activity

None

**12.5 Will your study directly impact study participants by offering them what is considered “goods and services” according to the GDPR? Examples include making available a product, device, survey, mobile application or providing study results to study participants, or collecting specimens from subjects located in the EEA, analyzing the specimens as part of a research project, and returning the results of the analysis to a research subject or his or her treating clinician.**

Yes ***(see below)***

No

***If “Yes” explain what “goods and services” will be offered:***

|  |
| --- |
|  |

**12.6 Will the study require the use of Mobile Apps?**

Yes ***(see below)***

No

***List the names of each Mobile App:***

|  |
| --- |
|  |

**12.7 Will the study use a web-based survey tool?**

Yes ***(see below)***

No

***List the names of each web-based tool:***

|  |
| --- |
| Qualtrics |

**12.8 Select the device(s) that will collect study data:**

Laptop

Desktop or other non-portable computer

Tablet & Smartphone

Other (specify: )

None

## Data storage

**12.9 Will the study involve study subjects using wearable technology as part of the study?**

Yes ***(see below)***

No

***List the names of the wearable technology:***

|  |
| --- |
|  |

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

Yes

No

**12.11 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 *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:***

|  |
| --- |
|  |

**12.12 In what format will the research data be stored?**

Paper

Electronic

Other – ***(see below)***

***If “Other” please specify:***

|  |
| --- |
|  |

**12.13 How will the consent forms be collected and stored?**

Paper

Electronic

Not applicable to this study

**12.14 Will subject contact information or other individually identifiable subject information be stored with the data set?**

Yes

No

**12.15 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.).**

|  |
| --- |
|  |

**12.16 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). ***Important! Data that is protected by GDPR must be destroyed at end of study.***

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:***

|  |
| --- |
|  |

## Data Transfer

**12.17 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 #12.19)***

***Important! Data transferred to or from international locations may have additional data restrictions.***

**12.18 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.**

|  |
| --- |
|  |

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

Yes (*If “YES” the data you obtain may be subject to the E.U. General Data Protection Regulation (GDPR). Click* [*here*](https://gdpr.eu/) *for more information.)*

No

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

## Data Controls

**12.20 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

**12.21 Does your protocol have (or will have) a Data Use Agreement?**

Yes

No

*If you are uncertain whether a data use agreement is needed for your study, please see information here -* <https://researchdatamanagement.harvard.edu/data-use-agreements>

# 13. sharing Data with others

**Check this box if this section is not applicable.**

*Complete this section if you will release study data to anyone who is not on the Harvard University Area research team. This includes OpenScience, Funding Agency data sharing requirements, and other data sharing frameworks.*

**13.1 Is your study required to share data because of Funding Agency requirements (i.e., NIH, NIMH, NIAAA, others)?**

Yes

No

**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

OpenScience or other framework (Specify: )

Other ***(see below)***

***If “Other” please specify:***

|  |
| --- |
|  |

**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 future sharing of 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

**Check this box if this section is not applicable.**

*Complete this section if you will you be submitting data to a national data repository (dbGaP, GEO, etc.) or other type of repository for broad sharing of data.*

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

Yes

No

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

|  |
| --- |
|  |

**13.8 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:**

|  |
| --- |
|  |

**13. 9 Describe the potential risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing:**

|  |
| --- |
|  |

**13.10 To the extent relevant and possible, describe the potential risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing:**

|  |
| --- |
|  |

*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*](https://osp.od.nih.gov/wp-content/uploads/NIH_guidance_elements_consent_under_gds_policy.pdf)*.*

*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.*