# Researcher information

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| Principal Investigator Name | David Yang |
| 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 | Seeing is Believing |
| ESTR Number |  |
| Version Number | 1.0 |
| 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 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.”

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 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)***

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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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***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

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

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# 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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***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).**

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**5.3 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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**5.4 Will you be using any survey software (such as Qualtrics)?**

Yes (see question below)

No

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

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

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**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.**

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

☐ Yes (*Refer to the consent template that you will be using for additional text to include.)*

☐ No

## observational/ethnographic research

*Skip this section if not applicable.*

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

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**5.10 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.)**

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**5.11** **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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**5.12**  **Will the data you collect contain any information that identifies specific individuals?**

Yes

No

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

Yes (*Refer to the consent template that you will be using for additional text to include.)*

No

**5.14**  **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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**5.15**  **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

*Skip this section if not applicable.*

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

**5.16**  **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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**5.17**  **Explain what types of data will be recorded or photographed.**

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**5.18**  **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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**5.19**  **Explain what will happen to the recordings/photographs at the end of the study.**

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## 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.***

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

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**5.21**  **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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**5.22**  **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

*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.*

**5.23 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)

**5.24**  **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.

**5.25**  **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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**5.26**  **Provide an overview of the types of variables that are contained in the dataset.**

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**5.27**  **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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**5.28**  **Will any of your data be obtained from internet sites (including data mining and data scraping activities)?**

Yes ***(see question 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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**5.29 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.*

**5.30 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.***

**5.31 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.***

**5.32**  **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.*

**5.33 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)

**5.34 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.

**5.35 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)***

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| ***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.*** |
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| ***If “another research study” or “Other” please specify:*** |
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**5.36 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

**5.37 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

*Skip this section if not applicable.*

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

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

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

Yes

No (if NO, go to item #5.41)

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

Yes

No (if NO, go to item #5.41)

**5.41 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

**5.42**  **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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***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.***

## drugs

*Skip this section if not applicable.*

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

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

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

Yes

No

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

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***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.***

# 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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**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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**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?**

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**6.5 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.**

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

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

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# 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.***

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**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.**

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**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):***

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| ***If “Other” please specify:*** |

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### *children*

*Skip this section if not applicable.*

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

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**7.5 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.***

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

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### *PRISONERS*

*Skip this section if not applicable.*

**7.7 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.**

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

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### *employees or students of harvard university*

*Skip this section if not applicable.*

**7.9 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.**

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# 8. recruitment

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

Yes ***(see below)***

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

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| ***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.*** |

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*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.*

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

Yes ***(see below)***

No

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| ***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.*** |

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***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.**

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**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)***

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| ***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.*** |

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# 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)**

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| ***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*** |

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

Yes

No ***(see below)***

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

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**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)***

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

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

In-person

Online

Over the telephone

Other ***(see below)***

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

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**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?***

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

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**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.**

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## 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.***

**10.8 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)***

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| ***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:*** |

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**10.9 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:***

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

Inked

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

Other ***(see below)***

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

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**10.11 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:***

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**10.12 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?***

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

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

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## PARENT PERMISSION

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

**10.15 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:***

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**10.16 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:***

|  |
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**10.17 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:*** |

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**10.18 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:***

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**10.19 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?***

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

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**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.**

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## Other types of participants

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

**10.22 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?**

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**10.23 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.**

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

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***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*](https://policies.fad.harvard.edu/pages/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 ***(see below)***

Other ***(see below)***

***If you chose “Lottery/Raffle”:***

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

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|  |

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

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|  |

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

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

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

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

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

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**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:***

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***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.***

**11.6 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.***

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|  |

# 12. data collection

## 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:.***

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**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

No

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

***\* 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

Criminal Activity

None

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

Yes

No

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

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|  |

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

Yes

No

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

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**12.7 Select any personal device that will collect study data:**

Laptop

Tablet & Smartphone

None

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

Yes

No

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

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|  |

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

Yes

No

**12.10 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:.***

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

Paper

Electronic

Other – ***(see below)***

***If ”Other” please specify:.***

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

Paper

Electronic

Not applicable to this study

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

No

Yes

**12.14 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.).**

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**12.15 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:.***

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|  |

***\* 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.*

## Data Transfer

**12.16 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.***

**12.17 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.**

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**12.18 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

**12.19 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

**12.20 Does your protocol have a Data Use Agreement?**

Yes

No

# 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

OpenScience or other framework (Specify: )

Other ***(see below)***

***If ”Other” please specify:.***

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**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.):***

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**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:**

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**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*](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.***

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