RESEARCHER INFORMATION

Principal Investigator Name	Jakob Troidl
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)	Hanspeter Pfister
Other Advisor Name (if applicable)	

STUDY INFORMATION

Study Title	Visual Neuronal Motif Analysis Case Study
ESTR Number	IRB22-1287
Version Number	2
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" (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 for more information.

2. RESEARCH COLLABORATIONS AND LOCATIONS

LOCATIONS

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

2.1 Where will this study take place?

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

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

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

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

☐ Yes ***(see below)***
☒ No

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

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

☐ Yes ***(see below)***
☒ No

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

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

☐Yes ***(see below)***

☒ No

If "Yes" describe:

COLLABORATIONS/SITES

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

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

☐ Yes

☒ No ***(skip to next section)***

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

☐Yes

☒ No ***(skip to next section)***

2.7 Will these collaborators receive their own IRB review?

☐Yes, all will receive their own IRB review (skip to next section)

☐No, none will receive their own IRB review

☐Some will receive their own IRB review and some will not

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

☐Yes ***(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)***

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

3. STUDY TEAM QUALIFICATIONS AND TRAINING

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

Jakob Troidl is a G2 Ph.D. student with experience conducting a survey as part of this same project. He has conducted several similar studies in previous research projects.

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

There is no staff, I will be directly involved.

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

☐ Yes ***(see below)***
☒ No

If "Yes" describe:

4. RESEARCH PURPOSE

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

The purpose of the research is to allow for the visual analysis of neuronal connectivity motifs in EM microscopy data. We are trying to create the means for neuroscientists to explore recurrent patterns in neuronal connectivity and visualize the results.

We would like to evaluate the utility of the system we have developed with domain experts, recording how they interact with the system and chronicling their analysis, as well as evaluating the system overall.

The evaluation is the final component of the project. This project is a "design study" where we collaborate with neuroscientists to design a system that helps them accomplish their domain-specific goals. We have been working closely with these individuals for the last year developing the system and now will have them use the system to see how it fits their needs.

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

In better understanding, the recurrent neuronal connectivity pattern in the brain we can help neuroscientists better analyze atomic units of computation in the brain, and help them better understand information flows in the brain.

The goal of this case study is to get feedback on our existing system and demonstrate the effectiveness of this system in helping domain experts with their research.

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.

Users will be asked to use the system to analyze a publicly available dataset containing neuronal connectivity of a fruit fly and vocalize findings and their experience using the system. Users will be asked to evaluate the various components of the system using a Likert scale and provide free-response feedback to help improve the system. This session will be held on Zoom. I will give a brief tutorial of the system before allowing the user to interact with the system itself. This will take 90 min.

1. Overview of goals of the study. Participant will be presented the Consent Form and can Opt out of the study if they wish to
2. Short introduction on how to use our visual motif analysis tool. I will introduce each participants to the tools functionality and demonstrate how to use it.
3. Time to ask clarifying questions regarding the functionality of our motif analysis tool.
4. Study part 1: Each participant will be asked to query and analyze a known connectivity motif using our tool. This will study, how well our tool can reproduce state of the art knowledge in the field. We will study known motifs in the Central Complex of the fruit fly brain as described by Hulse et al.
5. Participants will rate the (1) usability, (2) effectiveness, and (3) usefulness of our tool anonymously in a Google Forms sheet using a Likert Scale.
6. Study part 2: Participants will use our tool for exploratory analysis of neuronal connectivity motifs. Participants can search for motifs that they consider interesting and report their findings while thinking out loud.
7. Like in point 5, participants will rate the (1) usability, (2) effectiveness, and (3) usefulness of our tool anonymously in a Google Forms sheet using a Likert Scale.
8. Study end.

There will be no formal interview. I will ask each participant to think out loud while they are using our tool. Point 1 – 8 will be audio and screen recorded.

Hulse, B.K., Haberkern, H., Franconville, R., Turner-Evans, D.B., Takemura, S., Wolff, T., Noorman, M., Dreher, M., Dan, C., Parekh, R. and Hermundstad, A.M., 2021. A connectome of the Drosophila central complex reveals network motifs suitable for flexible navigation and context-dependent action selection. *Biorxiv*, pp.2020-12.

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.

a. 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).

Lickert scale assessment of the features of the system and experience using the system.

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

One 90-minute session.

c. Will you be using any survey software (such as Qualtrics)?
☒ Yes (see question below)
☐ No

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

Google Forms

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.)

The sessions will take place on Zoom.

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

I will interview only one participant at a time. Participants can choose to turn of their camera in Zoom and only share their screen.

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.

1 session per participant. Each session will be 90 min.

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.

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.)

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

☐ Yes ***(see below)***
☐ No

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

5.12 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)***

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

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?

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)***

If "Other" describe:

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

We will be recording the screen of the user as well as their words as they navigate the system.

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

N/A.

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

Videos will remain on saved on my Harvard google drive. The vidoes will be deleted upon publication of the related scientific paper.

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.

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.

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

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.

5.23When 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.

Experts will analyze a publicly available dataset that contains brain connectivity information of half the brain of a fruit fly.

I will record the screens of the users for the purpose of explaining how the tool can be used to analyze the connectivity data. This video will not be distributed, and I will use this video to write up a description of the session as a case study. This written version will be shared with the collaborators who can edit the text to ensure all claims are accurate and the biology is properly described. Only video of the datasets will be recorded. I will not be obtaining the actual datasets.

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

Tissue Imaging Data of Fruit Fly, Neuronal Connectivity Data of Fruit Fly.

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

☒ Yes ***(see below)***

☐ No

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

A Connectome of the Adult Drosophila Central Brain

Researchers: C. Shan Xu1, Michal Januszewski2, Zhiyuan Lu 1,3, Shin-ya Takemura1, Kenneth J. Hayworth1, Gary Huang1, Kazunori Shinomiya1, Jeremy Maitin-Shepard2, David Ackerman1, Stuart Berg1, Tim Blakely2, John Bogovic1, Jody Clements1, Tom Dolafi1, Philip Hubbard1, Dagmar Kainmueller1,4, William Katz1, Takashi Kawase1, Khaled A. Khairy1,5, Laramie Leavitt2, Peter H. Li2, Larry Lindsey2, Nicole Neubarth6, Donald J. Olbris1, Hideo Otsuna1, Eric T. Troutman1, Lowell Umayam1, Ting Zhao1, Masayoshi Ito1,7, Jens Goldammer1,8, Tanya Wolff1, Robert Svirskas1, Philipp Schlegel9, Erika R. Neace1, Christopher J. Knecht, Jr.1, Chelsea X. Alvarado1, Dennis A. Bailey1, Samantha Ballinger1, Jolanta A Borycz3, Brandon S. Canino1, Natasha Cheatham1, Michael Cook1, Marisa Dreher1, Octave Duclos1, Bryon Eubanks1, Kelli Fairbanks1, Samantha Finley1, Nora Forknall1, Audrey Francis1, Gary Patrick Hopkins1, Emily M. Joyce1, SungJin Kim1, Nicole A. Kirk1, Julie Kovalyak1, Shirley A. Lauchie1, Alanna Lohff1, Charli Maldonado1, Emily A. Manley1, Sari McLin3, Caroline Mooney1, Miatta Ndama1, Omotara Ogundeyi1, Nneoma Okeoma1, Christopher Ordish1, Nicholas Padilla1, Christopher Patrick1, Tyler Paterson1, Elliott E. Phillips1, Emily M. Phillips1, Neha Rampally1, Caitlin Ribeiro1, Madelaine K Robertson3, Jon Thomson Rymer1, Sean M. Ryan1, Megan Sammons1,

Anne K. Scott1, Ashley L. Scott1, Aya Shinomiya1, Claire Smith1, Kelsey Smith1, Natalie L. Smith1, Margaret A. Sobeski1, Alia Suleiman1, Jackie Swift1, Satoko Takemura1, Iris Talebi1, Dorota Tarnogorska3, Emily Tenshaw1, Temour Tokhi1, John J. Walsh1, Tansy Yang1, Jane Anne Horne1,3, Feng Li1, Ruchi Parekh1, Patricia K. Rivlin1, Vivek Jayaraman1, Kei Ito1,7,8, Stephan Saalfeld1, Reed George1, Ian Meinertzhagen1,3, Gerald M. Rubin1, Harald F. Hess1, Louis K. Scheffer1,*, Viren Jain2, and Stephen M. Plaza1

Institutions: Janelia Research Campus, HHMI, Google Research, Life Sciences Center, Dalhousie University, Max Delbrueck Center for Molecular Medicine, Department of Developmental Neurobiology, St. Jude Childrens Research Hospital, Two Six Labs 7University of Tokyo, Institute for Quantitative Biosciences, Institute of Zoology, Biocenter Cologne, University of Cologne, Department of Zoology, University of Cambridge

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

☒ Yes ***(see question below)***

☐ No

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

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

https://neuprint.janelia.org/

5.29 Is the data publicly available on the internet (i.e., freely available without permission, do not have to be a registered user of the site, sign-in, or other restrictions)?

☒ Yes

☐ No

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?

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

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

5.31 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)***

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

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

5.36 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).

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):

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)

5.41Has 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.

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):

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.

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.

We do not anticipate any risks associated with this study beyond the financial risk involved in users deciding to participate in this survey instead of spending that time on their own work. There's also the risk of loss of confidentiality of study materials are published. To mitigate that risk, we will use codes to identify participants identities.

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

Study participant identities will be coded.

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

☐ Yes

☒ No

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

N/A

6.5 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.

N/A

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

There are no expected direct benefits to individuals who take part.

6.7 Describe any potential benefits to society.

New methods for the analysis of neuronal connectivity motifs may help experts better understand the brain and treat psychological diseases.

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.*

6

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.

These study participants are known collaborators who have participated in such studies in the past.

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

- ☐ Children
- ☐ Wards of the State
- ☐ Prisoners/Detainees
- ☐ Pregnant Women
- ☐ Adults not Competent to Consent
- ☐ Non-English Speaking
- ☒ Employees of Harvard University (as a focus of the study)
- ☐ Undergraduate Students of Harvard University (as a focus of the study)
- ☐ Staff or students that are part of your lab or for whom you provide oversight
- ☒ Other – ***(see below):***

If "Other" please specify:

Researchers from other academic institutions.

CHILDREN

Skip this section if not applicable.

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

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

PRISONERS

Skip this section if not applicable.

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

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

EMPLOYEES OR STUDENTS OF HARVARD UNIVERSITY

Skip this section if not applicable.

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

The participants are frequent collaborators who have been aware of these case studies for some time, though in my correspondence I will make it as clear as possible that their active consent is needed to participate and participantion is completely voluntarily. I will not be recruiting from a more general public.

8. RECRUITMENT

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

☒ Yes ***(see below)***

☐ No ***(skip to next section)***

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

The participants are aware of these case studies for some time. I will provide them with a brief description of the study and remind them that they do not have to take part.

Please be aware that the Telephone Consumer Protection Act 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

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.

recruitment-letter.docx

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.

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

☐ Yes

☐ No ***(see below)***

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

10. INFORMED CONSENT PROCESS

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

ADULT PARTICIPANTS

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

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

☒ Yes, I will be obtaining informed consent or an agreement to participate.

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

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

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

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:

As this study will involve a "benign behavioral intervention" and determined to be exempt, a signature is not required.

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 an agreement to participate process take place?

☐ In-person

☒ Online

Over the telephone

☐ Other ***(see below)***

If other, please describe:

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?***

Principal Investigator

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

The form will be shared directly with collaborators as soon as they agree to participate via email and again right before the before session. Participants can give written consent via email, if they read the consent form before the study session begins. They can also give verbal consent right before the study session starts.

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.

I will ask participants if they have any questions about the study and what it means to participate.

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)***

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

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

10.9 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:

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)***

If other, please describe:

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:

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?***

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

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.

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:***

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:

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:

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:

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?***

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

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.

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?

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.

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.

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

11. PARTICIPANT COMPENSATION AND FINANCIAL OBLIGATION

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

☐ Yes
☒ No ***(skip to #11.6)***

11.2 What type of compensation will you provide to participants?

☐ Cash

☐ Check
☐ Gift Card/Gift Certificate
☐ Course Credit
☐ Lottery/Raffle ***(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?

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

11.5 Will you provide partial compensation for participants who do not complete all the study procedures?
☐ Yes **(see below)**
☐ No

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

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

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

☐ Yes ***(see below)***
☒ No

If "Yes" please explain.

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

☐ Yes ***(see below)***
☒ No

If "Yes" please explain.

12. DATA COLLECTION

INITIAL COLLECTION

12.1Describe 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)

12.2In what format will the research data be collected?

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

If "Other" please specify:.

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

☐ Yes
☒ No

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

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

12.4Will data collected from individuals located in the EEA 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
☒ None

12.5Will the study require the use of Mobile Apps?

☐ Yes
☒ No

List the names of each Mobile App:

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

☒ Yes
☐ No

List the names of each web-based tool:

Google Form

12.7Select any personal device that will collect study data:

☒ Laptop
☐ Tablet & Smartphone
☐ None

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

☐ Yes
☒ No

List the names of the wearable technology:

12.9Will 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:.

12.11 In what format will the research data be stored?

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

If "Other" please specify:.

12.12 How will the consent forms be collected and stored?

☐ Paper
☒ Electronic

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.).

Saved on Harvard google drive

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).

☐ Retained for study record keeping purposes per institutional policy.
☐ Retained by the investigator for future research use.
☐ Retained for future research use (create repository/bank).
☐ Restricted use data will be destroyed or will be returned to the source.
☐ No direct or indirect identifiers* are being collected. This anonymous data will be retained at the discretion of the investigator.
☐ This research is a clinical trial conducted under FDA regulations. Direct identifiers* and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.
☐ Other – ***(see below)***

If "Other" please specify:.

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

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

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)***

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.

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:.

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.):

Results will be shared as part of a publication. Two of the study participants where involved closely in the design of the system and therefore both of them will be listed as co-authors. Both of those participants are affiliated with the Harvard Center for Brain Sciences. Those two participants were only involved in the design of the system and not in the design of the user study.

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:

N/A

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

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

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

N/A