Perceptions of and Reactions to Sustainability Menu Label Designs

NCT07214792

Study Protocol

Version Date: 10/06/2025

BSPH IRB Research Plan for New Data Collection

IRB Version: 01Sep2023

For new data collection, new data collection plus secondary data analysis, biospecimen repositories, and data coordinating center protocols.

DO NOT DELETE ANY QUESTIONS FROM THIS TEMPLATE

PI Name: Dr. Julia Wolfson

Study Title: Understanding perceptions of and reactions to different food label designs among US adults

IRB No.: IRB00034378

PI Version No. / Date: V3 / October 6, 2025

I. Aims of the Study: *Describe the aims/objectives of the research and/or the project's research questions or hypotheses.*

The aims of this study are to assess reactions to and understanding of various menu label messages and designs related to sustainability and ultra-processed foods; understand food label usage; and understand knowledge and perceptions of sustainability and ultra-processed foods.

Additional measures will include food security, dietary intake, self-reported health status, and general demographic characteristics to examine the differences in reactions, knowledge and perceptions across subgroups.

II. Background and Rationale: *Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.*

Labels on food packages and restaurant menus are important public health tools to guide consumer choices. Ultra-processed foods and food additives are growing areas of public health concern, as ultra-processed food consumption is high in the United States and is increasingly linked to adverse health outcomes. This survey will explore "ultra-processed" and "food additive" labels by evaluating how US adults react to, understand, and interpret various label designs with these messages. Given the growing public interest in and concern surrounding ultra-processed foods, more information is needed to better understand adult consumers' knowledge and perceptions of these foods. There is also an increasing interest in the link between food and the environment, so this survey will examine reactions to and understanding of labels relating to sustainability and environmental harm. We had previously tested "climate-impact" menu labels, but due to changing priorities of the federal government we are no longer allowed to continue researching those labels. Thus, we are testing alternative label messages and designs to continue this research. This survey study is one step in deciding what direction we will go with our research moving forward.

Our study population is comprised of a large national sample of US adults to allow us to have sufficient sample sizes to measure effects among many different population subgroups.

III. Study Design:

A. *Provide a BRIEF overview of your study design and methods. The study design must relate to your stated aims/objectives. DETAILS WILL BE REQUESTED LATER. If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (BSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).*

This study is a single time point, cross-sectional study in which we will field an anonymous online survey of 12,400 US adults using the online panel provider CloudResearch. We will program the survey in Qualtrics. We will have no interaction with the study participants will not collect any personally identifiable information. We will only have the anonymous ID number associated with each participant. The survey will be ~15 minutes long. Surveys will be formatted to be accessible on mobile phones as well as computers.

B. Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample, distinguish the screening sample size from the enrolled sample size; a table may be helpful. For electronic survey studies involving online recruitment and survey completion: consider how you will set controls on how many people will join your study.

Our sample size of 12,400 US adults is large enough that we will be able to make several subgroup comparisons in our analyses. We are using Managed Research which will ensure we do not collect more responses than intended.

*C. Does your study meet the NIH definition of "clinical trial": "***"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 those interventions on health-related biomedical or behavioral outcomes"? *If yes, the study must be listed on clinicaltrials.gov, study personnel must complete GCP training, and federally funded studies must post consent forms on approved sites, like clinicaltrials.gov.*

Within the survey we will randomize participants to view different label designs and ask them questions about their reactions to and understanding of the labels. We will register this clinical trial on clinicaltrials.gov before fielding.

IV. Participants:

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care or who are wards of the State. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

A. Inclusion Criteria:

- 18 years of age and older
- Residing in the United States
- Member of the CloudResearch panel

B. Exclusion Criteria:

- Under 18 years of age
- Not residing in the United States
- Completed the survey implausibly quickly based on the distribution of the time to complete the survey among all participants (<1/3 of the median time to complete)
- Failed the built-in Qualtrics survey fraud detection measures
- Failed one attention check question

***NOTE**: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.*

V. Study Procedures:

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of BSPH clear. If you will collaborate with other institutions or organizations, or plan to subcontract BSPH responsibilities to others, make clear their responsibilities in the Study Oversight section of this document. Be aware that all recipients of federal funding for non-exempt human subjects research must have a Federal Wide Assurance (FWA), which is a promise to comply with human subjects research regulations.

*If the BSPH will serve as a **data coordinating center**, indicate in the sections below which procedures BSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section.*

If your study will develop in phases, address each item below by phase.

A. **Recruitment Process:**

1. *Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and their qualifications*.

   We will recruit participants via CloudResearch, an online survey research firm frequently used for academic survey research. We have used CloudResearch previously to reach national samples of adult participants. Participants are recruited by CloudResearch staff using a variety of market research platforms. Each platform has its own participant pool, referred to as an opt-in panel. Participants on these panels are profiled on hundreds of variables which are used for stratification and qualification purposes. Invitations are then sent via email and dashboards to qualified participants, where the study will appear available to them to take. They will be able to see the study description, length, and compensation before deciding whether to proceed. Participants will be compensated at a rate determined by CloudResearch.

2. *Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks*.

   This study poses minimal risk to participants. It is anonymous and researchers will have no contact with the participant or their personally identifiable information. No identifiable information is collected. Participants all have a unique, anonymous ID they get assigned when signing up for the platform. IP addresses will not be collected. Questions asked in the survey may make some participants feel uncomfortable, but this risk is minimal.

B. **Consent Process**:

1. *Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening*.

   a. *Who will obtain informed consent, and their qualifications*:

      We will seek consent through a written prompt at the start of the CloudResearch survey. We provide a brief description and offer participants the opportunity to consent or not by responding to a question. For those who do not consent, the survey will end at that point.

   b. *How, where, and when the consent discussion(s) will occur*:

      Consent will be on the online Qualtrics survey, before seeing or responding to any survey questions.

   c. *The process for determining whether a potential participant meets eligibility criteria. If you will collect personally identifiable information for screening purposes, collect only data needed for this purpose and explain what will happen to the data for individuals who are not eligible*:

      Cloud Research will screen participants for eligibility criteria listed above, but we will also ask participants to confirm these items of eligibility. If they do not meet eligibility criteria, they will immediately be taken to the end of the survey. If they are eligible, they will move forward with the remaining survey questions. However, no personally identifiable information will be collected.

d. Whether you will obtain a signature from the participant or will use an oral consent process:

No

C. **Study Implementation**:

1. *Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate*.

   Participants will complete an approximately 15-minute anonymous online survey. The survey will begin with a written consent statement to which participants can select a multiple-choice option to agree and proceed with the survey. Alternatively, participants can opt to decline to provide consent and end the survey. Participants who consent will be asked several questions about their reactions to different food labels and knowledge and perceptions of ultra-processed foods. They will also answer questions about their demographic information, as well as food security, federal benefits participation, and dietary intake.

2. *Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place*.

   Participants will take the survey online, on a computer or cell phone, at a place of their choosing. They will only take the survey once. The survey is expected to last ~15 minutes. Once the survey is complete, their participation in the study will be complete. There is no direct contact between the study team and the participant; all contact will be via CloudResearch.

3. *Describe the expected duration of the study from the perspective of the individual participant and duration overall*.

   The survey is expected to last approximately 15 minutes.

4. *Provide a brief data analysis plan and a description of variables to be derived.*

   We will investigate reactions to, understanding of, and the Perceived Message Effectiveness (PME) of various food label messages and designs via a randomized experiment within the survey. The labels will include messaging related to processing level, food additives, sustainability, and environmental harm, with a variety of schemes and messaging styles. Participants will be randomized to see certain labels, and experimental condition will be the key independent variable. We will examine people's perceptions of labeled foods by asking questions to measure their understanding of the label messages and their perceptions about the label effectiveness (perceived message effectiveness (PME)) and purchase intentions for menu items with that label. For sustainability and environmental harm labels, we will ask respondents about their perceived environmental impact of the labeled food.

VI. Data Custody, Management, Security, and Confidentiality Protections:

Data security and management plans must meet institutional standards. If you need assistance, contact [bsph_cybersecurity@jhu.edu]

Investigators are responsible for ensuring the security of data from the time of collection, through any transfers from one system to another, analysis, sharing, storage, and ultimate archiving and disposal. The questions below seek to elicit your plans for these protections. Feel free to add information.

1. Data Sources: Identify the source(s) of data.

- [☒] Participant/Parent-Guardian/Legally Authorized Representative
- [☐] JHM Medical Records (from Epic)

Note for JHM Data Users Only: *Please complete the* ***Data Trust Risk Tiers Calculator*** *available on the Applications and Forms page on the BSPH IRB website:* [*https://tinyurl.com/2p96md3s*] *and upload a copy of the documents to the "Miscellaneous- Other" section of your PHIRST application.*

In addition, review the ***Data Protection Attestation for Research and/or Healthcare Operations*** *at:* [*https://tinyurl.com/yszfkuur*] *and certify your attestation of compliance to those requirements.*

☐ **I certify my attestation of compliance to JHM Data Protection Requirements**

☐ Non-JHM Medical Records
☐ Outside Data Provider (CMS, National Death Index, Insurance Co., etc.)
☐ Other Existing Records (*please specify*): [ ]

2. Data Content: Will you collect, use, and/or record personal identifiers about study participants for any purpose? Please look at the list of identifiers in Question 3 to help answer this question. **Note: Limited Data Sets (including dates, ages, and zip codes) are considered to be "identifiable".**

☐ Yes: Continue with Question 3
☒ No: Skip to Question 6

3. Data Identification: Identify the Personally Identifiable Information (PII)/Protected Health Information (PHI) you will access/collect by checking the box(es) below for "Recruitment" and "Study Data" needs.

Recruitment	Study Data	PII/PHI to be Accessed/Collected
☐	☐	Name, signature, initials or other identifiable code
☐	☐	Geographic identifier (address, GPS location, etc.)
☐	☐	Dates (birth, death, clinical service, discharge, etc.)
☐	☐	Contact information (phone number, email address, etc.)
☐	☐	Identification numbers (SSN, driver's license, passport, etc.)
☐	☐	Health records identifiers (medical record #, insurance plan, etc.)
☐	☐	Text of clinical record notes
☐	☐	Device identifiers (implants, etc.)
☐	☐	Internet identifiers (IP address, social media accounts, etc.)
☐	☐	Biometric identifiers (fingerprints, retinal scan, voice print, etc.)
☐	☐	Audio Recordings
☐	☐	Video or full-face photographic images
☐	☐	Genomic / Genetic data
☐	☐	Other identifiers (*list here*): [ ]

4. Identifiers: If you have checked any of the boxes above, how will you protect personal identifiers?

☐ Will delete all identifiers (explain **when** you will delete identifiers): [ ]

☐ Will separate identifiers from analytic data and will store the link/code. Please explain where you will store the link/code: [ ]

☐ Will use a method to make it harder to connect the data with the study participant (jiggering date, use other methods to obfuscate, etc.). *Please explain:* [ ]

5. Data Transit Plans and Protections: Identifiable data may transfer, sometimes with multiple steps, from mechanisms for collection to storage. For example, participants may complete a web-based survey, which is then downloaded to a storage platform. Briefly identify these steps and the protections for each step (including encryption used at each step).

☐ Will delete all identifiers prior to transfer.

☐ Will separate identifiers from analytic data and will store the link/code prior to transfer. *Please explain where you will store link/code:* [ ]

☐ Other (*please specify*): [ ]

6. Device(s) used for <u>data collection</u>: Identify the computing device(s) being used for identifiable data receipt/collection. Check all that apply.

We understand that resources in low resource countries may require use of systems that are not pre-approved. The following are examples of platforms/storage solutions that are **<u>not pre-approved to store identifiable information</u>** and require a risk assessment from BSPH Data Security. Do not hesitate to contact [*bsph_cybersecurity@jhu.edu*] for an assessment.

- JHU Independent Departmental Servers
- Local Computer owned by JH
- Other computers or devices owned/managed by study team members and used for other than secure web access
- USB/Portable data storage device
- Other solutions not managed by IT@JH, e.g., commercial cloud storage (Box, Dropbox, iCloud, personal OneDrive, Google Drive, Amazon storage, etc.)

☒ Provided or managed by BSPH IT

☐ Study-provided, and not managed by BSPH IT. These must include the following protective controls:

- Data encrypted while "at rest" (on a storage device)
- Security patches and updates are routinely or automatically applied
- Devices have access controls so that:
  - Each person accessing the device is uniquely identified (username)
  - Passwords are sufficiently strong to prevent compromise
  - All access is logged and recorded
  - Unauthorized access is prevented
- Approved access list is reviewed periodically for correctness

☐ Other (*please specify*): [ ]

7. Data Collection: Describe the format of data received/collected. Check all that apply.

☐ Paper/Hard Copy (must be secured in transit and placed in a secure cabinet/room)

☐ Audio recording

☐ Video recording

☐ Received directly by research team member and entered into file/database

☐ Mobile or Web App (custom developed). *Review* [*guidance*] *and provide attestation of compliance*

☐ Mobile or Web App (purchased). *Specify product and version*: [ ]

☒ Online survey. *Specify mechanism/platform*: Qualtrics

☐ 3rd party collector (*please specify*): [ ]

☐ Existing data shared with BSPH by data provider via electronic access/transfer

☐ Duplicate and backup copies will be secured with same rigor as original data

☐ Other (*please specify*): [ ]

8. Devices/Platforms used for Analysis, Storage, Processing: Identify where the identifiable or de-identified data will be analyzed/stored. Check all that apply.

☒ Pre-approved storage and analysis platforms managed by JH/BSPH for which security and risk mitigation measures are known.

Identify pre-approved storage platform(s) being used:

JHM Preferred:

☐ JH SAFE Desktop ☐ JH PMAP

Other Approved Platforms:

☒ JH One Drive/BSPH OneDrive ☐ JH IT-Managed Network Storage ☒ JHM/BSPH Qualtrics

☐ BSPH HPCC ☐ BSPH SharePoint ☐ BSPH Shares ☐ JHU REDCap

☐ MARCC-Secure Environment

☐ Platform(s) not managed by JH/BSPH, not pre-approved, and require a risk assessment review from BSPH Data Security.

- Describe the not pre-approved platform(s) you plan to use: [ ]
- Describe the technologies you intend to use (software, hardware, connectivity) with a focus on the measures taken to secure collected data along the continuum of data collection, storage, transmittal and access: [ ]

9. Access to Data and Access Controls: How will you ensure that only authorized individuals can access the data? What access controls will you put into place to ensure that only authorized individuals may access and use the data. (For example, OneDrive [*guidance*] illustrates how to share files with "people you specify". [*BSPH Shares*] addresses providing permissions to individual people.) Check all that apply. Note: If you need assistance implementing secure access controls, contact [*bsph_cybersecurity@jhu.edu*]

☒ Will provide access to data in accordance with OneDrive/BSPH-Shares guidance posted on JHU IT websites

☐ Will use secure access controls to limit access to individual-level data

☐ Will use secure access controls to provide other researchers controlled access only to aggregated study data

10. Data Sharing: Clarify if data are to be shared externally with third parties, including sponsors and other investigators, and whether only aggregated data will be shared, or if you will share individual-level data. Describe sharing and protection plans for that sharing, including the proposed use of data agreements.

Consider the following:

- *Information about your data sharing in the consent forms*
- *Information about data sharing laws in the country where data will be collected, and if they limit sharing, how you will comply with those limitations?*
- *Whether data will be shared in aggregate only, or individual level data*
- *Whether you plan to make the data publicly available, and in what form.*

☐ Will not share data with outside investigators

☐ Will make publicly available

☐ Will share with restrictions/controls

☐ Will share aggregated data only

☒ Will share individual-level data without identifiers

☐ Will deposit data into an existing data repository for future research. *Please explain*: [ ]

☐ Future research use and data sharing will have limited purposes. *Please explain*: [ ]

☐ Other sharing information: [ ]

11. Duration and Destruction: Explain how long data will be retained and the plan for eventual return, deidentification or destruction of data, including moving data to an archive.

Data will be retained for 5 years per JHU guidelines. No identifiable information will be collected or stored at any point for this project.

A. Certificate of Confidentiality:

All NIH studies include Certificate of Confidentiality (C of C) protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. [*https://grants.nih.gov/policy/humansubjects/coc.htm*]

Does the study have Certificate of Confidentiality protections? Yes ☒ No ☐

VII. Risks of the Study:

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. Include risks beyond individuals to include the study population as a group and community risks. Ensure that the risks described in the consent documents are consistent with the risks outlined in the research plan.

Breach of confidentiality is a potential risk, but it is very low, given data security procedures at CloudResearch and the fact that we will not collect or have access to any personally identifiable information. The survey is anonymous and will collect no personally identifiable information at any stage. All contact with the participant will be from CloudResearch, not the research team. Participants may feel discomfort when answering questions about their food security and SNAP participation. To minimize this risk, we allow participants to refuse to answer or say "I don't know" to any questions they do not wish to answer.

B. Describe steps you will take to mitigate or minimize each of the risks described above. Include a description of your efforts to arrange for care or referral for participants who may need it.

We are not collecting any identifying information, including IP address information. We will have no way of identifying the participant or their location.

To minimize risk of discomfort with potentially sensitive questions, like those about food security status or SNAP participation, we allow participants to refuse or answer "I don't know" any questions they do not wish to answer.

C. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an

"anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

This risk of confidentiality breach could only occur at the point of participant engagement with CloudResearch, as no identifying information will be collected or received by JHU.

D. *Describe the research burden for participants, including time, inconvenience, invasion of privacy in the home, out of pocket costs, etc*.

This survey will be of minimal burden to participants, as we expect the total time spent reading the invitation email and taking the survey to be approximately ~15 minutes. Participants will be able to complete the survey at a time and place of their choosing.

E. *Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.*

N/A. We will not collect any personally identifiable information about the participant at any stage of the project.

VIII. Direct Personal and Social Benefits:

A. *Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).*

Participation in this survey does not provide any direct benefits to participants. However, participants may become more aware of food attitudes or behaviors that may shift their thinking about their food choices and may learn more about ultra-processed foods and what they are from certain questions in the survey which may improve food choices in the future.

B. *Describe potential societal benefits likely to derive from the research, including value of knowledge learned.*

The results from this survey will contribute to understanding adults' perceptions of and reactions to different food label designs, which will in turn inform the design of effective labels – an area of growing industry and policy interest that could contribute to reducing consumption of foods that are ultra-processed or impose greater environmental harm.

IX. Payment or Token of Appreciation:

A. *Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If no payment is provided, the BSPH IRB strongly encourages providing such tokens. If yes, please describe below.*

N/A

B. *If you plan to provide a monetary payment, describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain*.

All participants will be paid for their completion of the survey. Payment will be determined by CloudResearch staff and the panels they work with and will be provided directly by CloudResearch. JHU will not provide compensation to participants directly. CloudResearch determines the amount of compensation based on the survey length.

No identifiable information is collected. Participants all have a unique, anonymous ID they get assigned when signing up for the platform. Payment is sent to their account by CloudResearch (linked to their anonymous ID) upon study completion.

C. Include the possible total remuneration and any consequences for not completing all phases of the research.

Participants who do not complete the survey will not be compensated. Participants will be allowed to refuse to answer any questions they do not feel comfortable answering without that adversely affecting their compensation. Participants will be compensated even if they skip some questions. However, participants who don't answer at least 75% of the questions or who speed through the survey will be rejected and will not receive compensation.

X. Study Management:

A. Oversight Plan:

1. *Describe how the study will be implemented. List all parties, including collaborators and subcontractors, who will be "engaged" in the human subjects research project and their roles .*

   Dr. Julia Wolfson, Associate Professor in International Health, SPH, is the PI of the study, and Erin Choi, 2nd year MSPH student in IH who is filling in as study coordinator for Nina Carr, MPH, MBA, Senior Research Program Coordinator. Nina will be added to the IRB when she returns from maternity leave and at that point will be the study coordinator. Their roles will be to lead implementation including study design, data collection, and analysis without actively being involved with participants. We will provide a link to the survey, programmed in Qualtrics, to CloudResearch and respondents will be able to access the survey without any contact or interaction with the study team.

   Anna Claire Tucker and Abigail Barquera, who are both PhD students in International Health and Dr. Wolfson's advisees, will assist with survey development and design and data analysis under the direction of Dr. Wolfson.

2. *What are the qualifications of study personnel implementing the project*?

   Dr. Julia Wolfson, PhD MPP, is an Associate Professor in the Department of International Health at the Johns Hopkins Bloomberg School of Public Health. Dr. Wolfson has 10+ years of experience conducting online survey research. The research team has extensive expertise in online experiments testing various food labels.

   Erin Choi is a 2nd year MSPH student who has worked with Dr. Wolfson over the last year on related research projects and is filling in as Program Coordinator. Erin will remain on the study team when Nina returns as a student Research Assistant.

   Nina Carr is a Senior Research Program Coordinator II in the Human Nutrition Program within the Department of International Health. As a direct report of Dr. Wolfson, she assists with the coordination of studies aimed at food systems change. Ms. Carr holds master's degrees in public health and business administration and has 9 years of professional experience managing projects focused on health promotion.

   Anna Claire Tucker, MPH is a fourth-year PhD student in International Health. Abigail Barquera, MD is a second-year PhD student in International Health with experience in label design. Both students have experience in survey development and have taken biostatistics to prepare them for data analysis using the data from this survey.

B. **Protocol Compliance and <u>Recordkeeping</u>:**

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation (for assistance, contact: [*housecalls@jhu.edu*]).

<u>Please provide information about study oversight to ensure compliance with IRB approval and regulatory and institutional requirements.</u> If the study team does not follow study procedure, what is your plan for reporting protocol non-compliance?

The study team will have a shared OneDrive folder in which all study documents and protocols will be saved. The study team will have weekly meetings, and every person brought on to the study team will have an orientation meeting with Dr. Wolfson. Dr. Wolfson will be responsible for all correspondence with the IRB and all other study documentation.

C. **<u>Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (*all studies must complete this section*)</u>**:

*NOTE: The IRB does not require PROMPT reporting of all AEs, only those that are **<u>unanticipated, pose risk of harm to participants or others, and are related to the study</u>**. **Anticipated** AEs may be reported with the Continuing Review/Progress Report.*

Describe your plan for reporting to the BSPH IRB, local IRBs, and (if applicable) to the sponsor. Include your plan for government-mandated reporting of child abuse or illegal activity.

While we do not expect any adverse events, should any occur we will report them immediately to the IRB.

F. **"Engaged" in Human Subjects Research:**

For studies that involve collaboration with non-BSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the BSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

Insert collaborator names and FWA numbers, if available. Note who will be "engaged" in human subjects research by filling in the following table:

	BSPH	[ ]	[ ]
For federally funded studies, collaborators' FWA	00000287	[ ]	[ ]
Primary Grant/Contract Recipient	[ ]	[ ]	[ ]
Grant/Contract Subrecipient	[ ]	[ ]	[ ]
Hiring Data Collectors	[ ]	[ ]	[ ]
Training Data Collectors	[ ]	[ ]	[ ]
Obtaining Informed Consent and/or Identifiable Data	[ ]	[ ]	[ ]
Accessing/Analyzing Identifiable Data	[ ]	[ ]	[ ]