Climate impact label design and fast-food meal selection

NCT06678178

Study Protocol

Version Date: 10/18/2024

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: **Testing climate impact menu labels influence on nutrition quality of fast food selections: a pilot study**

IRB No.: **IRB00030419**

PI Version No. / Date: **V1/October 18, 2024**

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

Our primary objective of this study is to compare the effects of different climate-label menu designs on the healthfulness of hypothetical fast-food meal orders. We hypothesize that: (1) compared to orders from menus with control labels, participants ordering from menus with all other climate-impact labels will select more healthiful meal, and (2) the effect of healthifulness of meal orders will differ by climate-impact label condition, with high-impact warning labels performing best, followed by the traffic light labeling scheme, then by the grade labeling scheme, and finally the numeric labels.

As a secondary outcome, we will also seek to compare perceived message effectiveness (PME) of different climate-label menu designs to communicate the environmental impact associated with fast-food menu items. We hypothesize that: (1) participants will perceive climate-impact labels as more effective compared to control labels, and (2) PME will differ by climate-impact label condition, with high-impact warning labels performing best, followed by the traffic light labeling scheme, then by the grade labeling scheme, and finally the numeric labels.

Additional secondary outcomes will include examining total greenhouse gas emissions per meal order, total calories per meal order, and selection of a sugar-sweetened beverage within order.

This is a pilot study to help us determine the label types we will include in our next study using the NORC AmeriSpeak panel (IRB00027451). A separate application exists and will be amended for the next study for IRB approval, prior to its initiation.

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.*

Climate change and diet-related non-communicable diseases (including many cancers, obesity, diabetes, and heart disease) are among the most pressing global public health issues. The modern food system is responsible for more than 30% of global anthropogenic Greenhouse Gas Emissions (GHGE), including 14.5% of global GHGE from food animal production alone. In the United States (U.S), meat consumption, and red meat consumption in particular, is consistently far above recommended levels based on national Dietary Guidelines. On a typical day, more than one-third of Americans eat out in fast-food restaurants which are a common source of red meat in American's diets and are associated with numerous adverse health outcomes. Therefore, fast-food restaurants will be a key environment for any efforts to shift Americans towards a 'win-win' 'planetary-health' diet that benefits both climate change and individual health. Similar to calorie menu labels, which have been a key public health tool to facilitate healthier choices in restaurant settings, menu labels that either provide a negative signal that an item is environmentally unsustainable (i.e. high GHGE), or menu labels that provide a positive signal that an item is an environmentally sustainable choice (i.e., low GHGE) are a potential tool to shift consumer food choices towards a 'planetary-health' diet. Evidence suggests that products labeled as environmentally sustainable receive a 'health halo' even in unrelated domains, like improved perceptions of health and tastiness. Whether sustainability-focused menu labels (either negative or positive) are effective at encouraging sustainable food choices in fast-food restaurants, and whether such labels also encourage healthier food choices, has never been tested. Therefore, in this study we will test whether sustainability labels on a fast-food restaurant menu nudge consumers towards healthier food choices by comparing four labeling schemes on main menu items:

(1) Red negative nudge labels [WARNING: HIGH CLIMATE IMPACT] displayed on high-GHGE items
(2) A traffic light nudge labeling scheme [HIGH CLIMATE IMPACT; MED. CLIMATE IMPACT; LOW CLIMATE IMPACT] displayed on high-, medium-, and low-GHGE items in red, yellow and green, respectively
(3) A grade labeling scheme [A; B; C; D; F] on all items by level of impact, with A indicating the lowest level of impact and F indicating the highest level of impact
(4) A numeric labeling scheme that demonstrates the estimated climate-impact associated with the life cycle of each menu item in kilograms of carbon dioxide equivalent (kg CO_2e).

We will also compare effects of these labels against a control condition with a Quick Response (QR) code label on all menu items.

III. <u>Study Design</u>:

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 <u>Secondary Data Analysis of Existing Data/Specimens</u>).

We will conduct a randomized controlled experiment in which participants are randomly assigned to view one of five versions of a fast-food menu based on a well-known burger-focused fast-food chain, and instructed to select an entrée they would hypothetically like to order for lunch. Each menu version will differ by labeling condition assigned to main menu items to demonstrate the climate impact associated with each item. Climate-impact label menu designs in the study will include a QR code label (control), a high-impact warning label, traffic-light labeling of high, medium, and low impact, grade labeling (five-tiers; grades A-F) and a numeric label describing the estimated amount of kg CO_2e associated with each menu item. Following the meal ordering task, we will also ask questions about the perceived message effectiveness of the label for which each participant was randomized, their perception of the relative effectiveness of all labels in this experiment, and their personal values, dietary patterns, and other demographic information.

This trial will first be conducted as a pilot study via CloudResearch, an online panel provider, before fielding a larger study with NORC AmeriSpeak, another online panel provider. A separate application (IRB00027451) exists and will be amended for the next study for IRB approval, prior to its initiation.

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.*

The CloudResearch initial sample will be 6,250 people, evenly divided with approximately 1,250 people in the control arm and each of the four experimental arms, respectively. This sample size will give us >80% power to detect a small effect size (d=0.12) with a conservative Bonferroni adjusted alpha of 0.0125, which was determined based on our prior research would be sufficient to see differences between all label arms. The CloudResearch sample will be broadly representative of the U.S general population, but carry the possibility of a 25% skew tolerance across demographic lines. We will recruit individuals until the target sample size has been reached by working with the managed research partner with CloudResearch.

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.*

Yes.

IV. Participants:

Describe the study participants and the population from which they will be drawn. Specify the inclusion and uusion 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 or 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
- Failed the built-in Qualtrics survey fraud detection measures

***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*.

   The survey job will be posted on CloudResearch and participants will be able to click on it and complete the survey. CloudResearch panel members have an internal ID and can only take each survey once. Individuals not in CloudResearch panels will not be able to take the survey.

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*.

   There are no privacy concerns associated with this study. We will have no interaction with participants. All surveys are anonymous, and we will not collect any identifying information.

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 will end at that point.

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

      N/A

   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*:

      CloudResearch engages tens of millions of participants worldwide. We will provide our study inclusion criteria, which is solely demographic, to CloudResearch, and they will recruit from their pool of participants based on these requirements.

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

      No

e. *Whether you will obtain a legally authorized representative's signature for adults lacking capacity*:

No

f. *If children are included in the study, if and how you will obtain assent from them*:

N/A

g. *If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision). If any of the children are "wards of the state", additional regulatory requirements will apply:*

N/A

h. *If you are seeking a waiver of informed consent or assent, the justification for this request*:

N/A

i. *Whether you will include a witness to the consent process and why*:

N/A

j. *If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials*:

N/A

2. Identify the countries where the research will take place and the languages that will be used for the consent process.

Country	**Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)**	**Languages**
United States	Written adult consent will be included electronically at the beginning of the survey	English

C. **<u>Study Implementation</u>**:

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

Participants will complete an approximately 3-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 automatically randomized into one of five trial arms and presented with a survey, which mimicks a fast-food menu based on a well-known burger-focused fast-food chain, and instructed to select an entrée they would hypothetically like to order for lunch. Participants in each trial arm will be exposed to a menu version that differs by labeling condition assigned to main menu items (e.g., burgers, wraps, salads, etc.) that describes the climate impact associated with each item. Climate-impact label menu designs in the study will include a QR code label (control), a high-impact warning label, traffic-light labeling of high, medium, and low impact, grade labeling (five-tiers; grades A-F) and a numeric label describing the estimated amount of kg CO_2e associated with each menu item. Following the meal ordering task, participants will be presented with several questions about the label for which each participant was randomized to view, followed by a question about relative effectiveness of all labels in the experiement. Finally, participants will answer several demographic questions, after which the survey will conclude. CloudResearch will provide information about participants' age, sex, and race and ethnicity, so these questions will not need to be asked.

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 approximately 3 minutes or less. There is no direct contact between the study team and the participant.

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 3 minutes or less.

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

The primary outcome measure will be the healthfulness of the fast-food meal selections, measured with a modified Nutrient Profile Index (NPI) score. NPI scores are based on the UK Ofcom Nutrient Profiling Model, which is used to score

individual foods in the U.K. to determine which ones can be marketed to children. For this study, we will generate a modified NPI score to evaluate the healthfulness of full meals comprised of multiple food items. This measure will be determined by calculating the weighted mean NPI score of all food items selected per meal, with each item's NPI score weighted by its proportionate contribution of mass in grams to the total mass of the meal. Beverages will be excluded from the modified score and assessed through secondary outcomes.

The key independent variable will be a five-category indicator of the experimental arm to which the participant is randomized. Using logistic regressions, we will explore differences in primary outcome between climate-impact label conditions (arms 2, 3, 4, and 5) vs. the QR label control, and between the label conditions (arm 2 vs. arm 3; arm 2 vs. arm 4; arm 2 vs. 5; arm 3 vs. arm 4; arm 3 vs. 5; arm 4 vs. 5).

As secondary outcomes, we will also compare total greenhouse gas emissions (kg CO_2e) associated with hypothetical orders across labeling conditions, perceived message effectiveness, total calories per meal order, and selection of a sugar-sweetened beverage within order.

5. *Answer the following **if they are relevant to your study design**:*

   A. *If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.*

      Randomization will be enabled as a function of the survey software (Qualtrics). Participants will be randomized into one of five study arms, as described above.

   B. *If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected for use in future research (beyond this study), complete the "Biospecimen Repository" section below.*

      N/A

   C. *If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.*

      N/A

D. *If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.*

N/A

E. *If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.).* ***For clinical tests of human biospecimens, no results may be returned unless completed in a certified lab.*** *Explain the failure rate and under what*
circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.

N/A

F. *If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:*

a. *Will the study staff be blind to participant intervention status*?

N/A

b. *Will participants receive standard care or have current therapy stopped*?

N/A

c. *Will you use a placebo or non-treatment group, and is that justifiable*?

N/A

d. *Explain when you may remove a participant from the study*.

N/A

e. *What happens to participants on a study in which there is a medical intervention when the study ends*? *Will participants continue to have access to the study intervention? What happens if they leave the study early?*

N/A

f. *Describe the process for referring participants to care outside the study, if needed.*

N/A

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 Pprovider (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 via CloudResearch
☐ 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.

We will retain data for a minimum of 7 years. All data is deidentified.

A. <u>Certificate of Confidentiality</u>:

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. <u>Risks of the Study</u>:

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. <u>Ensure that the risks described in the consent documents are consistent with the risks outlined in the research plan</u>.*

Breach of confidentiality is a potential risk, but it is very low, given data security procedures at CloudResearch and the fact that they will only share de-identified data with JHU.

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.

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.*

Participants will take an online survey that will span approximately 3 minutes, at a time that is convenient to them.

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

F. *Levels of COVID-19 community transmission will vary considerably by geography and over time, and therefore, the responses to the pandemic may also vary. The risk of COVID-19 to study staff and participants from in-person research activities can be mitigated by appropriate study procedures. If you are conducting in-person research activities, please indicate the protections you plan to implement at your research site(s):*

- [☒] Not applicable
- [☐] COVID testing of staff
- [☐] COVID testing of study participants
- [☐] Indoor masking/wearing PPE
- [☐] Social distancing for indoor activities
- [☐] Symptom screening of staff
- [☐] Symptom screening of study participants
- [☐] Vaccination of research team members
- [☐] Other procedures/comments: [ ]

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 the study may increase participant awareness of and knowledge about the connection between food choices and climate change.

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

This research supports a larger inquiry about the potential usage of fast-food menu labeling to promote healthier and more environmentally sustainable food choices at-scale. If effective, thereby improving dietary quality and lessening demand for foods that disproportionately contribute to greenhouse gas emissions, this pilot study and the research it scaffolds will meaningfully contribute to strategies that address diet-related disease and climate change. The implications could include increased consumer awareness and knowledge to support healthier and more sustainable choices, efficient leveraging of cross-sectoral resources to simultaneously address two major public health crises, the adoption of voluntary practices within industry, and considerations for regulatory and policy action.

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.*

Participants will be compensated through CloudResearch according to their guidelines.

Should we determine that a participant's response is not valid, we will alert CloudResearch and they will determine, per their guidelines, whether a participant receives compensation. Participants we exclude due to our eligibility criteria will be replaced by CloudResearch.

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*.

The level of compensation is set by CloudResearch, per their guidelines.

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

None

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 Nina Carr, MPH, MBA, Senior Research Program Coordinator is the 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.

Dr. Alexandra Reimold, a postdoctoral scholar in the Department of Human Ecology at the University of California, Davis. She will conduct data analysis under the oversight of Dr. Jennifer Falbe, Associate Professor in the Department of Human Ecology at the University of California, Davis. Dr. Falbe will also serve as a consultant on study design and interpretation of results. Neither will be engage in data collection or have any interaction with participants.

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

Dr. Julia Wolfson, has a PhD in public health policy and 10 years of experience conducting online survey research. The research team has extensive expertise in online experiments testing effects of food labels on food choices.

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.

3. *How will non-professional personnel (data collectors) involved with the data collection and analysis be trained in human subjects research ethical protections? (Use the BSPH Ethics Field Training Guide available on the BSPH IRB website. If* the study is a clinical trial, consider using the BSPH Good Clinical Practice (GCP) For Social and Behavioral Research Field Guide).

   N/A

4. *If the BSPH PI is responsible for data collection and will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team*.

   N/A

B. **Protocol Compliance and Recordkeeping:**

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]).

Please provide information about study oversight to ensure compliance with IRB approval and regulatory and institutional requirements. 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. **Safety Monitoring:**

1. *Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role and what is that person's specific charge?*

Participation in this study does not pose any safety risks. The study engages participants in a very brief, 3-minute survey task that asks non-sensitive questions.

2. *If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following*:

   a. *The DSMB membership, affiliation and expertise*.

      N/A

   b. *The charge or charter to the DSMB*.

      N/A

   c. *Plans for providing DSMB reports to the IRB*.

      N/A

3. *Describe plans for interim analysis and stopping rules, if any*.

   N/A

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

*NOTE: The IRB does not require PROMPT reporting of all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**. **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.

E. Other IRBs/Ethics Review Boards:

If other IRBs will review the research, provide the name of each IRB/ethics review board and its Federal Wide Assurance number, if it has one (available on [*OHRP's Website*]). ***For federally funded studies, subrecipients MUST have a Federal Wide Assurance (FWA) number from the OHRP. The IRB overseeing the subrecipient should be registered with the OHRP. The BSPH IRB will not have oversight responsibility for international subrecipients, and generally will not oversee data collection at external U.S. institutions Please contact the*** [*BSPH IRB Office*] ***with questions.***

Non-BSPH IRB/REC	FWA Number

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			
Overseeing storage, access and use of biospecimens			

COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:

XI. Secondary Data Analysis of Existing Data:

A. **Study Design:**

1. *Describe your study design and methods. The study design must relate to your stated aims/objectives.*

2. *Provide an estimated sample size and an explanation for that number.*

[ ]

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

[ ]

B. **Participants:**

1. *Describe the subjects who provided the original data and the population from which they were drawn.*

[ ]

Note: If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. 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. If either of these conditions is met, check "yes" to the HIPAA question in the PHIRST application.

2. *If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is "consistent with" the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial.*

[ ]

3. *Explain whether (and how) you plan to return results to the participants either individually or as a group*.

[ ]

XII. Oversight Plan for Student-Initiated Studies:

A. For student-initiated studies, explain how the PI will monitor the student's adherence to the IRB-approved research plan, such as communication frequency and form, training, reporting requirements, and anticipated time frame for the research. Describe who will have direct oversight of the student for international studies if the PI will not personally be located at the study site, and their qualifications.

[ ]

B. *What is the data custody plan for student-initiated research? (Note: Students may not take identifiable information with them when they leave the institution.)*

[ ]

XIII. Creation of a Biospecimen Repository:

Explain the source of the biospecimens, if not described above, and what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.

A. *Describe where the biospecimens will be stored and who will be responsible for them.*

[ ]

B. *Describe how long the biospecimens will be stored, and what will happen at the end of that period.*

[ ]

C. *Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Include your plans, if any, for commercial use. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens*.

[ ]

D. *Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.*

[ ]

E. *If future research could yield unanticipated incidental findings (e.g., an unexpected finding with potential health importance that is not one of the aims of the study) for a participant, do you intend to disclose those findings to the study participant? Please explain your position.*

[ ]

F. *Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form*.

[ ]

G. *Explain whether the repository will have Certificate of Confidentiality protections.*

[ ]

H. *Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.*

[ ]

I. *Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.*

[ ]

XIV. <u>Data Coordinating Center</u>:

Complete if BSPH serves as the Data Coordinating Center.

A. *How will the study procedures be developed?*

[ ]

B. *How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?*

[ ]

C. *Will each local clinical site be overseen by its own IRB with an FWA, or will a Single IRB review the study? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.*

[ ]

D. *How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?*

[ ]

E. *What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?*

[ ]

F. *What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, the Coordinating Center, the Steering*

Committee, or a Data and Safety Monitoring Board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.

[ ]

G. *Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?*

[ ]

H. *Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?*

[ ]

XV. Drug Products, Vitamins, Food and Dietary Supplements:

Complete this section if your study involves a drug, botanical, food, dietary supplement or other product that will be applied, inhaled, ingested or otherwise absorbed by the study participants. If you will be administering drugs, please upload the product information.

A. *List the name(s) of the study product(s), and the manufacturer/source of each product.*

Name of Study Product	Manufacturer/Source
[ ]	[ ]

B. *List each study product by name and indicate its approved/not approved status.*

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name)	Cleared for Use at Local Study Site

C. *If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number, and the Investigators Brochure.*

[ ]

Who will hold the IND?

[ ]

D. *If your study product is a marketed drug, provide the package inserts or other product information. If the study product WILL NOT be used for its approved indication, dose, population, and route of administration, provide a detailed rationale justifying the off-label use of the study product.*

[ ]

E. *If the study product does not require FDA approval (e.g., dietary supplements, botanicals, products not subject to the U.S. FDA, etc.), provide safety information (as applicable) and a certificate of analysis.*

[ ]

F. *Explain who will be responsible for drug management and supply, labeling, dispensing, documentation and recordkeeping. Complete and upload into PHIRST the Drug Data Sheet available on the* [*BSPH IRB Website*]

[ ]

G. *What drug monitoring and/or regulatory oversight will be provided as part of the study? Please describe.*

[ ]

XVI. Medical Devices:

*Complete this section if your study will involve an approved or investigational medical device (**diagnostic**, non-significant risk, significant risk).*

A. *List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval or its equivalent from a local authority, to ensure that the device is in good*

working order.

Name of Study Product	Manufacturer/Source	Powered?

B. *List each study product by name and indicate its status as approved by a government authority or not approved.*

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name and approval information)	Not Approved

C. *If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a* ***diagnostic device****, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so, and explain how those results will validated (or not) against the current "gold standard".*

[ ]

D. *If you believe the investigational device is not IDE exempt under 21CFR 812.2(c), but is a "Non-Significant Risk" device considered to have an approved IDE application, provide information from the manufacturer supporting that position.*

[ ]

E. *If you are using an investigational device that is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study. Provide a description of the device, and upload a picture or manufacturing schematics into PHIRST. Provide any other information relevant to a determination of its safety to be used for the purposes outlined in this research plan.*

[ ]