MENU Study: Online Experiment

NCT06909019

Study Protocol

Version Date: 02/25/2025

BSPH IRB Research Plan for New Data Collection

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

Aim 1: Compare the effects of different climate-impact menu label designs on the healthfulness of hypothetical fast-food meal orders in a nationally representative sample of US adults. In an online experiment, we will randomly assign 6,000 adults to view menus from two fast-food restaurants (one burger, one sandwich) that display one of five types of climate-impact label designs: 1) control (QR code); 2) green 'low climate impact' label; 3) red 'high climate impact' label; 4) 'climate-grade' label; and 5) traffic-light label. Our large and national sample will enable us to explore differences in effects by self-reported gender, age, education, income, region, and political views. 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 healthful meal, and (2) the effect of healthfulness of meal orders will differ by climate-impact label condition, and specifically, that 'high climate impact' labels will be most effective, followed by traffic-light labels, at improving the healthfulness (Nutrient Profile Index (NPI) score) of restaurant meal selections. Secondary outcomes evaluated based upon responses to the hypothetical meal ordering task include: a total greenhouse gas emissions per meal order, total calories per meal order, and selection of a sugar-sweetened beverage within order.

Via a survey following the meal ordering task, additional secondary outcomes will be evaluated. We will 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 labels performing best, followed by the traffic light labeling scheme, then by the grade labeling scheme, and finally the numeric labels. We will also evaluate the noticeability of labels on menus, perceived healthfulness and perceived deliciousness/tastiness if labeled menu items, and emotional responses to labels.

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.*

Shifting dietary patterns in the United States (US) toward more environmentally sustainable 'planetary health' diets has the potential to improve dietary quality and prevent nutrition-related chronic diseases like obesity and type-2 diabetes. Fast-food restaurants are a key environment to promote 'planetary health'-aligned food choices given the frequency of fast-food consumption,

the poor dietary quality of fast-foods, and their associations with adverse health outcomes. Numerous restaurants and food companies have recently implemented climate-impact labels that inform consumers of each menu item's carbon footprint (i.e., climate impact). Climate-impact menu labels are also garnering interest among policymakers. Several European countries are implementing a national climate label for food; there is federal- and state-level policy interest in the US; and multiple universities, hospitals, and workplaces have voluntarily adopted climate-labeling systems in food service settings. However, evidence is lacking on how climate-impact labels affect the healthfulness of dietary intake. Existing research shows that nutrition labels can change behavior, but we lack evidence on whether climate labels can promote healthier as well as more climate friendly food choices. Climate labels could improve dietary quality via lower red and processed meat intake but could also promote undeserved perceptions that unhealthy food items are healthy (i.e., a 'health-halo' effect). Given the rapid development and growing food industry and policy interest in climate-impact labels, there is a critical need for timely, rigorous evaluation of the real-world effects of climate labels in different types of restaurants, and the optimal design to maximize behavior change. Therefore, in this study we will test the effectiveness of climate labels to nudge consumers towards healthier food choices by comparing four labeling schemes on two different fast-food restaurant menus:

(1) Red negative nudge labels [HIGH CLIMATE IMPACT] displayed on high-GHGE items
(2) Green positive nudge labels [LOW CLIMATE IMPACT] displayed on low-GHGE items
(3) 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
(4) 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

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

III. Study Design:

A. *Brief overview of study design and methods*:

The objective of this aim is to evaluate the degree to which four different types of climate-impact labels influence the healthfulness of fast-food orders compared to a control label (QR code). To accomplish this aim, we will recruit a large, nationally representative sample of U.S. adults (N=6,000) through the NORC AmeriSpeak panel to participate in a randomized, controlled experiment. Participants will be randomized to view two restaurant menus (one popular burger chain and one popular sandwich chain) presented successively in a randomized order. Each menu will display either the control label or one of the four climate-impact labels (a green 'low-climate-impact' label, a red 'high-climate-impact' label, a 'climate-score' label, or a traffic light label). Participants will then order a hypothetical meal for lunch from each restaurant that they have a chance to actually receive the monetary value of if they are selected via a 1:25 lottery. After ordering, participants will complete a 10-minute survey to assess label perceptions and sociodemographic characteristics.

B. *Sample size and a justification:*

For primary analyses, our sample size of 6,000, 1,200 per experimental condition, provides 80% power to detect Cohen's d=0.14, a small effect size, with a conservative Bonferroni adjusted alpha of 0.0125 to account for multiple comparisons (4 experimental conditions each compared to control). This effect size is small compared to the magnitude of the effects we saw in our preliminary study of climate-impact labels in an online fast-food restaurant. In that study the limited menu had little variation in the NPI scores of items, however we still saw an effect size of Cohen's d=0.21 for the difference in NPI scores of items ordered between the 'high climate impact' label and the control condition. The broader literature on randomized trials of other menu labels on continuous outcomes, including a meta-analysis of SSB warning labels finds larger effects than we are powered to detect in this study (Cohen's d=0.32 for hypothetical behavioral outcomes and Cohen's d=0.17 for actual behavioral outcomes). For environmental outcomes, based on our preliminary study in which there was a 23% difference between the 'high climate impact' label and control in the proportion of participants ordering a sustainable item, the minimum detectable effect between label and control conditions is 6.8% at alpha=0.0125 and 80% power. Additionally, a recent randomized online experiment of a GHGE label, found an effect size of Cohen's d=0.50. In that study, participants in the GHGE label condition made more sustainable food choices compared to the control group. Therefore, we will have adequate power to detect small effects between labels.

The sample will be recruited from the NORC AmeriSpeak panel and nationally representative of the U.S. adult population. We will recruit individuals until the target sample size has been reached by working with the managed research partner, NORC.

C. *Does the study meet the NIH definition of "clinical trial":*

Yes. The study will be listed on clinicaltrials.gov prior to beginning any data collection.

IV. Participants:

A. Inclusion Criteria:

1. Member of the NORC AmeriSpeak panel
2. Aged □18 years of age or older
3. Residing in the United States

B. Exclusion Criteria:

1. Not a member of the NORC AmeriSpeak panel
2. <18 years old
3. Not residing in the United States
4. Completed the survey implausibly quickly based on the distribution of time to complete the survey among all participants

V. Study Procedures:

A. Recruitment Process:

1. Plan for identifying, approaching, and informing potential participants about the study:

We will recruit a nationally representative sample of 6,000 US adults through the NORC AmeriSpeak panel. The NORC AmeriSpeak panel is a nationally representative probability-

based panel used frequently in academic research. Households are selected randomly, with a known, non-zero probability of selection, from a sampling frame that represents >97% of the US population. The current panel size includes >54,000 individuals in >43,000 households. The AmeriSpeak panel includes an oversampling of Hispanic and African American household and households with lower socioeconomic status and employs robust methods to recruit and retain panelists from underrepresented groups. Panelists typically complete 1-2 surveys per month. Our team has extensive experience fielding and analyzing large experimental surveys such as the one proposed here. We have previously worked with NORC AmeriSpeak on a study of climate-impact menu labels, and data were collected in about two weeks. Following data collection, NORC AmeriSpeak provided clean datasets with survey weights to produce nationally representative estimates within three weeks. Therefore, we anticipate data collection for this aim to be complete in one month.

2. Privacy issues associated with recruitment:

There are no privacy issues associated with recruitment. The survey will be distributed to NORC AmeriSpeak panel members by NORC staff. The research team will have no direct interaction with participants and will only receive deidentified data

B. Consent Process:

1. Who will obtain informed consent, and their qualifications:

NORC AmeriSpeak panel participants provide consent when they enroll in the panel. AmeriSpeak's recruitment procedures for protecting the rights of human research subjects have been reviewed and approved by NORC's IRB. NORC obtains and documents research subjects' informed consent for panel participation (including receiving and completing surveys) and agreement to the study's Privacy Policy and Terms and Conditions during the registration process. The AmeriSpeak team provides minimum key information on subject matter at the introduction of every survey. This functions as the consent. For surveys that do not cover sensitive topics study-specific consent is not generally required. The AmeriSpeak Privacy Policy and Terms and Conditions documents are available on the panel member website (www.amerispeak.org). Therefore, these key documents are always available online to AmeriSpeak Panel members. The AmeriSpeak Panel Operations team has also obtained a Certificate of Confidentiality (CoC) covering the adult AmeriSpeak Panel. Information can be found here: https://www.amerispeak.org/privacy.

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

NORC obtains and documents research subjects' informed consent for panel participation and agreement to the study's Privacy Policy and Terms and Conditions during the registration process. We will not obtain a signature from the participant or will use an oral consent process. We will not include a witness to consent process.

3. The process for determining whether a potential participant meets eligibility criteria.

NORC staff will determine if study participants are eligible to participate based on demographic information in the panel member's profile.

4. **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
USA	Adult consent has already been granted by AmeriSpeak panel members.	English

C. Study Implementation:

1. Procedures that participants will undergo:

Randomization: Upon initiation of the survey, participants will be randomized to one of five labeling conditions: 1) control (QR code) label, shown on all food items; 2) green 'low climate-impact' label, shown on all low climate-impact food items; 3) red 'high climate-impact' label, shown on all high-climate-impact food items; 4) 'climate-grade' label, shown on all food items (one of five 'grades' will be shown for each labeled item'; and 5) traffic light label, with one of three levels shown on all food items. All label conditions will also display 1) a statement at the top of the menus describing the meaning of label in the condition and 2) calorie labels, as is required by law in all large chain restaurants in the US.

Restaurant ordering procedure: We will program two realistic fast-food restaurant menus, modeled after Burger King and Subway, into Qualtrics, as we have done in prior studies. Participants will be instructed to imagine they are ordering a meal for themselves for lunch. They will view and order from the two realistic fast-food menus presented in random order that will display the labeling scheme to which the participant has been randomized. Participants will select the items they want to order for their meal from each of the restaurant menus and then complete a brief survey (described below) that will include questions about the meals, the labels, their attitudes about climate change and healthy eating. To encourage realistic food selections and enhance external validity, we will use a minor deception procedure that has been approved by the IRB for other labeling studies we have completed. At the beginning of the study, participants will be told that 1 in 25 individuals will be selected via lottery to receive a coupon for one of the meals they ordered. In reality, upon completing the study, participants who won the lottery will be provided with compensation equivalent to the displayed value of the meal selected rather than being restricted to a coupon for the items in the meal. This compensation will be delivered immediately after survey completion via the normal way panelists are compensated by NORC.

Survey procedure: After the restaurant menu ordering task, participants will complete a brief, ~10-minute survey designed to assess the degree to which the labels influence the potential mechanisms of behavior change that we identified in our conceptual framework. Participants will answer questions on 7-point Likert scales designed to assess how healthy, appealing, and tasty participants perceive the items of varying healthfulness and climate impact to be. Participants will also be asked if they noticed the climate-impact labels on the restaurant menus, and whether they used them when making their food selections. We will ask participants questions

to assess their knowledge of the climate-impact of their food choices. Participants will also answer questions about their environmental values and their perceived subjective norms about climate change. Finally, participants will be shown the label to which they were randomized, and we will assess their 1) emotional reaction to it, and 2) the perceived message effectiveness, which has been shown to predict consumer behavior. Additionally, we will ask for select demographic information. NORC AmeriSpeak will provide information about participants' age, sex, and race and ethnicity, so these questions will not need to be asked.

Post-Survey: After being debriefed about the study purpose, all participants will have the ability to indicate whether they want their data to be used. In our studies that use this procedure, it is extremely rare for someone to not allow us to use their data after the study debriefing.

2. ***Number and type of study contacts between the study team and the participant, how long they will last, and where/how they will take place*:**

Participants will participate in one online survey in which they will select items to hypothetically order from two fast food restaurants and respond to a brief survey following the ordering task. Total participation will be ~10 minutes. The participant can access the survey from their computer or mobile device at a time and place of their choosing.

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

~10 minutes.

4. ***Brief data analysis plan and a description of variables to be derived:***

Outcomes: The primary dietary outcome 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 foods in the U.K. to determine which ones can be marketed to children. The NPI generates a 0–100-point score for foods and beverages where scores □64 are considered healthy. NPI scores are based on points awarded from nutrients to encourage (e.g., percent fruits and vegetables, grams of fiber and protein) and nutrients of concern (e.g., sodium, sugar) per 100 grams. The NPI has been validated and used previously to quantify the nutrition quality of chain restaurant menu items and packaged food items in the US and United Kingdom. We chose NPI score rather than other dietary quality indices because it is the most feasible given publicly available nutrition and serving size information and we have used it in prior research in large chain restaurants. 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).

Our other secondary dietary outcomes will include the total energy (kcal), grams of saturated fat, sugar, protein, fiber, milligrams of sodium ordered at each restaurant, and whether the meal contains a red meat item (yes/no) and a sugar sweetened beverage (yes/no). In addition, we will examine the climate impact of the menu choices by calculating the GHGE of the meal selections using the Cool Food Calculator method. Our other knowledge and perception secondary outcomes are described above in Survey Procedures.

Statistical analyses: To determine the effects of the four climate-impact labels compared to the control label on our continuous primary outcome of dietary quality, we will regress the outcome onto a categorical indicator representing experimental condition. If the primary outcome is not normally distributed, we will perform appropriate transformations and use robust standard error estimates to preserve valid standard errors and p-values. We will use this approach for secondary kcal and GHGE outcomes. For dichotomous secondary outcomes, we will use Poisson regression with a robust error variance to directly estimate the probability ratio (i.e., risk ratio). This method is preferred over calculating the odds ratio which is a poor estimate of the probability ratio when the prevalence of the outcomes is □10%. In exploratory analyses, we will use interaction terms to examine whether label effects differ by participant socio-demographic characteristics. All analyses will use AmeriSpeak-provided sample weights to produce nationally representative estimates. To ensure transparency, reproducibility, and rigor, we will pre-register our analyses on both clinicaltrials.gov and aspredicted.org, and we will follow CONSORT guidelines.

5. Arms and process for assigning participants:

Randomization will be enabled as a function of the survey software. Participants will be randomized to one of five labeling conditions, as described above, upon initiating the survey

6. Removal of participants from the study:

Participants may be removed for poor data quality (e.g., a high number of incomplete responses) as determined by NORC AmeriSpeak staff.

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

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 JHSPH 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 JHSPH 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 JHSPH IT

☐ Study-provided, and not managed by JHSPH 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*): [NORC AmeriSpeak will collect the data from their panel members via online survey in their system]

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*: [NORC AmeriSpeak panel.]
☐ 3rd party collector (*please specify*): [ ]
☐ Existing data shared with JHSPH 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/JHSPH 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/JHSPH OneDrive ☐ JH IT-Managed Network Storage ☐ JHM/JHSPH Qualtrics

☐ JHSPH HPCC ☐ JHSPH SharePoint ☐ JHSPH Shares ☐ JHU REDCap

☐ MARCC-Secure Environment

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

We will share individual-level data without identifiers with co-investigators and members of our study team who will participate data analysis. After we have published our findings, per our Data Management and Sharing Plan, we will upload de-identified datasets to the Open Science Framework (OSF) repository, a free open platform to share research. Stored data on OSF will have a unique, persistent URL for citing and sharing.

☐ 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. **Certificate of Confidentiality: T**his study has a Certificate of Confidentiality.

VII. Risks of the Study:

A. ***Risks, discomforts, and inconveniences associated with the study and its procedures:***

This study does not involve any major risks to study participants. The potential risks to participants are minimal. A potential risk could be a data breach, which is possible but very unlikely. The study team will never have access to participant names or other identifying information. NORC AmeriSpeak, the survey research firm, will provide de-identified data to the research team when data collection is complete, so any data breach would be to de-identified data. Given this, and the data security procedures at NORC, the risk of a confidentiality or data breach is very low.

B. ***Steps taken to mitigate or minimize each of the risks described:***

Study team members will not have any interaction with participants and will only receive deidentified data. We are not collecting any identifying information and will not be collecting IP Address information either. We will have no way of identifying the participant or their location.

C. ***Anticipated frequency and severity of the harms associated with the risks identified:***

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

VIII. Direct Personal and Social Benefits:

A. ***Potential direct benefits the study offers to participants:***

This study does not provide any direct benefit to participants.

B. Potential societal benefits likely to derive from the research:

The benefits to society and the scientific community include greater understanding of the effectiveness of climate-impact menu labels in fast-food restaurants at promoting healthier and more sustainable dietary choices. Results will inform the design of effective labels- an area of growing industry and policy interest that could result in prevention of diet-related chronic diseases such as type-2 diabetes.

IX. Payment or Token of Appreciation:

A. Plan to provide non-monetary token of appreciation:

None to be provided.

B. Plan to provide a monetary payment:

Randomization will be built into the survey to randomly select 4% of participants. At the end of the survey, each participant will be notified whether they were selected to receive the additional compensation, and the AmeriSpeak team will provide us with the associated variables in the final data file indicating whether a participant received the additional compensation or not. Payments will pass through AmeriSpeak (as AmeriSpeak points) immediately after survey completion. This is a system in which participants are accustomed to receiving various amounts of compensation.

C. Possible total remuneration and consequences for not completing all phases of the research:

Level of compensation is set by the survey firm, NORC AmeriSpeak, according to their guidelines. There are no consequences for not completing all phases (there is only 1 phase).

X. Study Management:

A. Oversight Plan:

1. 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 will lead data collection and analysis. Nina Carr, Research Program Coordinator, will coordinate the study under the supervision of Dr. Wolfson. Other individuals or students may assist with data analyses, and will be added to the IRB at that time.

2. 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 non-professional personnel (data collectors) involved with the data collection and analysis will be trained in human subjects research ethical protections:

NORC AmeriSpeak staff will be involved in data collection. All staff are trained and certified in human subjects research.

4. **PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.**

The PI will be in regular communication with NORC AmeriSpeak staff during study planning and data collection.

B. ***Protocol compliance and recordkeeping 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 and details on study oversight to ensure compliance with IRB approval and regulatory and institutional requirements:***

Data, IRB correspondence, and other study documents will be stored on permission-restricted shared OneDrive folders on password protected computers. The study team will have regularly scheduled 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. ***Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB:***

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

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

Collaborators and roles and responsibilities:

	BSPH	NORC	
For federally funded studies, collaborators' FWA	00000287	00000142	
Primary Grant/Contract Recipient			
Grant/Contract Subrecipient			
Hiring Data Collectors			
Training Data Collectors			
Obtaining Informed Consent and/or Identifiable Data		X	
Accessing/Analyzing Identifiable Data		X	
Overseeing storage, access and use of biospecimens			