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University at Buffalo
The State University of New York
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Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

# Complete Research Protocol (HRP-503)

## Table of Contents

## *Template Instructions*

***Sections that do not apply:***

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 19, 20, 22, 23, 24, 25, 31, and 32 do not apply.*
    - *For exempt research: Sections 31 and 32 do not apply.*

***Studies with multiple participant groups:***

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response:

Intervention Group:

Control Group:

***Formatting:***

- *Do not remove template instructions or section headings when they do not apply to your study.*

*If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.*

***Amendments:***

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

## PROTOCOL TITLE:

*Include the full protocol title.*

Response:

Promoting healthier eating among children in restaurants (Full study)

## PRINCIPAL INVESTIGATOR:

*Name*
*Department*
*Telephone Number*
*Email Address*

Response:

Stephanie Anzman-Frasca, Ph.D.

Pediatrics, Division of Behavioral Medicine

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## VERSION:

*Include the version date or number.*

Response: Version 9

## GRANT APPLICABILITY:

*Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.*

*NOTE: This question does not apply to studies funded by a sponsor contract.*

*Include a copy of the grant proposal with your submission.*

Response:

This study is being funded by the National Institutes of Health (NIH) Research Project Grant Program (R01) (1 R01 HD096748).

## RESEARCH REPOSITORY:

*Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.*

Response:

*Location:* Child Health and Behavior Lab, Division of Behavioral Medicine

*Address:* 151 Farber Hall

*Department:* Pediatrics

## 1.0 Objectives

*1.1 Describe the purpose, specific aims, or objectives of this research.*

Response:

Pilot Phase: The purpose of this phase is to conduct taste tests to determine children's reactions to foods that are being considered for the subsequent experimental phase.

Experimental Phase: The objective of this research is to make healthier kids' meal options more appealing and easier to choose via an in-restaurant intervention that combines repeated exposure and choice architecture strategies. This phase has 2 main aims:

Aim 1: To test effects of a healthier kids' meal intervention on children's meal orders.

Aim 2: To test effects of a healthier kids' meal intervention on children's dietary intake.

*1.2 State the hypotheses to be tested, if applicable.*

*NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.*

Response:

Pilot Phase: There is no explicit hypothesis during this exploratory pilot phase.

Experimental Phase:

Hypothesis 1a: 4-to-8-year-old study participants in intervention restaurants will be more likely than controls to select one of the promoted healthier kids' meals at post-test.

Hypothesis 1b: 4-to-8-year-olds in the intervention group will order fewer calories and desserts and less saturated fat, sodium and sugar at post-test versus controls.

Hypothesis 1c: The promoted healthier meals will make up a greater percentage of kids' meals ordered in intervention restaurants versus controls, based on sales data across the study period.

Hypothesis 2: Compared to controls, 4-to-8-year-old study participants in the intervention group will consume fewer calories and less saturated fat, sodium, and sugar in the restaurant at post-test.

## 2.0 Scientific Endpoints

*2.1 Describe the scientific endpoint(s), the main result or occurrence under study.*

*NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should* ***not*** *be a date.*

Response:

Pilot Phase: The primary outcome is which menu items children prefer. The secondary outcome is what improvements can be made so the child will like an item more, if applicable.

Experimental Phase: The primary outcomes are children's meal items ordered (i.e. healthier promoted meal? yes/no), and the total calories, saturated fat, sodium, and sugar in children's orders. Secondary outcomes include children's in-restaurant consumption of total calories, saturated fat, sodium, and sugar.

## 3.0 Background

*3.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.*

Response:

On average, US children's diets are energy dense and of poor quality (1). Moreover, consumption of fast food and sweetened beverages is greater among those at disproportionate risk for obesity, including African American and Hispanic/Latino children (2). While children readily accept sweet and salty foods that tend to be less nutrient dense and higher in calories, research shows that their taste preferences are malleable, and regular exposure to healthier foods can promote acceptance of these foods beginning early in life (3, 4). Yet regular exposure to healthy foods is not normative within many environments where children currently spend time.

Restaurants are one setting in which environmental shifts could promote healthier eating among children. Restaurant meals tend to be higher in calories and lower in nutritional quality than those prepared at home, with many children's menus featuring items that should be eaten only occasionally, such as fried foods and sugary drinks (5, 6). Correspondingly, consumption of restaurant food has been linked with increased daily energy intake and poorer diet quality among children (6). Restaurants are normative eating contexts for many families: 33% of children

ate fast food on a given day, with consumers obtaining 576 calories, or 31% of their daily energy intake, from fast food (7). Targeting children's food selection in restaurants has the potential to improve diet quality, attenuate excess energy intake, and shape healthy habits. Research is needed to develop restaurant-based health promotion efforts that are efficacious and have the potential for widespread reach and sustainability over time.

Providing nutrition information is one approach aiming to impact dietary intake, however providing nutrition information via calorie labeling has not demonstrated widespread effects on behavior in restaurants to date (8). A more implicit approach, supported by extensive behavioral economics research in other domains (9-13), involves making healthy choices easier by positioning them as normative and/or prominent. There is little research examining interventions intended to nudge children toward healthier meals in restaurants, but in a recent randomized pilot study of 58 families in a quick-service restaurant, we demonstrated the promise of such interventions. Children provided with placemats promoting two healthier kids' "Meals of the Day" ordered a greater number of healthier foods than controls, and children who ordered promoted healthier entrees consumed less saturated fat than those who did not (14).

The current study aims to build on this successful pilot research, bolstering effects on children's meal selection and intake by adding a repeated exposure strategy to our "choice architecture" placemat intervention. Repeated exposure to healthier kids' meals will be encouraged using frequent diner cards, an approach already used in restaurant settings, with similar rewards programs demonstrating effects on purchasing (15). Together, repeated exposure and choice architecture have the potential to make healthier options more appealing and easier to choose. Given how frequently children eat food from restaurants, the typical unhealthy consumption patterns while there, and the potential of repeated exposure to impact eating behaviors broadly, this intervention has the potential for meaningful impact on children's diets and health.

*3.2 Include complete citations or references.*

Response:

1. Ford CN, Slining MM, Popkin BM. Trends in dietary intake among US 2-to 6-year-old children, 19892008. Journal of the Academy of Nutrition and Dietetics. 2013;113(1):35-42. e6.

2. de Hoog ML, Kleinman KP, Gillman MW, Vrijkotte TG, van Eijsden M, Taveras EM. Racial/ethnic and immigrant differences in early childhood diet quality. Public Health Nutrition. 2014;17(06):1308-17.

3. Birch LL, Anzman SL. Learning to eat in an obesogenic environment: a developmental systems perspective on childhood obesity. Child Development Perspectives. 2010;4(2):138-43.

4. Cooke L. The importance of exposure for healthy eating in childhood: a review. Journal of Human Nutrition and Dietetics. 2007;20(4):294-301.

5. Batada A, Bruening M, Marchlewicz EH, Story M, Wootan MG. Poor nutrition on the menu: children's meals at America's top chain restaurants. Childhood Obesity. 2012;8(3):251-4.

6. Powell LM, Nguyen BT. Fast-food and full-service restaurant consumption among children and adolescents: effect on energy, beverage, and nutrient intake. JAMA Pediatrics. 2013;167(1):14-20.

7. Powell LM, Nguyen BT, Han E. Energy intake from restaurants: demographics and socioeconomics, 2003–2008. American Journal of Preventive Medicine. 2012;43(5):498-504.

8. Long MW, Tobias DK, Cradock AL, Batchelder H, Gortmaker SL. Systematic review and meta-analysis of the impact of restaurant menu calorie labeling. American Journal of Public Health. 2015;105(5):e11-e24.

9. Downs JS, Loewenstein G, Wisdom J. Strategies for promoting healthier food choices. The American Economic Review. 2009;99(2):159-64.

10. Johnson EJ, Bellman S, Lohse GL. Defaults, framing and privacy: Why opting in=opting out. Marketing Letters. 2002;13(1):5-15.

11. Johnson EJ, Bellman S, Lohse GL. Cognitive lock-in and the power law of practice. Journal of Marketing. 2003;67(2):62-75.

12. Johnson EJ, Goldstein DG. Defaults and donation decisions. Transplantation. 2004;78(12):1713-6.

13. Park CW, Jun SY, MacInnis DJ. Choosing what I want versus rejecting what I do not want: An application of decision framing to product option choice decisions. Journal of Marketing Research. 2000;37(2):187-202.

14. Anzman-Frasca S, Braun AC, Ehrenberg S, Epstein LH, Gampp A, Leone LA, Singh A, Tauriello S. Effects of a randomized intervention promoting healthy children's meals on children's ordering and dietary intake in a quick-service restaurant. Physiology & Behavior. 2018; 192(1):109-117.

15. Taylor GA, Neslin SA. The current and future sales impact of a retail frequency reward program. Journal of Retailing. 2005; 81(4): 293-305.

# 4.0 Study Design

*4.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).*

Response:

Pilot Phase: A cross-sectional study design will be used. About 25 children from 1-3 restaurant locations will participate in taste tests to inform food selections for the subsequent experimental phase. Families will be asked if they want to

participate in taste tests during a regular visit to a location of the study restaurant (Anderson's Frozen Custard). Participating children will taste up to 5 side dishes (e.g. applesauce, carrot sticks, mandarin oranges) and up to 5 main dishes (e.g. turkey sandwich, peanut butter and banana sandwich). They will then use a visual face scale to rate their liking and rank ordered preferences for presented options and be asked for their opinions on the foods (e.g., why they liked/disliked the food items). Parents will be asked to complete a brief demographic survey on an electronic tablet or with pen and paper.

Experimental Phase: A cluster-randomized design will be used. 6 locations of Anderson's, a regional quick-service restaurant in the Buffalo, New York, area will be paired based on income levels in the surrounding census tracts. A location from each pair will be randomized to each study group (intervention, control). Recruitment and data collection will be conducted across about 3 to 5 cohorts, with recruitment conducted either in person or remotely during a family's regular visit to Anderson's.

We will be prepared to conduct remote assessments in addition to originally-planned in-person assessments as appropriate. For example, if due to the status of COVID-19, in-person assessments are not feasible, we will follow remote methods described herein which allow us to still pursue our original aims but without in-person interaction with participants. Generally, variables of interest and procedures are the same for remote cohorts compared to those participating in recruitment and data collection in-person. Minor changes include: all study procedures completed via online survey; omission of child survey (i.e. parent is the only participant); and a change in dietary intake assessment, specifically the replacement of initial/baseline and post-test plate waste methodology with a midpoint and post-test assessment of dietary intake via remote food photography. In each section of the current IRB protocol, we specify any modifications to the original in-person plan that will be incorporated when data are collected remotely.

Following recruitment, study participation will involve 7 more visits to the Anderson's location where the family was recruited, 6 of which will be during an exposure period of about 2 months. After baseline data collection during the recruitment/initial time period, participating families in intervention restaurants will receive placemats promoting healthier featured kids' meals, as well as a frequent diner card, which, after purchasing a featured healthier kids' meals across 6 occasions, makes them eligible for a free kids' meal of their choice during a predetermined redemption period. In the control group, generic placemats will be provided, and interested, eligible families will be provided with frequent diner cards that can be used for any kids' meals during the exposure period. Placemats will remain available in the restaurants throughout the exposure and redemption/post periods that follow, and signs with similar content as the placemats will be displayed in the restaurants during and exposure and redemption/post periods. Study outcomes will be measured via restaurant sales data (de-identified aggregate data), as well as data collected directly from study participants: survey questions, plate waste (when data are collected by research

staff in person), food photographs, and dietary recalls, each of which is described in more detail herein.

## 5.0 Local Number of Subjects

*5.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.*

Response:

Pilot Phase: In total, we will enroll about 25 4-to-8-year-old children and their parents/guardians from 1-3 Anderson's restaurant locations.

Experimental Phase: We will enroll about 930 families across all 6 participating Anderson's locations.

*5.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).*

Response:

Both Phases: In our previous pilot study conducted at Anderson's Delaware Ave location, we screened 297 participants and enrolled 120 participants over 2 months. We expect the screen failure rate for the current study to be comparable given the child age range and inclusion/exclusion criteria will be similar. Therefore, we expect to screen approximately 60 and 2,300 families in the pilot and experimental phases respectively, with the latter occurring over about 3-4 years.

*5.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*

Response:

In both phases, we will recruit within the restaurant locations and via advertisements on the restaurant's social media platforms, either in-person or remotely, with approval of the restaurant owner as well as the managers of the specific restaurant locations. With regards to social media, the study will be advertised via Facebook/Instagram using Anderson's social media account only. The advertisement to be uploaded to Facebook is attached. We believe recruiting a sample of about 25 (pilot phase) and 930 families (experimental phase) with 4-to-8-year-old children will be feasible based on our conversations with the restaurant owner about typical traffic, naturalistic observations and past research in Anderson's restaurant locations, and our past experience conducting research in restaurants generally. We have allocated about 3-4 months of recruitment time across the 3 – 5 cohorts in the experimental phase, with a plan to study 2 restaurant locations per cohort. This timeline was informed by prior observations indicating that about 10 families eat at Anderson's per evening as well as the fact that we were able to recruit 120 participants from 1 location of Anderson's over 2 months in our past research. The prior observation suggests the possibility of about 3600 families being present in the restaurant during the recruitment period

across cohorts, which is greater than the anticipated 2300 families who will need to be screened, as indicated above.

## 6.0 Inclusion and Exclusion Criteria

*6.1 Describe the criteria that define who will be **included** in your final study sample.*

*NOTE: This may be done in bullet point fashion.*

Response:

Eligibility criteria for both phases include: English-speaking parent/guardian at least 18 years old; an English-speaking child who is 4-8 years old at the time of recruitment (child may turn 9 years old during the study time period); and the child must eat food from restaurants at least 2-3 times each month. In addition, during the experimental phase, they must be eating a meal at one of the Anderson's locations specific to that cohort on the day they are recruited (i.e. day of baseline data collection). We will also ensure that the child does not have allergies that would preclude their safe participation in the study. These criteria were selected with the goals of results being generalizable to children who eat in these settings regularly and demographics of the geographic area in which we plan to conduct the study.

*6.2 Describe the criteria that define who will be **excluded** from your final study sample.*

*NOTE: This may be done in bullet point fashion.*

Response:

We will exclude anyone who:

- Is under 18 years of age (parent/legal guardian)
- Does not have a child in the range of 4-8 years at the time of recruitment
- Does not speak English fluently (both parent and child)
- Does not eat food from a restaurant at least 2 – 3 times per month (child)
- Is not eating a meal at one of the Anderson's locations specific to the cohort on the day recruited (child; experimental phase only)
- Has food allergies that preclude safe participation in the study (child)

For participants recruited remotely, we will exclude anyone who:

- Does not have regular internet access.

*6.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.*

***NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.***

Response:

☐ Adults unable to consent

☒ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

*6.4 Indicate whether you will include non-English speaking individuals in your study.* ***Provide justification if you will exclude non-English speaking individuals.***

*In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may* ***not*** *be routinely excluded from research as a matter of convenience.*

*In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.*

Response:

We designed our inclusion/exclusion criteria for both phases of the study to match the population that lives in the neighborhoods of the study restaurant locations we plan to work with. We will only have materials in English as census data for the census tracts in which the study restaurants are located indicate that 93%-97% of residents speak English. Additionally, the menu boards and other written materials within the study restaurant are currently in English only. Thus, having our materials in English for the taste tests as well as the intervention study matches the current context in which the intervention will be implemented and will include the vast majority of individuals that reside in the surrounding neighborhoods.

## 7.0 Vulnerable Populations

*If the research involves special populations that are considered vulnerable,* ***describe the safeguards included to protect their rights and welfare.***

*NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.*

*7.1 For research that involves* ***pregnant women,*** *safeguards include: NOTE CHECKLIST: Pregnant Women (HRP-412)*

Response:

☒ **N/A**: This research does not involve pregnant women.

*7.2 For research that involves **neonates of uncertain viability or non-viable neonates,** safeguards include:*
*NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)*

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

*7.3 For research that involves **prisoners**, safeguards include:*
*NOTE CHECKLIST: Prisoners (HRP-415)*

Response:

☒ **N/A:** This research does not involve prisoners.

*7.4 For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*
*NOTE CHECKLIST: Children (HRP-416)*

Response:

This study is minimal risk and does not include any risks to children any greater than those encountered in everyday life.

☐ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*7.5 For research that involves **cognitively impaired adults**, safeguards include:*
*NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)*

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

*7.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable.* ***Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response:

A portion of our sample may be of a lower socioeconomic status, including a lower level of education. We will take great care to ensure we give each potential participant a thorough explanation of the study and what it entails prior to consent, that we answer any questions they may have, that materials and measures are at an appropriate reading level, and that assistance in completing them is available as needed. We will also have paper versions of any electronic forms for

any participants who prefer this mode of completion during in-person data collection sessions. For those who are recruited remotely, we will be available by phone, text, or email for any potential participants to answer questions they may have.

## 8.0 Eligibility Screening

*8.1 Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

*Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).*

Response:

Potential subjects will be screened in person (or via online survey if participating remotely during the experimental phase) at Anderson's restaurant. During in-person recruitment, research assistants will verbally conduct screener, entering responses into an electronic tablet or a paper form. Any screeners completed on paper during the experimental phase will be entered into the online form at a later time by research staff using the participant's indicated responses, so that all responses are stored together (securely, as indicated herein).

During any remote recruitment conducted during the experimental phase, potential participants will access the online screening questionnaire on their own electronic device if they are interested in doing so after reading about the study in the restaurant (e.g., on table tents and/or signs; see attachments) or on social media. These potential participants can access the online screening questionnaire using a link provided by study staff, who will be available via phone or email during specified evenings during specified dinner hours (e.g., 4:30-8:00pm).

☐ **N/A:** There is no screening as part of this protocol.

## 9.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

*9.1 Describe when, where, and how potential subjects will be recruited.*

*NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).*

Response:

For both phases potential subjects will be recruited at participating Anderson's restaurants, either in person or remotely. We aim to begin recruiting for the pilot phase around November 2019 and for the experimental phase around May 2022, following IRB approval.

Pilot Phase: Study staff will approach families with at least one child who might plausibly be in the target age range (4-8 years) after they have placed their order and will invite them to join a study where they can taste test different main dishes and sides. Those interested will complete screening questions and will be provided with consent forms as described herein.

Experimental Phase: Recruitment will be conducted across approximately 3 – 5 cohorts. Families will be informed that study participation involves 7 more visits to the Anderson's location where they were recruited, 6 of which will be during an exposure period lasting about 2 months. Families entering study restaurants will be invited to join a study with incentives including earning a free kids' meal at Anderson's. Families will also be recruited via advertisements from Anderson's social media account on Facebook. The ad that will be used is attached and will be uploaded to Anderson's Facebook page, directing them to contact the study team for more information and screening.

Those interested will complete screening questions and will be provided with consent forms to complete on paper or online and will be given adequate time to ask any questions they may have. Initial/baseline data will then be collected and will include experiences during that initial restaurant visit, as described herein.

Those participating in remote data collection will complete screening questions using online forms accessed through website links shared by study staff during their restaurant visit. If eligible, they will proceed to consent forms on which they can indicate their consent electronically, and then they will be provided with the online baseline survey. Phone numbers and emails of study staff will be prominently displayed throughout screening and consent documents, so participants can call, text or email to ask any questions they may have.

*9.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.*

*NOTE: Privacy refers to an individual's right to control access to him or herself.*

Response:

We will keep all recruitment and screening information confidential.

*9.3 Identify any materials that will be used to recruit subjects.*

*NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.*

*For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.*

Response:

Pilot Phase: Study staff will approach families in-person at each participating restaurant location and invite them to join a study where they can taste test different main dishes and sides. A sample script is available in the attachments.

Experimental Phase: Study staff will approach families in-person at each participating restaurant location and invite them to join a study on what children like to eat in restaurants. Information about the study will also be placed in the restaurant to clarify to any interested patrons why UB researchers are in the restaurant.

For remote recruitment, social media ads, table tents and/or signs in the restaurant will invite families to join a study on what children like to eat in restaurants. These tents and signs will include information about the study, in addition to contact information for study staff, who will send website links to the screening questionnaire to interested parents. The Facebook/Instagram ad will direct participants to contact study staff, mirroring the signs/posters in the restaurant. Sample recruitment scripts and samples of the study information to be placed on table tents/signs in the restaurant and the Facebook/Instagram advertisement are available in the attachments.

## 10.0 Procedures Involved

*10.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

*NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.*

Response:

Pilot Phase: If families meet the criteria gathered from the initial screen, research staff will review the details of the study procedures, and the parent/legal guardian of each child will be asked to review and sign consent forms as described herein. After consent procedures, children will be asked to taste test up to 5 main dishes (e.g. turkey sandwich, peanut butter and banana sandwich) and up to 5 sides (e.g. applesauce, carrot sticks, mandarin oranges). A visual face scale with 3-points (4-5 year-olds) or 5-points (6-8 year-olds) will then be used to aid children in rating their liking and rank-ordered preference for presented options (see attached Data Collection Form Pilot Phase and Script Pilot Phase documents). While children are completing the taste tests, participating parents will be asked to complete a brief demographic survey using either an electronic tablet or pen and paper (see attached Pilot Parent Demographic Survey Questions). After data collection is complete, families will receive $10 in cash to thank them for participating and children will receive a small prize like a sticker.

Experimental Phase: The experimental phase will be a cluster-randomized trial. Six locations of Anderson's will be paired based on income levels in the surrounding census tracts. A location from each pair will be randomized to each study group (intervention, control). Phased data collection will occur, with each pair of restaurants assigned to a cohort (see Figure 1 below). Within-restaurant measures will be collected using electronic devices (or with paper/pen if that is preferred by the participant during in-person data collection).

*Recruitment Period (about 3-4 months per cohort).* Families entering study restaurants during the recruitment period will be informed about the study opportunity and recruited into the study if interested and eligible. Consent forms will be completed electronically or on paper by parents granting permission for their child's participation as well as their own. These will also be signed by the study staff member obtaining consent. The original will be kept by the study personnel, and a copy will be given to the participants for their records. Hard copies obtained by study personnel will be kept in a locked cabinet separate from any participant data; electronic copies will be stored on a secure server separate from/not linked with participant data. Study staff will also administer assent procedures to children.

For those recruited remotely, procedures will generally be the same except potential participants entering the restaurant during the recruitment period will view written information about the study in the restaurant (e.g., on signs, table tents) rather than being informed by study staff directly. Potentially interested participants can contact study staff to receive a website link to access a screening questionnaire. Consent forms will be completed electronically by parents. For those who participate remotely, the parent only has to grant permission for their own participation, and not the child's, given that we are not including any child surveys for participants recruited remotely. In other words, for any families participating remotely, data will be collected from the parent only (see measures for more information on specific measures, as well as the attachments). Electronic copies of participant's screening and consent information will be stored on a secure server separate from/not linked with participants' study data.

After in-person recruitment, families will be asked to order and eat like they normally would and to alert study staff after they finish eating for their initial assessment, during which study staff will administer baseline study measures as described below assessing orders, intake, and demographics. Those participating in remote data collection can complete screening and consent procedures at any point in their study visit and then will be provided with a link to complete baseline measures via an online survey assessing orders and demographics, completed by the parent. There is no child survey or baseline intake assessment in remote cohorts. Parents who contact the study team but do not immediately take the survey will be sent a follow-up text about 24 hours later to see if they are still interested in participating (see recruitment scripts).

After baseline data collection, families will receive study materials in-person or via postal mail, including their debit card for study payment and related instructions, as well as intervention materials (see Sample Marketing Materials; Minor changes may be made to these for each cohort (e.g., to reflect the correct dates each year). If any changes greater than these minor changes are to be made, we will resubmit the materials to the IRB). Intervention materials include placemats – either placemats promoting special healthier featured kids' meals (intervention group; see attached Sample Marketing Materials_Menu) or generic placemats depicting the restaurant's entire children's menu (control group; Sample Marketing Materials_Menu). Intervention placemats will also promote the

upcoming opportunity for children to redeem the token that comes with all kids' meals at this restaurant for a toy instead of a dessert. Families recruited into the study will also receive paper or electronic frequent diner cards (see attached Sample Marketing Materials_Punch Card). In the intervention group, participating children must order a featured healthier meal 6 times during the exposure period to earn a free kids' meal. Information about the two featured meals will appear on the cards. Restaurant staff will validate the cards when a target meal is purchased and the card is presented (e.g., by marking an image of the meal using a novelty stamp when that meal is purchased and a paper card is presented or by scanning the image when an electronic frequent diner card is presented). Control group cards will be similar but can be used during purchases of any kids' meal. When either card is marked, the child will also receive a small prize (e.g., sticker). Restaurant staff will be trained to know which items come with the two featured meals, to allow use of the intervention group's healthy frequent diner cards only for purchases of those meals, and to only allow one purchase per card per visit.

*Exposure Period (about 2 months per cohort).* Participating families will return to the Anderson's location where they were recruited on a weekly basis during an exposure period lasting about 2 months (they will be asked to visit at least 6 times during this period). Placemats will be available at the restaurant entrance, and signage with corresponding information will be displayed. In intervention restaurants, the placemats and signs will advertise promoted meals and the opportunity for children to redeem their "dessert" token for a toy. In intervention restaurants, boxes of small assorted toys (e.g., yo-yo, action figure, mini puzzle) will be available. This opportunity will not be advertised in control restaurants, but we will offer to provide them with toys in case a customer should request one.

Participating children will be able to use their frequent diner card during this time to earn a free meal during the subsequent redemption period. Families will also be asked to complete a brief (<20 min) online survey (described below; see attachment Midpoint Online Parent Survey Questions) once per week to monitor restaurant patronage. During at least one cohort of in-person data collection, one of the midpoint assessments will also feature remote food photography (see measures), to train and prepare the participants to provide dietary intake data via remote food photography at post-test during this/these cohort(s). During at least one cohort of in-person data collection, study staff will also conduct observations of parents and children in the restaurant during this time period, within a subsample of participating families as described below (see attachments; Observation Data Collection Form and Dyadic Parent-Child Interaction Coding System (DPICS) Form).

*Redemption Period & Post Assessment (about 3 months per cohort).* Study staff will be in the restaurant throughout this period, and entering families will identify themselves to study staff using their electronic or paper frequent diner cards. Study staff will photograph or collect (if paper) or confirm the presence and status of the cards (if electronic) and ask families to order and eat like they normally would and to not throw out any food or leftovers. Families will be able to redeem

any earned free kids' meals during this time. When the family is done eating, they will take a photograph of the child's food using remote food photography methods, which involves using their electronic device (e.g., cell phone or iPad), if they are participating in a cohort in which this measure is being implemented. For all families, study staff will then approach the table to administer study measures as described below assessing orders, perspectives on the meal, and intake. Two days later, families will also be prompted to complete an online dietary recall (ASA24) about the child's dietary intake the day after their post assessment. Study materials (placemats and signs) will remain in the restaurants during the redemption/post period.

Families redeeming frequent diner cards as a part of the remote data collection will first send images of the completed diner card with ID numbers to study staff. Staff will then ask families to order and eat like they normally would and to not throw out any food or leftovers. When the family is done eating, they will alert study staff via phone, text, or email and be sent links to complete an online survey on which parents report on orders as well as take a photograph using remote food photography methods, which involves using their electronic device (e.g., cell phone or iPad), to capture the child's dietary intake at post-test (see attached mid-point Remote Food Photography one-sheet). As mentioned above, child-report survey data will not be collected for remote cohorts. These families will also be prompted to complete the online dietary recall (ASA24) about the child's dietary intake the day after their post assessment.

*Compensation.* Participating families can receive up to $300 for participating in the study ($265 for all standard assessments; plus an additional $35 if in the observed subsample). Families will receive up to $50 for completing measures at the initial time point. Then, throughout the exposure period (midpoint), they can receive up to $120: $90 of the $120 will be provided during the exposure period for completion of weekly online surveys (divided up and paid weekly), and an additional payment will be provided later for each of the weekly exposures indicated on their frequent diner card ($5 x number of exposures, max = 6; determined upon collection of the card at post-test). After the midpoint assessments, families will receive one more payment; this payment will be administered following post-test and will include up to $50 for completion of in-restaurant post-test measures (final survey; intake measures used during their cohort – i.e., weighed plate waste and/or remote food photography), plus a $20 bonus for following post-test procedures as instructed (i.e., turning in their frequent diner card at post-test if paper version; coming to originally-scheduled appointment time if in-person), $25 for completion of the online dietary intake survey (ASA24), and the aforementioned midpoint payments from frequent diner card use. Families will also receive their free kids' meal at post-test if frequent diner cards are completed, and those randomly selected to be included in the observed subsample will receive an additional $35. Children will receive a small prize (e.g., stickers) each time their frequent diner card is used. Payments will be made via a prepaid debit card provided by the study.

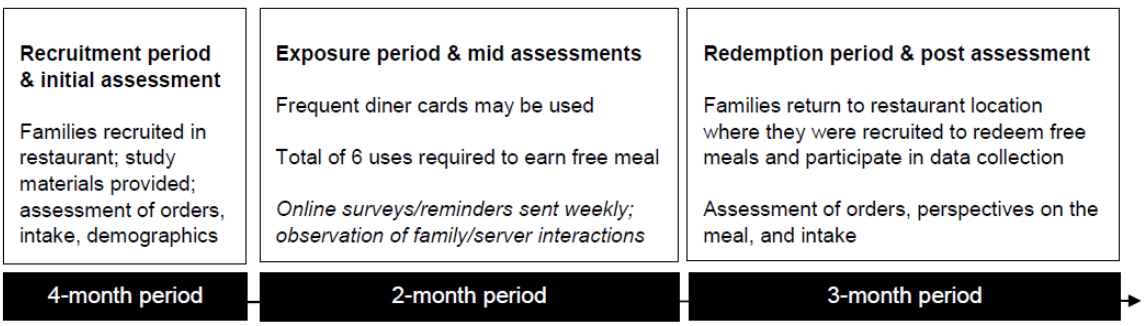


**Figure 1.** Data collection timeline for an individual cohort with main measures. These procedures will happen repeatedly over about 3-4 years to collect data from about 3-5 cohorts.

*10.2 Describe what data will be collected.*

*NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.*

Response: Data collected are detailed below. In addition, please see attachments for corresponding forms/surveys with specific questions to be administered.

Pilot Phase: We will collect data on children's liking of and preferences for the foods they taste during taste tests, as well as parent-reported demographics.

Experimental Phase: *Orders.* At initial and post-assessment time points, researchers will ask the participating parent to identify all items ordered for and eaten by the child that day and will record: 1) whether or not one of the healthier featured kids' meals was ordered, and 2) the specific main dish(es), side dish(es), beverage(s), and dessert(s) ordered for/ eaten by the child, noting whether each item was shared, taken to go, or was finished in the restaurant. Total calories, saturated fat, sugar, and sodium ordered for the child will be calculated using nutrition information available from the restaurant. At post-test, families' frequent diner cards will also be photographed or collected (if paper version) or confirmed via our electronic records (if electronic version). Researchers will record the number of marks/punches on the card, and in the intervention group, which of the healthy meals the marks correspond to. Questions about orders will also be asked via online survey at midpoints (see attachments). For those participating in the remote data collection, orders will be collected at all of these same time points via online surveys sent to participants' electronic devices.

*Sales Data.* We will collect aggregated sales data from the restaurant to monitor sales of kids' meals across all patrons in Anderson's restaurants during the recruitment, exposure, and redemption periods and parallel time points one year prior. These data are aggregated and de-identified and do not require IRB approval; therefore, the sales data are not described further herein.

*Dietary Intake at the Restaurant.* Children's dietary intake will be measured using plate waste methodology, a gold standard for measuring dietary intake. Study staff will ask the parent which items were ordered for and consumed by the target child, recording the names of the items, and will collect all uneaten food and

containers from the child's meal, sealing them in plastic bags labeled with the child's ID and the item name. Items will be post-weighed in the laboratory following data collection using a digital scale. Pre-weights will be measured by purchasing 3 replicates of each food/beverage item ordered and averaging their weights to arrive at a standard pre-weight. Grams consumed will be converted to percentages using total grams from pre-weights, and these percentages will be multiplied by the total calories, saturated fat, sodium, and sugar found in the full item to calculate calories and nutrients consumed.

Children's dietary intake will also be measured using Remote Food Photography methodology during at least one cohort of in-person data collection during the post assessment, with the opportunity to practice this at one of the midpoint visits. This will be the only measure of dietary intake in participants participating remotely, since weighted plate waste is not possible in those instances. For the Remote Food Photography assessment the parent will take a photograph (approximately 24 inches from the meal using a 45-degree angle) of the child's meal before it is eaten and a second photograph of any uneaten food following procedures outlined in the remote food photography guide and the training video (mid-point Remote Food Photography training video script attached). Photographs will be checked by study staff for proper data capture. Amount consumed will be estimated as percentages using pre-weights and photographs of menu items.

Parents will also be prompted to follow these procedures at one of the weekly midpoint assessments during at least one cohort of in-person data collection as a way to practice and receive feedback on the process prior to the main post-test dietary intake assessment. Parents will receive detailed instructions and watch a short instructional video (see mid-point Remote Food Photography training video script and mid-point Remote Food Photography one-sheet attachments) explaining how to take proper photographs of their child's meal. Parents will then practice the remote food photography method on their child's meal, sending the photographs to study stuff to check for clarity and completeness of data. Dietary intake will not be assessed at the initial/baseline time point for remote cohorts to streamline the initial assessment in the absence of in-person support.

*Total Daily Dietary Intake.* Parents will report children's daily dietary intake using the Automated Self-administered 24-hour Dietary Assessment Tool (ASA24; https://asa24.nci.nih.gov/) at post-test (focusing on the day after the post-test restaurant visit).

*Parent Perspectives & Demographics.* Using an electronic device, parents will complete survey questions. At the initial assessment these will include demographics (e.g. parent age, sex, race/ethnicity, education level, income, target child age, sex, race/ethnicity, height, weight). At initial/baseline and post-test assessments parents will indicate who selected the child's meal, the reason for the meal choice, and how often the child eats at restaurants in general and this specific restaurant. At post-test, parents will also report on their child's visits to locations of the study restaurant since our last contact with them and perspectives on the intervention components (placemats, frequent diner cards).

*Parent Mid-Point Surveys.* In an online survey parents will answer questions about their visits to locations of the study restaurant since last contact and child meal selection. They will also be asked about visits to restaurants in general, parent meal selections, parent and child liking of the meals, and general parenting practices. Parents will also complete remote food photography during one of the midpoint assessments as described above.

*Child Perspectives.* At initial/baseline and post-test assessments, study staff will interview the participating child, entering answers into an electronic tablet. Child questions will include: whether the child knew what s/he would have before arriving at the restaurant; whether s/he had been to this restaurant before; whether this was the meal s/he typically ordered; who selected the meal; and how it tasted. At post children will also answer questions about the intervention components. The child will not be interviewed (i.e. there will be no child-report survey) for remote cohorts.

*Observations of Family Interactions.* Parent-child interactions will be unobtrusively observed in a random subsample during the exposure period. Two study staff members will be at a table in the restaurant to unobtrusively observe parent-child interactions, for a total of about 10 minutes (about 5 minutes before the meal and about 5 minutes during the meal; see attachments Observation Data Collection Form, modified from those previously used by Suchi Ayala and colleagues, and Dyadic Parent-Child Interaction Coding System (DPICS) Form). This portion of the study will be conducted with a subsample of participants during select, in-person cohorts. It will not be completed (i.e. there will be no observations of family interactions) for remote cohorts. Following the brief in-restaurant observation, families in the observed subsample will complete a brief online survey (see attachment: 2023 Observation Parenting Survey). The survey will include a few questions about their experience in the restaurant during the observation as well as a few questions about parenting that used to be part of the Midpoint 1 survey, which was reduced slightly as communicated in prior modifications.

*Implementation.* At the conclusion of each cohort's data collection period, tracking of intervention components will occur (e.g. number of placemats and toys distributed). In addition, we will monitor implementation during the exposure and post periods (e.g., are study materials displayed as specified). This is not a human subjects research component and therefore it is not discussed further herein.

**Table 1.** Study outcomes by time point and measure

| | *Initial Assessment* | *Midpoint Assessment* | *Post Assessment* |
|---|---|---|---|
| **Orders (Primary outcomes)** | | | |
| Items ordered for children in study sample and their parents | P | P/F | P |
| Total calories, saturated fat, sodium, and sugar in children's orders | P/N | P/F/N | P/N |
| Children's meal orders in study restaurants overall during study period | S* | S* | S* |
| **Children's consumption (Secondary outcomes)** | | | |
| Total calories, saturated fat, sodium, sugar consumed in restaurant | W^/N | | W/N |
| Total daily calories, saturated fat, sodium, and sugar consumed | | | P (recalls) |

| **Other Variables of Interest** | | | |
|---|---|---|---|
| Demographics | P | | |
| Parent perspectives on restaurant/study experience | P | P | P |
| Child perspectives on restaurant/study experience | C^ | P | C^ |
| Observations of family interactions | | O** | |
| Other implementation measures (e.g., tracking placemats) | | | O*** |

P: parent report; F: frequent diner cards; N: nutrition information from restaurant; S: sales data; W: plate waste or food photography (remote cohort only); C: child report; O: observation. Shaded bars depict individual measures. *Colleccted throughout/ from 1 year prior to study start. **Random subsample. ***Collected after each post period. ^Not collected for remote cohort.

*10.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).*

*Include copies of these documents with your submission.*

Response:

Pilot phase:

- Script Pilot Phase
- Data Collection Form 4-5 year-olds (Pilot Phase)
- Data Collection Form 6-8 year-olds (Pilot Phase)
- Pilot Parent Demographic Survey Questions

Experimental phase:

*All in-person participants*

- Initial Visit Script (Experimental Phase)
- Initial Visit Parent Survey Questions (Experimental Phase)
- Initial Visit Parent Survey Questions QR Version (for parents who wish to leave the restaurant early without completing the interview) – (Experimental Phase)
- Initial Visit Child Survey Questions (Experimental Phase)
- Plate Waste Form (Experimental Phase)
- Post Assessment Script (Experimental Phase)
- Post Assessment Parent Survey Questions (Experimental Phase)
- Post Assessment Child Survey Questions (Experimental Phase)

*Remote cohorts only*

- Consent, Screening & Initial Visit Parent Survey Questions (Experimental Phase) [REMOTE]
- Recruitment Script (Experimental Phase) [REMOTE]
- Post Assessment Script (Experimental Phase) [REMOTE]
- Post Assessment Parent Survey Questions (Experimental Phase) [REMOTE]
- Reminder Call Email Script (Experimental Phase) REMOTE

*Both in-person and remote cohorts:*

- Mid-Point Online Parent Survey Questions

*Select participants/cohorts:*

- Mid-Point RFPM Training Video Script
- Mid-Point RFPM Participant Training One-Sheet
- Post Assessment Remote Food Photography Methodology (RFPM) Form (Experimental Phase)
- Family/ Server Observation Data Collection Forms

*10.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).*

Response:

N/A, no source records will be used to collect data about subjects.

*10.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response:

N/A, no individual subject results will be shared with subjects or others.

*10.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response:

No, study results will not be shared with subjects or others besides publication of study results in scientific journals and accompanying write-ups (e.g., conference presentations, press releases to promote published articles). All such publications will feature data in aggregate and no identifying information.

## 11.0 Study Timelines

*11.1 Describe the anticipated duration needed to enroll all study subjects.*

Response:

We anticipate it will take about 5 years to enroll all study subjects, with enrollment of each cohort taking about 3-4 months.

*11.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.*

Response:

Pilot Phase: Children will participate individually in one in-restaurant taste test session for up to 30 minutes.

Experimental Phase: Families will be recruited and enrolled during the recruitment & initial assessment period which will occur across a span of about 3-4 months per cohort. In the subsequent exposure period (a predetermined period of about 2 months to follow recruitment), families will return 6 times to the restaurant they were recruited in for a meal and will complete a brief online survey (<20 min). After this, families will return once during a predetermined period of up to 3 months for a final meal and assessment. Families will also be prompted to complete an online survey about their child's dietary intake the day after the last session. Across study periods, each family will participate for about 6 months total. The total duration of participation is the same for families recruited remotely, with minor differences in specific procedures as described herein.

*11.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).*

Response:

We estimate it will take about 6 years to complete this study.

## 12.0 Setting

*12.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.*

*NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."*

Response:

Pilot Phase: Research will be conducted at 1-3 Anderson's restaurant locations in the Western New York area. Anderson's is a quick-service restaurant open to the public.

Experimental Phase: Research will be conducted at all of Anderson's restaurant locations in the Western New York area. At the time of this writing, there are 6 locations.

*12.2 For research conducted outside of UB and its affiliates, describe:*

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

*NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.*

Response:

The sites for both research phases are local restaurants in the Western New York area. All restaurant sites adhere to health standards and codes. The study will be conducted with approval of the restaurant owner and specific location managers. The restaurant does not require its own ethical review process, so the sole review process will be that of the UB IRB.

☐ **N/A:** This study is not conducted outside of UB or its affiliates.

## 13.0 Community-Based Participatory Research

*13.1 Describe involvement of the community in the design and conduct of the research.*

*NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.*

Response:

☒ **N/A:** This study does not utilize CBPR.

*13.2 Describe the composition and involvement of a community advisory board.*

Response:

☒ **N/A:** This study does not have a community advisory board.

## 14.0 Resources and Qualifications

*14.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the*

*research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

*NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.*

Response:

All faculty, staff, and students on this protocol have completed CITI training, and all personnel interacting with children will also undergo a Background Check prior to their first data collection session, which is standard procedure for our team. At least one team member with CPR/first aid training will be at every data collection session, and multiple team members will be present at every in-person data collection session.

For remote data collection, teams will be assigned so that ~2 study staff are assigned to be "on call" during times that the participants may be in the restaurant completing study procedures, to assist as appropriate. We have set up our screening procedures so that only potential participants contacting the study team during times we plan to be available to provide support (approximately 4:30-8:30pm) will receive a link to the screening questionnaire, to ensure that we are available to support those who move forward to consent and baseline procedures. Postdoctoral associate, Mackenzie Ferrante, has experience providing support electronically during similar remote data collection and will serve as a project manager, training others on protocols and providing oversight (along with the PI).

Dr. Stephanie Anzman-Frasca (PI) has extensive experience working with parents and children and has experience in behavioral research using similar methodology to that included in this study, including collecting data from families in Anderson's and other restaurants. Dr. Leonard Epstein has extensive experience with child eating behavior research, and Dr. Lucia Leone has experience with community research related to healthy eating.

***Describe other resources available to conduct the research.***

*14.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.*

*NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.*

Response:

It is planned for the PI to devote about 40% effort to this study while it is taking place, leading and managing the project.

Co-investigators Dr. Epstein and Dr. Leone will devote about 10% and 20% effort respectively as co-investigators. Their primary roles are in the areas of study design and data interpretation. Rocco Paluch will devote 10% time as data manager.

Other research staff/students will devote between 5-40 hours a week to this project, depending on their specific role. Their primary roles will be recruitment, data collection, and data entry.

*14.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.*

*NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.*

Response:

We do not anticipate that subjects will need medical or psychological resources as a result of the study. Personnel certified in cardiopulmonary resuscitation (CPR) and first aid will be present during in-person assessments, and these individuals are trained to contact appropriate emergency medical personnel in the case of a serious event.

*14.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

Response:

All personnel working on the project are required to complete the CITI training as required by IRB. Additionally, there are procedure manuals that are read and followed by all personnel. The PI and Project Coordinators are responsible for training all staff on data collection and recording procedures.

## 15.0 Other Approvals

*15.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).*

Response:

The owner of Anderson's restaurant has indicated her approval in partnering with us on this study. She submitted a letter of support to us at the time of our NIH grant submission and has confirmed her continued interest and support prior to each study phase to date, with our most recent communication indicating her continued support in April 2022.

☐ **N/A:** This study does not require any other approvals.

## 16.0 Provisions to Protect the Privacy Interests of Subjects

*16.1 Describe how you will protect subjects' privacy interests during the course of this research.*

*NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.*

*Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."*

Response:

In both study phases all recruitment details will be kept confidential and private. Participants may complete the screening of their own free will, and thus are controlling access to their privacy. Participants will be reminded they have the right to refuse to answer any question that makes them uncomfortable, and prefer not to answer is an option on all sensitive survey questions. None of the questions that we plan to administer verbally in the public restaurant space are considered sensitive (nonetheless, participants have the option to opt out of these and any other questions/procedures involved in the study if they chose to do so). Study staff will be trained to discreetly collect the foods needed for the plate waste measurements with the goal to ensure the comfort and privacy of the participants.

*16.2 Indicate how the research team is permitted to access any sources of information about the subjects.*

*NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question **does apply** to records reviews.*

Response:

N/A, we will not be accessing any sources of information about the subjects.

## 17.0 Data Management and Analysis

*17.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.*

Response:

Pilot Phase: Child feedback will be used to determine which food components will be used in the experimental phase.

Experimental Phase: Descriptive statistics, normality plots, and study group differences will be examined for all variables, with results informing analyses (e.g., using non-parametric statistics if appropriate). Planned analyses corresponding to each aim are described below. Analyses incorporate random effects for restaurant location as required in cluster-randomized trials.

*Aim 1.* A mixed model with a binomial distribution will test whether intervention children are more likely to order a healthier promoted meal compared to controls,

with study group, time point (initial, mid1-mid6, and post), and the group-by-time interaction as fixed effects, a random effect for restaurant location, and a contrast focused on study group differences at post. Mixed models with linear distributions will compare the groups on calories, saturated fat, sodium, and sugar ordered, with the same factors. We will use sales data and chi-square analyses to compare the percentage of kids' meals ordered that were healthier featured meals in intervention versus control restaurants across the study period and separately by recruitment, exposure, and redemption periods. We will also summarize child and parent orders at each time point and the frequency of behaviors of interest (e.g., who ordered for the child) during parent-child interactions in intervention and control groups and will compare the number of kids' meals ordered in each group of restaurants against initial sales data from parallel time periods one year prior, overall, by cohort, and by recruitment, exposure, and redemption periods.

*Aim 2.* We will use mixed models with linear distributions to compare study groups on calories, saturated fat, sodium, and sugar consumed in the restaurant, with study group, time point (initial, post), and the group-by-time interaction as fixed effects and a random effect for restaurant location. We will repeat these analyses using data from repeat 24-hour dietary recalls to examine intervention effects on daily energy, saturated fat, sodium, and sugar intake among participating children (post-test only). We will also explore associations between ordering of the promoted meals and children's dietary intake within the meal and total day and will repeat aforementioned models testing intervention effects on orders and intake, incorporating child sex, age, and weight status (overweight/obese vs. normal weight) as potential covariates and effect moderators. We will also plan ancillary analyses that explore dining at Anderson's locations besides the assigned location and number of exposures as additional factors in the mixed models described above; if there are substantial missing data on number of exposures, we can treat this variable as categorical with "missing" retained as a category, to retain our sample size. Finally, if substantial demographic differences between groups are revealed, we will incorporate propensity scores into our analyses to account for this potential source of bias. Analyses will incorporate multiple imputation methods as appropriate, depending on the extent of missing data.

*17.2 If applicable, provide a power analysis.*

*NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.*

Response:

Pilot Phase: No power analysis is required for this qualitative exploratory phase.

Experimental Phase: To determine the sample size needed to test effects on orders of healthier meals, we used findings from our preliminary research, showing that 27.8% of participants exposed to study placemats and 6.7% of the control group ordered the featured healthier entrees (1). Using these values, an alpha of .05,

power of 80%, 6 cluster, and an intraclass correlation of .01 based on prior restaurant research (2), it is estimated that 124 participants will be needed to test intervention effects on meal selection.

Repeating this calculation for calories consumed in the restaurant (Aim 2), we used calories consumed among children ordering a healthier entrée (473.3 ± 197.4) or less healthy entrée (556.6 ± 199.4) in our preliminary research and the same alpha, power, intraclass correlation, and cluster values used above for an estimate of 684 participants (d=.42). To retain adequate power in the event that some recruited participants do not return at post-test, we increased this estimate by ~35%, a figure informed by show rates from prior restaurant research (3), for a final target sample of 930 families (465 per study group).

References:


1. Anzman-Frasca S, Braun AC, Ehrenberg S, Epstein LH, Gampp A, Leone LA, Singh A, Tauriello S. Effects of a randomized intervention promoting healthy children's meals on children's ordering and dietary intake in a quick-service restaurant. Physiology & Behavior. 2018; 192(1):109-117
2. Anzman-Frasca S, Mueller MP, Sliwa S, Dolan PR, Harelick L, Roberts SB, Washburn K, Economos CD. Changes in children's meal orders following healthy menu modifications at a regional US restaurant chain. Obesity. 2015; 23(5): 1055-62.
3. Kirkpatrick SI, Subar AF, Douglass D, Zimmerman TP, Thompson FE, Kahle LL, George SM, Dodd KW, Potischman N. Performance of the automated self-administered 24-hour recall relative to a measure of true intakes and to an interviewer-administered 24-h recall. American Journal of Clinical Nutrition. 2014; 100(1): 233-40.


*17.3 Describe any procedures that will be used for quality control of collected data.*

Response:

All data will be entered and quality controlled by trained staff. Data that are entered manually, which in this study includes entering data from study forms (experimental phase; e.g. plate waste measurements) will be double entered by study staff, with double entry compared and cleaned as needed.

# 18.0 Confidentiality

## A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*18.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls,*

*authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper)* ***and*** *electronic files.*

Response:

In the restaurant, all study data will be kept secured within a password-protected electronic tablet and in folders that stay with a study staff member at all times, and after a given day's session in the restaurant, data will be immediately brought back to the lab and secured as indicated below (or brought to the PI's home and kept in a locked safe and brought to the lab the next business day if needed). Foods will be labeled with participant ID numbers, stored in plastic bags in coolers, and weighed and then discarded each day in the laboratory immediately following each data collection session (applies in Experimental phase only).

Online survey data will be recorded via secure online survey software (e.g., REDCap) and downloaded to a secure location (e.g., the S drive and/or UBBox).

Paper data will be stored in a locked file cabinet in 151 Farber. Only study staff associated with the project will have access to the data. All computer files containing identifiable data will be secured, and only the PI and members of the research staff will have access to the password-protected data. Participant identities will be coded and will not be associated with any published results. Each code number and identity will be kept in a locked cabinet for up to ten years in 151 Farber after the study, at which point they will be destroyed. Any paper consent forms will be in a separate filing cabinet from data. All de-identified data will be kept indefinitely.

*18.2 A. How long will the data be stored?*

Response:

Identifiable data will be stored for up to ten years following study completion, after which the data will be destroyed. De-identified data will be retained indefinitely.

*18.3 A. Who will have access to the data?*

Response:

Only study staff working on the project will have access to the data.

*18.4 A. Who is responsible for receipt or transmission of the data?*

Response:

Dr. Anzman-Frasca is responsible for the transmission of data locally.

*18.5 A. How will the data be transported?*

Response:

Data will be transported from Anderson's restaurant back to the local site in the secure vehicle of the project coordinator or study lead.

## B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 19.0)*

*18.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.*

Response:

*18.7 B. How long will the specimens be stored?*

Response:

*18.8 B. Who will have access to the specimens?*

Response:

*18.9 B. Who is responsible for receipt or transmission of the specimens?*

Response:

*18.10 B. How will the specimens be transported?*

Response:

## 19.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

***NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.***

*19.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.*

Response:

Since the proposed study poses no greater than minimal risk to participants, a DSMB is not necessary. The Principal Investigator, Stephanie Anzman-Frasca, will be responsible for ensuring data integrity and safety monitoring of human subjects who are involved in the research.

*19.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.*

Response:

Data will be checked to make sure that:

A. All study data, including surveys and foods/plate waste forms, are coded with a unique participant ID. The ID will be linked only by name through a master list kept by the project coordinator in a password-protected file.

B. All electronic data are stored securely on password-protected server, UBBox, and/or an external hard drive locked in a cabinet in a secure room (Farber 151). All forms with participants' names, such as paper consent forms, will be kept in a locked file cabinet separate from the data.

C. When the results of the study are presented and/or published, no individual participant will be identifiable. Data will only be presented in aggregate. Identifiable data will be retained for up to ten years.

*19.3 Describe any safety endpoints.*

Response:

There are no safety endpoints.

*19.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*

Response:

Participants will be encouraged to call, text, or email study personnel if they experience any problems or difficulties, and if any adverse events (AE) are reported in a phone call, the study personnel receiving the call will record the AE. AE can also be recorded at scheduled data collection visits. AE will be recorded as soon as they are reported, and the PI and study coordinator will be made aware. The study coordinator will summarize the AE in a memo; the family will be called and the summary will be read to them to ensure that the information is accurate. The memo will then be submitted to the University at Buffalo IRB and the PI. If the PI or the IRB decide that further action is warranted, the PI and study coordinator will then formulate and carry out a plan to respond to the AE. The study coordinator will write a memo summarizing such actions; this memo will then be forwarded to the IRB.

*19.5 Describe the frequency of safety data collection.*

Response:

Pilot Phase: Recruitment will start around November 2019 pending IRB approval. Data collection will occur one time, with each participant attending only one session.

Experimental Phase: Recruitment will start around May 2021, pending IRB approval. Families will be recruited using the recruitment methods specified herein, will complete initial assessments, and will return to the same restaurant for 7 additional data collection sessions during pre-specified periods.

*19.6 Describe who will review the safety data.*

Response:

Data will be reviewed regularly and secured in 151 Farber Hall. A weekly review of study progress will be conducted by Dr. Anzman-Frasca during regular meetings with study personnel. Serious events and problems will be monitored by Dr. Stephanie Anzman-Frasca and reported to the IRB in the time frames outlined by the IRB.

*19.7 Describe the frequency or periodicity of review of cumulative safety data.*

Response:

Since the proposed study poses no greater than minimal risk to participants, a DSMB is not necessary. The Principal Investigator, Stephanie Anzman-Frasca, will be responsible for ensuring data integrity and safety monitoring of human subjects who are involved in the research.

*19.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.*

Response:

This study poses less than minimal risk; therefore, there are no stopping criteria.

*19.9 Describe any conditions that trigger an immediate suspension of the research.*

Response:

This study poses less than minimal risk; therefore, there are no stopping criteria.

## 20.0 Withdrawal of Subjects

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*20.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response:

Subjects may be withdrawn from the research if they fail to follow study procedures (i.e. failure to follow study-related directions). Subjects also have the

ability to stop participating at any time if they so choose. This includes both parents and children deciding to stop the child's participation.

*20.2 Describe any procedures for orderly termination.*

*NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.*

Response:

Participants will be debriefed about the nature of the study and the reason for their removal.

*20.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.*

Response:

Participants can withdraw from the research at any time. If participants withdraw, no further data will be collected, but any information that had been provided may be retained and analyzed.

## 21.0 Risks to Subjects

*21.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.*

*NOTE: Breach of confidentiality is always a risk for identifiable subject data.*

Response:

There are no greater than minimal physical, psychological, social, or legal risks associated with participating in the study. Children may experience some anxiety when interacting with unfamiliar study staff; however, we anticipate this feeling to be temporary.

We password protect our data in files on our secure server only accessible to study staff.

*21.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.*

Response:

Children will be with their families and will have been in the restaurant for a period of time before participating in any procedures. Thus this should increase their comfort. We do not anticipate children reaching high or prolonged levels of distress as a result of participating in this study, but if this were to occur, they would be given an opportunity to "take a break", and if still distressed, their participation would be terminated.

*21.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response:

The study involves no more than minimal risk. Subjects can refuse to answer any questions and refuse to participate in any procedures that they are not comfortable with.

*21.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.*

Response:

NA

*21.5 If applicable, describe risks to others who are not subjects.*

Response:

There is no risk to others who are not subjects.

## 22.0 Potential Benefits to Subjects

*22.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.*

*NOTE: Compensation **cannot** be stated as a benefit.*

Response:

Potential benefits include: children being more likely to choose healthy options later on after exposure to our intervention materials and enjoying interacting with the study team.

## 23.0 Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*23.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

*23.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.*

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

## 24.0 Economic Burden to Subjects

*24.1 Describe any costs that subjects may be responsible for because of participation in the research.*

*NOTE: Some examples include transportation or parking.*

Response:

Participants must be able to get to the study location of Anderson's restaurant and will purchase their family's meals there. We are recruiting families who were already in Anderson's restaurant at the time of recruitment. Therefore participants decided to patronize Anderson's as part of their usual routines and with no influence of the study. As a result, the aforementioned costs are not expected to be different from those they would have incurred without participating in the study, given that they already patronize this restaurant and dine at restaurants frequently (given screening criteria). Other than this, subjects will not be responsible for any costs as a result of participation in the research.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

## 25.0 Compensation for Participation

*25.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.*

Response:

Pilot Phase: Families will receive $10 in cash for participating and children will receive a small prize like a sticker.

Experimental Phase: Participating families can receive up to $300 for participating in the study. Families will receive up to $50 for completing measures at the initial time point. Then, throughout the exposure period (midpoint), they can receive up to $120: $90 of the $120 will be provided during the exposure period for completion of weekly online surveys (divided up and paid weekly), and an additional payment will be provided later for each of the weekly exposures indicated on their frequent diner card ($5 x number of exposures; determined upon collection of the card at post-test).

After the midpoint assessments, families will receive one more payment; this payment will be administered following post-test and will include up to $50 for completion of in-restaurant post-test measures, plus a $20 bonus for following post-test procedures as instructed (i.e., turning in their frequent diner card at post-test if paper version; coming to originally-scheduled appointment time if in-person), $25 for completion of the online dietary intake survey (ASA24), and the aforementioned midpoint payments from frequent diner card use. Families will also receive their free kids' meal at post-test if frequent diner cards are completed,

and those in the observed subsample will receive an additional $35. Children will receive a small prize (e.g., stickers) each time their frequent diner card is used. Payments will be made via U.S. Bank Card.

Payments for the remote cohort will parallel those for the in-person cohort, although the total will be slightly less ($265) due to measures that cannot be completed remotely and the goal to pay all participants equitably for the completion of the same measures.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

## 26.0 Consent Process

*26.1 Indicate whether you will be obtaining consent.*

*NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 27.0.*

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 27.0)*

*26.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.*

Response:

For both phases:

a) Screening on site: At participating Anderson's restaurant locations we will approach families who appear to have a child 4-8 years old. We will ask them if they would like to hear more about our study; if they say yes and have a child 4-8 years old we will give them some information verbally about the study. If they are interested in the study, study staff will ask screening questions, recording the information on the electronic tablet or on paper, and will be trained to determine eligibility based on the response. Eligible participants will then be invited to complete consent and enroll in the study at that time.

b) Consenting on site: The parent will fill out either an electronic consent form on an electronic tablet or a paper and pen version. They will either sign for their participation electronically or by hand on paper. Either way, the information will be kept with study personnel while in the restaurant and immediately brought back to the laboratory after data collection and secured as discussed herein.

c) Screening online: At participating Anderson's restaurant locations families will view information about the study via table tents and/or signs. Interested

families will contact study staff to receive a website link to the online screening questionnaire. Eligibility will be determined through the online screening form. Eligible parties will be invited to complete an online consent form and enroll and complete baseline data collection via online survey at that time.

d) Consenting online: The parent will fill out an electronic consent form on their personal phone, tablet, or computer. They will indicate their consent electronically. The information will be secured electronically as discussed herein.

*26.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.*

*NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.*

Response:

We will allow all subjects to take as much time as they need to read and understand the consent documents. We will readily answer any questions they may have either in person or via text, phone, or email.

*26.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.*

Response:

Subjects will only consent once to participating in the study.

*26.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:*

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

<u>Pilot Phase:</u>

☐ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

We do not plan to follow the SOP for consent. A parent will provide written consent by signing a permission form featuring study information (see attachment – Consent Pilot Phase). Parents can have as much time as they need to read the form and ask any questions they may have. We will readily answer any questions that are asked. Parents decide of their own free will to participate and agree to

allow their child to participate in the study and to participate themselves (completion of demographic questions) by signing the bottom of the form and returning it to study staff.

Experimental Phase:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)." For remote cohort(s) only we do not plan to follow the SOP for consent. Instead, study information will be provided to participants electronically upon initiation of the online survey (See attachment Screener & Initial Visit Parent Survey Questions (Experimental Phase) [REMOTE]), as we have done in similar studies (with online survey measures of parents only). Potential participants can have as much time as they need to read the study information and will be provided with contact information in case they would like to speak with study staff regarding any questions they may have. Potential participants will decide on their own free will to participate in the study, and if they decide to do so, they will indicate their agreement electronically before moving on to study procedures. This approach is planned because alternative approaches would interfere with the ability to practically carry out this minimal risk, remote (online only) study during COVID-19. We have previously provided such adapted, shortened consent documents in prior studies with similar justification pertaining to the environment in which the consent forms are reviewed. All participants will be encouraged to call or email the study team with any questions and to take as much time as they need to discuss such questions before deciding whether or not they would like to participate.

We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090).

***Non-English Speaking Subjects***

☒ **N/A:** This study will not enroll Non-English speaking subjects. *(Skip to Section 26.8)*

*26.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.*

*NOTE: The response to this Section should correspond with your response to Section 6.4 of this protocol.*

Response:

*26.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects*

*will be in that language. Indicate the language that will be used by those obtaining consent.*

*NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."*

Response:

***Cognitively Impaired Adults***

☒ **N/A**: This study will not enroll cognitively impaired adults.
*(Skip to Section 26.9)*

*26.8 Describe the process to determine whether an individual is capable of consent.*

Response:

***Adults Unable to Consent***

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 26.13)*

*When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10)* ***and, where possible, assent of the individual should also be solicited*** *(Sections 26.11 and 26.12).*

*26.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.*

*NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.*

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

*26.10* ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of*

*"legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

*26.11 Describe the process for **assent of the adults**:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.*

Response:

- *If assent will not be obtained from some or all subjects, provide an explanation of why not.*

Response:

*26.12 Describe whether **assent of the adult** subjects will be documented and the process to document assent.*

*NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.*

Response:

***Subjects who are not yet Adults (Infants, Children, and Teenagers)***

☐ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 27.0)*

*26.13 Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

*NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.*

Response:

Four to 8-year-old children are the subjects of this research study (both phases). The participating caregiver (parent/legal guardian) will be asked

to provide permission for their child to take part in the research study. Only one caregiver will be asked to provide permission for their child to participate. The participating caregiver must be at least 18 years of age.

This does not apply for any families participating remotely during the experimental phase: i.e. for those families, we are not collecting any data from children.

*26.14* ***For research conducted outside of New York State****, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

The research study will not be conducted outside of New York State.

*26.15 Describe whether parental permission will be obtained from:*

Response:

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

*NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."*

*26.16 Describe whether permission will be obtained from individuals* ***other than parents****, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

One parent or legal guardian will be required to provide permission for their child to participate.

*26.17 Indicate whether assent will be obtained from all, some, or none of the* ***children****. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

Assent will be obtained from all children participating in data collection. For families participating in the experimental phase remotely, the child will not be a participant (parent only).

*26.18 When assent of children is obtained, describe how it will be documented.*

Response:

Assent will be obtained for all children participating in data collection (see attached Script and Assent forms; see also prior response). The data collectors will follow scripts, asking for the child's assent before proceeding with data collection. The data collectors will indicate with the child's records whether assent has been obtained (see Consent Forms, both phases). In all phases, if the child does not assent, data collection will be terminated. Children's parents will have also consented for the child's participation and will be present in the restaurant at all times during all phases.

## 27.0 Waiver or Alteration of Consent Process

***Consent will not be obtained, required information will not be disclosed, or the research involves deception.***

☒ **N/A:** A waiver or alteration of consent is not being requested.

*27.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.*

*NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.*

Response:

*27.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:*

Response:

## 28.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
*(Skip to Section 29.0)*

*28.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.*

*NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.*

*If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).*

Response:

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

Note: See notes above and attachments for the different forms to be used in Pilot versus Experimental phase.

For remote experimental cohorts only we do not plan to follow the SOP for consent. Instead, study information will be provided to participants electronically upon initiation of the online survey (See attachment Screener & Initial Visit Parent Survey Questions (Experimental Phase) [REMOTE]). Potential participants can have as much time as they need to read the study information and will be provided with contact information in case they would like to speak with study staff regarding any questions they may have. Potential participants will decide on their own free will to participate in the study, and if they decide to do so, they will indicate their agreement electronically before moving on to study procedures. This approach is planned because alternative approaches would interfere with the ability to practically carry out this minimal risk, remote (online only) study during COVID-19. We have previously provided such adapted, shortened consent documents in prior studies with similar justification pertaining to the environment in which the consent forms are reviewed. All participants will be encouraged to call or email the study team with any questions and to take as much time as they need to discuss such questions before deciding whether or not they would like to participate.

## 29.0 Multi-Site Research (Multisite/Multicenter Only)

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

*29.1 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as:*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

*29.2 Describe the method for communicating to engaged participating sites:*

- *Problems*
- *Interim results*
- *Study closure*

Response:

*29.3 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.*

Response:

*29.4 If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.*

Response:

## 30.0 Banking Data or Specimens for Future Use

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*30.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

*NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).*

Response:

*30.2 List the data to be stored or associated with each specimen.*

Response:

*30.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*

Response:

## 31.0 Drugs or Devices

☒ **N/A:** This study does not involve drugs or devices. This section does not apply.

*31.1 If the research involves drugs or devices, list and describe all drugs and devices used in the research, the purpose of their use, and their regulatory approval status.*

Response:

*31.2 Describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.*

Response:

***If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:***

*31.3 Identify the holder of the IND/IDE/Abbreviated IDE.*

Response:

*31.4 Explain procedures followed to comply with FDA sponsor requirements for the following:*

| | *Applicable to:* | | |
|---|---|---|---|
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** | |
| ***21 CFR 54*** | ***X*** | ***X*** | |
| ***21 CFR 210*** | ***X*** | | |
| ***21 CFR 211*** | ***X*** | | |
| ***21 CFR 312*** | ***X*** | | |
| ***21 CFR 812*** | | ***X*** | ***X*** |
| ***21 CFR 820*** | | ***X*** | |

Response:

## 32.0 Humanitarian Use Devices

☒ **N/A:** This study does not involve humanitarian use devices. This does not apply.

*32.1 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.*

Response:

*32.2 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.*

Response: