

Official Title:	Developing Tailored Clinical Resources for Promoting Children's Healthy Food Preferences
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University at Buffalo Institutional Review Board (UBIRB)

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)

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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 6, 21, 22, 24, 25, 26 and 27 do not apply.*
 - *For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.*

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 Example

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: Developing tailored clinical resources for promoting children's healthy food preferences

PRINCIPAL INVESTIGATOR:

Name

Department

Telephone Number

Email Address

Response:

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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response: Version 3, 3/20/2025

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	2/6/2025	Additional inclusion criteria for parents/guardians such that they must be the primary caregiver to the child to participate. Changes to surveys and consent form to reflect this change. Changes to scripting to clarify procedures for participants. Additional questions asked to parents/guardians regarding their child's behavior the day of the visit. Additional materials (script cards, taste test tips card, parent packet) to facilitate procedures and clarify instructions for participants.	Yes

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response: This study is funded by a Pilot Studies grant from Buffalo's Clinical and Translational Science Institute.

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 pilot work will be funded by the University at Buffalo's Clinical and Translational Science Award (CTSA).

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: Division of Behavioral Medicine

Address: 151 Farber Hall, University at Buffalo South Campus

Department: Pediatrics

1.0 Study Summary

Study Title	Developing tailored clinical resources for promoting children's healthy food preferences
Study Design	Interventional
Primary Objective	To identify feasible and acceptable food preference learning approaches for families with young children who are likely to need strategies beyond simple repeated exposure
Secondary Objective(s)	To conduct an initial test of the efficacy of the alternative food preference learning approaches, associative conditioning and modeling To develop initial clinical resources for promoting healthy child food preferences

Research Intervention(s)/ Investigational Agent(s)	Families will be randomly assigned to either an associative conditioning (AC) or modeling group. Parents will complete 2 vegetable taste exposures with their child in each of the 4 intervention weeks. In the associative conditioning group, during exposures, a target vegetable will be served to the child with a liked dip. In the modeling group, the vegetable will be served to both the child and parent and enjoyed by the parent. 8 servings of the target vegetable will be provided to each family, with tastings to occur at home.
IND/IDE #	
Study Population	Young children aged 18-36 months and one of their parents (or legal guardians)
Sample Size	Approximately 40 parent-child dyads
Study Duration for individual participants	About 6 weeks
Study Specific Abbreviations/ Definitions	Associative conditioning (AC)

2.0 Objectives*

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

Response:

Aim 1. To examine the feasibility and acceptability of 2 alternative food preference learning approaches among families with 18-to-36-month-olds who are less likely to respond to mere repeated exposure

Aim 2. To conduct an initial test of the efficacy of the alternative food preference learning approaches

Aim 3. To develop initial clinical resources for promoting healthy child food preferences

2.2 *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:

Hypothesis: In both the associative conditioning and modeling groups, children will show greater liking and intake of the target food post-intervention compared to baseline.

3.0 Scientific Endpoints*

3.1 *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:

The main scientific endpoints are the child's vegetable acceptance and intake.

4.0 Background*

4.1 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:

Children's diets are poor quality, with implications for the development of diet-related diseases, such as obesity and diabetes. Diet-related diseases disproportionately affect low-income and racial and ethnic minority families, creating a health equity issue. Repeated taste exposure is a strategy with a rigorous evidence base supporting its effectiveness in increasing liking and intake of new or previously disliked foods. This has promoted acceptance of nutritious foods like vegetables, which are often initially rejected by children due to their lower levels of sweetness and/or higher levels of bitterness relative to other foods. While robust, the evidence base has had a limited consideration of individual differences and of ecologically-valid interventions that mirror the contexts in which children encounter target foods [1]. Filling these gaps could address missed opportunities to translate experimental food preference learning research to tailored, evidence-based, user-friendly clinical guidance.

While repeated exposure has been effective overall, some children do not respond to the approach as well. For example, children who are higher on "food fussiness" are likely to refuse to taste new or previously disliked foods. Families living with low incomes may also find repeated exposure to be infeasible if initial exposure attempts result in food waste. In 18 focus groups conducted with low-income African American and Hispanic parents, a key theme that emerged was that parents generally avoided serving previously rejected foods to avoid food waste [2]. In a rare study examining how individual traits relate to repeated exposure effects, young children aged 4 to 38 months who had been repeatedly exposed to artichoke purée demonstrated 4 distinct patterns of eating behavior. While the largest group (40%) was comprised of "learners" who increased their intake over time as expected, most children did not. Three additional patterns of behavior were observed, including "non-eaters", with results suggesting that approaches beyond repeated exposure are needed, particularly for children higher on food fussiness [3].

Children who do not respond to mere repeated exposure, or non-responders, have largely been ignored in food preference learning literature, resulting in a need to

understand which alternative food preference learning strategies promote acceptance of healthy foods among children who are unlikely to respond to simple repeated exposure and to assist clinicians in translating learnings to practice. Potential alternative strategies in the literature include associative conditioning, in which a target food becomes more well-accepted after repeated pairings with a liked food, such as a dip, and modeling, in which the child learns to accept a target food after watching someone else enjoy it [4]. Research provides some support for these strategies, but they have not been tested specifically among children who are less likely to respond to repeated exposure. Efforts to identify alternative strategies that meet the needs of this population would have a meaningful impact on research and practice related to food preference learning. The current pilot study is designed to inform the selection of programs for an adaptive intervention (“SMART”) trial, which will expedite our understanding of which food preference learning strategies are the best fit for different subgroups of young children. We also aim to provide clinicians with tailored, user-friendly resources that could help a broad population of young children establish healthy food preferences, including those children who require strategies beyond simple repeated exposure and thus may need these interventions the most.

4.2 Include complete citations or references.

Response:

1. Anzman-Frasca S, Moding KJ, Forestell CA, Francis LA. Applying developmental science concepts to improve the applicability of children’s food preference learning research. *Child Development Perspectives*. 2022;16(3):180-7.
2. Goodell LS, Johnson SL, Antono AC, Power TG, Hughes SO. Strategies low-income parents use to overcome their children’s food refusal. *Maternal and Child Health Journal*. 2017;21:68-76.
3. Caton SJ, Blundell P, Ahern SM, Nekitsing C, Olsen A, Moller P, et al. Learning to eat vegetables in early life: the role of timing, age and individual Eating Traits. *Plos One*. 2014;9(9):1-10.
4. Anzman-Frasca S, Ventura AK, Ehrenberg S, Myers KP. Promoting healthy food preferences from the start: A narrative review of food preference learning from the prenatal period through early childhood. *Obesity Reviews*. 2018;19(4):576-604.

5.0 Study Design*

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

Response:

The study will be interventional. Families, stratified by child age and sex, will be randomized to 1 of 2 study groups: associative conditioning or modeling. Both groups will attend two laboratory visits, one for baseline and one post-intervention assessment, and will complete eight target vegetable taste exposures across four intervention weeks.

6.0 Study Intervention/Investigational Agent

6.1 *Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

Response:

During the four-week intervention period, children in the associative conditioning group will be served the target vegetable with a liked dip. In the modeling group, the target vegetable will be served to both parent and child and enjoyed by the parent. The target vegetable will be a vegetable that is typically non-preferred in prior food preference learning research. During screening, parents will be asked questions that will help us to select their child's target vegetable (and dip if applicable). Using 2-3 vegetables from the literature, parents will report on whether they have served each of those vegetables and whether their child tasted it. They will be asked to rank those vegetables in order of preference for whether they would like their child to eat that vegetable, which will inform which vegetable will be chosen as the target vegetable to be tasted by the child during the study. Our goal is to assign a vegetable that the child could use help learning to like/eat, that the parent would also like to serve at home. During screening, parents will also be asked to rate their child's liking of specific dips, which will inform which dip is provided to those that are assigned to the associative conditioning group (i.e. a dip we think they will like). Vegetables, and dips if applicable, will be provided for both study groups.

6.2 *Drug/Device Handling: If the research involves drugs or device, 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.*

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Response:

N/A

6.3 *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:*

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	<i>Applicable to:</i>		
<i>FDA Regulation</i>	<i>IND Studies</i>	<i>IDE studies</i>	<i>Abbreviated IDE studies</i>
<i>21 CFR 11</i>	<i>X</i>	<i>X</i>	
<i>21 CFR 54</i>	<i>X</i>	<i>X</i>	
<i>21 CFR 210</i>	<i>X</i>		
<i>21 CFR 211</i>	<i>X</i>		
<i>21 CFR 312</i>	<i>X</i>		
<i>21 CFR 812</i>		<i>X</i>	<i>X</i>
<i>21 CFR 820</i>		<i>X</i>	

Response:

N/A

7.0 Local Number of Subjects

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

Response:

We will enroll approximately 40 parent-child dyads with approximately half of the sample randomly assigned to the associative conditioning group and half to the modeling group.

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

Response:

Our inclusion criteria are that children in participating families must be 18-36 months old and not diagnosed with a serious physical or mental health condition that would impact study participation (e.g., allergies to study foods, diagnosed ARFID or autism). The participating adult must be the parent or legal guardian of the child, the primary caregiver of the child, and be 18 years or older. Families must also be English speaking.. Children also must be higher on food fussiness, defined as a 2.5 or above on the Child Eating Behavior Questionnaire for toddlers. We will recruit across the socioeconomic spectrum with no restrictions on income. We anticipate that about 100 families would need to be screened in order to identify 40 eligible families.

7.3 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:

Parents (or legal guardians) will be recruited from the Buffalo, New York area, via one or more of the following methods: Secure databases of interested families maintained by the Division of Behavioral Medicine and approved for use by previous IRB committees, the Buffalo Research Registry (CTSI), or Research

Match. Postcards or flyers sent via direct mail. Flyers, brochures and drop boxes for participant contact information placed in areas within the Greater Buffalo community that are frequently visited by families such as community centers, libraries, community health/WIC clinic bulletin boards, grocery/convenience stores, community events, university campuses, childcare centers. In-person recruitment may also take place at community sites as needed (and only when permission is granted by the sites). Our lab staff may also connect with local schools and childcare centers and, if these facilities are willing, send children home with recruitment materials. Advertisements using our laboratory's social media accounts (Facebook, Twitter, and Instagram) and website, or email/text advertisements distributed to contact lists via our partner organizations (e.g., 211 Western New York). Corresponding materials have been uploaded (Recruitment Flyer, Recruitment Postcard, Email Text, Text Message Text). Recruiting the proposed number of subjects during this 1-year study is feasible. For example, in a recent 1-year study of parents with young children (in this case 2-5 years old), we used 211 Western New York contact lists as a key recruitment method, as well as some other avenues named herein, and received more than 2000 responses to our screening questionnaire. Screening will be completed online or via phone.

8.0 Inclusion and Exclusion Criteria*

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

NOTE: This may be done in bullet point fashion.

Response:

Families will be eligible if they meet all of the following criteria:

- Child is 18-36 months old
- Parent/guardian is 18 years of age or older
- Parent/guardian participating is the primary caregiver of the child
- Child is not diagnosed with a physical or mental health condition (e.g., allergies to study foods, ARFID or autism diagnosis) that would impact safe or feasible participation
- Participants are English speakers
- Child is high on food fussiness, defined as a 2.5 or above on the Child Eating Behavior Questionnaire for toddlers

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

NOTE: This may be done in bullet point fashion.

Response:

Families will be ineligible if:

- The child is outside the age range of 18-36 months at enrollment, as verified by birth date
- Child is diagnosed with a physical or mental health condition that precludes safe or feasible participation
- The parent/guardian is <18 years old
- The parent/guardian participating is not the primary caregiver of the child
- Participants are not English speakers
- Child is low on food fussiness, defined as below a 2.5 on the Child Eating Behavior Questionnaire for toddlers

8.3 *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

8.4 *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:

Given the pilot nature of this study, we will restrict participation to those parents and children who speak English. At this stage, the sample and scope are small enough that conducting the study in more than one language (e.g., having non-

English speaking staff, developing intervention materials in other languages) is not feasible.

9.0 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.

9.1 For research that involves **pregnant women**, safeguards include:

NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

The focus of this study is not pregnant women; however, a child's parent may be pregnant while participating in this study. There is no more than minimal risk for pregnant women, as their only involvement includes interacting with their child and completing survey questionnaires.

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

9.2 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.

9.3 For research that involves **prisoners**, safeguards include:

NOTE CHECKLIST: Prisoners (HRP-415)

Response:

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

9.4 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 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").

9.5 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.

9.6 *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:

While we are recruiting broadly, this study will include at least some families living with low income. 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 that they may have, that 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 (e.g., surveys) for any participants who are more comfortable with this mode of completion.

10.0 Eligibility Screening*

10.1 *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 online through a survey or over the phone for eligibility criteria (see attachments "CTSI Screener"). Child age will be confirmed by verification that the child would be between 18-36 months old at enrollment based on reported child date of birth at screening.

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

11.0 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.

11.1 *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:

Children and one of their parents (or legal guardians) will be recruited in 2025 from the Buffalo, New York area, via one or more of the following methods: Secure databases of interested families maintained by the Division of Behavioral Medicine and approved for use by previous IRB committees, the Buffalo Research Registry (CTSI) or Research Match. Postcards or flyers sent via direct mail. Flyers, brochures and drop boxes for participant contact information placed in areas within the Greater Buffalo community that are frequently visited by families such as community centers, libraries, community health/WIC clinic bulletin boards, grocery/convenience stores, community events, university campuses, childcare centers. In-person recruitment may also take place at community sites as needed (and only when permission is granted by the sites). Our lab staff may also connect with local schools and childcare centers and, if these facilities are willing, send children home with recruitment materials. Advertisements using our laboratory's social media accounts (Facebook, Twitter, Instagram) and website or email/text advertisements distributed to contact lists via our partner organization (e.g., 211 Western New York).

11.2 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 not contact anyone who has requested to be removed from our Division's database of contact information, and we will keep all recruitment and screening information confidential.

11.3 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:

For recruitment, materials we will use include email/text invitations, flyers, and advertisements on social media. Phone call and text communications will be conducted via Google Voice. Sample recruitment text that would appear in these different formats for each phase of the study is available in the attachments (see "Recruitment Flyer", "Recruitment Postcard", "Email Text, Text Message Text")

12.0 Procedures Involved*

*12.1 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:

After screening, a ~1 hour baseline laboratory visit will be scheduled. During the visit, written informed consent (parent) and verbal assent (child) will be completed. The child will be able to play with toys in the waiting room with the research staff and parent prior to the assent procedures to allow the child to acclimate to the environment and staff.

Children will then be told that it is time to taste foods, and that they will come to a different room, with study staff and their parent, if they would like to do this activity. Vegetables will then be served to children (without any accompaniments/dip or modeling), and children's liking and intake will be measured via parent perceptions of liking and weighed plate waste, respectively. The child will be asked to try a bite of the vegetable. Then one-half cup of the study vegetable will be provided to the child, and they will be told they can eat as much or as little of the vegetable as they like. Parents will be asked to rate how much they think their child liked the vegetable, and the vegetable will be pre and post weighed to indicate consumption.

At this visit, parents will also complete a survey that includes questions about demographics (see Baseline Survey). At the end of the session, families will receive their U.S. Bank Cards, and will be randomized (i.e., associative conditioning or modeling groups) and provided with the intervention materials needed to complete the at-home exposures, including the target vegetable, instructions, and dips if applicable. Study staff will provide and explain the activity materials to families. Parents will be given opportunities to ask any questions, and staff will be trained to provide guidance and help problem solve implementation barriers as needed. Staff will also confirm participants' preferred contact information.

During the 4-week intervention period, parents will complete 2 exposures per week (8 total). During exposures, children in the associative conditioning group will be served a target vegetable with a liked dip. In the modeling group, a target vegetable will be served to both parent and child, with specific instructions provided to the parent on how to taste and react to the vegetable. Text reminders will be sent prior to each week to remind parents about the exposures. We will recommend conducting the exposures at a consistent, convenient time on each exposure day that is prior to a planned mealtime. Parents will also complete brief, <5 minute, surveys at the end of each week that will be sent via text message (or email if preferred). Surveys will be sent at the end of each week at the same time of day, and families will receive one reminder text/email the following day if they have not completed it yet (see attachment "Reminder Script"). Surveys will assess whether the tastings were implemented as assigned, whether the child tasted/ate the vegetable, and parent perceptions of the child's liking of the vegetable.

Following the 4-week intervention period, families will attend a post-intervention assessment in the lab (~1 hr). Children's liking and intake of the target will be assessed. The target vegetable will be served without dip or modeling, as at baseline, and parents will complete an audio-recorded, structured interview regarding their thoughts on the program they received during the study, strategies they use to feed their child, and views on potential clinical tools. Study staff will play with the child with toys in the waiting area while the parent completes the interview.

12.2 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.

Demographics. Parents will answer demographic questions including child age, sex, and race/ethnicity, as well as parent age, sex, race/ethnicity, education level, and annual household income. Some demographic questions are included in the screening questionnaire and others are included in the baseline survey, as shown in the attachments.

Food Insecurity Screener. The Food Insecurity Screener is a two-question screening tool used to determine food insecurity status.

Child Food Fussiness. The Food Fussiness subscale of The Child Eating Behaviour Questionnaire (CEBQ), a validated parent-report measure, will be used to examine child food fussiness. The Food Fussiness subscale is a 6-item assessment of children's rejection of familiar and/or novel foods. Ratings range from 1 (never) to 5 (always), with greater total scores indicating higher levels of food fussiness. This measure will be administered at screening given inclusion criteria (see Screener).

Intervention Implementation. Implementation fidelity. Parents will report on exposure completion via brief, <5 minute weekly online surveys (e.g., whether the tastings were implemented as assigned, whether the child tasted/ate the vegetable and how much was eaten, and perceptions of the child's liking). Intervention acceptability. During post-test, parents will complete a brief structured interview with study staff on vegetable feeding strategies they have tried in the past, their thoughts on the program they received during the study, and views on potential clinical tools. Interviews are estimated to take 15-20 minutes and will be recorded, transcribed verbatim, and coded for themes.

Weighed Intake: Children's vegetable intake will be measured using plate waste methodology, a gold standard for measuring dietary intake. Pre-weights will be measured in the laboratory using a calibrated digital scale before items are served. Items will be post-weighed after the child is done eating. Grams consumed will be converted to percentages using total grams from pre-weights, and these

percentages will be multiplied by the total calories in the item to calculate calories consumed.

Food Liking: After the child tastes the vegetables and prior to the ad-libitum intake portion of the session, the parent will be asked to indicate using a Likert scale how much they think the child liked the vegetables.

12.3 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:

- Screener
- Baseline Visit Script
- Baseline Parent Survey
- Baseline Plate Waste Form
- Intervention Period Instructions/Scripts for Parents' Intervention Implementation
- Intervention Period Parent Surveys
- Post Parent Survey
- Communications Scripts (ex. text reminders)
- Post Visit Script
- Post Plate Waste Form
- Post Interview Guide

12.4 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.

12.5 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:

No individual subject results will be shared with subjects or others.

12.6 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). All such publications will feature data in aggregate and no identifying information.

13.0 Study Timelines*

13.1 Describe the anticipated duration needed to enroll all study subjects.

Response:

Enrollment will occur on a rolling basis over about 8 months. Recruitment will begin in early 2025, pending IRB approval. Recruitment will continue to Fall 2025 or until sample size goals are reached.

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

Response:

Families will attend one baseline lab visit which will last about 1 hour. Following this visit, there will be a 4-week intervention period. Families will then attend a final post-intervention lab visit, also about 1 hour in duration. The total duration of the study for each individual participant is approximately 6 weeks.

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

Response:

The proposed project will take place over approximately 1 year.

14.0 Setting

14.1 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: Research will be conducted in the Child Health and Behavior Laboratory located in 151 Farber Hall. The Child Health and Behavior Lab is a locked suite with multiple private rooms.

14.2 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:

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

15.0 Community-Based Participatory Research

15.1 *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.

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

Response:

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

16.0 Resources and Qualifications

16.1 *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 for human subjects research. 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 data collection session.

Dr. Stephanie Anzman-Frasca (PI) has extensive experience working with parents and young children and has experience in behavioral research with methodology included in this study. The project coordinator for this study has experience in

behavioral research with human subjects and is serving in a lead role in data collection with children and families. All research assistants and study personnel will be trained by the Project Coordinator and/or PI before interacting with human subjects.

Describe other resources available to conduct the research.

16.2 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 10% effort to this study while it is taking place, and for the Project Coordinator to devote 25-50% effort. Together, these individuals will lead and manage the project on a day-to-day basis.

Student research assistants will each devote approximately 8 hours a week to this research during the recruitment and data collection periods; their primary roles will be assisting with recruitment, data collection, and data entry.

16.3 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 at study visits, and these individuals are trained to contact appropriate emergency medical personnel in the case of a serious event.

16.4 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 Coordinator are responsible for training all staff on data collection and recording procedures.

17.0 Other Approvals

17.1 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:

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

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 *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:

The recruitment procedures described in this protocol make use of posted flyers and web posting. Participants may call the laboratory or complete the online screening questionnaire of their own free will, and thus are controlling access to their privacy. Other participants will be recruited using the secure database of interested participants maintained by the Division of Behavioral Medicine and approved for use by previous IRB committees. During the initial phone or online screening, data will be collected in the secure laboratory environment and will be recorded within password-protected files, to which only select staff have access. All information will be treated in strict confidence to the extent provided by the law. Participants' identities will be coded and not associated with any published results. Each code number and identity will be kept in locked cabinets for up to 10 years after study completion, at which point all identifiable information will be destroyed. In addition, all computer files containing identifiable data will be secured, and only the PI and members of the research staff will have access to the data.

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.

18.2 *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:

Participants will be recruited using a secure database of interested participants maintained by the Division of Behavioral Medicine and approved for use by previous IRB committees. Potential participants will be contacted if they had

indicated previously that they would be willing to be contacted for participation in future studies and thus control their own participation. The database is a powerful recruitment tool and will help in rapidly recruiting enough parent-child dyads to participate.

19.0 Data Management and Analysis*

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

Response:

Data will be reviewed by the study team.

Aim 1: Feasibility and acceptability will be summarized using descriptive statistics (survey data) and thematic analysis (interview data). We will examine the percentage of assigned tastings that were implemented as intended and whether this varies by group or individual or family characteristics. We will summarize parent feedback including barriers and facilitators to implementing programs and refinements that may improve the programs.

Aim 2: We will use paired samples t-tests to test whether children's liking and intake of the target food increase from baseline to post-test (or an analogous non-parametric test if appropriate). Liking and intake are defined as parent perceptions of the child's liking of the food and weighed plate waste, respectively.

19.2 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:

No power analysis is required for this exploratory phase.

19.3 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, will be double entered by trained study staff members and subsequently compared/cleaned.

20.0 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.

20.1 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:

Data collected during the study 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 encrypted, 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 10 years following study completion either in 151 Farber or in one of the PI's team's secure offices in the same building, at which point they will be destroyed. Paper consent forms will be in a separate filing cabinet from data. In addition to being stored in REDCap, online survey data will be extracted and stored securely (e.g., on our S drive or UBBox) and protected as described herein.

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

Response:

Identifiable data will be stored for up to 10 years after study completion, after which the data will be destroyed. De-identified data will be retained indefinitely.

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

Response:

Only study staff working on the project will have access to the data. Study staff will primarily access the data in 151 Farber Hall.

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

Response:

Dr. Anzman-Frasca (PI) is responsible.

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

Response:

No transportation will occur.

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 21.0)

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

Response:

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

Response:

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

Response:

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

Response:

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

Response:

21.0 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.*

21.1 *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.

21.2 *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 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, including audio data, are stored securely on password-protected server and/or UBBox. 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. Names will not be used in any sample quotes drawn from open-ended questions. Data will only be presented in aggregate. Identifiable data will be retained for up to 10 years after the study's completion.

21.3 Describe any safety endpoints.

Response:

There are no safety endpoints.

21.4 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 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 contacted and the summary shared with 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.

21.5 Describe the frequency of safety data collection.

Response:

N/A, this study involves less than minimal risk so there will be no safety data collection.

21.6 Describe who will review the safety data.

Response:

Data will be reviewed regularly and secured in 151 Farber Hall and electronically as described herein. 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.

21.7 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.

21.8 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.

21.9 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.

22.0 Withdrawal of Subjects*

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

*22.1 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.

22.2 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.

22.3 *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.

23.0 Risks to Subjects*

23.1 *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 this study. Children may experience some anxiety when interacting with unfamiliar study staff and may dislike foods that they are asked to try during the study; however, we anticipate this feeling to be temporary, and children can decide at any time that they no longer wish to participate or try offered foods.

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

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

Response:

There will be a “warm-up period” for children to become acclimated to the environment while their parents complete consent forms and surveys. 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. Children in this age group often have separation or stranger anxiety and therefore we have built in this “warm up period” and also will ensure their parent is nearby and visible to them throughout all study tasks.

23.3 *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.

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

Response:

Pregnant women are not the focus of this study, but it is possible that one of the children's parents could be pregnant. There are no risks to an embryo or fetus beyond those in everyday life.

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

Response:

There is no risk to others who are not subjects.

24.0 Potential Benefits to Subjects*

24.1 *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: enjoying participating in the study procedures and interacting with study staff and children being more likely to eat vegetables after participating.

25.0 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.

25.1 ***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:

25.2 *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:

26.0 Economic Burden to Subjects

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

NOTE: Some examples include transportation or parking.

Response:

To participate in the study, subjects must be able to get to our laboratory on South Campus. We will offer reimbursement for bus/train fare if the participant expresses that they need assistance with reimbursement to campus. Subjects will not be responsible for any other costs as a result of participation in the research. They will be paid for their time, with all study supplies provided.

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

27.0 Compensation for Participation

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

Response:

Families will receive \$150 for successfully completing all components of the 6-week study: \$30 for the baseline visit, up to \$15/week for successfully completing intervention period activities and assessments, \$50 for successfully completing the post assessment, and a \$10 bonus if all appointments were kept as originally scheduled. Families will also receive everything they need to complete the intervention activities (e.g., vegetables, instructions). Financial reimbursement for public transportation costs will be provided if needed, so that transportation challenges are not barriers to participation.

☐ **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.

28.0 Consent Process

28.1 *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 29.0.

☒ **Yes** (If yes, Provide responses to each question in this Section)

☐ **No** (If no, Skip to Section 29.0)

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

Response:

a) Initial email or phone screen –

Upon receiving an inquiry from a prospective participant, the study will be explained. If the prospective participant is interested in joining the study, they will be asked (on the phone or via online survey) if they would like to continue to eligibility screening. The initial screening questionnaire can be done via phone or online; in both cases, information will be recorded through the online survey and stored in password-protected files. If the adult consents to the information from the phone screen being stored, there is a button to click that indicates they have been asked and agreed.

b) Baseline –

If families meet the criteria gathered from the initial screen, they will be scheduled for their first laboratory session. At the session, there will be an overview of the study. Consent forms will be signed by all parties involved: the person obtaining consent and the parent. Signed copies of each will be obtained by the study personnel, and copies will be given to the participants for their records. The copy obtained by study personnel will be kept in a locked cabinet as described herein.

28.3 *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.

28.4 *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.

28.5 *Indicate whether you will be following “SOP: Informed Consent Process for Research (HRP-090).” Pay particular attention to Sections 5.4-5.9. 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:

- ☒ 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 28.8)

28.6 *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 8.4 of this protocol.

Response:

28.7 *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, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. 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 28.9)

28.8 *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 28.13)

*When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) **and, where possible, assent of the individual should also be solicited** (Sections 28.11 and 28.12).*

28.9 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).”

28.10 **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:

28.11 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:

28.12 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 29.0)

28.13 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:

18-36-month-old children are the subjects of this research study. The participating caregiver (parent/legal guardian) will consent for their own participation and will also 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 and be a parent or legal guardian of the child. Participants will be asked to indicate their age on the initial phone/in person screen, and only parents 18 and older will be invited to take part in the study.

28.14 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.

28.15 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)."

*28.16 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.

*28.17 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:

Verbal assent will be obtained from all children in a developmentally appropriate manner. After the warm up period, we will explain to children that we will move on from the waiting room where they are playing to another room where they can do some food tastings, and that their parent will come with them. We will ask them if they'd like to follow us to do the tasting. If children do not wish to follow us to the study room and proceed with the study procedures, their participation can be terminated. We will treat the baseline period as a run-in period and replace any families who do not make it to randomization (i.e. who do not successfully complete the tasting portion of the baseline visit).

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

Response:

Since children are all under the age of 7, their assent will be confirmed as described above (see Scripts). Assenting children will follow us to the study room and engage in the tastings. If children do not wish to do so, study procedures would end, and their lack of assent will be noted in our records.

29.0 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.

29.1 *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:

A consent waiver is requested for our screening process for the following reason: in order to recruit participants using the option of the Division of Behavioral Medicine’s secure database of interested study participants, the study requires access to identifiable records (potential participants’ names, phone numbers) without participants’ consent to participate in this particular study. These individuals have, however, indicated that they would be interested in participating in future studies, which is why they are included in the database.

This study is not greater than minimal risk. Participants will be recruited using a secure database of interested participants maintained by the Division of Behavioral Medicine and approved for use by previous IRB committees. Potential participants will be contacted if they had indicated on a previous phone call that they would be willing to be contacted for participation in future studies and thus controlling their own participation. There is no risk to calling these individuals and asking if they would like to participate.

In addition, participants may see our lab’s information via another recruitment avenue (e.g., on a flyer or ad) and call or email us to participate in our study. From there, we will conduct a screening phone call or direct them to an online survey.

The research cannot practically be carried out without the waiver or alteration of consent because the database is anticipated to be a powerful recruiting tool and is anticipated to play a central role in recruiting the dyads for the study. It has also been used for many IRB-approved studies in the Division of Behavioral Medicine in the past.

No deception is used in this research protocol.

29.2 *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:

This research does not involve a waiver for planned emergency research.

30.0 Process to Document Consent

- ☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 31.0)

30.1 *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).

31.0 Multi-Site Research (Multisite/Multicenter Only)*

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

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

Response:

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

- *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 in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

31.3 *Describe the method for communicating to engaged participating sites.*

- *Problems (inclusive of reportable events)*
- *Interim results*
- *Study closure*

Response:

31.4 *If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality.*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Response:

31.5 *If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.*

- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Response:

32.0 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.

32.1 *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).

NOTE: If the UBIRB has approved this study to bank data and/or specimens for potential future use outside the scope of this research study, any future use or disclosure of the data that is not described within the approved study must be submitted for review to the UBIRB.

Response:

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

Response:

32.3 *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: