Cover Page for Protocol, Statistical Plan and ICF

Official Title:	Enhancing Alternatives to Eating in Infancy
NCT number:	NCT02936284
Document Type:	Study Protocol and Statistical Analysis Plan
Date of the Document:	12/9/2020

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 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: Infant Environment Study

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

Kai Ling Kong

Pediatrics, Division of Behavioral Medicine

829-6815

Kkong4@buffalo.edu

VERSION:

Include the version date or number.

Response: 15

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 grant is funded by NIH.

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: University at Buffalo, South Campus

Address: 3435 Main St, Buffalo

Department: Pediatrics, Division of Behavioral Medicine

1.0 Objectives

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

Response:

Specific Aim 1: To examine the effects of enhancing alternatives to eating on the motivation to eat or engage in alternative behaviors (the food reinforcement ratio or FRR) by using a music enhancement program.

Specific Aim 1a: To examine the effects of a music enhancement program on infant dietary intake.

Specific Aim 2: To examine the effects of a music enhancement program on infant weight status.

Specific Aim 3: To examine the effects of a music enhancement program on home environment enrichment score.

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:

We hypothesize that infants in the music enhancement program will have a lower FRR during the intervention and maintenance periods compared to control infants.

We hypothesize that infants in the music enhancement program will have a lower daily energy intake during the intervention and maintenance periods compared to infants in the control arm.

We hypothesize that infants in the music enhancement program will have a lower weight for length z-score (zWFL) during the intervention and maintenance periods compared to infants in the control arm.

We hypothesize that infants in the music enhancement program will have a more enriched home environment during the intervention and maintenance periods compared to infants in the control arm.

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:

The primary study outcomes are change in infants' FRR, zWFL, and home environments enrichment scores. The secondary outcome is infants' dietary intake.

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:

Food is a strong motivator of behavior and is a primary reinforcer as it satisfies a basic biological need, is present at birth, and does not need to be learned (Saper, Chou, & Elmquist, 2002). However, the degree of motivation to obtain food varies in infants, children, and adults, and the balance of the motivation to eat versus engage in other behaviors is cross-sectionally related to weight for length z-score in infants and Body Mass Index (BMI) in children, adolescents, and adults (Epstein, Carr, Lin, Fletcher, & Roemmich, 2012), and predicts weight gain in adults (Carr, Lin, Fletcher, & Epstein, 2014). The motivation to eat has been related to energy intake in the laboratory (Epstein et al., 2007) and natural environment (Epstein et al., 2012), and we posit that changing the motivation to eat can influence energy intake and prevent excessive weight gain.

Nine to eighteen-month-old infants who have greater motivation to eat versus engage in alternative behaviors have a greater weight for length z-score (Kong, Eiden, et al., 2015; Kong, Feda, Eiden, & Epstein, 2015). Interestingly, in our two infant studies the increased motivation to eat in heavier infants is primarily driven by the low motivation to work for access to non-food alternatives (Kong, Eiden, et al., 2015; Kong, Feda, et al., 2015). These observations suggest that it may be the lack of alternatives to food puts some children at risk for excessive weight gain. In support of this idea is the observation that children who grow up in home environments that are enriched, or that provide many stimulating non-food alternatives, gain less weight over time. Prospective research has

shown reduced access to cognitive enhancement activities at home between the ages of 0-8 years is associated with a greater than twofold increased risk of becoming obese six years later (Strauss & Knight, 1999). It has long been known in basic animal research that providing stimulating environments is protective against the development of drug self-administration (Cosgrove, Hunter, & Carroll, 2002), also consistent with the hypothesis that providing stimulating alternatives to food may be protective against the development of obesity.

We recently conducted a pilot study to test whether strengthening alternatives to eating can shift the balance of the motivation to eat or engage in alternative behaviors. The motivation to eat or engage in alternative behaviors was operationalized by the relative reinforcing value of food versus alternative behaviors, a well-validated approach in behavioral economics. Twenty-seven infants with high motivation to eat were randomized to music engagement versus attention play date control. Results showed a reduction in food reinforcement and a reduction in reinforcing value of food versus alternatives to eating after the treatment (Kong, Eiden, et al., 2015).

The proposed study extends this research in a larger sample of infants studied over a two year period to provide a better test of the short and long-term efficacy of this intervention approach on obesity-related outcomes. We propose a randomized, controlled trial to assess the effects of a 24-month music enhancement program versus an attention placebo play date in 92 9-15-month-old healthy infants who are strongly motivated to eat versus engage in other behaviors. The 12 month intervention includes 4 semesters of intervention (Winter, Spring, Summer, and Fall), comprised of 37 once per week group meetings of 10-12 infant-parent dyads. A 12-month maintenance phase with monthly meetings will be followed after the intervention phase.

3.2 Include complete citations or references.

Response:

Carr, K. A., Lin, H., Fletcher, K. D., & Epstein, L. H. (2014). Food reinforcement, dietary disinhibition and weight gain in nonobese adults. Obesity (Silver Spring), 22(1), 254-259. doi:10.1002/oby.20392

Cosgrove, K. P., Hunter, R. G., & Carroll, M. E. (2002). Wheel-running attenuates intravenous cocaine self-administration in rats: Sex differences. Pharmacol Biochem Behav, 73(3), 663-671. doi:10.1016/S0091-3057(02)00853-5

Epstein, L. H., Carr, K. A., Lin, H., Fletcher, K. D., & Roemmich, J. N. (2012). Usual energy intake mediates the relationship between food reinforcement and BMI. Obesity (Silver Spring), 20(9), 1815-1819. doi:10.1038/oby.2012.2

Epstein, L. H., Temple, J. L., Neaderhiser, B. J., Salis, R. J., Erbe, R. W., & Leddy, J. J. (2007). Food reinforcement, the dopamine D2 receptor genotype, and energy intake in obese and nonobese humans. Behav Neurosci, 121(5), 877-886. doi:10.1037/0735-7044.121.5.877

Kochanska, G, Murray, K, Jacques, TY, Koenig, AL, & Vandegeest, KA. (1996). Inhibitory control in young children and its role in emerging internalization. Child Development, 67, 490-507. doi:

Kong, K. L., Eiden, R. D., Feda, D. M., Stier, C. L., Fletcher, K. D., Woodworth, E. M., . . . Epstein, L. H. (2015). Reducing relative food reinforcement in infants by an enriched music experience. Obesity (Silver Spring), In press.

Kong, K. L., Feda, D. M., Eiden, R. D., & Epstein, L. H. (2015). Origins of food reinforcement in infants. American Journal of Clinical Nutrition, 101(3), 515-522. doi:10.3945/ajcn.114.093237

Putnam, SP, Gartstein, MA, & Rothbart, MK. (2006). Measurement of fine-grained aspects of toddler temperament: The Early Childhood Behavior Questionnaire. Infant behavior and development, 29, 386-401. doi:

Rothbart, MK, Ahadi, SA, Hershey, KL, & Fisher, P. (2001). Investigations of temperament at three to seven years: The Children's Behavior Questionnaire. Child development, 72, 1394-1408. doi: Saper, C. B., Chou, T. C., & Elmquist, J. K. (2002). The need to feed: Homeostatic and hedonic control of eating. Neuron, 36(2), 199-211. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12383777

Strauss, R. S., & Knight, J. (1999). Influence of the home environment on the development of obesity in children. Pediatrics, 103(6), e85. doi:10.1542/peds.103.6.e85

4.0 Study Design

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

Response:

Interventional

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:

We plan to randomize 94 healthy infant dyads aged 9-15 months who are high in motivation to eat versus engage in alternative behaviors. Families will be randomly assigned to the music program or the play date control group.

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

Response:

In order to recruit 94 dyads, we will need to screen 683 families; this is due to ineligibility at screening, dropped out participants, and ineligible participants during lab activities.

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:

Subjects will be recruited from our pediatric clinical research network, targeted direct mailing, newspaper advertisements, flyers posted around the University at Buffalo campuses and the neighboring community, and from a laboratory maintained database on families with obesity that has over 10,000 families. We are confident we can recruit the number of participants required. We recruited more than 150 infants over a period of 9 months in five different infant studies conducted in our laboratory. Coinvestigator Kai Ling Kong is an active member of the Infancy Leadership Circle of Erie County, under the New York Zero-to-Three Network. This leadership circle is a collective of professionals from all fields who provide services to infants and toddlers and their families to facilitate professional networking, development, and communication in the Erie Country area. This leadership circle has been providing strong support in our research endeavor, particularly in helping with subject recruitment. Additionally, one of our co-investigators, Rina Das Eiden, has been working with infants and families for over two decades around Erie County, New York. She has a long history of successful recruitment and retention across a wide age range of children and their families. For example, Dr. Eiden has successfully recruited three large samples of infants at high risk due to parental substance abuse from the community using a range of recruitment methods. These include recruitment through New York State birth records, through advertisements and flyers, at delivery from local area hospitals, and from prenatal clinics during pregnancy.

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:

-Infants 9-15 months

-infants with high FRR scores

- Must appear to be healthy

- Infant of singleton (i.e. not twin or multiple)

- Not allergic to puffed grains

*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:

-infants on special diets

-infants born preterm (<37 weeks gestation)

-low birth weight (<2500 grams)

-developmental delays or disabilities

-Infants with medical problems at birth or current medical problems that may affect eating or digestive behaviors

-Infants who are currently participating or previously participated in Music Together® or similar music program

Infants that have not been vaccinated

-Maternal age <18 years

- Mother who smoked, used controlled substances (i.e. opiates, cocaine, marijuana) or consumed excessive alcohol during pregnancy

- Mother who had a high-risk pregnancy

- Infants who could not complete the FRR task during the further screening/pre-intervention assessment

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:

Since all study materials are in English, we will be excluding individuals who do not speak English. This study is non-therapeutic and offers no direct benefit to non-English speaking participants.

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:

Caregivers and infants are the subjects of this research study. Great care will be taken to explain the consent process to the caregivers prior to getting permission to study both the caregiver and the infant. At least one parent will sign parental permission for the infant to participate in the study.

☐ **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:

Other specifically targeted populations will not be used in this study.

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:

Interested families will be screened via telephone interview or online screener for initial eligibility. After the initial screen, families will be scheduled for further screening and baseline data collection (3 appointments). These three appointments will be scheduled within 4 days of each other if possible, and at the same time of day to control for alertness, hunger cues, and mood. Before the laboratory visit, the parent will be asked to list one of his/her baby's favorite solid foods and rank the favorite food on a 7 point Likert-type scale. Only food that is ranked between 6 and 7 will be used as the test food. The parent will indicate during the initial screening if his/her infant has yet to try solid foods. The parent will be instructed to avoid feeding his/her child one hour prior to the visit and to provide the infant's favorite solid food for the food portion of the task. Upon arrival in the lab, the

parent will be given a brief description of study protocols and will be asked to complete a consent form for his/her infant's participation. During the first visit, the infant will perform both computerized food and non-food tasks, sequentially, to allow the infant to become familiar with the lab setting and the game. During the second two appointments, the infant will perform the computerized food/non-food reinforcement task, one task each visit, and research staff will obtain anthropometric measures of both the parent and the infant. The infant will qualify for the study if he/she has high relative food reinforcement.

☐ **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:

Subjects will be recruited primarily from Erie County, New York. Subject recruitment for the intervention involves recruitment from our pediatric clinical research network, targeted direct mailings, newspaper advertisements, flyers posted around the University at Buffalo campuses and the neighboring community, and from a laboratory maintained database on families with obesity that includes over 10,000 families. To facilitate the recruitment of minority participants flyers will be posted at community centers (such as Gloria Parks), community health clinic bulletin boards, libraries, the train station, bus routes, and bulletin boards at grocery stores on the bus routes. Direct mailings of the flyers will provide us with the opportunity to target notification of studies to specific zip codes, and thus target large populations of specific ethnic and minority groups. Research on direct mailings has shown that the use of personalized notification of studies enhances the percentage of subjects entering a study and is more cost effective compared to newspaper ads and posters when comparing methods of recruitment. Electronic bulletin boards such as Craig's list and Facebook will also be utilized to recruit from the community using our flyers.

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:

The recruitment method (flyers, University at Buffalo Behavioral Medicine laboratory database, and targeted direct mailings) will ensure that researchers have only the names of participants who have agreed to be contacted. Prospective subjects have the right to disregard recruitment materials. No personal information is collected on individuals prior to their expression of interest in participation in the study. Any identifying information collected in the process of screening potential participants will be kept in a locked file. The information provided in the screening questionnaire will be saved regardless of if individuals qualify for the study. All personally identifiable information collected during recruitment and screening will be locked in a file, which only research personnel have access to.

Only the interviewer and the participant will be present in the room during the interviews. Participants are provided with questionnaires and tasks that they can complete in the room where enough space exist to allow for participant's responses to remain private. When physical contact with participants is required in order to collect measurements, data will be collected so as to minimize invasion of privacy by training research personnel and by providing private spaces and using non-invasive procedures.

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:

Recruitment materials include: flyers, email recruitment, and a phone script (attached)

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:

Interested families will be screened via telephone interview or online screener for initial eligibility. After the initial screen, families will be scheduled for further screening and baseline data collection (3

appointments). These three appointments will be scheduled within 10 days of each other if possible, and at the same time of day to control for alertness, hunger cues, and mood. Before the laboratory visit, the parent will be asked to list one of his/her baby's favorite solid foods and rank the favorite food on a 7 point Likert-type scale. Only food that is ranked between 6 and 7 will be used as the test food. The parent will indicate during the initial screening if his/her infant has yet to try solid foods. The parent will be instructed to avoid feeding his/her child one hour prior to the visit and to provide the infant's favorite solid food for the food portion of the task. Upon arrival in the lab, the parent will be given a brief description of study protocols and will be asked to complete a consent form for his/her infant's participation. During the first visit, the infant will perform both computerized food and non-food tasks, sequentially, to allow the infant to become familiar with the lab setting and the game. During the second two appointments, the infant will perform the computerized food/non-food reinforcement task, one task each visit, and research staff will obtain anthropometric measures of both the parent and infant, and have the participating parent complete the reinforcing value of food and activities questionnaire and the Block food frequency questionnaire (FFQ), and Infant daily health Survey. The infant will qualify for the study if he/she has high relative food reinforcement (as described below). After baseline data collection, eligible families will be randomly assigned to the music program or play date control group. After the baseline data collection (0-m) laboratory visit of the Infant Toddler-Home Observational Measurement of Environment and randomization, participating families will attend laboratory assessments of infant and toddler food/non-food reinforcement task and anthropometrics, parental anthropometrics, dietary intake using Block FFQ and reinforcing value of food and activities questionnaire, as well as infant dietary intake phone interviews at 3-m, 6-m, 12-m, and 24-m. The IT-HOME will also be taken at 6-m, 12-m, and 24-m.

The intervention and control programs are scheduled during the first year of the study (Intensive phase) for 37 weekly sessions structured into four semesters: Winter (10-week), Spring (10-week), Summer (7-week) and Fall (10-week). During the second year (maintenance phase) families will attend monthly sessions. Families will be run in groups of 10-12 families, with opportunities for makeup sessions.

The music program/intervention group will be the Music Together® program designed in collaboration with a local music studio, Betty's Music Together®. This program introduces infants to the pleasure of music making with their parents rather than passively receiving it from CDs or TV. This program provides a rich variety of music and playful activities, which will encourage infants and parents to participate at their own level in singing, moving, listening, or exploring musical instruments. Participating parents and infants will attend 45-minute classes as a group. Besides attending classes, parents will be encouraged to listen and sing

together with their infants at home during everyday home activities such as bath time, meal time, and bed time using the CD and instructional song book provided by the program. There are three enhancements to the usual Music Together® program that will be incorporated into treatment. First, to enhance practice during the first 3 months each family will be sent a text reminder every morning to engage in music at home, and parents are asked to respond every evening if they engage in home practice or not. This method was used in our pilot, and 85.4% of families in the music group and 84.8% in the play date group filled out the daily home practice surveys. Second, we will train parents to use music as a reinforcer for other behaviors, such that parents will be encouraged to play music and sing with their children when their children engage in good behaviors. This turns the tables on the usual parenting approach, to use food as a reward, which increases the value of food that could potentially lead to childhood obesity Third, families who completed the home practice surveys will be entered into monthly drawings during the intensive phase and bi-monthly during the maintenance phase for a $50 gift card to a local grocery or coffee shop.

Play date control. Using methods derived from our pilot study, the active control group will consist of 45-minute group play dates at the same intervals as the music group. Two research staff will be facilitating these play dates. Before the arrival of parents and children, different stations will be set up and the play date rooms will be child proofed. We will provide a variety of age-appropriate toys (excluding musical toys) for participating parents and infants to play with and enjoy. Parents will be encouraged to interact with other parents and children during the 45-minute play time. Research staff will be present at the play dates, but they will not interact with parents or children unless concerns or questions arise. Besides attending play dates, families will receive toys to play with at home. Parents will be told it is a way for them to spend time and bond with their children. Each family will be provided with two toys to play with at home each semester (8 different toys total) for the first year, and a total of two toys for the second year. Parents will be encouraged to play with their child at home during everyday home activities such as bath time, meal time, and bed time using the toy provided by the program as well as other toys the child has. As with the music group, for the first 3 months families will be provided text message reminders to play with their children using the play date toys, and will respond daily after completing playing, and families who completed the required home practice surveys will be entered each week into monthly drawings (during intensive phase) and bi-monthly (during maintenance phase) for a $50 gift card to a local grocery or coffee shop.

During time of mandated social distancing, classes will become virtual for via Zoom for participants. This will involve participants meeting with their perspective groups for 30 minutes. The 30 minutes is a change from the typical 45 minutes because of having to be virtual and not being able

to interact the same way. Additionally, music/play surveys will be sent out on a weekly basis in order to get an understanding of the participant's home life. A perceived stress questionnaire will also be given to determine any stress that may be going on in the family. ITHOMEs normally done in the lab will be conducted via ZOOM. Verbal consent or consent via email confirmation will be done to obtain permission to do this. When social distancing mandate is lifted, groups may be asked to repeat questionnaires and tasks so that they can be done in person rather than online. Therefore, we are offering an additional $15 for participants to complete questionnaires and tasks online/virtually, with hopes they may get repeated in person.

At Home Height & Weight Measures. Participants will be asked if they are able to take their children's height/weight and their weight in their home. Materials including a scale, stadiometer or foldable yardstick and carpenters square, will be provided to the family for these measures. Participants will be contacted to schedule a time for materials to be dropped off at their homes. They will receive a phone call explaining the procedures verbally, as well as an instructional video or a video conference call to explain and demonstrate the procedures. The day before/day of the scheduled appointment, a staff member will ask the COVID-19 check questions to identify families that may have been asked to self-quarantine and will reschedule those appointments. A staff member will drop off the measuring tools, instructions and cleaning products to an area recommended as safe by the participating family during scheduling that allows the family to pick up the materials and the staff member to stay 6-feet away. All materials will be sanitized prior to drop off by a staff member with products recommended by the EPA (*https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2*). Staff members will use personal protective equipment when disinfecting materials. If personal protective equipment is not available, staff will reschedule drop offs for when supplies are available again. Families will also be instructed to disinfect the materials before and after use for an extra precautionary measure. Staff members will wait outside, in their vehicle or at least 6 feet away from any entrances, as the family records height and weight measures for the participating child and weight measures for the participating parent. If the family needs additional time to complete the measures, a staff member will be scheduled to pick up the materials 24-28 hours later.

The scales will be calibrated with the 50 lb weight prior to distribution. Upon returning to normal in-lab appointments, 25% of families whose data was collected at home will be asked to repeat the height measurement in person so we can validate their at-home measurement for quality control purposes.

Once the child turns 2-4 years of age, families, regardless of if they were randomized to the intervention classes, will be invited back to complete additional tasks. These tasks include games that measure impulsivity and effortful control. Along with these games, parents will be asked to complete additional questionnaires: the temperament questionnaire, early childhood behavior questionnaire, and children's behavior questionnaire. The child will complete the food reinforcement game again, height and weight will be collected, and skinfold thickness will be measured.

If for any reason the participant is unable to attend an assessment period at the South Campus, we will plan to visit them at their home in order to obtain the child's height/weight. They will be provided $15 compensation for this visit.

If for any reason they are unable to attend the assessment period at the South Campus and we are unable to come to their home, we will contact their child's Pediatrician office to learn the child's most recent height/weight for that time period.

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:

Months						
Item	**0**	**3**	**6**	**12**	**24**	**2-4y**
Demographic and socioeconomic variables	X					
Pregnancy History and Feeding Practices Questionnaire	X					
Baby Eating Behavior Questionnaire (BEBQ)	X					
Infant Daily Health Survey	X	X	X	X	X	X
Infant Behavior Questionnaire- Revised (IBQ-R)	X					
Infant food/non-food reinforcement task	X	X	X	X	X	X
Infant Diet and energy intake	X	X	X	X	X	X
Infant and Parental anthropometrics	X	X	X	X	X	X

Infant Toddler-Home Observational Measurement of Environment (IT-HOME) (During COVID-19 social distancing, this will be virtual)	X		X	X	X	
Parental Reinforcing Value of Food and Activities Questionnaire	X	X	X	X	X	X
Block Food Frequency Questionnaire	X	X	X	X	X	X
Child Health and Medical Care Questionnaire				X	X	X
Skinfold Thickness Measurement						X
Effortful control tasks						X
Temperament Questionnaires						X
Music/Play surveys (during COVID-19 social distancing) as needed at whatever assessment groups are in				X	X	X
Perceived stress scale (during COVID-19 social distancing) as needed at whatever assessment groups are in				X	X	X

a) Anthropometric data

Participants' (both caregivers' and infant) weight will be assessed using a digital scale; participating parent's height will be assessed using a digital stadiometer and infant's length will be measured with an infantometer. We will request the participanting parent to report the height and weight of the non-participating parent. Based on the height and weight data, BMI will be calculated according to the following formula: BMI = kg/m2. For the infant, we will further calculate the BMI percentile and z-score, according to the World Health Organization Growth chart. For at-home height and weight measurement, participants will be provided a scale and a stadiometer, along with instructions on how to complete the procedure. Parents will be asked to take a photo of the child's weight on the scale and the stadiometer showing the child's height. The parent will take a photo of the parent's weight on the scale. Parents will then text the photos to the study's phone number or to the study's email account.

b) Demographic variables

Demographic and socioeconomic status will be assessed using the MacArthur Questionnaire developed by the MacArthur Foundation (San

Francisco, CA). This questionnaire assesses objective measures of socioeconomic status, including years of education, and subjective measures of the family's social standing in the community. Measurements also include both individual and household income levels, along with household size. Years of education will be coded separately for each parent, as well as developing a highest education score for each family.

c) Pregnancy History and Infant Feeding Practice Questionnaire

This questionnaire will be used to collect information about the pregnancy history of the mother, and the baby's current and future diet. The amount and type (i.e. breastfeeding, formula feeding, or mixed feeding) of feeding will be asked in this questionnaire too.

d) Baby Eating Behavior Questionnaire (BEBQ)

These 18 items questions are about baby's appetite over his/her first few months of life. This questionnaire specifically ask questions related to period during which baby was fed milk only, before the introduction of solid foods or prepared baby food.

e) Food Reinforcement Task

The motivation to eat or engage in alternative behaviors is assessed by use of a computerized task. The task was originally developed to assess the reinforcing value of food in children and adults, and we made developmentally appropriate modifications for infants. All visits will be scheduled during a time the caregiver feels the infant would be awake, alert, and willing to do the food/non-food reinforcement task. Infants at this age can hit/press a large button with intentionality. While deliberate button presses on a conventional 3-button computer mouse would likely be unfeasible, we use a touch sensitive single button mouse that has a large surface area (Logitech® T620 Wireless Touch Mouse, Newark, CA) as the response manipulandum. The mouse will be placed within reach of the infants and secured using Velcro strips. While parents are completing study forms, researchers will interact with the infants by playing with toys and reading books to establish a relationship to facilitate task completion. This orientation period will last 10-20 minutes, until the infant has acclimated to their surroundings, as confirmed by the caregiver. Then, the infant will be placed in a high chair next to the parent to avoid separation anxiety and anxiety around strangers experienced by infants at this age group, but the parents are informed not to interact with the child during any of the decision tasks. Research staff then direct the infant's attention to the mouse button. To reduce responding for novelty, infants will be exposed to the computer mouse prior to starting of the task. To train infants to respond on the mouse, research staff will demonstrate how to

press the mouse button to create a “funny noise,” and infant button presses will activate the noise when the mouse is pressed. Once the infant appears to understand how to control the noise with a button press, they are allowed 30 seconds to play with the mouse button. Training is repeated prior to studying each type of reward. Throughout the experiment researchers remain neutral in their instructions to the infant and only use scripted cue phrases. To remove any parental bias, parents are instructed to only interact with the child during the training using scripted phrases or phrases used by the researchers.

After training, the task will begin. A reward (portion of food or access to music) will be presented after the infant meets the response criteria. The schedules will begin with one button press to earn a reward, and will increase linearly every two trials, up to a maximum of 15 responses (i.e., 1,1,2,2,3,3,…,15,15). The number of responses, number of rewards earned, and time spent in each session will be recorded. When food is earned during the task, the researcher will place a piece of the infant’s favorite solid food (approximately 1 cm x 1 cm x 1 cm) in front of them. When the non-food alternative is earned, researchers will play a song for approximately 10 seconds. Infants will work for access to the food or music in a counterbalanced order. Infants will continue the task until they give signs of wanting to stop (e.g., crying, signing or saying ‘all done’, head turning away, etc.). The session will end when the infant no longer wishes to earn points for access to food or music or he/she fusses or cries for more than 60 seconds. The total amount of food consumed by the infant will be measured and recorded at the end of visit, including the total amount of food removed from the infant’s tray during the reinforcement task.

The dependent measure is a standard measure of reinforcing value, operationalized by Pmax, or the highest schedule requirement the infant completes to earn a food or non-food alternative. To assess the ratio of reinforcing value of food to alternatives, or the FRR, we will assess the proportion of responding for food [Pmax food/(Pmax food + Pmax non-food alternative)]. Pmax can be positively skewed, and if not normally distributed, the natural log of Pmax will be used as the primary dependent variable. Infants will be defined as high in food reinforcement at baseline if they choose to allocate more effort to obtain food than the alternative behaviors being studied (FRR [Pmax food/(Pmax food + Pmax non-food alternative)] > 0.5). Each child will be tested for the FRR of food versus music.

f) Infant Diet and Energy intake

We will measure child diet and energy intake with three 24-hour dietary recalls (2 weekdays and 1 weekend) via telephone using a modified approach from the Feeding Infants and Toddlers Study. Information on the time, type, brief description (i.e., brand name, preparation, additives), and amount of each food or beverage consumed by the child from midnight

through midnight on the previous day will be collected from the participating parent (or the most knowledgeable adult). The participating parent will receive a booklet with drawings of cups, bowls, jars, and spoons to assist him/her to recall the actual amount of foods and drinks consumed, excluding spillover or leftover by the infant. The dietary recalls should include foods and drinks fed by parents at home and also by other caregivers (i.e., daycare) if applicable. Infant use of vitamin and mineral supplements will be recorded. We plan to use the nutrient analysis software Nutritionist Pro or NDSR to enter and analyze data collected from the 24-hour recalls. Food and nutrient analyses can be conducted at the ingredient-, food-, meal-, or daily total level. For breastfed infants, interviewers will document the duration of each feeding in minutes. For infants 7 months and older, we will assume an intake of 600 mL per day as the quantity of breast milk for those being fed only breast milk. The volume of formula or cow's milk will be subtracted from 600 mL for infants who consume both breast milk and other milk products to estimate the quantity of breast milk consumed. A dietetics professional will review all 24-hour recalls for missing foods, unrealistic quantities reported, supplement use, including brand name and type, and breastfeeding status. Nutrient calculations will be performed using the Nutritionist Pro Software or NDSR software. We will calculate the average daily energy intake by averaging the three 24-hour energy intakes, which has been shown to be an optimal method for estimating energy intake.

g) Infant Toddler- Home Observational Measurement of Environment (IT-HOME)

The quality of the home environment will be assessed using a modified for laboratory visits infant-toddler questionnaire/observational version of the HOME Inventory during the lab visits. Meta-analysis has shown that a positive parent-child relationship among children and adolescents and higher levels of parental responsiveness assessed by the IT-HOME were associated with lower weight, healthier eating, and more physical activity of the child. The HOME Inventory is a widely used and well-validated measure of the home environment, using both direct observation and parental interview. The infant-toddler version of the HOME Inventory consists of a set of 45 binary items describing eight dimensions of the home environment yielding eight separate sub scores and a total HOME score: availability of learning materials, language stimulation, physical environment, parental responsiveness, learning stimulation, modeling of social maturity, variety in experience, and acceptance of the child. The HOME Inventory has been used extensively in research studies, and has well-established psychometric properties. An abbreviated version of the full HOME assessment (HOME-SF) had been used to demonstrate the relationship between home environment and obesity risk in children. Increased cognitive enrichment in the home assessed using the HOME-SF is associated with lower obesity rates, and the home environment has been shown to interact with food reinforcement to predict weight loss in older

children. Observers blind to group status will be trained to complete the HOME by interviewing parents and observing parent-infant interactions in the laboratory. We have shown high inter-rater reliability of the lab version of the IT-HOME (intra-class correlations of 0.88 to 0.98).90

During mandated social distancing, this will be done virtually via ZOOM.

h) Infant Behavior Questionnaires-Revised (IBQ-R)

This questionnaire is used to measure temperament in infants between the ages of 3 and 12 months. It is one of the most widely used parent-report measures of infant temperament, which has good internal consistency, reliability, and inter-rater reliability between mothers and fathers. Parents will be asked to rate the frequency of specific temperament-related behaviors observed over the past week (or 2 weeks). The IBQ-R assesses the following domains: activity level, distress to limitations, approach, fear, duration of orienting, smiling and laughter, vocal reactivity, sadness, perceptual sensitivity, high-intensity pleasure, low-intensity pleasure, cuddliness, soothability, rate of recovery from distress, and arousal. We previously showed that high food reinforcement is significantly associated with lower scores of cuddliness ($p = 0.03$) and rate of recovery from distress and arousal ($p = 0.015$) (unpublished). Anzman-Frasca and colleagues demonstrated that infant temperament measures moderated the effect of obesity interventions during infancy.

g) Parental Reinforcing Value of Food and Activities Questionnaires

The food choice questionnaire will be used to measure the reinforcing value of food and non-food alternatives of the participating parent at baseline, 3-m, 6-m, 12-m, and 24-m. This questionnaire has been validated against the standard concurrent schedule laboratory task, and has been used with children to study the relationship between child and parent relative reinforcing value of food

. The questionnaire involves asking participants how much work they would do on 3 choice trials. The amount of work (i.e., button presses on a handheld counter) to earn snack foods increases with each choice, but the work required to obtain the alternative reinforcer, which is 10 min of watching a DVD, does not change. The same alternative, videos, is used for all choices so a common metric can be used to quantify all reinforcers. The snack food or alternative reinforcer choice begins at 20 button presses on the first trial, and responding increases by 20 presses on each successive trial for the snack food, with 640 presses required to obtain snack food on the last trial. The questionnaire will be used to assess reinforcing value of 1 out of 6 options of highly palatable, high energy-dense snack food that adult participants have chosen in previous studies and 2 non-food alternatives, which will include 1 physical activity and 1 sedentary leisure time activity, also chosen for a list of possibilities by the participant. Based on our experience using this questionnaire to test multiple reinforcing options in adults, we estimate 3 options would take

approximately 10 minutes. Since we will be including single parent families, we will only assess parental relative reinforcing value for one parent. The focus of data collection will likely be on the mother, as she is more likely to bring in the child than the father, and data suggest that maternal pre-pregnancy BMI is strongly associated with infant's weight. There is only one study on the relationship between parental and child food reinforcement, and this study focused primarily on maternal food reinforcement. There is no research on the relationship between parental and infant food reinforcement

i) Block Food Frequency Questionnaires (FFQ)

An extensively studied and validated paper and pencil version of Block FFQ will be used to assess parent's usual food intake at baseline, 3-m, 6-m, 12-m, 24-m, and 2-4 years old. It will take approximately 30 minutes for the caregiver to complete. There are approximately 110 food items in the questionnaire designed to estimate usual and customary intake of a wide range of nutrients and food groups. Individual portion size is used for each food, and pictures are given to enhance the accuracy of amount consumed. The food list of this questionnaire was developed from NHANES 1999-2002 dietary recall data, and the nutrient database was developed from the USDA Food and Nutrient Database.

j) Infant Daily Health Survey

The Infant Daily health Survey, completed by the participating parent, provides information about the infants' current health and emotional status, including information about medications the infant is taking and the infants' level of fussiness.

h) Child Health and Medical Care Questionnaire

This questionnaire will provide information about the child's current health and medical information; this includes questions about any new mental or medical diagnosis or any developmental delays.

i) Effortful control tasks

Effortful control is a measure of inhibitory control and impulsivity in children and toddlers. For the three-year old children, seven tasks will be used to measure effortful control. All tasks will be video-recorded for scoring. (Kochanska, Murray, Jacques, Koenig, & Vandegeest, 1996).

- Snack Delay. Children will be asked to wait for the experimenter to ring a bell before retrieving an M&M (or other candy/snack, based on preference) from under a glass cup. Four trials will consist of different delays (e.g. 10, 20, 30, and 15 seconds) over 4 trials. At each delay's half-way point, the experimenter will lift the bell, but not ring it. Children will be able to eat the M&M during/after each trial.

- Lab Gift. Children will be asked to face away from an experimenter wrapping a gift for approximately 1 minute. Peeking latency will be scored. Children will be provided the gift after waiting.
- Home Gift. Children will be asked to close their eyes/wear an eye mask while the experimenter wraps a gift for approximately 1 minute. Peeking, removing and adjusting the blindfold will be scored for latency. Children will be able to take the gift home. Gifts will consist of age-appropriate, inexpensive toys (e.g. ball, etc).
- Turtle-and-Rabbit. Children will be asked to move three dolls/figures (human, turtle, rabbit) around a path on a board for about 2 trials. Children will be asked to move the turtle slowly and the rabbit quickly and the human at a normal pace.
- Tower. Children will be asked to take turns with the experimenter while building a block tower using approximately 20 blocks. The experimenter will wait for their turn until the child signals that it is the experimenter's turn.
- Whisper. Children will be asked to whisper the names of cartoon characters (about 10 trials). Characters may include Mickey mouse, Minnie mouse and Paw patrol, or other age-appropriate media that children should be familiar with.
- Prize in a box. Children will be asked not to open a clear box that contains a desirable toy for 2 minutes and time touching, looking at box, and signs of frustration will be coded.
- High Chair. Children will be place in a high chair for approximately 5 minutes with no available toys. Frustration, whining, and self-soothing behaviors will be coded.

j) Temperament questionnaire

The Early childhood behavior questionnaire and the children's behavior questionnaire (Putnam, Gartstein, & Rothbart, 2006; Rothbart, Ahadi, Hershey, & Fisher, 2001) will be used to measure up to 18 temperament dimensions including; discomfort, fear, frustration, high intensity pleasure, impulsivity, inhibitory control, low intensity pleasure, motor activation, perceptual sensitivity, positive anticipation, sadness, shyness, sociability, and soothability. Parents will complete the age appropriate questionnaire (ECBQ 18 – 36 months, CBQ 3 – 5 years) of up to 201 items.

k) Skinfold Thickness

A practical clinical tool used to assess adiposity. This will be measured along with height and weight at the child's appointment for 2-4 years old.

l) Measurement of Ad Libitum food intake for 2-4-year olds.

Age appropriate food will be provided to the child to be able to eat or not eat, whatever they choose, for a time limit of 10-15 minutes.

m) Music/Play Survey

Surveys are given during time of social distancing due to COVID-19 in order to understand what music/play is being done at the home.

n) Perceived Stress Scale

This survey is given during times of social distancing due to COVID-19 in order to understand any stressers the family may be under. It can be given out periodically based on the duration of social distancing.

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:

All documents will be attached along with this protocol submission.

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.

*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, individual subject results will not be shared.

*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:

Study results will not be shared with subjects.

11.0 Study Timelines

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

Response: It is anticipated it will take 3 years to enroll all study subjects.

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:

Prior to participation, subject will complete a five minute screening over the phone or through an online questionnaire. Subjects that pass the initial screening will complete three further screening sessions lasting 45 minutes each and three dietary recalls, lasting 15 minutes each. Eligible participants will then attend one

laboratory visit for the IT-HOME, lasting about 45 minutes, and 45 minute intervention sessions once a week for 37 weeks. In addition, subjects will complete 3 dietary recalls over the phone, each lasting 15 minutes, and three laboratory sessions to collect anthropometrics, FRR, and parental reinforcing value of food, lasting about 45 minutes, at 3-m, 6-m, 12-m, and 24-m, and IT-HOME, lasting about 45 minutes, at 6-m, 12-m, and 24-m. During the second year, subjects will attend twelve 45-minute intervention sessions, one per month, for the maintenance phase. Between the ages of 2-4 years of age, you will attend three laboratory sessions which will last about 45 minutes long each, with 3 dietary recalls lasting about 15 minutes each. This is a total of 55.5 hours per subject over 2 years with the additional time at 2-4 years of age.

At home height/weight measurements due to COVID-19 should take approximately 30 minutes. Validation checks during in-lab follow up appointments should take approximately 15 minutes.

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:

It is estimated to take approximately 5 years to complete the study (see above table). We propose to complete our randomized trial in 4 cohorts (Cohort 1: n = 20; Cohort 2; n = 24; Cohort 3: n = 24; Cohort 4: n = 24). Months 0-3 will provide time for IRB approval, protocol development, and staff training; months 3-6 for subject recruitment and baseline data collection of Cohort 1. We propose completing the one year intensive phase of Cohort 1 families by month 18, and the maintenance phase by month 30. During months 12 – 15 we will initiate recruitment and baseline measurements of Cohort 2, and the intensive and maintenance phases will be done by month 36. During months 18 – 21 we will initiate recruitment and baseline measurements for Cohort 3, and the intensive and maintenance phases will be done by month 45. The same fashion of subject recruitment and data collection timeframe will be followed by families of Cohort 4. All data collection is expected to finish by month 54. We will complete data entry and data analysis, generate new grant preparation based on ideas developed in the funding period, and compile manuscripts for publication and follow up grants during months 48 – 60.

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:

The research, including will be conducted in the Behavioral Medicine Laboratory located in G56, G58, G90. Each laboratory room is equipped with computers and is child-friendly with age-appropriate toys, rugs, and wall-hangings. The Music Together® Intervention will take place in Betty's Music Studio. The play date intervention will take place in one of the lab rooms at the Behavioral Medicine Laboratory.

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:

☒ **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:

The Principal Investigator is an expert on applying basic behavioral science paradigms to ingestive behavior, including research on food reinforcement. The Principal Investigator has published a variety of empirical and theoretical papers and has experience in administration and coordination of studies.

The Co-Investigators have extensive experience conducting human studies in the field of maternal health and nutrition, food reinforcement, and/or caregiver-infant observational and interview protocols.

The data manager/statistician has the training, ability, expertise, and experience in exercise science, clinical trials, and/or longitudinal trials. The data manager/statistician has experience with traditional statistical methods, as well as more sophisticated methods such as Mixed-Effect Regression Models, resampling techniques, and/or intention to treat approaches of longitudinal data.

The project coordinator will have experience conducting human research, scheduling test sessions, IRB submissions, and overseeing staff.

The research support specialists will have experience implementing study protocols and procedures.

The play date leader will have experience in child-care and child-safety.

The coders of observational assessment will have experience conducting observational studies.

The programmer will have a background in social media and recruitment, as well as the ability to manage the components of ecological momentary intervention.

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:

Principal Investigator: will have an appointment of 2.0 FTE

Co-Investigators: will have an appointment of .40 FTE

Data Manager/Statistician: .25 FTE for years 01-03 and .50 FTE for years 04-05.

Project Coordinator: 1.0 FTE

Research Support Specialists: 1.0 FTE in years 01-03, .5 FTE in year 04, and .25 FTE in year 05.

Play Date Leader: .50 FTE for years 01-03, .25 FTE for year 04, and .05 for year 05.

Coders of Observational Assessment: .50 FTE for years 01-04, and .05 FTE for year 05.

Programmer: .25 FTE for all 5 years

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:

There are minimal potential physical, psychological, social, legal, or other risks. As such, there are no medical or psychological resources available to participants.

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 extensive procedures manuals that are read and followed by all personnel. The Project Coordinator is 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:

Approval will be obtained from our funding agency, NIH.

☐ **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:

The recruitment procedures described in this protocol make use of posted flyers, and web posting. Participants may call the laboratory, of their own free will, and thus are controlling access to their privacy. The participant is reminded that they are free to refuse to answer any questions they do not feel comfortable answering.

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:

17.0 If subjects are unable to come to the south campus and unable to have us visit them at home, the research team will be permitted to contact the child's Pediatrician to obtain an up-to-date height/weight.

18.0 Data Management and Analysis

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

Response:

Descriptive statistics will be determined, and the distribution of each variable will be examined to assess normality. Appropriate transformations based on the distribution will be considered prior to analysis. Mixed model analysis of covariance (ANCOVA) will be used to examine the changes in the motivation to eat versus motivation to engage in alternative behaviors (FRR), infant daily energy intake, zWFL and home environment between the music and control groups. All analyses will be intention to treat, and will include all families that are randomized. The primary outcomes will be analyzed using SAS PROC MIXED (mixed ANCOVA), which will include random intercepts and time effects clustered within participants, adjusting for any family, parental, and infant temperament confounders that are different between the groups. Mixed ANCOVA accounts for repeated observations over time of participants,

and allows analysis with missing data. The models examine group (music or control), time in months (0, 3, 6, etc.) and their interaction as class variables and planned comparisons will be done assessing group differences to specific measurement interval after randomization (3, 6, 12, and 24 months). FRR, daily energy intake, zWFL, and home environment enrichment score are expected to be different between groups from baseline through the 2-year study. We predict that the relative reinforcing value of music will increase as the program is extended from 6 weeks to one year, and the reinforcing value of food will decrease during the year of intervention. Since the intervention is designed to enrich the home environment to support greater involvement in music, we expect the increased reinforcing value of music and the decreased reinforcing value of food to be maintained during maintenance period. In addition, we predict infants in the music group will show less weight for length gain over time compared to the control group at 12 and 24-month assessments. All analysis will be computed using SYSTAT and SAS .

18.2 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:

The sample size for this proposal is based on the effect size of our pilot randomized controlled trial of an enriched music experience versus play dates on reducing relative food reinforcement and standardized weight for length in 9-15-month-old infants who were high in food reinforcement. Between groups differences in FRR showed an effect size (ESd) of 0.978. To detect differences for an ESd = 0.978 between the music and control groups with power at 0.80 and alpha at 0.05, 18 subjects per group are needed. The effects for standardized weight for length showed an ESd of 0.712 in zWFL differences between groups. Differences this large with power at 0.80 and alpha at 0.05 can be observed with 32 subjects per group. To be conservative, we will use a lower ESd = 0.667 for differences in infant weight (zWFL) change between groups. At power at 0.8 and alpha at 0.05, 37 subjects per group are needed. To control for attrition, we will recruit an additional 25% of parent-infant dyads at baseline, which will bring our total amount to be 46 subjects per group, or 92 subjects total. We feel as if this is a conservative estimate of treatment effects since this is a smaller effect size than we observed at six weeks in the pilot study, and we realistically think that the effects will be greater after a year of intervention.

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

Response:

The primary investigator will be responsible for monitoring data safety at the weekly meetings. This includes ensuring confidentiality procedures are being followed in both recruitment and data collection. The types of data that will be monitored include demographic information and responses to questionnaires and assessments. The primary investigator will also be responsible for reporting serious events that occur during the laboratory sessions to the SBSIRB within 48 hours. The only anticipated serious event would be an allergic reaction to a food, previously unknown to the participant

19.0 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****.*

19.1 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:

Hard copies of raw data collected during the study will be stored in a locked file cabinet in the Division of Behavior Medicine. Only study staff associated with the project will have access to the data and all computer files containing identifiable data will be password protected and only the PI and members of the research staff will have access to the data. Participant identities will be coded and will not be associated with any published results. Electronic files will be stored on the secure shared drive of the Division of Behavioral Medicine, which is assessable with a password that is only known by study personnel.

19.2 A. How long will the data be stored?

Response:

Identifiable data will be stored for at least 3 years following study completion. De-identified data will be retained indefinitely.

19.3 A. Who will have access to the data?

Response:

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

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

Response:

The Principle Investigator and Co-Investigators will be responsible for the receipt or transmission of data.

19.5 A. How will the data be transported?

Response:

Data will not be transported locally; the data will remain at the local site.

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)*

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

Response:

19.7 B. How long will the specimens be stored?

Response:

19.8 B. Who will have access to the specimens?

Response:

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

Response:

19.10 B. How will the specimens be transported?

Response:

20.0 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.

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

Response:

Data will be reviewed weekly and secured in staff offices'. Since the proposed study poses no greater than minimal risk to participants, a DSMB is not necessary. The Primary Investigator and Co-Investigators will be responsible for ensuring data integrity and safety monitoring of human subjects who are involved in the research, along with the Data Safety officer.

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

Response:

Study questionnaires, experimental sessions, measurements, and videotape data that are collected by study personnel will be monitored.

20.3 Describe any safety endpoints.

Response:

Since this study does not involve more than minimal risk, there are no primary or secondary safety endpoints.

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

Response:

Safety information will be collected by the project coordinator and reported to both the UBIRB and the Safety Officer in the time frames outlined by the UBIRB.

20.5 Describe the frequency of safety data collection.

Response:

Data, including all follow up data, will be collected through 2022 at the University at Buffalo.

20.6 Describe who will review the safety data.

Response:

The Principle Investigator and Co-Investigators will review the data.

20.7 Describe the frequency or periodicity of review of cumulative safety data.

Response:

The primary investigator will be responsible for monitoring data safety at the weekly meetings with study personnel.

20.8 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

20.9 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

21.0 Withdrawal of Subjects

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

*21.1 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). With some reason, if the infant's discomfort (i.e.: fuss and cry) persisted throughout the procedure, the parent will be given permission to stop their infant from continuing the study.

21.2 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.

21.3 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 by the researcher and analyzed.

22.0 Risks to Subjects

22.1 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. Caregivers may feel uncomfortable answering some of the demographic, infant feeding and behavior questions. Additionally, the infant may experience some anxiety when entering a new environment- the laboratory and/or interacting with new people- the experimenters; however, we are hoping that this feeling will be temporary. A breach of confidentiality is also possible, although unlikely, due to the identifiable subject data.

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

Response:

Caregiver's discomfort toward questionnaires will be minimized by telling participants that they do not have to answer any questions that they are uncomfortable with, and that all responses will be kept strictly confidential.

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

Response:

The food reinforcement task may have unforeseeable risks if the infant has an unknown food allergy.

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

Response:

N/A

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

Response:

N/A

23.0 Potential Benefits to Subjects

23.1 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:

There are no potential benefits to individual subjects.

24.0 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.

24.1 ***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:

24.2 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:

25.0 Economic Burden to Subjects

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

NOTE: Some examples include transportation or parking.

Response:

Subjects will not be responsible for any costs as a result of participation in the research. Subjects will be reimbursed for public transportation. Subjects who choose to drive will be provided with free parking passes outside of our building.

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

26.0 Compensation for Participation

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

Response:

In order to randomize 92 families to our study, we are expecting to screen 222 families. Those who do not qualify for the study (n =~130) will be paid $15 per visit. Those families who are qualified for the intervention will earn a $15 check for each completed laboratory visit ($15 x 16), and $15 for each completed 3-day dietary recall ($15 x 5).

Qualified families will also get $85 bonus for completing the entire study. The maximum a qualified family could earn for participation in the study is $400.

Additionally, during the two years intervention families who filled out the required home practice surveys will be entered each week into monthly drawings (during intensive phase) and bi-monthly (during maintenance phase) for a $50 gift card to a local grocery or coffee shop.

The play date group and Music Together® classes are offered to participants free of charge.

If we are required to go to the participant's home to obtain height/weight, we will compensate $15.

If able to complete all tasks and appointments at 2-4 years of age, an additional $60 will be provided.

During mandated social distancing, $15 will be compensated for potential additional online questionnaires and tasks.

☐ **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.

27.0 Consent Process

27.1 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)*

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

Response:

Upon receiving an inquiry from a prospective participant, the study will be explained. If the prospective participant has an infant age 9 to 15 months, and he/she is interested in joining the study, a verbal consent will be obtained in order to screen for eligibility criteria. The initial screening questionnaire could be done via phone or online via Survey Monkey. If the adult consents to the information from the phone screen being stored in the database, there is a button to click that indicates they have been asked and agreed.

If families meet the initial criteria gathered from the initial screen, they will be scheduled for an orientation. At the orientation, there will be an overview of the study. If interested, parents will be asked to review and sign consent forms. Two copies of the consent forms will be signed by all parties involved, person obtaining consent, and the participating parent. One copy will be obtained by the study personnel and one copy will be given to the participants for their records. The copy obtained by study personnel will be kept in a locked cabinet. Consent forms will be signed in a private laboratory room to ensure privacy.

27.3 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:

There will not be a significant interval of time between obtaining and documenting consent and the actual participation in the initial research procedures (i.e. shortly after the person signs the document they will begin research procedures at their scheduled convenience.

27.4 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 not turn 18 over the duration of the study, so updating consent will not be required. Each year families will be contacted for scheduling appointments and will determine their participation.

27.5 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:

We will be following SOP: Informed Consent Process for Research.

☒ 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)

27.6 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:

27.7 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)

27.8 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).*

27.9 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)."

27.10 ***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:

27.11 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:

27.12 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)*

27.13 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:

Infants are the subjects of this research study. The participating parent will be asked to provide permission for their child to take part in the research study. Only one parent will be asked to provide permission for their infant to participate. The participating parent must be over the age of 18. Participants will be asked to indicate their date of birth on the initial phone screen and only individuals 18 and older will be invited to take part in the study. Participants filling out the screening survey online will be asked to read online consent information that asks for persons who are over 18 to participate and clicking on an I agree button to indicate that they are over 18.

27.14 ***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.

27.15 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)."

*27.16 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:

Permission will not be obtained from individuals other than parents.

*27.17 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:

None of the children in our study will be able to provide assent because they are infants between 9 to 15 months old. However, once they reach the 24-month assessment period, verbal assent will be required by the child in order to proceed with the visit.

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

Response:

Assent of children will be documented on the data sheet for the appointment.

28.0 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.

28.1 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:

The study does not involve a waiver or alteration of the consent process.

28.2 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:

The study does not involve a waiver or alteration of the consent process.

29.0 Process to Document Consent

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

29.1 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: During times of mandated social distancing due to COVID-19, verbal consent will be utilized in order to change classes to a 30-min virtual class. Additionally, they will be consenting to questionnaires regarding stress and their music/play at home. They will also be asked to complete ITHOMEs virtually during this time. Documentation of consent will be kept which can include, date/time/who was spoken to/who on the study team obtained consent. If they do not consent, this will also be documented.

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

30.0 Multi-Site Research (Multisite/Multicenter Only)

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

*30.1 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:

30.2 Describe the method for communicating to engaged participating sites:

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

Response:

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

Response:

30.4 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:

31.0 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.

*31.1 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: De-identified data will be stored indefinitely in filing cabinets in G58, G90, and G91 Farber Hall. Digital de-identified data will also be stored on the shared S drive. The PI and research team are the only people that will have access to the filing cabinets and folders on the S drive.

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

Response: Data stored includes all de-identified data collected, such as anthropometric measurements, infant questionnaires, and RRV.

31.3 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: Banked data will only be used at the discretion of the PI. Any releases or approvals to obtain data will be sanctioned by the PI.

32.0 Drugs or Devices

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

32.1 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:

32.2 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:

32.3 Identify the holder of the IND/IDE/Abbreviated IDE.

Response:

32.4 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:

33.0 Humanitarian Use Devices

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

33.1 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:

33.2 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: