Official Title:	The Intersection Between Loss of Control Eating and Obesity: The Role of Restriction and Food Reinforcement
NCT number:	NCT05177705
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Complete Research Protocol (HRP-503)

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PROTOCOL TITLE:

Include the full protocol title.

Response: *Food-ittude Study*

PRINCIPAL INVESTIGATOR:

Response: See Below

Name: Katherine N. Balantekin
Department: Exercise and Nutrition Sciences
Telephone Number: (716) 829-5578
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VERSION:

Include the version date or number.

Response: June 2024

GRANT APPLICABILITY:

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

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

Include a copy of the grant proposal with your submission.

Response: This study is funded using funds from NIH (K01 DK120778).

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: Research files will be kept within the Principal Investigator, Katherine Balantekin's, laboratory in locked filing cabinets. The files will remain within the laboratory until the appropriate amount of time has passed (3 years) after the conclusion of the study.

Location: 12 Sherman Hall

Address: 3435 Main St, Buffalo NY, 14214

Department: Exercise and Nutrition Sciences

1.0 Objectives

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

Response: The purpose of this study is to examine the relationship between disordered eating, specifically loss of control (LOC) eating, and obesity among children. We will also examine additional factors known to independently increase the risk of child overweight/obesity and/or LOC eating such as parental use of restrictive feeding practices and the relative reinforcing value of food.

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:

Hypothesis 1: Restriction of a High Energy Density (HED) food will lead to both increased energy intake and more frequent self-reported LOC eating during the LOC test meal.

Hypothesis 2a: Children who self-reported LOC eating will have higher RRV of HED food

Hypothesis 2b: Children who reported LOC eating during the LOC test meal will have higher RRV of HED food.

Hypothesis 3: Children with self-reported LOC eating will consume greater calories during the LOC test meal.

Hypothesis 4: Children self-reporting symptoms of depression or anxiety will have more frequent self-reported LOC eating during the LOC test meal.

Hypothesis 5: Children with higher caloric intakes based on reported dietary recalls will be more likely to self-report LOC eating during the LOC test meal.

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:

Primary endpoints: We will measure height/weight of parent/ guardian and child, energy intake at a buffet meal, relative reinforcing value of a preferred, HED snack food using a computer based task, average daily energy intake using dietary recalls, and questionnaire responses related to eating behavior. The additional optional parent/ guardian only visit would allow us to see if HbA1c values have any relationship to food parenting.

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: The study is designed to explore the relationships between LOC, eating, restriction, RRV, and overweight/obesity (OW/OB) risk, and assess whether RRV of HED food and restriction are key mechanisms that moderate the bidirectional relationship between LOC eating and obesity risk/weight gain over time. OW/OB in children remains a leading public health concern and is associated with increased risk for co-morbid health concerns (e.g. hypertension, diabetes, stigma, adult obesity)[1]. Furthermore, children with OW/OB are more likely to engage in disordered eating behaviors, such as LOC eating[2], which increases their risk for OW/OB and excess weight gain over time[3]. Parental use of restrictive feeding practices also increases the risk for OW/OB over time[4,5] and has been identified as a trigger for binge eating[6], a form of disordered eating. High RRV of food has additionally been identified as a risk factor for OW/OB, and may be further exacerbated by periods of food restriction[7]. While the relationship between RRV and LOC eating has yet to be examined for the most part, individuals with binge eating have altered neural reward circuitry[8], which may increase the RRV of food, leading to weight gain over time. Therefore, understanding the relationships among LOC eating, restriction, RRV and weight gain is critical to reducing the risk for OW/OB and its associated co-morbidities.

3.2 Include complete citations or references.

Response:

1. Dietz WH. Health consequences of obesity in youth: Childhood predictors of adult disease. *Pediatrics* 1998; 101 (Supplement 2): 518-525.

2. Tanofsky-Kraff M, Goossens L, Eddy KT, et al. A multisite investigation of binge eating behaviors in children and adolescents. *Journal or consulting and clinical psychology* 2007; 75(6):901.

3. Tanofsky-Kraff M, McDuffie JR, Yanovski SZ, et al. Laboratory assessment of the food intake of children and adolescents with loss of control eating-. *The American journal of clinical nutrition* 2009; 89(3): 738-745.

4. Epstein LH, Wright SM, Paluch RA, et al. Food Hedonics and reinforcement as determinants of laboratory food intake in smokers. *Phsiol Behav* 2004; 81:511-517.

5. Saelens BE, Epstein LH. Reinforcing value of food in obese and non-obese women. *Appetite* 1996; 27(1):41-50.

6. Temple JL, Legierski CM, Giacomelli AM, Salvy SK, Epstein LH. Overweight children find food more reinforcing and consume more energy than do nonoverweight children. *The American journal of clinical nutrition* 2008; 87(5): 1121-7.

7. Hill C, Saxton J, Webber L, Blundell J, Wardle J. The relative reinforcing value of food predicts weight gain in a longitudinal study of 7-10-y-old children-. *The American journal of clinical nutrition* 2009; 90(2):276-281.

8. Tanofsky-Kraff M, Cohen ML, Yanovski SZ, et al. A prospective study of psychological predictors of body fat gain among children at high risk for adult obesity. *Pediatrics* 2006; 117(4):1203-1209.

4.0 Study Design

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

Response: Experimental, within-subjects, cross-over design, with participants tested in each of two conditions with the order of conditions randomized.

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: 110 participants will be enrolled.

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

Response: Based on past recruitment efforts, we typically enroll approximately 60% of the children we screen due to a variety of factors including ineligibility, scheduling conflicts, and/or inability to complete all

appointments. We will likely have to screen 250 participants in order to complete 150 parent/ guardian - child pairs for the study.

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: Our current database includes 2,127 families and will be used for recruitment for this study. This database includes individuals who have filled out screening surveys for our studies in the past and, in those surveys, agreed to be added to our list for future studies. Therefore, this list includes individuals who may not have been eligible for prior studies. Additionally, this list includes individuals who contacted our laboratory with interest in participating in various studies, but for whom we did not have a study opportunity at that time but agreed to be added to our list for future studies. No personal health information is attached to this list aside from name, phone number, and email address and in many cases only includes an email address. In the event that we contact a potential participant whose email address is no longer valid or indicates to us that they would like to be removed from the list, we remove their email address and any other contact information. We will also recruit by sending emails to list-serves, hanging flyers in the community and passing out handouts in elementary schools. We have a strong record of successful recruitment from this population. We also plan on utilizing recruitment help from the CTSI, who utilize methodologies such as distributing flyers at local libraries, etc.

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:

-Children (male and female) ages 8-11

-At risk for obesity or with obesity (defined as either having a BMI percentile that classifies the child as having overweight-BMI ≥85th percentile but <99th OR one + biological parent with overweight/obesity-BMI >25)

-Rating of neutral or higher for 50% of the study foods

- Consumption of one of the study foods at least twice/week

*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:

-Children below age 8 or above age 11

-Not at risk for obesity (defined as having a BMI percentile that classifies the child as having normal weight-BMI <85th percentile)

-Allergic to study foods

-Dislike of study foods (Less than 50% of the study foods rated neutral or higher)

- Does not consume at least one study food at least twice/week

-Current diagnosis of a psychiatric disorder or clinical eating disorder (ED)

-Use of medications known to affect appetite (Ritalin, Adderall, Concerta, Wellbutrin, Prednisone, etc)

-Unwillingness to complete study visits

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: This study will not include individuals who do not speak English (parent or child). The study requires accurate completion of questionnaires that have been validated in English, by both parent and child. Participants must speak English to fully participate.

7.0 Vulnerable Populations

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

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

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

Response:

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

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

Response:

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

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

Response:

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

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

Response: This study is recruiting children who have not yet reached the age of consent. In order to ensure they are aware of all of the study parameters, obligations, and any risks, the child will be present during the Parental Consent process. Furthermore, the child will be provided with an age-appropriate Assent form along with explanation of

expectations. Children at the lower end of our age scale or those who may have difficulty reading will have the assent form read to them. The families will be given a private moment to discuss their child's participation before signing any forms. Also, the research assistant will insist that any question be asked and answered before signing the consent and assent forms. Finally, the families are notified that they are able to withdraw from the study at any time without penalty.

*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: N/A. This research does not involve other disadvantaged persons.

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: A REDCap questionnaire will be used to screen all participants with a consent process included prior to screening, inquiring about age, liking of study foods, health conditions, and current use of medications.

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: Upon approval, we will email a description of the screening survey along with a hyperlink to access the survey to our contact database

(see below for details). If additional participants are needed, we will also post flyers throughout the UB campus, in the community and distribute flyers to local schools. This flyer contains both a website URL address to take the screening survey and contains a QR code that an individual can scan with their phone's camera. Scanning the QR will open up the survey on their phone's internet browser.

The contact database is comprised of previously screened potential participants (screen-ees) from the Nutrition and Health Research Lab who opted in to "being contacted for future studies" during their online Survey Monkey screening for the study they chose to screen for. This database includes members who have opted in from all UB IRB approved studies using Survey Monkey screenings conducted through the Nutrition and Health Research Lab where Dr. Jennifer Temple was an investigator since 2009. This list does not include anyone that has asked to have their contact information removed or unsubscribed. The database includes contact information ONLY (no additional screening information); the study the potential participant screened for, the first and last name of the screen-ee (plus that of parent and guardian where applicable), phone number, email address, and date of birth (when that information was available).

For the purposes of recruitment we will only be emailing those database contacts whom have an email address listed, so that we can simply send them an announcement about the study, which they can choose to follow up on if they wish (see recruitment email template).

The Clinical and Translational Science Institute's (CTSI) Community Engagement Team (CET) hosts the Buffalo Research Registry (BRR, IRB Approved STUDY00000806), a resource that connects researchers looking to recruit participants and community members looking to get involved with research. To participate in the registry, volunteers complete a voluntary intake form. Volunteers have agreed to be contacted about potential research opportunities based on their self-reported information.

As described in the BRR's IRB Approved Protocol (STUDY00000806), key personnel from the CTSI will serve as the conduit between our research team and the registry volunteers. Key personnel will verify our IRB study approval, review inclusion and exclusion criteria and will sort the registry data accordingly.

In terms of recruiting for our study, key personnel will pull volunteer reports using the inclusion and exclusion criteria. Key personnel will centrally invite volunteers to participate in the study and provide a warm

hand off to our team. There are two ways we are sharing our study. These include:

Electronically- Using the volunteer report from REDCap, key personnel from the CTSI will send initial e-mail invites to introduce our study to registry volunteers.

Post Mail- Key personnel from the CTSI will provide our team with contact information (i.e. first name, last name, post mail address) to prepare a mailing. This information will be shared in a password protected excel spread sheet. The password to the spreadsheet will be sent in a separate follow-up e-mail. We will only use the list for this protocol and we agree to destroy the list once recruitment for the study has closed.

We also plan on conducting follow-up by phone/email after initial contact. This contact information will be provided in a password protected excel spread sheet. The password to the spreadsheet will be sent in a separate follow-up e-mail. We will only use the list for this protocol and we agree to destroy the list once recruitment for the study has closed.

We will have no access to the health information provided in the registry.The CET also tables at many events in the community throughout the year and may display the IRB approved flyer for this project at their table at community events. Examples of events the CET attends include Good for the Neighborhood hosted by Independent Health Foundation, UB on the Green, Juneteenth, Elmwood Arts Festival and many others. We will post our recruitment flyer on facebook and use the facebook paid advertisement feature, with the same approved flyer.

This study will be publicized on the UB Participate in Research (PIR) portal (www.research.buffalo.edu/portal/clinicaltrial/) while in the active recruitment period. Once study accruals have been met, the study will be removed from the portal. A lay title and study description will be included on the portal and have been included as an attachment in Click for approval. Once approval is received, the study will be populated onto the portal and will receive its own unique hyperlink. The UB PIR Portal was determined to be not research involving human subjects (see STUDY00006316 for more information).

HbA1c Parent/ Guardian only extra visit:

Upon approval, parent/ guardians of active participants and participants who have completed involvement in the study will be contacted over phone and email. See document titled, “Extra parent/ guardian only HbA1c Visit Recruitment Script/ email and text correspondence.”

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: Only research assistants will know the identity of participants. They will not share the participation status or any information with anyone outside the research team. Additionally, all participant information will be attached via numeric code, and will not be linked to an individual name.

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:

-Eligibility Survey (REDCap Questionnaire) – Filled out by a parent/ guardian.

If a potential participant is unable to access the internet, the research assistant will conduct the eligibility screening survey via telephone following the language from the REDCap questionnaire.

-Email/Text Documents – sent to the parent and/or guardian:

Information

Contact Log V5/6

Contact Log V7

-Recruitment Flyer

- Extra parent/ guardian only visit HbA1c visit recruitment phone script, email, and text correspondence

- Contact Log parent- only visit

10. 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:

Baseline

Visit 1 (2 hours):

The Parent will:

-Complete a consent form

-Have their own height and weight measured to ensure eligibility of the child.

-Help their child complete a 24 hour food recall based on everything consumed the previous day

-Fill out additional questionnaires assessing parental feeding practices, child typical disordered eating, including LOC eating, Parent Encouragement of Child Weight Loss Scale (PEWL)., and general parenting.

The Child will:

-Be asked not to eat or drink anything other than water for 2 hours prior to the appointment

-Complete an assent form

-Have their own height and weight measured

-Complete a 24 hour food recall based on everything consumed the previous day

-Fill out additional questionnaires (Liking of Seated Activities, Liking of Junk Food, preference for study foods rating, Loss of Control, DEBQ)

-Complete computer tasks for a small food reward or activity time (RRV task) and Adjusting Amount Discounting Task)

Visit 2 (1.0 hour):

The child will:

-Be asked not to eat or drink anything other than water for 2 hours prior to the Appointment

-Complete a 24 hour food recall based on everything consumed the previous day

-Eat a buffet meal (Loss of Control Test Meal)- *procedures described below*

-Fill out a post-meal survey (assessing LOC)

-Be instructed to keep track of their study food intake (see below) during the next two weeks using a provided checklist

In between Visit 2 and 3, the participant will have two weeks of either a restricted period (the parent will be asked to restrict intake of their child's preferred study food and related foods) or an unrestricted period (the parent will be provided servings of the child's preferred study food to distribute throughout the week to consume at home). The restricted period will be guided by printed instructions provided by the lab-see below. This completes the restricted access paradigm to induce low and high levels of parental restrictive feeding practices, with the order of restriction and no restriction randomized.

Restrictive (Period A)/Non-restrictive (Period B) period procedures*: participants will rate their preferences for high energy dense snack foods by measuring their liking of them and reporting how often they eat them. A target food will then be selected that is liked at least 60mm out of 100mm on the questionnaire scale and is eaten at least one time per week. During the restriction period, participants (with the help of parents) will be instructed not to eat the target food or closely related foods (a list will be provided by the lab) for the entire two weeks. For example, if the target food is M&M's, the participant will be asked to not eat any M&M's, Reeses Pieces, Plain Chocolate Candy Bars, or Hershey Kisses. During the non-restriction week, parents will be provided with eight bags of 150-200 kcal portions of the target food and will be told to give them to their child on different days over the course of the two weeks. They will be instructed not to give them the day before their next laboratory visit and not to give more than one portion in a single day.*

Visit 3 (1.0 hour):

The Child will:

-Be asked not to eat or drink anything other than water for 2 hours prior to the appointment

-Complete a 24 hour food recall based on everything consumed the previous day

-Eat a buffet meal (Loss of Control Test Meal)- *procedures described below*

-Fill out a post-meal survey (assessing LOC)

- Be instructed to keep track of their study food intake (see below) during the next two weeks using a provided checklist

In between Visit 3 and 4, the participant will have whichever of the following conditions they did not experience between Visits 1 and 2: two weeks of either a restricted period (the parent will be asked to restrict intake of their child's preferred study food and related foods) or an unrestricted period (the parent will be provided servings of the child's preferred study

food to distribute throughout the two weeks to consume at home). The restricted period will be guided by printed instructions provided by the lab.

Visit 4 (1.0 hours):

The parent will:

-Be paid for their participation for the baseline visits at the conclusion of the appointment

The Child will:

-Be asked not to eat or drink anything other than water for 2 hours prior to the appointment

-Complete a 24 hour food recall based on everything consumed the previous day

-Eat a buffet meal (Loss of Control Test Meal)-*procedures described below*

-Fill out a post-meal survey (assessing LOC)

-Be paid for their participation for the baseline visits at the conclusion of the appointment

6-month follow-up

Visit 5 (70 minutes)

The Parent will:

-Have their own height and weight measured to ensure eligibility for the child.

-Help their child complete a 24 hour food recall based on everything consumed the previous day

-Fill out additional questionnaires assessing parental feeding practices, child typical disordered eating, including LOC eating, Parent Encouragement of Child Weight Loss Scale (PEWL), and general parenting.

The Child will:

-Be asked not to eat or drink anything other than water for 2 hours prior to the appointment

-Have their own height and weight measured

-Complete a 24 hour food recall based on everything consumed the previous day

-Fill out questionnaires (Loss of Control, DEBQ)

-Complete computer tasks for a small food reward or activity time (RRV task) and Adjusting Amount Discounting Task)

Visit 6 (1 hour)

The parent will:

-Be paid for their participation for the 6-month follow-up visits at the conclusion of the appointment

The Child will:

-Be asked not to eat or drink anything other than water for 2 hours prior to the appointment

-Complete a 24 hour food recall based on everything consumed the previous day

-Eat a buffet meal (Loss of Control Test Meal)-*procedures described below*

-Fill out a post-meal survey (assessing LOC)

-Be paid for their participation for the 6-month follow-up visits at the conclusion of the appointment

12-month follow-up

Visit 7 (70 minutes)

The Parent will:

-Have their own height and weight measured to ensure eligibility for the child.

-Help their child complete a 24 hour food recall based on everything consumed the previous day

-Fill out additional questionnaires assessing parental feeding practices, child typical disordered eating, including LOC eating, Parent Encouragement of Child Weight Loss Scale (PEWL), and general parenting.

-Be paid for their participation for the 12-month follow-up visits at the conclusion of the appointment

The Child will:

-Be asked not to eat or drink anything other than water for 2 hours prior to the appointment

-Have their own height and weight measured

-Complete a 24 hour food recall based on everything consumed the previous day

-Fill out questionnaires (Loss of Control, DEBQ)

-Complete computer tasks for a small food reward or activity time (RRV task) and Adjusting Amount Discounting Task)

-Be paid for their participation for the 12-month follow-up visits at the conclusion of the appointment

Parent Only Visit:

-Upon approval, the parent/ guardian of every participant who completed, or is actively participating (not including previous participants who have dropped out), in the study will be contacted by lab staff over the phone informing them of the extra parent- only visit.

-If they are interested in coming in for this extra visit, we will schedule them to come into the lab at a time that is convenient for them.

-The parent will:

- Complete a consent form

- Fill out a questionnaire inquiring about their current medication use

- Get their HbA1c measured- *procedures described below*

- Be paid for their participation in the parent- only visit at the conclusion of the appointment.

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:

-Demographic variables, medical hx

Race/ethnicity (child and parent/ guardian), household income (parent/ guardian), educational level (parent/ guardian), medical history (child), medication (child), weight and current medical problems including psychiatric diagnoses and eating disorders will be assessed and obtained using a standardized questionnaire given through REDCap (child and parent/ guardian).

-Weight, height, BMI (child and parent/ guardian).

Weight will be assessed by use of a digital scale, calibrated weekly. Height will be assessed using a SECA stadiometer. On the basis of the height and weight data, we will calculate body mass index (BMI = kg/m2). Among other methods of measuring adiposity, BMI is considered a reliable method for

estimating overweight or obesity, and BMI is strongly related to more direct measures of body composition and is related to health risks associated with excess adiposity.

-Relative Reinforcing Value of Food

The RRV of food is assessed by evaluating the number of responses made for food or alternatives on progressive ratio schedules of reinforcement. The experimental environment will include two computer stations. At one station is the computer on which participants can earn food. The other station will have a different computer on which participants can work for access to reading material. This alternative activity is provided to reduce the likelihood that the subjects' engage in the RRV task simply out of boredom. The reinforcement schedule will be set at a progressive ratio schedule with the following fixed ratio response requirements; 20, 40, 80, 160, 320, 640, 1280, 2560, and 5120. This means that subjects will be able to earn a portion of food or reading time after 20 responses for the first requirement, with the response requirements doubling thereafter.

-Adjusting Amount Discounting Task

Participants will complete the Delay Discounting task for different commodities (e.g. money, preferred food, physical activity, and health gains) and between different types of commodities (e.g. sweets now versus health later, watching TV now versus health later). Computerized/Experimenter administered assessments will provide participants with choices between a smaller amount of a hypothetical commodity available immediately or a larger amount available later. The magnitude of the immediate commodity is adjusted until it is subjectively equivalent to the larger amount. Subjective equivalence will be obtained at delays such as; 1 day, 1 week, 1 month, 3 months, 6 month and 1 year. To ensure comparison between money and non-monetary rewards, prior to running the discounting programs for food, physical activity and health, participants will indicate the amount of the commodity whose receipt "right now" would be equally valuable to the participants as receiving a set amount of money, for example $100.

-Loss of control test meal

Participants will be given access to a multiple-item buffet test meal containing a wide variety of low-energy dense and high-energy dense foods and will include standard meal foods. An audio recording will be played for participants that says, "All of this food is for you, let yourself go. Please open the door when you are done eating." Immediately before and after the test meal, participants will be asked to report on their mood and

feelings. After the LOC test meal, participants will be specifically asked whether they felt a loss of control during the test meal. Both energy intake and feelings of LOC will be assessed.

-Restricted access

In order to mimic the effect of parental restrictive feeding practices, each participant will undergo two weeks of restricted access and two weeks of no restricted access, before completing a LOC test meal. During the restricted access, parents will be instructed not to let their child consume any of the restricted food or any related foods. The food chosen as the restricted food will be the food the participant rated the highest (while also reporting consuming at least twice/week) during the baseline visit. During the weeks of no restricted access, families will be given 8 servings of the food and parents will be instructed to give the child 8 servings on different days during the two weeks.

-Subjective ratings of hunger/fullness and food hedonics

Subjective ratings for hunger/fullness and food hedonics will be collected before and after each session using 100mm visual analogue scales anchored by "Not at all" at 0mm and "Extremely" at 100mm. Participants will be asked to draw a line along the continuum that best describes how hungry they are, how full they are, and how much they like the food.

-Measurement of dietary intake

To ensure compliance with the snack food instructions, participants will be given a checklist to complete and be told to document all study food intake during the restriction and non-restriction periods. They will also be told to call or text the laboratory every day and state that they have not eaten any of the restricted foods (during the restriction period) or that they have eaten the foods (during the non-restriction period). We have used daily phone calls to measure compliance in the past. At all visits, 24 hour dietary recalls will be completed to assess energy intake. The dietary recalls will be conducted using a multi-pass interview that is regarded as effective for eliciting the most accurate information from dietary recall.

-Parent Feeding Practices

Parent feeding practices will be assessed using both the Structure and Control in Parent Feeding (SCPF) and the Child Feeding Questionnaire (CFQ). The CFQ is the most widely used instrument to assess parent feeding practices and has been used in numerous studies with children in middle childhood. The SCPF is a newer instrument, designed to assess multiple dimensions of parent feeding practices, including more positive aspects (e.g., limit

setting, providing structure) as well as more controlling aspects (e.g., use of restrictive feeding practices) of child feeding.

- Parent Encouragement of Child Weight Loss (PEWL)

Parental encouragement of child weight loss or dieting behavior will be assessed using the Parent Encouragement of Child Weight Loss questionnaire. This question asks about parent perceptions of weight status and any direct (e.g., removing snack foods from the home) or indirect (e.g., the parent going on a diet themselves) behaviors that parents use to shape their child's weight status or encourage them to diet. The PEWL was developed for use with parents of children and adolescents, and has been used with parents of children ages 7 and older.

-Parental Eating Disordered Examination Questionnaire (EDE-Q)

Parental Eating Disordered Examination Questionnaire (EDE-Q) is a 28-item self-reported questionnaire designed to assess eating disorder behaviors and symptoms. The EDE-Q was developed and valid for those ages 14 and older.

- Preference for Study Foods

Children will fill out a preference for study foods survey that assesses their liking and frequency of consuming different snack foods. This will be used to select the food that they will earn portions of during the RRV and will be the food used during the restricted access task. The food chosen will be the one that the like the most and consume at least once a week.

- Parenting Styles

Parenting style will be assessed using the Comprehensive General Parenting Questionnaire (CGPQ). The CGPQ was designed to examine parenting style of 5-13 year old children at risk or with obesity. It assesses parenting style across 5 domains: nurturance, structure, behavioral control, coercive control, and overprotection.

-Hemoglobin A1c (HbA1c)

HbA1c will be measured using the A1CNow+® system (PTS Diagnostics, Sunnyvale, CA) or the Alere AfinionTM AS100 Analyzer System (Abbott, Abbott Park, IL. A research assistant thoroughly trained on the HbA1c procedure will be conducting this measurement.

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: The screening survey will be completed online from any device that the participant chooses. All instruments will be administered online, via REDCap, from a laboratory computer in a private experimental room. If a potential participant is unable to access the internet, the research assistant will conduct the eligibility screening survey via telephone following the language from the REDCap questionnaire.

Parent:

-Demographics

-Child Feeding Questionnaire (CFQ)

-Structure and Control in Parent Feeding Questionnaire (SCPF)

-Child Behavior Checklist (CBCL)

-Eating Questionnaire **Parent Version* (YEDEP-P)

-Parental Control Scale (PCS)

-Parental Feeding Style Questionnaire (PFSQ)

-Parent Encouragement of Child Weight Loss Scale (PEWL)

- Comprehensive General Parenting Questionnaire (CGPQ)

-Eating Disorder Examination Questionnaire (EDEQ)

Child:

-24 Hour Food Recall

-Hunger/thirst and Food/activity liking

-Preference for study foods rating

-Feelings about Eating Questionnaire (DEBQ)

-LOC-ED Screening Questionnaire (LOC-C)

-LOC Post-LOC Test Meal Questionnaire

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

*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

*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: When the study is completed, we may present the findings at a scientific conference and a journal article. No identifying information about participants will be shared.

11.0 Study Timelines

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

Response: We anticipate that it will take no more than 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: The duration of an individual subject's participation in the study will be approximately one year, including 7 in-person visits.

Visit 1: 1.5hours

Visit 2: 1 hour

Visit 3: 1 hour

Visit 4: 1 hour

Visit 5: 70 minutes

Visit 6: 1 hour

Visit 7: 70 minutes

Parent only visit: 20 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: We estimate that it will take approximately 4 years for the study to be completed in entirety.

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: UB South Campus; Eating Behaviors Research Lab (10/12 Sherman Hall); 24 Farber Hall, 10/12 Sherman Hall

Farber Hall and Sherman Hall arelocked during non-business hours, accessible only to those with an ID card coded for entrance24 Farber and 10/12 Sherman Hall will be locked at all times when a researcher is not present. All participant data will be locked or under the direct supervision of the researchers on staff.

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: PI, Katherine Balantekin has experience with this type and topic of research. Additionally, all lab staff have been trained by the PI to take height and weight measurements in accordance with those used for NHANES national data collection.

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: We anticipate the PI will devote 50% of her time (approximately 20 hours per week) to completing the research. The research assistant will devote 50% of their time (approximately 20 hours per week) to completing the research We will recruit undergraduate assistant to help with the study.

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: Due to the low risk nature of this study, we do not have any additional medical or psychological resources on hand. However, participants are made aware that they may call the study team at any time with questions or concerns. In case the participants report discomfort from answering some of the questions and parents have concerns about their child's mental health, we will provide all parents with a letter containing references for

Erie County Crisis Services, Niagara County Services, the National Eating Disorders Association and Mental Health America.

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: Staff researchers will be trained on protocol, research procedures and responsibilities prior to assisting with study tasks and running participants.

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:

✓ **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: Only research assistants will know the name of participants. They will not share the participation status or any information with anyone outside the research team. Additionally, all participant information will be attached via numeric code, and will not be linked to an individual name. Furthermore, when participants come in for appointments, they will meet the researcher in the privacy of the laboratory where no one can overhear.

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: Assent/Consent of the parent and subject. The research team will only have access to information that is directly provided by the participants. Participants will be informed that all information they provide will be confidential.

17.0 Data Management and Analysis

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

Response: Data will be entered and managed using REDCap. In the analyses we will examine LOC eating in two different ways; energy intake during the LOC test meal, and self reported feelings of LOC eating during the LOC test meal. The RRV of HED food will be examined as the breakpoint, or the highest schedule of reinforcement on which a participant made a response. In the analyses, we will examine loss of control (LOC) eating three different ways: self-reported typical LOC eating, energy intake during the LOC test meal, and self-reported feelings of LOC eating during the LOC test meal. The relative reinforcing value (RRV) of HED food will be examined as the breakpoint, or the highest schedule of reinforcement on which a participant made a response. All standard anthropometrics and demographics (e.g., sex, age, pubertal status, zBMI) will be considered as potential covariates in all aims. Parental style will also be considered as a potential covariate.To examine whether RRV of HED food moderates the relationship between LOC and zBMI one year later, mixed effects models (i.e., growth curve models) will be used to examine the relationship between the interaction of LOC and RRV of HED food (i.e., moderation) on changes in zBMI from baseline to one year. The model will include main effects of LOC and RRV, and will include the interaction between LOC and RRV. While it is anticipated that RRV of HED food and parental restriction with both moderate the relationship between LOC eating and zBMI, both will also be explored as mediators. The other data will be explored used repeated measures ANOVAs and paired t-tests.

17.2 If applicable, provide a power analysis.

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

Response: In order to determine sample size for this study, we conducted a power analysis for the primary aim, to explore whether RRV moderates the relationship between LOC eating and zBMI changes. We used preliminary data from Dr, Temple's longitudinal study of 77 children who were given the EDE-Q to assess global ED pathology, which was used as a proxy for

LOC eating given the known association between the two, had RRV of HED food measured, and had zBMI measurements (from measured weight and height) at baseline and again after 6 months. We split the groups into "high" and "low" categories for RRV of HED food and global ED pathology using median splits. This resulted in four groups (low RRV – low ED pathology; low RRV – high ED pathology; high RRV – low ED pathology; and high RRV – high ED pathology). The zBMI changes from baseline to 6 months for the 4 groups were: - 0.025 ± 0.298, 0.010 ± 0.322, -0.095 ± 0.181, and 0.186 ± 0.268, respectively. We found that with a power of 0.80, p = 0.05, and an effect size f of 0.38, statistically significant relationships among RRV of food, ED pathology, and BMI percentile would be achieved with 80 participants. In Dr. Temple's ongoing longitudinal study with similar measures but a more intensive design, there is 85% participant retention at 1 year. As such, in order conservatively account for possible attrition, we plan on recruiting 100 participants.

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

Response: Data will be entered by research assistants as it is collected. During the study, the research assistant will regularly check for data inconsistencies and errors, consulting with the study team if outliers or unusual values are observed.

18.0 Confidentiality

A. Confidentiality of Study Data

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

*18.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response: Data will be stored in a password protected database (REDCap). The eligibility survey and payment information survey are only data that will be stored with personal identifiers. After eligibility is confirmed, the participant information will be de-identified and assignment a subject ID number. Therefore, all other electronic data (surveys, data collection) stored in REDCap will not contain any identifying information, instead electronic data will be identified by subject ID.

The payment information surveys are used to ensure participants have not moved throughout the duration of the study in order to keep their address correct in the US Bank Card service program. All other information for the US Bank Card service program will be taken from the eligibility survey.

Physical files, will not contain any identifying information, they will instead be identified by subject ID. The files will be stored in a locked filing cabinet in 10 Sherman. This room will additionally locked and limited access provided only to the PI research team members. No information will be removed from the laboratory.

Physical files containing identifying information, such as the W9, will be kept in a locked filing cabinet in 12 Sherman at all times. This cabinet will be minimally accessed and the room additionally locked. Only the research team will be able to access the files.

The master key pairing participant information with their subject ID will be stored in a separate location (12 Sherman). Access to this room is also limited to the research team and is kept locked at all times.

18.2 A. How long will the data be stored?

Response: IRB correspondence including approval, determination letters and consent documents will be maintained for 3 years after the conclusion of the study. The master list containing participant identification will be deleted as soon as it is no longer necessary (when the study is concluded). Data analysis files that do not contain identifiable information will be kept until the PI decides they no longer need the information.

18.3 A. Who will have access to the data?

Response: Only the PI and research team will have access to the study data.

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

Response: No data will be removed from the computers.

18.5 A. How will the data be transported?

Response: No data will be moved.

B. Confidentiality of Study Specimens

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

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

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

Response: N/A. No specimens will be collected or analyzed in this research.

18.7 B. How long will the specimens be stored?

Response: N/A. No specimens will be collected or analyzed in this research.

18.8 B. Who will have access to the specimens?

Response: N/A. No specimens will be collected or analyzed in this research.

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

Response: N/A. No specimens will be collected or analyzed in this research.

18.10 B. How will the specimens be transported?

Response: N/A. No specimens will be collected or analyzed in this research.

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

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

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

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

Response: The Principal Investigator, Dr. Katherine Balantekin, will be responsible for ensuring data integrity and safety monitoring for human subjects who are involved in the research.

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

Response: Any participant comments and possibly reportable events will be reviewed.

19.3 Describe any safety endpoints.

Response: N/A

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

Response: N/A

19.5 Describe the frequency of safety data collection.

Response: Data will be reviewed monthly.

19.6 Describe who will review the safety data.

Response: PI, Dr. Katherine Balantekin.

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

Response: The data from the proposed project will be reviewed by the PI and research coordinator in one month intervals. Research assistants will monitor for issues daily.

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

Response: N/A

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

Response: N/A

20.0 Withdrawal of Subjects

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

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

Response: Anyone unable to attend their appointments or a participant that frequently canceled appointments will be withdrawn due to the time-sensitive nature of the study and data collection. Should they drop out or be withdrawn from the study, they can do so without consequence.

20.2 Describe any procedures for orderly termination.

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

Response: N/A

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

Response: Anyone that is withdrawn from the study will be paid for their time. They will not be contacted for future data and their data will be coded as a withdraw. Their data will stay on file for the study term, unless they ask for their data to be withdrawn.

Withdrawal after completion of partial visits will result in compensation of $25 per completed appointment for the child and $10 per completed appointment for the parents in the form of US Bank PrePaid Debit Card.

21.0 Risks to Subjects

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

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

Response: The level of risk encountered by the participants in this experiment is NO GREATER THAN MINIMAL. There are no invasive techniques being used or substances that are potentially harmful. They may feel some embarrassment during this process from some of the questions that they will be asked. They will not be required to answer any questions that make them feel uncomfortable. Breach of confidentiality is a foreseeable risk.

There is also some risk associated with the buffet meals, which are completed during Visits 2 and 3. The participant may not like some of the foods that they eat or they may feel some discomfort if they overeat.

For the extra parent only visit:

- Participants may have a small, bruised area on the finger from the pinprick site. The bruise should fade over time without treatment. There is also a risk of participants feeling uncomfortable regarding questions on their medication history. Participants can refuse to answer any questions that they are not comfortable answering.

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

Response: The level of risk encountered by the participants in this experiment is no greater than minimal. Procedures performed to mitigate risk of confidentiality breach are described in section 18.1.

In order to further minimize this risk, all questionnaires will be completed using the REDCap survey program. This allows for the participants to complete the questionnaires without the use of names and reduces the likelihood potential psychological discomfort that can occur with paper questionnaires.

During the buffet meal, the participants will be alone in the lab space. For this reason, in order to minimize risk, a research assistant will monitor the participant through video surveillance. The research assistants will only observe and will not intervene unless necessary. This footage will not be recorded or stored. The procedure is additionally reflected in the Consent and Assent forms.

For the extra parent only visit:

Parent/ guardian will be informed over the phone that the procedure will involve using a small needle to obtain a drop of blood, so they can make the choice if they want to come in or not. Should an emergency situation occur, access to further medical care is available via a telephone located in the laboratory and the following emergency plan will be followed:

1. Have the participant immediately stop any activity and lay down.
2. Call for help! ON CAMPUS EMERGENCY (716-645-2222) or POLICE (911).
3. If the participant is unconscious – assess breathing and heart rate. Initiate CPR and call on campus emergency services or police as necessary.
4. If the participant is conscious – continue to observe participant.

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

Response:

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

Response: N/A

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

Response: N/A

22.0 Potential Benefits to Subjects

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

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

Response: There is no direct benefit to being involved in the study. Some parents and children may view participation in this research a positive opportunity to learn more about the scientific process.

23.0 Compensation for Research-Related Injury

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

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

Response: N/A

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

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

Response: N/A

24.0 Economic Burden to Subjects

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

NOTE: Some examples include transportation or parking.

Response: All participants will be offered day bus passes for transportation to every appointment. If they do not want to use the bus passes, they will be responsible for obtaining transportation to appointments.

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

25.0 Compensation for Participation

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

Response:

All participants will be offered day bus passes for transportation to every appointment.

Child:

After completion of all visits, participants will earn a total of $200 in the form of US Bank PrePaid Debit Card.

Visit 1 ($25)

Visit 2 ($25)

Visit 3 ($25)

Visit 4 ($25)

Baseline total: $100

Visit 5 ($25)

Visit 6 ($25)

6-month follow-up total: $50

Visit 7 ($25)

12-month follow-up total: $25

Bonus for completing all visits ($25)

Possible total: $200

If a participant is determined ineligible at visit 1 they will be mail a $35.00 US Bank Debit card ($25.00 for the child and $10.00 for the parent) the next business day.

Participants receiving a $200 US Bank PrePaid Debit Card for completing all visits will be required to complete an IRS Form W-9. This form will be held confidentially by the research team and those responsible for administering research funds.

Parent.

Parents will receive $10 per study visit for a possible total of $70 if they complete the entire study.

Parent only visit:

Parents will receive an additional $10.00 for completing the extra parent-only visit.

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

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

26.0 Consent Process

26.1 Indicate whether you will be obtaining consent.

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

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

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

Response: The consent and assent process will take place within 24 Farber. No other participants or community members, etc will have access to the room, which therefore will be private for the duration of the consent process. The consent process can be, and is often completed, electronically via REDcap. The electronic consent process allows participants to move backward, forward, or pause for review later.

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

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

Response: Subjects arrive to 24 Farber. Participants will have an extended period of time to consider participating in the study between being informed via email/flyer and requesting to be screened for the study. The consent video will be used to supplement the consent process, where the research assistants will also read through the consent form and assent to the parent and child. Participants will have the opportunity to ask any questions and have them answered fully prior to signing the consent/assent.

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

Response: Participants will be reminded of the voluntary nature of the research with each reminder email and text for appointments, which will be sent to the parent/ guardian. The following statement is included in the email, "This study is voluntary and if your availability to participate changes at any time, please feel free to contact the study team. You can reach us at (716) 829-5820." The following statement is included in the text, "Your participation is voluntary. Please response if you need to change your appointment".

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

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

Response:

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

Non-English Speaking Subjects

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

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

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

Response: N/A. This study will not enroll Non-English speaking participants.

26.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

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

Response: N/A. This study will not enroll Non-English speaking participants.

Cognitively Impaired Adults

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

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

Response: N/A. This study will not enroll cognitively impaired adults.

Adults Unable to Consent

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

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

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

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

Response: N/A. This study will not enroll adults unable to consent.

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

26.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response: N/A. This study will not enroll adults unable to consent.

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

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

Response: N/A. This study will not enroll adults unable to consent.

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

Response: N/A. This study will not enroll adults unable to consent.

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

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

Response: N/A. This study will not enroll adults unable to consent.

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

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

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

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

Response: All participants will fall within the criteria of being below the legal age for consent to treatments or procedures involved in the research as recruits will be within the ages 8-11 years.

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

Response: N/A

26.15 Describe whether parental permission will be obtained from:

Response:

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

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

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

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

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

Response: Permission can be obtained from a legal guardian in place of consent of a parent. In the screening survey, we indicate that a parent or legal guardian will need to be present for all visits. We additionally ask parents to indicate, in writing, on the consent form if they are the parent or legal guardian of the child. When scheduling appointments, we ask to speak with a parent or legal guardian. No formal check of documentation will be required for participation in the study.

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

Response: Assent will be obtained from all children.

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

Response: Assent will be documented and stored in each participant's folder with the rest of the relevant study paperwork.

27.0 Waiver or Alteration of Consent Process

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

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

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

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

Response: N/A

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

Response: N/A

28.0 Process to Document Consent

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

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

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

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

Response:

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

29.0 Multi-Site Research (Multisite/Multicenter Only)

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

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

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*

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

Response: N/A. This study is not an investigator-initiated multi-site study.

29.2 Describe the method for communicating to engaged participating sites:

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

Response: N/A. This study is not an investigator-initiated multi-site study.

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

Response: N/A. This study is not an investigator-initiated multi-site study.

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

Response: N/A. This study is not an investigator-initiated multi-site study.

30.0 Banking Data or Specimens for Future Use

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

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

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

Response: N/A. This study is not banking data or specimens.

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

Response: N/A. This study is not banking data or specimens.

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

Response: N/A. This study is not banking data or specimens.

31.0 Drugs or Devices

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

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

Response: N/A. This study does not involve drugs or devices.

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

Response: N/A. This study does not involve drugs or devices.

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

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

Response: N/A. This study does not involve drugs or devices.

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

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

Response: N/A. This study does not involve drugs or devices.

32.0 Humanitarian Use Devices

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

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

Response: N/A. This study does not involve humanitarian use devices.

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

Response: N/A. This study does not involve humanitarian use devices.