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PROTOCOL TITLE : Study of Nutrition and Activity in Kids (SNAK)

INSTRUCTIONS: Complete Research Protocol (HRP-503)

- *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, you must provide the reason why the section is not applicable for the response. For example, most behavioral studies would answer all questions in section 30 with words to the effect of "drugs and medical devices are not used in this study."*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *Do not remove the italics instructions or headings.*
- *If you are pasting information from other documents be sure to use the "Merge Formatting" paste option so that the formatting of the response boxes is not lost. If information is presented outside of the response boxes, it will not be accepted.*
- *If this study involves multiple participant groups who participate in different research procedures, consent processes, etc., be certain to provide information in each applicable section for each participant group and clearly label each participant group within a section or subsection.*

PROTOCOL TITLE:

Include the full protocol title.

Response: *Study of Nutrition and Activity in Kids (SNAK)*

PRINCIPAL INVESTIGATOR:

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Response:

VERSION NUMBER:

Include the version number of this protocol.

Response: 17

DATE:

Include the date of submission or revision.

Response: Sept 2020

Grant Applicability:

Describe whether or not this protocol is funded by a grant or contract and if so, what portions of the grant this study covers.

Response: This Study is funded by a grant from NIH- NIDDK R01-DK106265

Table of Contents

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives.

1.2 Response: *The purpose of this study is to measure the reinforcing value of a preferred health snack food and an unhealthy snack food. We will also look at the reinforcing value of exercise and how these values may lead to long term weight gain in adolescents.*

1.3 State the hypotheses to be tested.

Response: *We hypothesize that sensitization to HED food will be associated with greater weight at the time of testing as well as greater weight gain over time, while sensitization to LED food will be associated with lower BMI percentile at the time of testing in adolescents.*

2.0 Background

2.1 Describe the relevant prior experience and gaps in current knowledge.

Response: *While a substantial body of research suggests that RRV is related to obesity, there is very little research on factors that contribute to the RRV of food, particularly how patterns of eating can increase or decrease the motivation to eat specific foods. Our previous work has demonstrated that a subset of obese individuals show increases in RRV of food after repeated consumption of large portions of HED snack foods, which we have conceptualized as sensitization. Our preliminary data suggest that sensitization of the RRV of HED food is a predictor of weight gain over time. However, more work needs to be done to address this relationship using a planned, prospective study design, using adolescent research subjects, and examining potential moderators of this relationship.*

2.2 Describe any relevant preliminary data.

Response:

We have strong preliminary data to suggest that increases in the RRV of food after repeated administration of LED and HED snacks meet the criteria for sensitization. Furthermore, sensitization to HED food is associated with greater weight at the time of testing as well as greater weight gain over time, while sensitization to LED food is associated with lower BMI percentile at the time of testing in adolescents. Finally, the relationship between sensitization to repeated food intake and BMI percentile is moderated by Delay Discounting, supporting previous work suggesting that reinforcement pathology is a risk factor for obesity [32]. Our work and that of others from the past decade provides the foundation for this theoretical approach. The proposed studies will allow us to determine the

extent to which sensitization of the RRV of snack foods is predictive of weight gain and the development of obesity in adolescents. In addition, our preliminary data in adolescents suggest that sensitization to LED food may protect against weight gain.

2.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Response: This line of research will allow us to not only identify factors that increase risk for weight gain, but may also allow us to determine factors that protect against weight gain and obesity. If sensitization to LED food confirmed as a protective factor against weight gain in adolescents, future studies may focus on determining ways in which to sustain long-term increases the RRV of LED foods in order to promote LED food consumption and reduce weight gain. Finally, the proposed studies will also examine the independent and moderating effects of the RRV of physical activity to include a more comprehensive understanding of energy balance. If RRV of physical activity moderates the impact of sensitization of the RRV of HED food on weight change over time, developing strategies to increase the RRV of physical activity may provide an alternate pathway to prevent obesity among adolescents who do not find LED foods very reinforcing.

2.4 Include complete specific citations/references.

Response:

3.0 Inclusion and Exclusion Criteria

3.1 Describe the criteria that define who will be included or excluded in your final study sample.

Response: *Two hundred twenty-six participants (113 boys, 113 girls) ages 12 – 16 will be studied.*

Part 1:

INCLUSION:

-between 12-14yoa (male and female)

-zBMI: -1.5 to +2.0 (*determined by Height/weight measurement at Visit 1)

-neutral or higher liking of the study foods

EXCLUSION:

-Under/over age 12-16

-metabolic or endocrine disorder

- use of medications known to effect appetite (Ritalin, Adderall, Concerta, Wellbutrin, Prednisone, etc)

-Unwilling to complete the study visits

-allergy to study foods

-dislike of study foods (*determined via Preference for Study foods forms at Visit 1)

-parent report that child reads below 4th grade reading level

-parent report that child cannot complete light physical activity without assistance

-No English Speaking parent or legal guardian (therefore cannot provide consent in English nor answer questionnaires for this study)

* all other exclusion criteria are assessed from Survey monkey screening in advance of the first appointment vis parental report. At the first appointment the child is directly asses for height, weight, and The linking of study foods.

Part 2: Any subject completing V9 of part one who signed an addendum giving permission for future contact, will be invited to participate in Part 2 of the SNAK study. All interested former participants will be eligible to participate until age 18.

Part 3: Any subject completing V12 of part two who signed an addendum giving permission for future contact, will be invited to participate in Part 3 of the SNAK study.

At the age of 18 they may still participate, but will then be consented as an adult (rather than assented). If their parents are willing, they can accompany the participant to the appointment for collection of parent data (surveys, height/weight) or the forms can be sent to the parent for submission remotely.

3.2 Describe how individuals will be screened for eligibility.

Response: A survey monkey questionnaire "*SNAK Screening Survey 6.25.18.pdf"* will be used to screen all participants. This screening begins with a consent process prior to screening. The online screening (or phone screening when someone discloses that they do not have internet access) inquires about child date of birth, height/weight, liking of study foods, health conditions, allergies, and current use of medications. A participant is not eligible if they are allergic to a critical mass of the study foods, they are on medications effecting their eating.

At the first appointment the child is directly asses for height, weight, and The linking of study foods. They must like at least one of the health and one of the junk foods 50% or more in order to participant. Additionally the BMI z score must fall into the range of -1.5 to 2.0 in order to stay in the study after Visit 1. For those that qualify at the end of Visit 1, they will not be reassessed for these criteria after Visit 1. Therefore the only exclusion criteria after visit 1 will be ability to schedule and attends study appointments.

3.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.)

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

Response: Including individuals who are not yet adults.

3.4 Indicate whether you will include non-English speaking individuals. 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. 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: e.g., pilot studies, small unfunded studies with validated instruments not available in other languages, numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.)

Response: This study will not include children that do not speak English, while we may be able to include families where English is the second language of the parent. This study is longitudinal and requires many questionnaires that have been validated in English, so it is a requirement that the participant speak English.

4.0 Study-Wide Number of Subjects (Multisite/Multicenter Only)

4.1 If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

Response: n/a

5.0 Study-Wide Recruitment Methods (Multisite/Multicenter Only)

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

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

Response: Part 1: Upon approval, we will email a description of the screening survey along with a hyperlink to the survey to our contact database. We will also post flyers up on UB campus', in the community and distribute flyers to local schools, ever few months until all 226 participants have had their initial appointments. Facebook may be utilized for recruitment by simply posting our approved 4x6 refer a friend flyer on Facebook and asking people to like and share the flyer image.

5.2 Describe the methods that will be used to identify potential subjects.

Response: Part 1: Passive advertising via flyers and emails to our lab's consented contact database. We will also distribute flyers to schools and after school programs who have approved distribution of the study materials.

Part 2: Those that gave permission for future contact, should the SNAK study be extended, will be invited to participate in Part 2 of the SNAK study via email and phone script (attached).

Part 3: Those that gave permission for future contact, should the SNAK study be extended, will be invited to participate in Part 3 of the SNAK study. At this time, we will schedule their follow up appointment at the end of their previous appointment and only call families to notify them if the study is NOT extended (NIH grant extension not funded).

Those currently enrolled in the SNAK Part 1 will receive a flyer announcement about the future opportunity.

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

Response: Email recruitment and flyers to schools will be the main form of recruitment used for this study.

6.0 Multi-Site Research (Multisite/Multicenter Only)

6.1 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 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 reported in accordance with local policy.*

Response: n/a

6.2 Describe the method for communicating to engaged participating sites:

- *Problems.*
- *Interim results.*
- *The closure of a study*

Response: n/a

7.0 Study Timelines

7.1 Describe the duration of an individual subject's participation in the study.

Response: Part 1: The participant will participate in 9 visits over 2 years.

Part 2: Participants completing part 1 will be invited to take place in Part 2. This may include up to 3 visits; 1 every 9 months (up to a total of 3 appointments) prior to the participant turning 18 yoa. Should a scheduled appointment occur after the participant's 18th birthday, they will be given a new consent process, upon arrival, for the legal adult participant.

7.2 Describe the duration anticipated to enroll all study subjects.

Response: We expect that it will take 3 years to enroll all participants in part 1 of the study.

7.3 Describe the estimated date for the investigators to complete this study (complete primary analyses)

Response: We expect that Part 1 of this study will be completed 5 years from the start date (approximately 2021).

Those that complete Part 1 in early 2021 and elect to participate in Part 2, may be participating until early 2023.

8.0 Study Endpoints

8.1 Describe the primary and secondary study endpoints.

Response: The primary endpoint is enrolling all 226 participants, and the secondary endpoint is completing all of their follow up visits for each participant.

8.2 Describe any primary or secondary safety endpoints.

Response: n/a

9.0 Procedures Involved

9.1 Describe and explain the study design.

24 hours before the scheduled appointment participants will be called to ask COVID screening questions. Parents will be spoken to unless the child has research age 18 and has signed consent to participate in the study as an adult. Should no one respond to our call, and automated email will be set to the email address on file and a redcap survey will administer the COVID screening survey. Staff will review responses and reschedule families if anyone in the household has had symptoms in the past 14 days. (see attached survey)

Upon arrival for a scheduled appointment, participants will ring the door bell and a staff member in PPE will meet them for touchless temperature screening and COVID screening questions. A Yes to any of the questions or recording a temperature >100 on Parent or child will lead to suggesting the family call their health care provider immediately and rescheduling of the appointment to a date 14days+ after symptoms have subsided for anyone in the household.

Only one family will be scheduled at a time. Appointments will be separated by 30 min to allow for deep cleaning and sanitation.

SNAK STUDY PART 1 (Visits 1-9)

Appointment 1 (2.5-3 hrs) (TODAY)

- *Consent and Assent Process*
- *Parent/guardian and child will answer some questions separately. Including, completing a pubertal assessment of child's current development, as well as a food security survey.*
- *Parents/guardians will then complete a Demographic Questionnaire and a Child Feeding Questionnaire and have their own height and weight measured.*
- *The child will:*
    1. *answer a stress questionnaire, a risk taking questionnaire, food consumption, and a healthy eating questionnaires*
    2. *have their body composition measured in the BODPOD*
    3. *have their heart rate and blood pressure measured*
    4. *be asked to exercise on a variety of gym equipment for a few minutes*
    5. *be asked to rate a variety of snack foods*
    6. *provide a recall previous 24-hour diet and physical activity*

Appointment 2 (30-45min)
The child will:

1. be asked not to eat or drink anything other than water for 2 hours prior to the appointment
2. *be asked to eat a granola bar and play a computer game for a small snack food reward or activity time*
3. *provide a recall of previous 24-hour diet and physical activity*
4. *sent home with 2-weeks' worth of snacks and asked to eat a snack each day*
5. *be instructed to answer 7 short survey questions via email, text or online survey each evening*

Appointment 3 (30-45min)
The child will:

1. be asked not to eat or drink anything other than water for 2 hours prior to the appointment
2. *be asked to eat a granola bar and then play a computer game for a snack food reward (30g each) or activity time*
3. *provide a recall of same day diet and physical activity and fill out a short online survey*
4. *be sent home with a watch that tracks activity and asked to wear it for 1 week, without removing it, until their next appointment*
5. *be instructed to keep track of their food and beverage intake during the week using a provided booklet*

Appointment 4 (30-45min)
The child will:

1. be asked not to eat or drink anything other than water for 2 hours prior to the appointment
2. *be asked to eat a granola bar and play a computer game for a small snack food reward or activity time*
3. *provide a recall of previous 24-hour diet and physical activity*
4. *sent home with 2-weeks' worth of snacks and asked to eat each day*
5. *be instructed to answer 7 short survey questions via email, text or online survey each evening*

Appointment 5 (30-45min)
The child will:

1. *be asked not to eat or drink anything other than water for 2 hours prior to the appointment*
2. *be asked to eat a granola bar and then play a computer game for a snack food reward activity time*
3. *provide a recall of same day diet and physical activity and fill out a short online survey*
4. *Parent and child will be paid for your first wave of participation (Appointments 1-5).*

FOLLOW UP VISIT

Appointment 6 (90min, 6 months after initial appointment)
The Parent will:

1. *complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, and have their height and weight measured.*

The child will:

1. *complete the pubertal assessment, stress questionnaire, and eating questionnaires*
2. *have their body composition measured*
3. *have their heart rate and blood pressure measured*
4. *provide a recall of previous 24-hour diet and physical activity*
5. *be paid for their follow up visit participation*

<u>Appointment 7 (90min, 15 months after initial appointment)</u>
The Parent will:

1. *complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, and have their height and weight measured.*

The child will:

1. *complete the pubertal assessment, stress questionnaire, eating questionnaires, and adolescent risk questionnaire*
2. *have their body composition measured*
3. *have their heart rate and blood pressure measured*
4. *provide a recall of previous 24-hour diet and physical activity*
5. *be paid for their follow up visit participation*

<u>Appointment 8 (75-90min, 24 months after initial appointment)</u>
The Parent will:

1. *complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, a contact form and have their height and weight measured*

The child will:

1. *be asked not to eat or drink anything other than water for 2 hours prior to the appointment*
2. *complete the pubertal assessment, stress questionnaire, eating questionnaires, and adolescent risk questionnaire*
3. *have their heart rate and blood pressure measured*
4. *be asked to play a computer game for a snack food reward or activity time*
5. *provide a recall previous 24-hour diet and physical activity*
6. *be sent home with a watch (and log book) that tracks activity asked to wear it for 1 week, without removing it, until their next appointment*
7. *be instructed to keep track of their food and beverage intake during the week using a provided booklet*

<u>Appointment 9 (75-90min, 24 months + 1 week after initial appointment)</u>
The parent will:

1. *be presented with a consent addendum regarding future contact.*

The child will:

1. *be asked not to eat or drink anything other than water for 2 hours prior to the appointment*
2. *have their body composition measured*
3. *provide a recall previous 24-hour diet and physical activity*

4. *answer questionnaires about sleep and physical activity*
5. *be asked to play a computer game for a snack food reward or activity time*
6. *be paid for their follow up visit participation*

SNAK STUDY PART 2 (VISITS 10-12)

Appointment 10 (90min, ~33 months after initial appointment, ~ 9 months from visit 9)

The Parent will:

1. *Complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, a contact form, and have their height and weight measured.*

The child will:

1. *complete the pubertal assessment, stress questionnaire, eating questionnaires, physical activity questionnaire, sleep questionnaires, and adolescent risk questionnaire*
2. *have their body composition measured*
3. *have their heart rate and blood pressure measured*
4. *provide a recall of previous 24-hour diet and physical activity*
5. *be paid for their follow up visit participation*

Appointment 11 (90min, ~42 months after initial appointment, ~ 9 months from visit 10)

The Parent will:

1. *Complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, and have their height and weight measured.*

The child will:

1. *be asked not to eat or drink anything other than water for 2 hours prior to the appointment*
2. *complete the pubertal assessment, stress questionnaire, eating questionnaires, physical activity questionnaire, sleep questionnaires, and adolescent risk questionnaire*
3. *have their body composition measured*
4. *have their heart rate and blood pressure measured*
5. *provide a recall of previous 24-hour diet and physical activity*
6. *be asked to play a computer game for a snack food reward or activity time*
7. *be paid for their follow up visit participation*

Appointment 12 (90min, ~51 months after initial appointment, ~ 9 months from visit 11)

The Parent will:

1. *Complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, a contact form, and have their height and weight measured.*

The child will:

1. *complete the pubertal assessment, stress questionnaire, eating questionnaires, physical activity questionnaire, sleep questionnaires, and adolescent risk questionnaire*
2. *have their body composition measured*
3. *have their heart rate and blood pressure measured*
4. *provide a recall of previous 24-hour diet and physical activity*
5. *be paid for their follow up visit participation*

SNAK STUDY PART 3 (VISITS 13-16) *~ 9 months from previous visit*

We anticipate SNAK part 3 visits looking the same as SNAK part 2 visits. At this time, we are only requesting approval to ask Participants if they would like to be contacted for SNAK Part 3 should the study be extended with further NIH Funding, between the time of their V12 and when they would be due for their next follow up appointment (~9-11 months later).

*Should the child turn 18 during the course of the study (SNAK Part 2 or Part 3) and provide consent to continue participation, parent components for Appointments 10-12 will have the option to be completely remotely (surveys and self-report weight) at the discretion of the consenting adult participant.
**Parents will be offered to complete surveys remotely prior to the appointment time if desired.

9.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

Response:

MEASURES

Additionally, all survey instruments, other than the Tanner and Pubertal, will be administered online, via Survey Monkey (for SNAK Part 1) and REDCap (for SNAK parts 2/3), from a laboratory computer in a private experimental room. In response to COVID 19 and in an effort to make more study aspects accessible via online formats, rather than paper-based, RedCap will be used to administer from surveys and tasks for Visit 7-9 (SNAK part 1).

Reinforcing Value TASK: The reinforcing value of the exercise will be tested on the first visit. Also, RRV of snack food will be tested at baseline and again after the two

weeks of exposure to the food. Later they will complete this task again for another food type versus reading time. Upon 2-year follow-up, the task will be implemented once again. This task provides an empirical measure of the amount of work individuals are willing to perform to gain access to these foods (Epstein et al., 2008). Participants will then be instructed in the use of the computer task where they will respond for an assigned snack food on one computer and reading time on the other. The task is similar to a slot machine where every time the mouse button is clicked, the shapes rotate and change color. When all of the shapes match, the participant receives a point. For every 5 points, they will receive a 30g portion of the snack food for which they are playing. Participants may go back and forth between computers per their preference of rewards they would like to earn. The schedule of reinforcement will be a progressive, variable ratio schedule of: VR4, VR8, VR16, VR32, VR64, VR128, VR256, VR512, VR1024 and VR2048. The session will end when the participant no longer wishes to earn points for either reward. At the end of the session, participants will be given the portions of food that they earned during the game.

Child and Parent Food availability and Scarcity Questionnaires (FIQ): The survey module and the associated Food Security Scale were developed by researchers at the National Center for Health Statistics and Centers for Disease Control and Prevention. It has been shown to identify food-insecure households and households with very low food security with reasonably high specificity and sensitivity and minimal bias. The surveys are phrased differently to address the separate perspectives of parent/guardian and child, with the child form being 5 item and the adult containing 24 items. The **VFS** will also be administered which has more questions related to the child experience.

Healthy Eating self-efficacy questionnaire (SEHE): Self-efficacy to make healthy food choices will be measured using a nine-item scale developed for use with American adolescents (French, Story, Neumark-Sztainer, Fulkerson, & Hannan, 2001). The self-efficacy scale was used to assess participants' self-confidence for making healthy food choices in social situations (e.g., with friends), in emotional situations (e.g., bored) and in normal situations (e.g., at family dinner). Responses are rated on a six-point scale ranging from "not at all sure" to "very sure."

Demographic: Parents will complete a demographic questionnaire providing information about household income, education, profession, and race/ethnicity for themselves and a secondary caregiver, if applicable. The parent will also be asked to self-report the current stature of the child's secondary care giver, as well as any other adult caregivers that the child lives with.

Tanner Stage Evaluation*:* Boys and girls will be given line drawings of the 5 stages of pubertal development and asked to circle the one that looks most like them. Girls will be given drawings of breast development and boys will be given drawings of genital and pubic hair development. Parents will independently be given the same

drawings and asked to circle the one that they feel best resembles their children. The average of the self and parental reports will be taken. These drawings will be given to the children in an envelope and they will be given verbal instructions to circle the picture that looks most like how they look and to return the questionnaire to the envelope. The experimenter will leave the room and return 2 minutes later. Self-assessment of pubertal stage has been shown to be accurate and an acceptable substitute when physical examinations are not feasible. Parents will no longer be asked to complete the Tanner after Visit 8.

Pubertal Development Questionnaire –modified (PDQ): This questionnaire asks questions about secondary sex characteristics for boys (growth of body hair, changes in voice, acne, and height) and girls (breast development, menstruation, and acne). This will be given along with the Tanner Stage drawings and will be used as a secondary measure of pubertal development. This questionnaire will be given to both child and parent, and the scores will be averaged together. A 6th question has been added to this questionnaire in order to assess child self-assessed perception of stature as well as the parent's assessment of the child's stature. The parent and child will independently be asked to circle one same-sex drawing from a series of nine somatotypes introduced by Stunkard (1983).

Hypothetical Delay Discounting Task (Delay Discounting Task): An operational definition of impulsivity is delay discounting, the degree to which a person will discount the value of a larger delayed reward in favor of a smaller immediate reward. In the delay discounting task, participants will make choices between a fixed reward available after a time delay and an immediate reward whose magnitude will be adjusted in specific dollar increments in either ascending or descending order. The task will be administered by the experimenter using paper cards. Cards that depict different hypothetical dollar amounts will be placed two at a time on a table in front of the participant. The card set depicting the delayed, fixed rewards will be placed to the participant's left and the card set depicting the immediate rewards will be located on the participant's right.

The values of the delayed (fixed) amounts will be about $50. The immediate reward value cards will depict 30 values ranging from 0.1 to 100% of the delayed reward with which they are compared. The trials will be presented across a series of time delays (e.g., 1 day, 1 week, 2 weeks, 1 month, 6 months, 1 year and 2 years). Participants will indicate their desired reward (either immediate or delayed) by pointing to the appropriate card. Upon making two choices for the opposite reward, an indifference point is determined by taking the average of the immediate reward values immediately prior to and immediately following a switch in choice to the other reward. As the amount of the immediate reward decreases, the participant may decide when he/she is willing to wait for the specified delay (i.e., one week) to receive the larger amount.

Adjusting Amount Discounting Task (Minute Task). Participants will complete the DD task for money. Computerized administered assessments will provide participants with choices between a smaller amount available immediately or a

larger amount available later. The magnitude of the immediate commodity is adjusted until it is subjectively equivalent to the later larger amount. Subjective equivalence will be obtained at delays such as; 1 day, 1 week, 1 month, 3 months, 6 month, and 1 year.

Adjusting Amount Discounting task (web based) DD will be measured using the adjusting-amount task, which involves making choices between different amounts of money over different amounts of time. The participant will be presented with two choices on the computer screen and asked to choose which one they would prefer if they were going to actually get the amounts shown. The delayed amount will be $50. The delay increases from 1 day to 2 years through the task. The immediate amount will vary through the task, adjusting based on the participants' choices in order to estimate the point of indifference between delayed and immediate amounts. * A link to this task will be emailed or texted to participants the day before their visit for remote completion. The completion should take <1 minute total.

The Child Feeding Questionnaire (CFQ): Parent feeding practices will be assessed using the Structure 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 across the age spectrum.

Perceived Stress Scale (PSS-10): Previous research has shown a positive association between childhood cumulative stress and BMI as well as decreased self-regulatory behavior (Evans, 2003). The inclusion of the c will allow us to control for the influence of general stress on BMI outcomes (Terzian, Moore, & Nguyen, 2010). We will also examine it as a potential moderator in the relationship between impulsivity and adolescent BMI.

Adolescent Risk taking Questionnaire (ARA): This questionnaire has been designed to assess the frequency of risk taking by the study population. The adolescent version will be administered to ensure that the questions asked are age appropriate. Adolescents (12-16 yoa) are asked 60 questions about the frequency of engaging in substance use, violence, and other risk taking behaviors over the past 12 months. This questionnaire has been updated to include some rewording and new questions from Youth Behavioral Risk surveillance Survey (from which it is based) 2019.

Dutch Eating Behavior Questionnaire (DEBQ): At the end of the sequence of visits, participants will complete an eating questionnaire that assesses knowledge about dieting practices and dietary restraint measurements.

Power of Food Scale (PFS): The Power of Food Scale (PFS) assesses the psychological impact of living in food-abundant environments. It measures appetite for, rather than consumption of, palatable foods, at three levels of food proximity

(food available, food present, and food tasted). It is comprised of 15 statements pertaining to the availability, presence, and taste of food. Examples of statements include: "If I see or smell a food I like, I get a powerful urge to have some." The aggregate PFS score suggests degree of vulnerability to the various aspects of an obesogenic food environment, one that is filled with readily available, high-kilojoule, highly palatable food.

Hunger, Thirst Rating Scale: Participants will be asked to rate their degree of thirst, hunger, liking of the study foods and desire to eat the study foods on a 100mm analog scale ranging from "not at all" to "extremely". This rating will be performed at three different time points during each RRV visit.

24-hour food and exercise recall: At each visit, the child (with the assistance of the parent) will recall his/her dietary intake and physical activity for the previous 24 hours and current day. Any participant who has not complied with the study protocol will be rescheduled.

Dietary habit books: During the course of the study participants will engage in two, separate weeks of wash out where they will not participate in any lab activities, but will be asked to wear an ACTi graph activity monitor for 1 week. During that week the participant will be asked to record their dietary history. Participants will be asked to indicate the time of day, portion sizes and brands of foods and beverages consumed.

Weight, height, and BMI: Youth and Parent/Guardian weight will be assessed by use of a digital scale (SECA). Height will be assessed using a SECA stadiometer. On the basis of the height and weight data, BMI, and BMI percentile is calculated using the CDC Child (or Adult) BMI Calculator according to the following formula: (BMI = kg/m^2).

Body Composition: Body composition will be calculated using air displacement plethysmography in the child only. The device used is called a Bod Pod. The BOD POD technology is fundamentally the same as underwater (hydrostatic) weighing, but uses air instead of water. The BOD POD measures the volume of air a person's body displaces while sitting inside a comfortable chamber, rather than measuring how much water his or her body displaces when dunked in a tank. The BOD POD itself is a dual-chambered, fiberglass plethysmograph that determines body volume by measuring changes in pressure within a closed chamber. Children will be asked to wear standardized athletic clothing for each BOD POD measurement over time.

Liking of Exercise and Seated Activities: Participants will be asked to use each piece of exercise equipment for 1 minute and they will have 3 minutes to explore the desk activities. They will be asked to rate how much they like each of these on a 100mm VAS scale.

Adolescent Sleep Hygiene Scale (ASHS) comprehensively assesses sleep hygiene through 8 subscales: physiological, behavioral arousal, cognitive/emotional, sleep environment, sleep stability, daytime sleep, substances, and bedtime routine. Six tier

frequency measure in which each increase in response suggests a 20% increase in frequency. Questions are asked about behaviors during the previous month.

Cleveland Adolescent Sleep Questionnaire (CASQ) This is meant to measure excessive daytime sleepiness in adolescents. The survey includes various statements about alertness and sleepiness, which the participant rates from 1-5 (never to almost every day).

The International Physical Activity Questionnaires (IPAQ) – short form is comprised of 7 items to assess self-report physical activity. The purpose of the questionnaire is to provide common instruments that can be used to obtain internationally comparable data on health–related physical activity. IPAQ-S will be used to assess the types and intensity of physical activity and inactivity in daily life to estimate total activity in MET-min/week and time spent sitting "over the past 7 days."

SNAK Part 2 only –Survey Additions

The Consideration of Future Consequences (CFC) scale measures the extent to which people consider the potential distant outcomes of their current behaviors and are influenced by those potential outcomes. The CFC is a 12- item scale using 5-point ratings. (1 = extremely uncharacteristic to 5 = extremely characteristic). For example, participants rate the statement "I consider how things might be in the future, and try to influence those things with my day to day behavior.

The French Weight Loss Scale (FWLS) was validated for use with adolescents and has been used with children, adolescents, and adults. It asks participants to report their use of various weight control behaviors over the past 9 months.

The **Parent Encouragement of Child Weight Loss (PEWL)** scale assesses parent-reported use of various strategies that can be used to both indirectly and directly encourage their child to lose weight Parents are asked to rate how they feel about questions from 1 (not) to 5 (definitely). The scale has primary been used with parents of female children, but the questions are appropriate for both boys and girls.

The **Weight Concerns Scale (WCS)** was validated in a sample of female adolescents, but has been used with both adolescent boys and girls. It asks 5 questions that all address different aspects of the importance of weight and body shape.

Measures timeline:

Visits	Survey Measure
1, 6, 7, 8, 10, 11, 12	*Pubertal (child self report)*

1, 6, 7, 8, 10, 11, 12	*Tanner (child self report)*
1, 6, 7, 8, 10, 11, 12	*Pubertal (parent)*
1, 6, 7, 8	*Tanner (parent)*
1, 8, 10, 12 (currently 1, 6, 7, 8, 10, 11, 12)	*Demographic (Parent)*
1, 6, 7, 8, 10	*Child Feeding Questionnaire (CFQ)*
1, 6, 7, 8, 10, 11, 12	*Food Insecurity Q (FIQ-Parent)*
1, 2,3,4,5, 6, 7, 8, 10, 11, 12	*Self Efficacy for Healthy Eating (SEHE)*
1, 6, 7, 8	*Power of Food Scale (PFS)*
1, 6, 7, 8, 10,11	*Dutch Eating Behavior-Hill (DEBQ)*
1, 6, 7, 8, 10, 11, 12	*Eating Disorder Evaluation (EDE-Q)*
1, 6, 7, 8, 10, 11, 12	*Child FIQ (FIQ-C)*
1, 6, 7, 8, 10, 11	*Venezuela Food (VFS)*
1, 6, 7, 8, 10, 11, 12	*Perceived Stress Scale (PSS)*
1, 8, 12	*Adolescent Risk Assessment (ARA)*
7, 8, 10, 12	*Contact Information Update (parent)*
9, 10, 12	*Adolescent Sleep Hygiene Scale (ASHS)*
9, 10, 12	*Cleveland Adolescent Sleep (CASQ)*
10, 11, 12	*Consideration of Future Consequences Scale (CFC)*
10, 11, 12	*The French (FWLS) (Child)*
10, 11, 12	*The French (FWLS) (Parent)*
9, 10, 11, 12	*Physical Activity Q (IPAQ-S)*
10, 11, 12	*Weight Concerns Scale (WCS)*
10, 11, 12	*Parent Encouragement of Weight Loss (PEWL) (Parent)*

Visits	Task/Assessment
1, 6, 7, 8, 10, 11, 12	Height/Weight (Child & Parent)
1, 6, 7, 8, 10, 11, 12	Blood pressure/Heart Rate (Child)
1, 6, 7, 9, 10, 11, 12	Body Composition-Body Fat %
1, 2, 4, 6, 7, 8, 9, 10, 11, 12	24 hour dietary recall
1, 2, 4, 6, 7, 8, 9, 10, 11, 12	24 hour physical activity recall
1, 6, 7, 9, 10, 11, 12	Minute Task
1, 6, 7, 9, 10, 11, 12	Delay Discounting Task
1	RRV PA
2, 3, 4, 5, 8, 9, 11 (HED only)	RRV HED/LED

9.3 Describe procedures performed to lessen the probability or magnitude of risks.

Response: The level of risk encountered by the participants in this experiment is *no greater than minimal*. We have taken several steps to mitigate any potential or perceived risk. First, the questionnaires are completed using survey monkey and redcap, which contains no personal identifying information and uses only a code that is maintained on a password protected computer. Second, the participants are told that they do not have to answer questionnaires that they are not comfortable answering. Finally, participants are reminded that none of the information that they provide will be shared with anyone, including parents or the authorities. Using these procedures, we have good response rates on our

questionnaires and have not had participants report feelings of discomfort in answering questions of this nature.

The only people who will have access to the questionnaire data are study staff. It will be entered by the participant directly into the secure, password protected Survey Monkey™ or redcap program. If the participant is uncomfortable answering the questionnaires, he/she does not have to complete them and can still participate in the remainder of the experimental sessions. In addition, if at any time the participant wishes to stop the experiment, he/she can do so without question and will be compensated for the time completed.

There is minimal risk associated with reporting of Tanner Stage & Pubertal Development Questionnaire. The children may feel embarrassed reporting about the stages of their genital and breast development. In order to minimize this, the experimenter will leave the room while the child completes the questionnaire and they will be given a folder to place the questionnaire into to give back to the experimenter. Furthermore, the Adolescent Risk Questionnaire and Eating Disorder Examination Questionnaire are administered (as with all surveys) are administered in a private room. We make clear in the directions that there are no right or wrong answers and that their responses will be kept confidential. These instruments are not meant to be diagnostic in the manner in which they are being administered and are being used in the context of the research to understand how desire to regulate food intake and engage in various forms of risk behavior and dieting may interact with our study measures to influence weight change over time. See section 14.1 for more discussion on this.
Furthermore, at the end of Visits 10-12 we will hand out a resource sheet which can provide information about how to get help regarding many concerns.

9.4 Describe all drugs and devices used in the research and the purpose of their use, and their regulatory approval status.

Response: n/a

9.5 Describe the source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)

Response: (see above)

9.6 What data will be collected including long-term follow-up.

Response:

Pubertal ratings, self-efficacy, height/weight/body compositions, scarcity ratings, risk taking propensity, impulsivity, child feeding practices and food frequency will all be assessed at visits 6, 7, 8 (6, 15, and 24 month follow up).

Pubertal ratings, self-efficacy, height/weight/body compositions, scarcity ratings, risk taking propensity, impulsivity, child feeding practices, physical activity and sleep will all be assessed at follow up visits 10, 11, 12.

9.7 For 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

10.0 Data and Specimen Banking

10.1 If data or specimens will be banked for future use, 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.

Response: Data will be stored for up to 3 years after data collection. No specimens will be collected.

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

Response: Data will be stored in a password protected database. The data will not contain any identifying information. No information will be removed from the laboratory.

10.3 Describe the procedures to release data or specimens, 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

11.0 Data Management

11.1 Describe the data analysis plan, including any statistical procedures.

Response:

Response: The data will be analyzed using SPSS and SYSTAT software once collection is complete.

2 Way ANOVAS with
Inde: Sex and BMI as predictors
Dep: Food reinforcement
Cov: SES

Variables of interest include:
BMI% pre/post
Sex
SES
Food reinforcement pre/post
Other analyses:
Assigned snack food
Self efficacy scores for health eating

11.2 Provide a power analysis.

Response: 3 level Dependent, 2-2level Independents.

Able to detect effect size of 0.25, 0.5, 0.75, 1.00, or 1.25 at alpha 0.05

>90 0.826 0.999 1.000 1.000 1.000

N>90 used to see small/medium to large effects and also have an even number of participants to evenly split recruitment groups (N= 226, 113 male, 113 female)

11.3 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

Response: The Principal Investigator, Dr. Jennifer Temple, will be responsible for ensuring data integrity and safety monitoring for human subjects who are involved in the research by training all staff to abide by appropriate protocols, including data security, password protection, and GRP/CITI training. The project coordinator will monitor these training steps.

All data that are collected by the investigators are stored in password protected databases or in locked filing cabinets, where the information is only associated with a numeric identifier and not a subject's personal information.

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

Response: Quality control checks are used for all calculations and manual data inputs. At least two experimenters will check all values via double data entry. Data collected via survey monkey or redcap will be downloaded.

11.5 Describe how data and specimens will be handled study-wide:

Response: Data will be stored in a password protected database. The data will not contain any identifying information. No Information will be removed from the laboratory.

11.6 What information will be included in that data or associated with the specimens?

Response: ID number associated with height and weight data. No specimens collected.

11.7 Where and how data or specimens will be stored?

Response: Data will be stored in a password protected database. The data will not contain any identifying information. No information will be removed from the laboratory.

11.8 How long the data or specimens will be stored?

Response: 3 years

11.9 Who will have access to the data or specimens?

Response: PI, research coordinator, Approved research assistants on the project will have access to the data.

11.10 *Who is responsible for receipt or transmission of the data or specimens?*

Response: n/a

11.11 How data and specimens will be transported?

Response: n/a

12.0 Provisions to Monitor the Data and Ensure the Safety of Subjects

12.1 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. Jennifer Temple, will be responsible for ensuring data integrity and safety monitoring for human subjects who are involved in the research. The project coordinator will bring any concerns or*

comments from the participants or research assistants to the attention of the PI.

This study asks students to answer a variety of surveys asking about their risk taking and eating behaviors. Because the questionnaires used in this study are not meant to be diagnostic and because the measures examine common, subclinical eating behaviors, we do not take any action in children who score high on disordered eating behavior. We lack the qualifications and the authority to perform diagnostic screening. Additionally, because we aim to protect privacy and confidentiality of our participants, we are not willing to share their response information with parents. We have added a notification at the end of the Adolescent Risk Questionnaire which provides contact information for the Crisis Services hotline, so that students may anonymously seek that support if they are interested. Furthermore, we will supply a resource sheet to all participants at the end of visits 10, 11, 12, should they participate in SNAK Part 2.

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

Response: participant comments will be reported

12.3 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

12.4 Describe the frequency of data collection, including when safety data collection starts.

Response: n/a

12.5 Describe who will review the data.

Response: n/a

12.6 Describe the frequency or periodicity of review of cumulative data.

Response: For the proposed project the data will be reviewed at 1 month and 2 months. For the previously conducted research, approximately every 6 months the data was reviewed by the PI.

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

Response: n/a

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

Response: n/a

13.0 Withdrawal of Subjects

13.1 Describe anticipated circumstances under which subjects will 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 data collection. Should they drop out or be withdrawn from the study, they will be asked to answer a 4-5 question exit survey about their experience.

13.2 Describe any procedures for orderly termination.

Response: N/A

13.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

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.

14.0 Risks to Subjects

14.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

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. There is a low probability of risks from completing some of our study instruments, including risk of disclosure of information outside the context of the research study. Sub-clinical disordered eating behavior, such as dieting and food restriction, is assessed on our instruments, such as the DEBQ and the EDE-Q. These instruments are not meant to be diagnostic in the manner in which they are being administered and are being used in the context of the research to understand how desire to regulate food intake and engage in various forms of dieting may interact with our study measures to influence weight change over time. These are commonly used measures in this population and are not known to cause physical, psychological, social, legal or economic harm. Food scarcity is being assessed using two instruments in this study (VFS and FIQ). It is critical that we gather information about the child's perceived food scarcity, as we have preliminary data showing that the child's perception is more strongly related to weight change than the parent's perception. The child may feel some embarrassment from answering questions about their food scarcity, but all other risks (physical, social, legal, and economic) remain extremely low probability.

Finally, the participants in our study complete the ARA questionnaire. This questionnaire is modeled from the Youth Behavioral Risk Surveillance study questionnaire which has been used in tens of thousands of adolescents from across the country for over a decade. There are no known or reported risks from the administration of this questionnaire. The participants are told that their answers will be kept confidential, including not being reported to their parents. They are at no legal risk from reporting this activity. It is common for studies of adolescent substance use to provide this type of disclaimer to participants completing questionnaires of this nature in order to encourage honesty and reduced undue concern from the participant that there will be punishment for their answers. We have added a pop up containing contact information about a local mental health hotline (Crisis Services) at the end of the ARA survey, so that any student has access to this confidential line if they are interested. Furthermore, we will supply a resource sheet to all participants at the end of visits 10, 11, 12, should they participate in SNAK Part 2 or 3.

Despite these surveys not being clinical assessments we will attempt to notify parents/guardians of potential ongoing high risk eating behaviors and mental health responses of their teenagers. Data from the EDE-Q and ARA will be reviewed at the end of SNAK Part 2 visits (Visits 10-12). Should responses indicate recent purging behavior, suicidal ideation or attempt, the parent/guardian of the child will be contacted using the "Parental Contact due to EDE or ARA Phone Script" based on the following assessment plan.

The EDE Q survey data will be reviewed by research assistant at the end of SNAK Part 2 (Visits 10, 11, 12). If an individual scores an average > 4.0 globally (average of EDE-Q

items #1-12 and 19-28), and endorses >2 on #16 (vomiting) or >2 on #17 (laxative use), the PI, Jennifer Temple, will call the parent/guardian of the child to suggest they talk to their child about their risky eating habits and consider seeking medical evaluation following the "Parental Contact due to EDE or ARA Phone Script" within one week.

The ARA survey data will be reviewed by research assistant at the end of SNAK Part 2 (Visit 12). Should a participant endorse thoughts of suicide (#15) greater than "once or twice" or any endorsement of "suicide attempt" (#16) in the past 12 months, the PI, Jennifer Temple, will call the parent/guardian of the child to suggest they talk to their child about their mental health and consider seeking medical evaluation following the "Parental Contact due to EDE or ARA Phone Script" within one week.

The "Parental Contact due to EDE or ARA Phone Script" will not specifically disclose the child's questions or responses, but will convey the nature of the concern as "high risk eating behaviors" or "mental health." The PI will make 3 documented phone calls attempts to parents over 3 weeks. If no contact is made, the research coordinator will mail a letter using the indicated script and include the "Resource letter" along with it.

Individuals will not be contacted for data from appointments that they have previously consented/assented to. The SNAK Part 2 Consent and Assent forms will include a statement about potential disclosure. Those that have already signed a SNAK Part 2 Consent will be provided a Consent/Assent Addendum notifying them of the change prior to the start of their next scheduled appointment. The child will not be dismissed from the study based on these survey responses.

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

Response: n/a

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

Response: n/a

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

Response: n/a

15.0 Potential Benefits to Subjects

15.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

Response: The participants may find the compensation to be a benefit to their participation.

Also, in order to support the involvement of families that may not have personal transportation available, we will reimburse the public travel cost of the parent, participant, and any siblings under 16 years of age that must travel with the parent to the appointment. The travel must be completed via NFTA bus or rail, on the date of appointment, and a receipt must be rendered in exchange for cash reimbursement for the fare. Those that have unlimited monthly NFTA passes will not reimbursed.

15.2 Indicate if there is no direct benefit. Do not include benefits to society or others.

Response: no direct benefit

16.0 Vulnerable Populations

16.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information.*
- *If the research involves neonates of uncertain viability or non-viable neonates, review "CHECKLIST: Neonates (HRP-413)" or "HRP-414 – CHECKLIST: Neonates of Uncertain Viability (HRP-414)" to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information.*
- *Consider if other specifically targeted populations such as students, employees of a specific firm or educationally/economically disadvantaged persons are vulnerable to coercion or undue influence. The checklists*

listed above for other populations should be used as a guide to ensure that you have provided sufficient information.

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. 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.

17.0 Community-Based Participatory Research

17.1 Describe involvement of the community in the design and conduct of the research.

Response: none

Note: "Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research 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.

18.0 Sharing of Results with Subjects

18.1 Describe whether or not results (study results or 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 physicians) and if so, describe how it will be shared.

Response: None. We will do our best to prevent subjects from learning their body fat % during our testing, so that it does not influence behavior. No survey information will be disclosed to parents and we will not comment on any survey responses made by parent or child.

19.0 Setting

19.1 Describe the sites or locations where your research team will conduct the research.

Response: UB South Campus, G62 Farber Hall, And Nutrition and Health Research lab, Farber G03, and Bod Pod Room (Kimball 119/120)

19.2 Identify where your research team will identify and recruit potential subjects.

Response: All participants will be those that completed studies in our laboratory in the past who have asked to be placed on our email list or are those that have seen a flyer for our study.

19.3 Identify where research procedures will be performed.

Response: UB South Campus, G62 Farber Hall, And Nutrition and Health Research lab, Farber G03 and Bod Pod Room (Diefedorf Annex Room G19 or Kimball 119/120)

19.4 Describe the composition and involvement of any community advisory board.

Response: n/a

19.5 For research conducted outside of the organization and its affiliates describe:

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

Response: n/a

20.0 Resources Available

20.1 Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. 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 people 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 person meets the qualifications described to fulfill their roles.

Response: PI, Jennifer Temple has extensive experience with this type of research. All lab staff been trained by the research Coordinator and PI to take height and weight measurements in accordance with those use for the NHANES national data collection.

Describe other resources available to conduct the research: For example, as appropriate:

20.2 Justify the feasibility of recruiting the required number of suitable subjects within the agreed 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: We have access to the contact information of over 2000 individuals that completed other studies in previous years. Additionally, have previously been approved to send flyers to local public schools in large numbers. Therefore, we believe we will be able to attain n=226 nonsmoking youth within the given 3-year period.

20.3 Describe the time that you will devote to conducting and completing the research.

Response: **Table 3. Planning for enrollment of participants from baseline (B) through three follow-up periods every 6 months (F)**

	Study Months									
	0-6	6-12	12-18	18-24	24-30	30-36	36-42	42-48	48-54	54-60
IRB, pilot testing, staff	10									Finish data collection, data analysis and manuscri
Enroll 1-58		B 1-	F 1–45	F 1 - 45	F 1 - 45					
Enroll 58 - 116			B 46-	F 46-90	F 46-90	F 46-90				
Enroll 116 -				B 91-	F 91-135	F 91-135	F 91-135			
Enroll 174 -					B 136-	F 136-180	F 136-	F 136-		
Enroll 232 -						B 181-226	F 181-	F 181-	F 181-	
Total/6	10	45	90	135	180	180	135	90	45	
Study Year	01		02		03		04		05	
Total Assessments/y	55		225		360		225		45	

B = baseline data collection; F = Follow-up weight re-checks

20.4 Describe your facilities.

Response: We are a research laboratory with many rooms, including a full kitchen and two study rooms. A third study room is located directly across the hall. All

height and weight measurements will be taken within G62 Farber Hall, UB South Campus. Exercise will Occur in Farber G03 and BODPOD measurements will be taken in Diefendorf Annex G19.

20.5 Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.

Response: n/a

20.6 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 research assistants are CITI human ethics and GRP certified and have gone through rigorous training and observation by managers in the Nutrition and Health Research lab prior to working autonomously.

21.0 Prior Approvals

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

Response:

22.0 Recruitment Methods

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

Response: n/a

22.2 Describe the source of subjects.

Response: see above

22.3 Describe the methods that will be used to identify potential subjects.

Response: see above

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

Response: see above

22.5 Describe the amount and timing of any payments to subjects.

SNAK PART 1:
After these 5 visits the child will be paid $55, and as long as all materials have been completed along the way, they will receive a bonus of $45, for a total of $100. This "bonus" is a compilation of money earned for doing activities outside of the laboratory. Children earn $1 per day for eating their snack and then completing their daily survey about the food. They also earn $1 per day for wearing their activity monitor and writing down their dietary intake in their habit book. Should more than 4 days snacking be missed in a 2 week periods, $1 will subtracted from their earnings per missed day. Once the child completes the first 5 visits, the parent will be entered into a drawing to win a $100 check. The drawing will occur once per every 10 families that complete the study.

Six months after the first appointment, they will come back into the lab, so that the child can have their body composition measured and to answer some questionnaires. The parent will also be re-weighed. The participant will be paid $25 for this appointment (90min). Another 9 months later, the child will be asked to come in again for another 90 min appointment. For this visit, the child will earn $30, and the parent/guardian will receive $10 to help offset the cost of transit.

Finally, 24 months after the first appointment, the child will be asked to come to the lab for 2 appointments (75-90 min each) again to answer questions, eat a granola bar, play the computer game, and to have their body composition measured. There will be a 1 week break in between the appointments when the child will again wear the activity monitor watch and record their diet. The child will come in for their last appointment and be paid $55 more, with an additional $15 parent compensation. Over the course of the study the child will earn up to $210. The parent may receive a total of $25 to help offset the cost of travel.

Those currently enrolled in SNAK Part I who have not yet completed visit 9 will be provided an updated SNAK infographic at their next appointment to

inform them of both child and parent compensation increases at Visits 7 and 9.

SNAK Part 2:

For the second phase of the study, families that have consented to be contacted for continuation (contingent upon further grant funding) will be called and offered to participant in Part II of the SNAK study. Should they choose to participate, we will be attempt to schedule 90min follow up appointments every 9 months until the child turns 18. For most children this would be amount to 3 follow up appointments (3 appointments maximum) but for children that enrolled in the program near age 15, they may be more likely to have only one follow up appointment prior to age 18. The first scheduled appointment after a participant turns 18 will involve a new consent process for the legal adult participant. If they would like to continue their participation in the study, the parent components will become optional.

Payment will be the same for each appointment regardless of how many follow up appointments a particular participant completes. Visit 10 (33months) -90min- $30 to the child and $10 transit to parent/guardian. Visit 11 (42 months) -90min- $30 to the child and $10 transit bonus to parent/guardian. Visit 12 (51 months) -90min- $30 to the child and $10 transit bonus to parent/guardian.

23.0 Local Number of Subjects

23.1 Indicate the total number of subjects to be accrued locally.

Response: all- n =226

23.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

Response: n/a

24.0 Confidentiality

Describe the local procedures for maintenance of confidentiality.

24.1 Where and how data or specimens will be stored locally?

Response: Information will be treated in strict confidence to the extent provided by law. The child's identity will be coded and will not be associated with any published results**.** A child's answers to sensitive questionnaires will

not be released to anyone, including a parent or guardian, except under very rare circumstances in which his/her answers suggest a danger to him/herself or to another person. We control access to the computer files that hold this information. The connection between name and accession number will be kept in separate files and will be destroyed after the study is completed and published.

24.2 How long the data or specimens will be stored locally?

Response: 3 years after the end of all data collection.

24.3 Who will have access to the data or specimens locally?

Response: PI, research coordinator, assigned research assistants

24.4 Who is responsible for receipt or transmission of the data or specimens locally?

Response: Assigned research assistants.

24.5 How data and specimens will be transported locally?

Response: n/a

25.0 Provisions to Protect the Privacy Interests of Subjects

25.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

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.

25.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Response: Response: We describe our confidentiality and privacy policies prior to consent. Subjects will complete the questionnaires

online in an environment that makes them most comfortable. All subjects will be told that all responses will be confidential.

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

Response: Participants have given their permission to be screened and also consented to participate in the outlined procedures. All have also indicated that they would like to be contacted for future studies. During the consent process they granted permission for their information to be connected to a unique identifier, and not associated to their name. The research team can access participant data by ID number only through participant folders and computer databases.

26.0 Compensation for Research-Related Injury

26.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

Response: n/a

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

Response: n/a

27.0 Economic Burden to Subjects

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

Response: n/a

28.0 Consent Process

28.1 Indicate whether you will be obtaining consent

Response: Yes, all subjects will be 12-16 at the time of enrollment so they will be providing assent while their parents provide consent for their participation. Age will be verified by asking the subject's date of birth.

28.2 Describe where the consent process take place

Response: Online, before the subject starts the research survey and then officially G62 Farber Hall, South Campus, Closed participant room

28.3 Describe any waiting period available between informing the prospective subject and obtaining the consent.

Response: The time between scheduling the appointment and appointment date.

28.4 Describe any process to ensure ongoing consent.

Response: n/a

28.5 Describe whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:

- *The role of the individuals listed in the application as being 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: Yes, will be following HRP-090 procedure.

Non-English Speaking Subjects

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

Response: n/a

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

Response: n/a

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

28.8 Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response: n/a

28.9 If the research involves a waiver 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

Subjects who are not yet adults (infants, children, teenagers)

28.10 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 NY state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."

Response: self-report birthdate and parental confirmation

28.11 For research conducted outside of NY 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

28.12 Describe whether parental permission will be obtained from:

- *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.*
- *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.*

Response: one parent or guardian

28.13 Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.

Response*: We will be following the HRP013 Standard Operating procedure for LAR, Children, & Guardians, thus it is possible that a LAR may provide consent in this study. The consent forms ask that the parent or guardian indicate their relationship to the child on the consent form.*

28.14 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: yes, all

28.15 When assent of children is obtained describe whether and how it will be documented.

Response: Child Assent form (see attached)

Cognitively Impaired Adults

28.16 Describe the process to determine whether an individual is capable of consent. The IRB sometimes allows the person obtaining assent to document assent on the consent document and does not automatically require assent documents to be used.

Response: n/a

Adults Unable to Consent

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent and, where possible, assent of the individual should also be solicited.

28.17 List the individuals from whom permission will be obtained in order of priority. (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.) For research conducted in NY state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the

definition of "legally authorized representative." The list in the consent template signature section corresponds to the priority list for NYS.

Response: n/a

28.18 For research conducted outside of NY 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 procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

Response: n/a

28.19 Describe the process for assent of the subjects. Indicate whether:

- *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
- *If assent will not be obtained from some or all subjects, an explanation of why not.*
- *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*

Response: n/a

28.20 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

29.0 Process to Document Consent in Writing

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.

(If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script.)

29.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

Response: yes, following

30.0 Drugs or Devices

30.1 If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

Response: n/a

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:

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

Response: n/a

30.3 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