Study Title: Study of Brain, Reward, and Kids' Eating (BRAKE)
NCT Number: NCT05456516
Date: 3/26/2024

1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

Specific Aims: Children from rural communities are at greater risk for obesity than children from more urban communities. However, some children are resilient to obesity despite greater exposure to obesogenic influences in rural communities (e.g., fewer community-level physical activity or healthy eating resources). Understanding the factors that promote resiliency to pediatric obesity despite these increased risks is essential to inform prevention efforts. In particular, it is a critical to understand the neurocognitive and behavioral determinants of excess food intake in childhood. Therefore, the proposed research will identify 1) neurocognitive processes that influence sensitivity to environmental food cues (e.g., food brands or images) and 2) eating behaviors that underlie resiliency to obesity, which may provide targets for strength-based prevention efforts. Additionally, the training plan will support my transition to an independent, translational research career with a focus on rural pediatric obesity.
Eating behaviors are learned through reinforcement, the process through which environmental cues become valued and influence behavior. Animal models have identified two reinforcement learning phenotypes that may have translational importance for understanding excess intake in humans: 1) goal-tracking—the cue has predictive value causing the animal to approach the source of reward; and 2) sign-tracking—the cue is both predictive and rewarding (i.e., incentive salience) causing the animal to approach the cue, not the source of reward. These phenotypes are relevant to pediatric obesity as both goal-tracking and lower child adiposity are associated with better attentional control, lower impulsivity, and greater reward-related prefrontal cortex (PFC) engagement. Therefore, this proposal's central hypothesis is that children who attribute less incentive salience to food cues will be more resilient to overconsumption. Hence, in rural children who experience greater exposure to obesogenic food environments, goal-tracking may be protective against excess food intake and adiposity. While impaired reinforcement learning has been implicated in the etiology of obesity, the role of goal- and sign-tracking in food cue reactivity, eating behavior, and adiposity has not been formally tested.

This mentored proposal provides the opportunity to build upon my NIH fellowship (F32) by examining resilience to pediatric obesity in 76, 8-10-year-old children in rural Pennsylvania. Child adiposity will be assessed via air displacement plethysmography using BodPod while reinforcement learning phenotype will be assessed using two behavioral tasks thought to translate goal- and sign-tracking to humans. Food cue reactivity will be assessed using functional near-infrared spectroscopy, which is more amenable to use with younger children and more flexible in the types of study designs that can be employed than functional magnetic resonance imaging. To identify modifiable behavioral targets, I will measure meal eating behaviors (e.g., bite size and speed). Together, this proposal will advance my research and allow me to develop expertise in translational neuroscience with a focus on identifying targets for prevention of pediatric obesity, establish a foundation in rural health, and extend my neuroimaging expertise to other modalities. The following aims will be tested:

Aim 1: Determine whether reinforcement learning phenotype (goal- versus sign-tracking) is associated with adiposity through its effect on neural food cue reactivity

Hypothesis 1a: Children who goal-track will have lower adiposity than children who sign-t rack

Hypothesis 1b: Individual differences in PFC engagement to high- than low-energy dense food images will mediate the association between reinforcement learning phenotype and adiposity

Aim 2: Determine whether reinforcement learning phenotype (goal- versus sign-tracking) is associated with overconsumption through its the influence on eating behaviors

Hypothesis 2a: Children who goal-track will consume less both when hungry (i.e., meal intake) and full (i.e., eating in the absence of hunger; hedonic overconsumption) than those who sign-track

Hypothesis 2b: Individual differences in eating behaviors associated with overconsumption (e.g., larger bites, faster bite rat and eating sped) will mediate the association between reinforcement learning phenotype and intake

Importance:

Although children from rural communities have 26% greater odds of developing obesity than children from urban communities, rural pediatric obesity has received little attention from child obesity researchers. Therefore, it is critically important to identify protective factors that confer resiliency to excess adiposity in rural youth. Understanding the role of reinforcement learning phenotype in food cue reactivity and adiposity will help elucidate the neurocognitive processes that contribute to obesity while the identification of eating behaviors that mediate the influence of reinforcement learning phenotype on food intake will highlight modifiable behavioral targets that may promote resiliency to obesity.

2.0 Background

2.1 Scientific Background and Gaps

Characterizing neurobiological differences in response to food cues will lead to more effective obesity prevention. Obesity remains a global health crisis that contributes to serious physical and psychosocial consequences. The prevalence of obesity remains high because the disease is resistant to behavioral treatments, so early identification and prevention − especially during childhood − is essential to reversing the epidemic. Current approaches to preventing obesity have yielded small effects with minimal clinical significance, underscoring the need to develop more effective programs tailored to specific populations. Although the ultimate cause of obesity is excess energy consumption, the underlying neural and behavioral traits that contribute to overeating in an obesogenic environment are heterogeneous and elusive.

Eating habits are learned through reinforcement, the process through which environmental food cues become valued and influence behavior. Therefore, understanding individual differences in reinforcement learning is essential to uncovering the causes of obesity. Preclinical models have delineated two reinforcement learning phenotypes that may have translational importance for understanding overeating in humans: 1) goal-tracking—the cue has predictive value, causing the animal to approach the source of reward (e.g., palatable food); and 2) sign-tracking—the cue has predictive and hedonic value (i.e., incentive salience), causing the animal to approach the cue itself rather than the source of reward. In response to reward cues (e.g., food cues), goal-trackers show greater activation of prefrontal cortex (PFC), a region that supports cognitive control, which may contribute to less attribution of salience. Thus, the central hypothesis is that attributing less incentive salience to food cues (i.e., goal-tracking) is protective against adiposity and overconsumption, potentially due to increased PFC engagement. This proposal will advance the field by formally testing the role of reinforcement learning phenotype (i.e., goal- vs. sign-tracking) in food-cue reactivity and adiposity, which will provide insight into neurocognitive processes implicated in obesity and inform interventions to prevent this serious disease.

2.2 Study Rationale

(Aim 1): The objective of Aim 1 is to determine whether reinforcement learning phenotype (goal- versus sign-tracking) is associated with adiposity through its effect on neural food cue reactivity. We will assess neural food cue reactivity by comparing children's neural activation to high vs low-energy dense foods. Reinforcement phenotype will be assessed using both the Space Game and the Shape Game tasks. The rationale for this aim comes from the similarities in studies comparing sign- and goal-tracking and studies comparing children with verses without obesity. Both goal-tracking and lower child adiposity are associated with better attentional control, lower impulsivity and compulsivity, and greater PFC engagement in response to reward (e.g., food cues). As high-energy dense foods images are more rewarding than those with low-energy density, it is hypothesized that goal-tracking will be associated with greater PFC engagement when viewing high- vs. low-energy dense food images and lower child adiposity. By determining the influence of reinforcement learning phenotype on food cue reactivity and adiposity, we can establish neural and behavioral profiles that are associated with greater resiliency to obesity children.

(Aim 2): Dynamic patterns of behavior within a meal, termed meal microstructure, have been associated with energy intake, weight status, and dysregulated eating. These patterns of eating behaviors are driven by reinforcement learning. Therefore, it is critical to understand how reinforcement learning phenotypes in children relate to child meal behaviors and overconsumption. A review published by PI Dr. Pearce highlights the association between childhood obesity and an obesogenic style of eating marked by faster eating rates, larger bites, and shorter meal durations. Therefore, we will assess reinforcement learning as stated above with the Space Game and the Shape Game tasks. We will also video record children's meals and use behavioral coding to asses meal microstructure. The purpose of Aim 2 is to determine the influence of reinforcement phenotypes on eating behaviors that may lead to overconsumption and excess adiposity.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

Child Inclusion Criteria:

1. In order to be enrolled, children must be of good health based on parental self-report.
2. Have no neurodevelopmental disorder (e.g., ADHD) or learning disabilities (e.g., dyslexia).
3. Have no allergies to the foods or ingredients used in the study.
4. Not be taking any medications known to influence body weight, taste, food intake, behavior, or blood flow.
5. Be 8-10 years-old at enrollment.
6. The child must speak English.

Parent Inclusion Criteria:

1. The parent who has the most knowledge of the child's eating behavior, sleep and behavior must be available to attend the visits with their child. This would be decided among the parents.

3.2 Exclusion Criteria

Children would be excluded if:

1. They are not within the age requirements (< than 8 years old or > than 10 years-old at baseline).
2. If they are taking cold or allergy medication, or other medications known to influence cognitive function, taste, appetite, or blood flow.
3. If they don't speak English.
4. If they are colorblind.
5. If they have a learning disability, ADD/ADHD, language delays, autism or other neurological or psychological conditions.
6. If they have a pre-existing medical condition such as type I or type II diabetes, rheumatoid arthritis, Cushing's syndrome, Down's syndrome, severe lactose intolerance, Prader-Willi syndrome, HIV, cancer, renal failure, or cerebral palsy.
7. If they are allergic to foods or ingredients used in the study.

Parent Exclusion Criteria:

1. if the parent is unable to attend the study visits

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

1. Failure to follow procedures
2. Unexpected development of medical problem which could affect study
3. Family moving from area

3.4 Identification of subjects

The Children's Eating Behavior Laboratory at Penn State has an excellent relationship with the surrounding community that is cultivated through our frequent outreach and community events. These activities have made it possible for us to recruit children from the local community and retain families across multiple visits and study years. Recruitment will be done by posting approved study flyers in and around the study site, and by placing approved advertisements on popular on ResearchMatch (researchmatch_text) internet sites, mom's groups, Facebook, family-oriented periodicals, newsletters, schools, newspapers, and on local public access television stations around Central, PA.

In addition to these sources, we also recruit by placing study flyers in Valpak coupon books that are mailed to local families. In addition, the First Families database managed by Penn State contains names of families interested in participating in research studies. The database will be used for recruitment. We will conduct recruitment at local churches and with sports clubs at the local YMCAs (with prior approval) by handing our approved recruitment study flyers.

3.5 Recruitment process

3.5.1 How potential subjects will be recruited.

The Children's Eating Behavior Laboratory at Penn State has an excellent relationship with the surrounding community that is cultivated through our frequent outreach and community events. These activities have made it possible for us to recruit children from the local community and retain families across multiple visits and study years. Recruitment will be done by posting approved study flyers (Study Flyer) in and around the study site

For the purposes of recruitment, a shorted study name is used that can be abbreviated using an acronym was created: Study of Brain, Reward, and Kids' Eating or Study BRAKE. This is used to identify our study on recruitment materials. We also recruit by placing study flyers in Valpak coupon books that are mailed to local families (Valpak Text). We place approved advertisement on ResearchMatch (researchmatch_text), Facebook (Facebook/Web Text), newspapers and periodicals (Facebook/Web Text). After getting permission from directors/managers, approved advertisements (either Facebook/Web Text or the Study Flyer) will also be posted to mom's groups (e.g., State College MOPS - https://www.newhopesc.org/state-college-mops), newsletters, or schools.

In addition, the FIRSt Families database managed by Penn State contains names of families interested in participating in research studies. The FIRSt Families has a mechanism to request access via their website (https://firstfamilies.la.psu.edu/information-for-researchers) and any initial contact made with interested families is managed through their website. Interested parents will call the study coordinator for an initial screening session done over the phone.

We will conduct recruitment events at local churches, with sports clubs at the local YMCA, and events on Campus and in State College, PA. We will hand out copies of the approved Recruitment Materials Study Flyer.

3.5.2 Where potential subjects will be recruited.

Desired participants will be recruited from the general area of Central Pa.

4.0 Consent Process and Documentation

4.1 Obtaining Informed Consent

After a brief telephone or email conversation with a parent of the potential participants to describe the study and determine their continued interest, prior to the screening questions and the baseline appointment, a Consent form is read or provided to the parent. This is due to the need for consent for an initial screening and for the child to fast for three hours prior to the first visit.

Signed consent will also then be attained from the parent at the beginning of the baseline visit before any data is collected. This signed consent is for the parent as guardian of the child, as well as the parent as a participant. Assent of the child will also be attained and the child will sign the Consent form. Consent procedures will clearly state that participation is voluntary and participants can withdraw from the study at any time without explanation or penalty. Consent forms will also contain information on the purpose and length of the study and parents will be given a chance to ask questions to project staff before agreeing to participate. Only trained project staff affiliated with this study and approved by the Penn State Institutional Review Board at each university (e.g., PIs, co-Investigators, research coordinators/technicians, graduate students) will be able to obtain informed consent. Consent will be documented by having a parent sign approved consent forms after they agree to participate. The researcher taking consent will also sign this form, and parents will receive a copy of this form for their records. The other copy will be stored in a locked filing cabinet in PI Pearce's laboratory.

Follow-up Visit (Visit 3):

After a brief email conversation with the parent of an enrolled participant to describe the follow-up visit and determine their continued interest, a Consent form is provided to the parent. This is due to the need for consent for the child to fast for three hours prior to the visit and to get consent to mail study materials prior to the visit. The implied consent will be obtained over REDCap. Consent for the Follow-up visit (visit 3) will be obtained at the visit in Noll Lab prior to the completion of any study procedures.

To minimize coercion, 1) we have set compensation at a modest rate to avoid undue coercion for families of lower socioeconomic means, 2) we have clearly outlined the voluntary nature of the study to parents in the consent form and the child in an Assent form, and we have parents ask questions before any testing is done with children or the parents act as subjects, and 3) we are asking for child voluntary verbal assent and signature on the consent form before any testing is completed, to ensure both parent and child want to participate.

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

Implied consent will be attained from parents before screening so that eligibility questions can be completed and so that children are able to fast for 3 hours prior to the first visit. Signed consent will occur at the beginning of Visit 1 before any data is collected. Consent procedures will clearly state that participation is voluntary and participants can withdraw from the study at any time without explanation or penalty. Consent forms will also contain information on the purpose and length of the study and parents will be given a chance to ask questions to project staff before agreeing to participate as both the child's guardian and as a subject. Only trained project staff affiliated with this study and approved by the Penn State Institutional Review Board at each university (e.g., PIs, co-Investigators, research coordinators/technicians, graduate students) will be able to obtain informed consent. The consent will be documented by having parents sign approved consent forms after they agree to participate. The researcher taking consent and the child will also sign this form, and parents will receive a copy of this form for their records. The other copy will be stored in a locked filing cabinet in PI Pearce's laboratory.

4.2.1 Assent of subjects who are not yet adults

The parent/legal guardian will be given the Consent Form, and the consent form will be explained to both the child and parent. If they choose to continue, the parent and the child will both sign the consent for. Trained research personnel will make sure the parent/legal guardian understands the study expectations and will answer any questions. This will be done for the child as well. If the child gives verbal assent, and the parent/guardian is still interested in continuing with the screening process, the parent / legal guardian, child and staff member will sign and date the Parent Permission Form. A copy of the document will be offered to the parent / legal guardian prior to leaving the appointment.

Additionally, prior to each visit, the child will be read the Child Verbal Assent Script for the visit. During the child, the child will be read a brief description of each visit prior to starting each visit and asked if they would like to continue at each visit.

5.0 Study Design and Procedures

5.1 Study Design

Human subjects will be participants in a 3 session, within-subjects, observational clinical research study to determine the neurobiological and behavioral contributors to food cue response and decisions during pre-adolescence. 76 healthy parent child dyads, for a total of 152 total participants, from diverse ethnic and socioeconomic backgrounds will be tested. To be enrolled, children must be between the ages of 8-10 years-old and fit the inclusion criteria listed in section One parent will be weighed and their height measured in Visits 1, but the second parent's height and weight will be estimated by the parent who attends the visits. We estimate that 85% of the children will be white, 5% black, 5% Asian, 3.5% Hispanic/Latino, and 1.5% other (two or more races). 18.1% of families are expected to be below the poverty line, based on recent Census data (www.census.gov). All children will be in good health, right handed, not color blind, speak and read

English, and not taking any medications known to influence cognitive function, taste, appetite, or blood flow (i.e., cold medications). A parent will also be enrolled in the study.

5.2 Study Procedures

The study will be done in 3 sessions. Prior to Visit 1, when parents express interest after reading or hearing our recruitment efforts, either an online or telephone interview will present details of the study, a consent form for waived written consent, and if they are interested in participating, eligibility questions. If they are eligible, they will be scheduled for Visit 1. Prior to their scheduled Visit 1, they will be sent an informational letter with directions and more information. Prior to both visits, children will be instructed to fast for at least 3 hrs. Children and parents will come to the laboratory at lunch or dinner time and the timing will be consistent for both visits.

In Visit 1, we will measure height and weight of both the parent and the child. Children will complete the Shape Game and then will have fNIRS while viewing images of high or low by energy density foods on a computer and while picking which foods they would want to eat. fNIRS is a child-friendly neuroimaging approach that is often used to measure brain activity during computer tasks. During this visit we will provide children with a snack, complete computer Food Rating Game and Food Choice Game tasks during fNIRS. After fNIRS we will provide children with Taste Test for Liking, a Test-Meal consumed to fullness, followed by exposure to a palatable snack buffet to assess the child's eating in the absence of hunger (EAH). Between the meal and EAH, children will play the List Sorting task on the NIH Toolbox.

- CAMS Anxiety: Children will be instruction on the use of this scale by trained research personnel who are listed on this IRB application. Children will be asked to rate their current anxiety twice, once before and once after the fNIRS computer tasks.

-fNIRS Food Rating Game and Food Choice Game tasks: A trained researcher will help the children get set up with the fNIRS cap. During the Food Rating Game task, children will view food images and rate wanting, liking, and health for each food. After that, they will complete the Food Choice Game task where they view pairs of food images and choose which they would like to eat. Prior to starting the Food Choice Game task, the children are told to consider health when making their choices. One of the chosen foods will be provided to the child as part of their snack. Eye tracking will be used during the Food Choice Task only to measure where children are focusing.

-Shape Game task: A trained researcher will help the children practice the computer Shape Game task and will monitor performance. After the Shape Game task is complete, the children will exchange the points they win for a preferred candy (e.g., skittles or chocolate candies) that they can consume at home. Eye tracking will be used to measure where children are focusing.

-The Taste Test for Liking: Before the Test Meal, children will be provided with a small sample of every food to be served that visit. The child will indicate their liking for the food by means of a visual analogue scale to report how much they like each test food before it is served.

- Freddy Fullness: Child fullness will be measured using a pictorial fullness scale. They are instructed on use of the scale by trained research personnel who are listed on this IRB application. Children will be asked to report current fullness on the scale. They will be asked to make a total of 4 ratings using this scale, one immediately before and after the meal and EAH buffet.

- Test Meal and EAH Snack Buffet. Children will eat a Test-Meal of common foods (chicken nuggets, mac and cheese, broccoli, grapes, and water) to satiety. After a 15-20 minute wait time, they will be allowed access to games and a range of palatable snacks (corn chips,

pretzels, crackers, cookies, brownies, candies, chocolate, ice cream) to assess eating in the absence of hunger (EAH). Intake from the Taste Tests, Test Meal and the EAH snack buffet will be measured. A digital recording of the Child eating the Test Meal and the EAH snack buffet will be saved. This recording will be made using a video camera mounted in the observation room of our 311 Chandlee Lab. We are interested in physical stance of the child, movements, bite speed and behavior towards the food. We will also be transcribing the audio.

An ActGraph watch will be used to record the child's activity and sleep levels from Visit 1 to Visit 2. At the end of Visit 1, parents will also be provided with a sample cup and instructions for the collection of a urine sample for their child on the morning of the second visit. The instructions have been uploaded. In the week between visits, parents will complete a home food inventory at home using a REDCap survey on their phones using the Wear-IT app, which is a Penn State survey application available through the Penn State Survey Research Center.

During Visit 2, we will measure child anthropometrics (i.e., BodPod scan). After the BodPod, children will consume a meal. Then children complete neuropsychological assessments (IQ, NIH Toolbox, and cognitive flexibility) and the Space Game task.

-The BodPod: Estimates of body composition (fat versus fat free mass) will be completed by applying measures of body volume and body density obtained from air displacement plethysmography (ADP) in the Bod Pod (Life Measurement, Inc. Concord, CA). Thoracic (body trunk) gas volume, and air displacement are measured inside the Bod Pod chamber. Children are required to wear a swimming cap and tight-fitting clothing or bathing suit during the test. The Bod Pod resembles an egg-shaped chamber, and has a window for the subject to look out and air will move in the enclosed space where the subject sits. While enclosed in this chamber, if the subject begins to feel uncomfortable, they can press a button located by the knee to open the door. The Bod Pod measures the air flow and the changes in the air flow that occur while the body is in the chamber. The child will be asked to sit quietly while the first measurements of air flow are conducted. They will be shown the stop button and told that they can press it any time if they are uncomfortable. Two measurements are taken with each measurement lasting about 30 seconds. After the first measurement is done, the door will be opened to check on the child. The whole procedure takes approximately 15 minutes.

- Freddy Fullness: Child fullness will be measured using the same pictorial fullness scale. They are instructed on use of the scale by trained research personnel who are listed on this IRB application. Children will be asked to report current fullness on the scale. They will be asked to make up to 4 ratings using this scale. First, they will rate fullness prior to fNIRS. If fullness falls below 25%, they will be given a snack (e.g., granola bar) and asked to rate fullness once again. After fNIRS, children will rate their fullness before and after their snack (e.g., popcorn, pretzels, corn chips, skittles, starbursts, chocolate, ice cream, brownies, oreos).

-Space Game: A trained researcher will help the children practice the computer Space Game task and will monitor performance. After the Space Game task is complete, the children will exchange the points they win for a preferred candy (e.g., skittles or chocolate candies) that they can consume at home.

-Neuropsychological Assessments: The child will be given an IQ test and measures of cognitive flexibility to determine cognitive ability. The NIH Toolbox tests used will be the Flanker task and an Executive Function task and administered on a tablet.

Prior to Visit 3, we will mail the family an ActGraph watch will be used to record the child's activity and sleep levels 1 week prior to Visit 3. Parents will also be provided with a sample cup and instructions for the collection of a urine sample for their child on the morning of Visit 3. The

instructions have been uploaded. In the week before the visit, parents will complete a home food inventory and a sleep log at home using a REDCap survey.

During Visit 3, children will arrive at the visit after a 3-hour fast. We will measure height and weight of both the parent and the child and we will measure child anthropometrics via a BodPod scan. After the BodPod, the family will be accompanied to Chandlee laboratory where the child will have fNIRS while tasting samples of foods that are of high or low by energy density foods. fNIRS is a child-friendly neuroimaging approach that is often used to measure brain activity during computer tasks. During this visit we will provide children with a snack and complete a taste-test during fNIRS. After fNIRS we will provide children with a Test-Meal consumed to fullness. After the meal, children will complete the Friends Game task.

-The BodPod: Estimates of body composition (fat versus fat free mass) will be completed by applying measures of body volume and body density obtained from air displacement plethysmography (ADP) in the Bod Pod (Life Measurement, Inc. Concord, CA). Thoracic (body trunk) gas volume, and air displacement are measured inside the Bod Pod chamber. Children are required to wear a swimming cap and tight-fitting clothing or bathing suit during the test. The Bod Pod resembles an egg-shaped chamber, and has a window for the subject to look out and air will move in the enclosed space where the subject sits. While enclosed in this chamber, if the subject begins to feel uncomfortable, they can press a button located by the knee to open the door. The Bod Pod measures the air flow and the changes in the air flow that occur while the body is in the chamber. The child will be asked to sit quietly while the first measurements of air flow are conducted. They will be shown the stop button and told that they can press it any time if they are uncomfortable. Two measurements are taken with each measurement lasting about 30 seconds. After the first measurement is done, the door will be opened to check on the child. The whole procedure takes approximately 15 minutes.

- CAMS Anxiety: Children will be instruction on the use of this scale by trained research personnel who are listed on this IRB application. Children will be asked to rate their current anxiety twice, once before and once after the fNIRS computer tasks.

-fNIRS taste-test: A trained researcher will help the children get set up with the fNIRS cap. During the Taste-Test, children will be provided will small samples of food to taste ((chicken nugget, macaroni and cheese, carrot, grape, cracker, fruit snack chew, green beans, chocolate, orange slice) and be asked to and rate liking and wanting for each food. Intake from the taste-test will be measured. A digital recording of the child eating the taste-test will be saved. This will be made using a camera in the fNIRS room in HEF. We are interested in movement of the child, bite and chewing speed.

- Freddy Fullness: Child fullness will be measured using a pictorial fullness scale. They are instructed on use of the scale by trained research personnel who are listed on this IRB application. Children will be asked to report current fullness on the scale. They will be asked to make a total of 3 ratings using this scale, one immediately before fNIRS and then before and after the meal.

- Test Meal. Children will eat a Test-Meal of common foods (chicken nuggets, mac and cheese, broccoli, grapes, and water) to satiety. Intake from the Taste Tests and Test Meal will be measured. A digital recording of the Child eating the Test Meal will be saved. This recording will be made using a video camera mounted in the observation room of our 311 Chandlee Lab. We are interested in physical stance of the child, movements, bite speed and behavior towards the food. We will also be transcribing the audio.

-Friends Game. During the Friends Game, children will learn which of 3 different cartoon friends are brining snacks or games to a play date. They will then be asked to help their friends pack enough snacks or game by pressing a button on a keyboard. At the end of the task, we will ask

them to remember which of the 3 friends brought snacks or games. This game is played on the computer.

Visits 1-3 will be conducted at similar times during the day (usually after school, during usual meal-times). For all visits, questionnaires and surveys will be filled out on a laptop or tablet via PSU REDCap. If the parent does not complete questionnaires assigned to a visit, they may continue filling them out on the next, with all of the questionnaires for the first visit being completed by the end of the second visit. The Freddy Fullness and CAMS Anxiety forms are filled out by the participant and kept. The Test meals and EAH snack buffets will be digitally recorded.

5.3 Duration of Participation

Participants will have a total of 2 visits over about 2 weeks and then a follow-up visit about 1 year after initial/baseline visits. We expect each visit to last approximately 2.5 hours, for a total of 7.5 hours.

6.0 Risks

Physical Risks: Children may feel uncomfortable when they are wearing the fNIRS cap, and this could result in mild physical symptoms like itchiness or pressure on the skin. These sensations are mild and will stop shortly after the cap is removed. Initial training and explanation before wearing the fNIRS cap should reduce any stress.

The foods used in the study are all common foods made with ingredients you could find at the market, but there is always a chance of a food borne illness or of uncovering an allergy in the child that was previously unknown. For the foods used in the study, the chance of any food borne illness are extremely low. All Graduate and other Research Assistants who prepare and serve the foods have received ServSafe certification and are closely supervised by the Research Coordinator.

An eye tracker is a machine uses infrared light (i.e., heat) to illuminate the participant's face and uses an infrared camera to record eye movements. The infrared light that will be used to illuminate the faces of the participants is far less than what would be experienced on any typical day spent outdoors. The total duration of the study should take no longer than 30 min.

Psychological Risks: Children may experience some anxiety when completing the clinical procedures (i.e., height, weight, and BodPod). We are asking parents and children some questions that can be considered sensitive, for example about pubertal development and loss of control eating. Some children may experience psychological consequences, including embarrassment or anxiety, when answering these questions.

Loss of confidentiality: With all research studies, there is a small chance that the family's confidentiality will be breeched, even though we take precautions to maintain confidentiality.

7.0 Potential Benefits to Subjects and Others

7.1 Potential Benefits to Subjects

There are no immediate benefits to participants.

7.2 Potential Benefits to Others

Participation in this study may help us understand more about how a child makes food related decisions and eating behaviors related to overconsumption. Outcomes of this proposal can be used to inform pediatric obesity intervention and prevention efforts.

8.0 Subject Payment and/or Travel Reimbursements

Participants will be paid $50 a visit for each of 3 visits, for a potential total of $150. Participants will only be paid for the visits they attend. If the participants choose not to complete a visit after arriving, they will be paid for that visit and not be scheduled for any further visits. Participants traveling >20 mile will be provided a $20 travel stipend per visit.

9.0 References

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10.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598 Research Data Plan Review Form." In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form."

In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all sub-sections of section 22.

For all other research: complete the following section. Please refer to PSU Policy AD95 for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State's Policy AD95 or standards or need a consultation regarding data security, please contact security@psu.edu.

10.1 Which of the following identifiers will be recorded for the research project? Check all that apply. If none of the following identifiers will be recorded, do not check any of the boxes.

	Hard Copy Data	Electronic Stored Data
Names and/or initials (including on signed consent documents)	☒	☒

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes,	☐	☒
All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	☐	☒
Telephone numbers	☐	☒
Fax numbers	☐	☐
Electronic mail addresses	☐	☒
Social security numbers	☐	☐
Medical record numbers	☐	☐
Health plan beneficiary numbers	☐	☐
Account numbers	☐	☐
Certificate/license numbers	☐	☐
Vehicle identifiers and serial numbers, including license plate numbers	☐	☐
Device identifiers and serial numbers	☐	☐
Web Universal Resource Locators (URLs)	☐	☐
Internet Protocol (IP) address numbers	☐	☐
Biometric identifiers, including finger and voice prints	☐	☐
Full face photographic images and any comparable images	☐	☒
Any other unique identifying number, characteristic, or code (such as the pathology number)	☐	☐
Study code number with linking list	☐	☒
Genomic sequence data	☐	☐
State ID numbers	☐	☐
Passport numbers	☐	☐
Driver's license numbers	☐	☐

10.2 If storing paper records of research data, answer the following questions:

10.2.1 Where will the paper records, including copies of signed consent forms, associated with this research study will be stored?

Paper records will be kept in a secure, separate locked file cabinets. All locked file cabinets are also kept in locked rooms in our research suite (Rooms 309 and 311 Chandlee lab).

10.2.2 How will the paper records be secured?

Signed consent forms will be kept in secure, locked file cabinets. Any de-identified paper records will be kept in a secure, separate locked file cabinet. All locked file cabinets are also kept in locked rooms in our research suite. Only fully trained and certified research assistants and additional staff are eligible to receive a key or key code for the locked file cabinets or rooms.

10.2.3 How will access to the paper records be restricted to authorized project personnel?

Only fully trained and certified research assistants and additional staff are eligible to receive a key or key code for the locked file cabinets or rooms.

10.3 If storing electronic records of research data, indicate where the electronic data associated with this research study will be stored. Check all that apply.

☒ Penn State-provided database application. Check which of the following database applications are being used (check all that apply):

☒ Penn State REDCap
☐ Other – Specify - provided and approved database application:

☐ Penn State, College, or Department IT file server
☒ Penn State OneDrive or SharePoint
☐ Penn State GoogleDrive
☐ Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:

☐☒ Other – Specify the database application or server:
Databrary

Provide details about the data security features or attach security documentation provided by sponsor or group:

Data will be stored with, and shared through, the Databrary managed archival system. Researchers are asked to avoid the inclusion of extraneous personally identifiable information (PII) in videos uploaded to Databrary. However, given the nature of video, it might still be possible to identify individuals based on first names, facial features, or details of the environment. Because of this, sensitive or identifiable data shared with Databrary will only be viewable and downloadable to authorized users who have been granted secure access by Databrary's administrators. Only researchers with Principal Investigator status from institutions with Institutional Review Boards or similar review entities, or researchers affiliated with Principal Investigators, will be authorized for access.

Authorized users will be required to sign a user agreement that specifies that they will: (1) be responsible for maintaining the confidentiality of the data; (2) abide by ethical principles for treatment of human subjects as mandated by their local Institutional Review Boards; (3) agree not use the data for commercial purposes; and (4) treat data in Databrary with the same high standards of care that they would treat data collected in their own laboratories.

Although Databrary will is a cloud-based service for storing complete study data, only videos and other identifiable data that have been permissioned for sharing by all the depicted individuals in each recording will be made available to the community of authorized users.

Data owners can choose to share their data at any point, either as they collect their data, or only once data collection has completed.

To ensure data and site security and continuous availability, Databrary employs software programs to monitor traffic and to identify unauthorized attempts to upload, change information, download, or to otherwise cause damage. Databrary also periodically monitors their system for possible vulnerabilities and attacks, consistent with industry standards. In the event of authorized law enforcement investigations, and pursuant to any required legal process, information from these sources may be used to help identify an individual.

Please visit datastoragefinder.psu.edu for assistance with identifying appropriate data storage options. If the software to be used does not appear on that site, a software request form must be completed.

If there is a list/key that links indirect identifiers (code numbers, participant IDs, etc.) to direct identifiers, that list must not be comingled (i.e., stored in the same location) as the identifiable data, including copies of signed informed consent forms. Additionally, access to that list/key must be restricted to authorized project personnel.

10.4 Is there a list/key that links code numbers to identifiers?

☒ Yes - explain how the list that links the code to identifiers is stored separately from coded data:
The list is stored separately in locked file cabinets.

☐ Not applicable, there is no list that links code numbers to identifiers. Skip to section 22.6.

10.5 Is there a list of people who have access to the list/key?

☒ Yes – explain how access to that list is restricted and why certain persons require access.
Only the PI and the Research Coordinator have access in order to issue reminders for upcoming visits and for data quality control.

☐ No – explain why not:

10.6 Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).

☒ Password-protected files
☒ Role-based security
☐ Specify all other mechanisms used to ensure only permitted users have access to the stored research data.

The use of mobile devices or wireless activity trackers to collect identifiable research data may have to be approved by the Office of Information Security.

10.7 Will any research data (such as survey data) be collected on a mobile device, such as an electronic tablet, cell phone, or wireless activity tracker?

☐ No
☒ Yes - answer the following questions:

10.7.1 Specify the provider of the mobile devices(s)

☐ Supplied by the sponsor
☒ Penn State owned device
☐ A personal device
☐ Other – Please specify source:

10.7.2 Specify the type(s) of mobile device(s) that will be used to capture data and all identifiers captured on the mobile device(s). Please list all devices, and if more than one, the identifiers to be collected on each.

Actilife Watch will be used to record activity and sleep habits over a week. A laptop will be used to collect answers to questionnaires and computer tasks. PSU laptops or

tablets may be used to collect data from questionnaires via PSU REDCap. PSU tablet will be used to collect NIHToolbox data.

10.7.3 Specify the type of data collected on the mobile devices(s).

Activity and sleep information, answers to questionnaires

10.7.4 Specify the application or website used to collect the data from the mobile device, if applicable.

The watch data is downloaded directly into Excel, with files stored in PSU supported cloud storage. PSU REDCap is used to collect the questionnaire data, with files stored in PSU supported OneDrive storage.

10.7.5 Describe the measures taken to protect the confidentiality of the data collected on mobile device(s). Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 22.3.

Any data collected on a PSU Laptop is securely transferred to PSU REDCap.

The use of online survey tools and email to collect or send research data containing identifiers that represent more than minimal risk to subjects may have to be approved by the Office of Information Security.

10.8 Will any research data be directly entered/sent by subjects over the internet or via email (e.g., data capture using on-line surveys/questionnaires, surveys via email, observation of chat rooms or blogs)?

☐ No
☒ Yes - answer the following questions:

10.8.1 Specify the identifiers collected over the internet or via email (Including IP addresses if IP addresses will be collected).

Participant Number

10.8.2 Specify the type of data collected over the internet or via email.

Answers to surveys and questionnaires

10.8.3 Describe the measures taken to protect the confidentiality of the data collected?

Data is collected via PSU REDCap and stored in PSU supported OneDrive storage, both of which are password protected.

10.8.4 Describe how the research team will access the data once data collection is complete.

PSU supported OneDrive storage is password protected and accessible to approved research assistants.

10.8.5 If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s) (e.g., REDCap, Penn State licensed Qualtrics, Survey Monkey, Zoomerang)? (Note: The IRB strongly recommends the use of REDCap for online surveys that obtain sensitive identifiable human subjects data.)

☒ Penn State REDCap

☐ Penn State Qualtrics
☐ Penn State Microsoft Forms
☐ Penn State Google Forms
☐ Other - Please specify:
Application:
URL (If applicable):

10.8.6 If the answer above is "Other" contact security@psu.edu for approval of an alternative data capture method

Depending on the nature of the subject matter involved, certain security requirements must be in place for the audio and/or video recording or photographing of subjects. If the subject matter presents more than minimal risk to the subjects, then, before completing the section below, please contact the Office of Information Security at security@psu.edu to confirm whether these requirements are required.

10.9 Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study?

☐ No - skip to section 22.10
☒ Yes - answer the following questions:

10.9.1 What will be used to capture the audio/video/images? Give a brief description of content.

☒ Audio – Describe the intended content of the audio recording:
Meal and snack intake - Both Audio and video recording of Test meals and snack buffets will be recorded by a camera installed in the ceiling of our observation room in 311 Chandlee Lab

☒ Video – Describe the intended content of the video recording:
Meal and snack intake

☐ Photographs of the subjects – Describe the intended content of the photographs:

☐ 3-D Images – Describe the intended content of the of 3-D images:

☐ Other - Specify:

10.9.2 How will the recordings/photographs/images be stored (electronically or physically)?

Electronically, on PSU supported OneDrive storage.

10.9.3 Where will the recordings/photographs/images be stored?

Electronically, on PSU supported OneDrive storage.

10.9.4 Who will have access to the recordings/photographs/images?

Approved faculty, staff and research assistants.

10.9.5 Will any of the recordings be transcribed?

☐ Not applicable

☐ No
☒ Yes – indicate who will be doing the transcribing?

Research Assistants who are well trained by Project Leaders, listed on our Research Team. Additionally, if consenst is obtained, images/videos may be used for future publications or presentations.

10.9.6 Will the recordings/photographs be used for purposes other than this research study?

☐ No
☒ Yes - specify purpose(s) (e.g., publication, presentations, educational training, future undetermined research):

These may be used for future undetermined research.

10.10 Certificate of Confidentiality (COC) - Is the research biomedical, behavioral, clinical or other research that is funded by the National Institutes of Health (NIH)?

☒ Yes - check one of the following:
- ☒ The research involves human subjects as defined by the DHHS regulations (See Worksheet HRP-310).
- ☐ The research involves collecting or using biospecimens that are identifiable to an individual.
- ☐ If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
- ☐ The research involves the generation of individual level, human genomic data.

Note: If <u>any</u> of the 4 items above are checked, a COC is automatically issued by NIH and applies to the research. Information about the COC must be included in the consent form.

☐ No - answer the following question.

If the research is not funded by NIH, will the investigator apply for a COC for this research study?
- ☐ No
- ☐ Yes

Note: For research not funded by NIH, the IRB may require a COC if the research is collecting personally identifiable information and the information is sensitive and/or the research is collecting information that if disclosed could significantly harm or damage the subject.

10.11 What steps will be taken to protect subjects' privacy interests? (Check all that apply.)

- ☒ Identification and recruitment of potential subjects follows procedures consistent with privacy standards
- ☒ Consent discussion and research interventions will take place in a private setting
- ☒ Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes
- ☒ Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process
- ☐ Other – Specify:

10.12 What is the process for ensuring correctness of data entry?

☒ Double data entry to reduce risk of errors

☒ Electronic edit checks to ensure data being entered are not obviously incorrect
☒ Random internal quality and assurance checking of research data
☒ Direct entry by subjects
☐ Other - Specify:

10.13 Does this research involve the generation of large-scale human genomic data as defined in NIH Genomic Data Sharing Policy (http://gds.nih.gov)?

☒ No
☐ Yes – If Yes, describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.

10.14 The European Union (EU) General Data Protection Regulation (GDPR)

10.14.1 To determine if the research is subject to the GDPR answer the following questions:

10.14.1.1 Will the Penn State principal investigator, or another entity under the Penn State principal investigator's direction, be collecting, recording, storing, using, any personal data* of any subjects physically located in the European Economic Area (EEA) at the time of data collection (even if the subject is NOT an EEA resident or EEA citizen)? (This includes recruitment through social media sites, use of third party internet sites, mobile devices or apps to collect data, and/or direct receipt of data from subjects.)**

☒ No
☐ Yes (This research may be subject to the GDPR)

10.14.1.2 Does this research involve the transfer of personal data collected under the GDPR from an EEA country? (This includes direct transfer of data from research collaborators.)

☒ No
☐ Yes (This research may be subject to the GDPR)

10.14.2 If the research may be subject to the GDPR as indicated in the answers to the questions above, answer the following:

10.14.2.1 Will any of the data fall into one of the following categories: health data, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data used for purpose of identifying an individual, sex life or sexual orientation?

☐ No
☐ Yes

10.14.2.2 Will any of the data be related to criminal convictions or offenses?

☐ No
☐ Yes

Comments on any of the above responses:

* "Personal data" means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

** European Economic Area (EEA) – Includes the 28-member states of the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia Spain, Sweden, UK) and Norway, Iceland, Lichtenstein.

10.15 Does this research involve transfer or disclosure of data and/or specimens to and/or from Penn State?

☐ No - skip the remainder of section 22.15.
☒ Yes - answer the following questions.

Check all that apply:

☐ **Data** are being transferred or disclosed **to** Penn State

What is the name of the third party(ies) (the institution, sponsor, etc.) sending or providing the data?

Is the third party requiring us to sign a contract regarding the data?

☐ Yes - If Yes, this contract must go through the Office of Sponsored Programs
https://www.research.psu.edu/osp/overview-pages/data-use-agreements

☐ No

☒ **Data** are being transferred or disclosed **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving or accessing the data?

Data will be uploaded to Databrary electronically via Databrary's secure cloud-based system.

Note: Data transfers or disclosures may require a Data Use Agreement (DUA).

☐ **Specimens** are being transferred **to** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) sending the specimens?

☐ **Specimens** are being transferred **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving the specimens?

Note: All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA). Please contact the Office of Technology Management for more information.

10.15.1 Describe how the data/specimens will be securely transferred or disclosed to/from the third party(ies).

Video of consented participants. Other family members who gave consent for incidental recording will not be shared/will be removed from video. Alongside videos, de-identified demographic and behaviors coded from videos will be shared. Data will be uploaded to Databrary electronically via Databrary's secure cloud-based system.

10.15.2 How are the research data/specimens being transferred from and/or sent to the third party(ies)? Complete the appropriate section(s) and check all that apply within each completed section.

10.15.2.1 Data being transferred or disclosed **to** Penn State**:**

- ☐ Data are being received in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded research data without any identifiers are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being received
- ☐ Other – Specify:

10.15.2.2 Data being transferred or disclosed **from** Penn State**:**

- ☐ Data are being sent in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded research data without any identifiers are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☒ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being sent
- ☐ Other – Specify:

10.15.2.3 Specimens being transferred or disclosed **to** Penn State**:**

- ☐ De-identified specimens are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

☐ Coded specimens without any identifiers are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list

☐ Coded specimens with identifiers along with the linking list are being received

☐ Other – Specify:

10.15.2.4 **Specimens** being transferred or disclosed **from** Penn State**:**

☐ De-identified specimens are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

☐ Coded specimens without any identifiers are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list

☐ Coded specimens with identifiers along with the linking list are being sent

☐ Other – Specify:

10.15.3 If transferring data/specimens with identifiers to or from Penn State, which of the following identifiers will be included with the data/specimens? Check all that apply:

☐ Names	☐ Medical record numbers
☐ Initials	☐ Health plan beneficiary numbers
☐ Street address	☐ Account numbers
☐ City	☐ Certificate/license numbers
☐ Driver's License numbers	☐ Passport numbers
☐ State	☐ State ID numbers
☐ Zip Codes	☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ County	☐ Device identifiers and serial numbers
☐ Geocodes	☐ Web Universal Resource Locators (URLs)
☐ Precincts	☐ Internet Protocol (IP) address numbers

☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death	☐ Biometric identifiers, including finger and voice prints
☐ Ages > 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	☒ Full face photographic images and any comparable images
☐ Telephone numbers	☐ Any other unique identifying number, characteristic, or code (such as the pathology number) Specify:
☐ Fax numbers	☒ Study code numbers
☐ Electronic mail addresses	☐ Master list linking study code numbers to subject(s)
☐ Social security numbers	☐ Genomic sequence data
	☐ Other – specify: