Study Name: Eating-related self-regulation and its neural substrates as mechanisms underlying the sleep/eating behavior association in children with overweight/obesity: An ecological momentary assessment study (Short name: Project REST)

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University of Pittsburgh

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Single Signature Parent Consent

University of Pittsburgh, UPMC Western Psychiatric Hospital

Title of Research Study: Eating-related self-regulation and its neural substrates as mechanisms underlying the sleep/eating behavior association in children with overweight/obesity: An ecological momentary assessment study (Short name: Project REST)

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Sources of Support: National Institutes of Health
National Heart, Lung, and Blood Institute

Contact Information:

For questions about the study or concerns, please contact the researcher (Andrea Goldschmidt, Ph.D.; see above for contact information) or call (412) 586-9066/email BITElab@upmc.edu.

KEY INFORMATION

What is the purpose of the research?
We want to understand more about how children think and how their thoughts may relate to their sleep and eating behaviors in real-time. This may help us learn how to help children develop skills to improve their eating behaviors.
What will my child do in this research?
This study has 5 visits, on site or remote, and 4 weeks of "tracking" over the next month and lasts 5 weeks. Today's visit will take 2-3 hours. During the "tracking" weeks, we will ask your child to:
1. complete food recalls over the phone
2. monitor their sleep with an "Acti-watch"
3. keep a paper sleep diary
4. respond to short surveys throughout the day on their personal or a study-provided smartphone.
5. have 2 fMRIs, which is short for *functional MRI*. This is a type of scan where we watch brain activity while your child does thinking tasks
6. change their sleep pattern for 2 different weeks. One week we will ask them to sleep 8 hours and another week sleep 11 hours.
What are the risks of being in the study?
Risks of sleep manipulation
Your child may injure themselves or have mood changes due to fatigue/sleepiness during the sleep manipulation weeks. For example, playing sports while fatigued may increase the risk of falling or failing to dodge a ball.
Risks of MRI scans
Your child might become bored or anxious while laying still for long periods of time during the MRI. We will be very sure to confirm your child has no metal in their body so they are safe to have an MRI.
Risks of study assessments
Your child may become bored or frustrated with the study interviews and surveys; sometimes children feel badly about themselves if they think they did poorly on a test.
What are the benefits?
There is no direct benefit for participating in this research. Your child may have increased awareness of their sleep patterns and eating behaviors.
Compensation is provided.

If you think this is a study you and your child would like to hear more about, please read the rest of this form. It give you more details about everything involved. Please listen to the study team explain the study and this form to you. Please ask questions about anything that is not clear.

1. INTRODUCTION

We are asking your child to take part in a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. This form contains information that will help you decide whether participating in this study is the best decision for you and your child. Taking part in this study is completely voluntary. Even if you decide to allow your child to take part in the study, you and your child are free to leave at any time if you change your minds. The researcher will explain the study to you and your child and answer any questions you may have. We encourage you to discuss this study with others (your family, friends, or other doctors) before you agree to have your child participate in the research.
To be in the study, you and child both must agree to participate. You will be given a copy of the consent form to keep. There are check boxes at the end of this document with the signature section. We need your input for those items after you review the consent form. We expect to enroll 120 children into this study.

2. STUDY PROCEDURES:

You and your child have already completed a phone screening and have been asked to complete the next step in the eligibility process. Visits can be on site at our study clinic or hybrid-virtual due to COVID, depending on current conditions and your comfort level; however, all fMRI visits must be conducted in person and several baseline assessment activities must be completed in person.

If you agree to participate, we will measure your child to be sure they are in the weight range that is eligible for the study. If you decide to do a hybrid-virtual visit, we will drop off or mail a scale and a stadiometer for you to check their height and weight. You will also receive:

- an ActiGraph watch
- a study-loaned smartphone, if needed
- a sleep diary
- an iPad to complete thinking tasks
- a calendar that will be used to complete a semi-structured interview with your child about their eating behaviors.

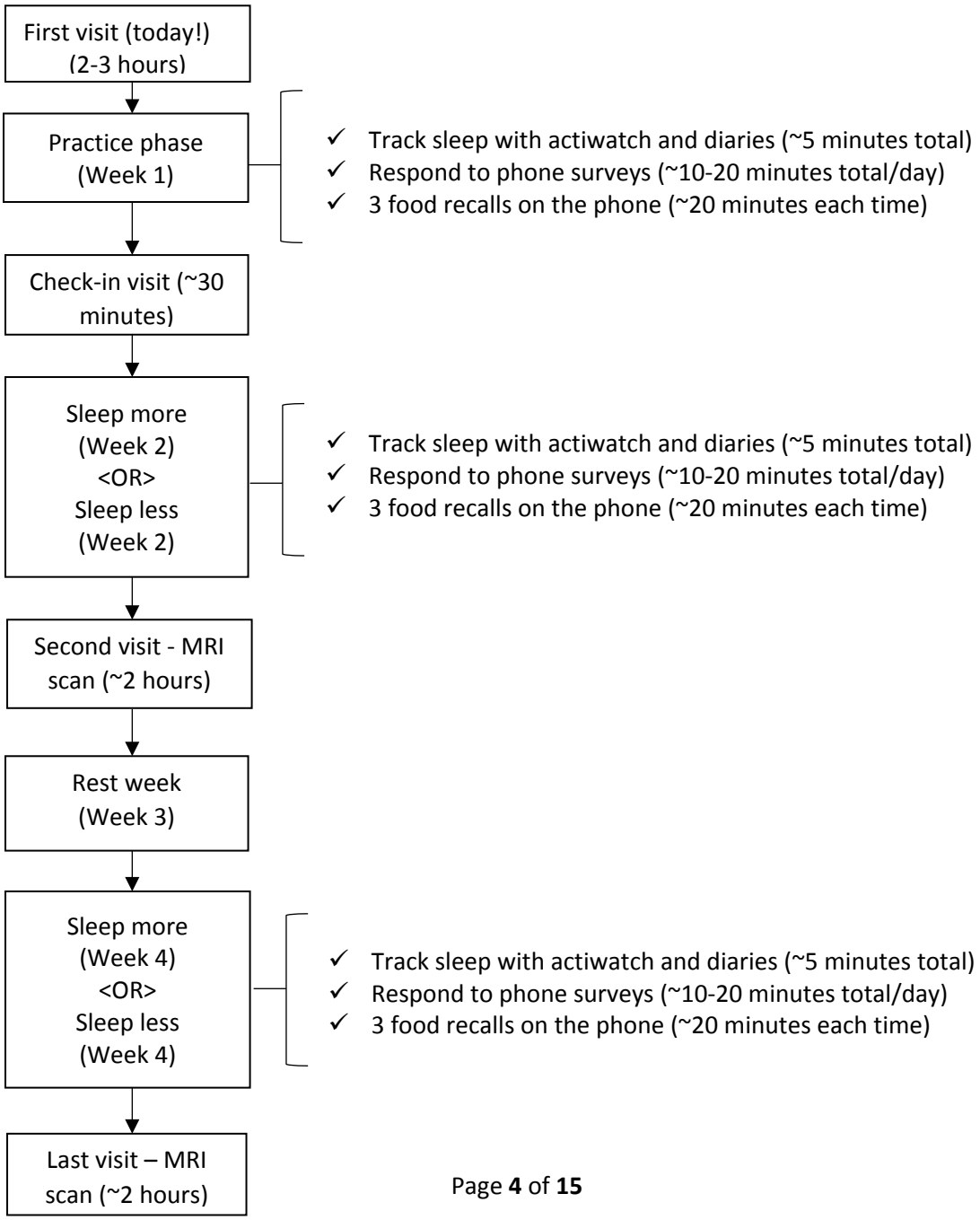
Your child will complete all measures on a secure online survey and data storage system. Your child will do some different tests:

- the Child Eating Disorder Examination (EDE), a test that measures eating behavior
- portions of the Wechsler Abbreviated Scale of Intelligence (WASI) with a Zoom or Teams call with a member of the research staff. This is an intelligence test.

You will complete questionnaires either on a computer/iPad at the study clinic, or on your home computer/loaner iPad that will be dropped off at your house (a member of the research team will email a link with questionnaires). These questionnaires measure mood, sleep, eating behaviors, and thought patterns. In addition, you or your child will be asked to complete a

questionnaire about progress in puberty (menstruation and breast development for girls and voice tone and body hair growth for boys). This allows the researchers to understand at what point in physical growth towards an adult body a child or adolescent has reached. Gathering these data helps us understand how your child's brain works at their stage in development. We will ask if you are comfortable letting your child complete the questionnaire. Otherwise, you may complete it for them. We would like to audio record part of the assessment for training purposes, but you can decline to have them recorded. If your child is eligible after today, they will proceed with the next study activities.

Here is a diagram with the 5 study visits and what we will ask your child to do during each week.



Data Reuse

If you recently participated in Project THINK, you may not need to complete the following study activities:

- Height and weight measurement
- Some questionnaires
- Child Eating Disorder Examination (EDE)
- Wechsler Abbreviated Scale of Intelligence (WASI)
- NIH Toolbox cognitive tasks (List Sorting Task, Flanker Test, Card Dimensional Sort Task)

We will use the data collected from Project THINK in this project. If the data collected are not recent enough (for example, more than 12 months old), we may ask you to repeat measures for more recent data. If your data are reused from Project THINK, you will still receive the same compensation for participating in Project REST with no change in payment. We will use your data with identifiers for other studies you may participate in with us.

Text Messaging

Text messaging is part of this research study. This will include you and your child receiving text messages from research staff and sending text messages to research staff. You have the option to receive scheduling and appointment reminders via text or phone. Please note that text message and data rates may apply and that these costs would not be paid for by UPMC or the study.

Throughout the study, your child will receive text messages. These messages will remind them of their bedtimes and dietary recall telephone appointments, as well as the option of completing self-initiated ratings at mealtimes. We will also check in with your child by text if we haven't received their responses to EMA prompts so that we can help troubleshoot any barriers that arise.

No sensitive information will be included in our text messages, and your responses should not include sensitive information. If, as a parent/guardian, you have sensitive information to share with the study, please call the study line, 412-586-9066, as opposed to texting information to our study staff.

Here is a review of the study activities during the weeks 2-4:
-increase sleep to 11 hours or decrease to 8 (whichever you do first, you will do the opposite in week 4)
-wear Acti-watch
-complete 3 phone calls on what your child ate

-complete phone surveys (after hours on school days, if preferred)
-complete tasks and questionnaires on phone
-complete sleep diaries

3. STUDY RISKS AND BENEFITS

The main risks of the study are in the KEY INFORMATION on page 2. Here are some other risks to note.

Use of smartphone and collection of private health information

The risk of using a smartphone is that information could be captured by someone who is not authorized, including by when it is transmitted by the internet. Other possible risks include the remote possibility that the information would be released outside of the research setting, which could be upsetting for you or your child. However, strong measures are taken to ensure that all information remains confidential. See the section called Confidentiality to see what we do to prevent this.

Text Messaging

UPMC can make no guarantees about the secure transmission of texts you send to us, nor can UPMC guarantee security after you receive the text message from UPMC. Please assist your child to keep their phone or study phone safe. For example, text messages that display on your phone screen may be seen by someone close by or by someone you have allowed to use your phone. Also, if you do not password protect your phone and it is lost or stolen, anyone who finds it might view the information in the texts about your health or other topics. To try to lessen these risks, you should make sure your phone is password protected, only open and view messages where no one will be able to view the screen and delete messages as soon as possible after reading them. Additionally, when you trade in your phone, remember the SIM card (memory card used in cell phones) should be cleared. Finally, it is also possible that the mobile phone company that transmits the text messages may keep copies of ALL your texts (those from the study, and your other texts) even after the study is ended. UPMC has no control over these companies and cannot make any guarantees about their conduct.

Other fMRI risks

MRIs are considered generally safe. MRI uses a powerful magnet to take pictures of the body (including the brain). The MRI uses a strong magnetic force to obtain these images. Your child will have to follow certain safety precautions to make sure they do not have any metal objects in or on their body. Before your child undergoes your MRI scan, a researcher or technician will ask whether or not their body contains any metallic medical devices or equipment, including braces, heart pacemakers, metal prostheses, implants or surgical clips. They also will be asked whether they have had any prior injury from shrapnel or grinding metal, and they will be asked whether their eyes may have been exposed to metal particles. Your child or the researcher or

technician will also complete a checklist that addresses issues of MRI safety. If your child has no metallic objects or particles in their body, they will be asked before entering the MRI room to remove from their person all metal objects, including jewelry, watches, hair holders, or eyeglasses; and they will be asked to empty their pockets of all materials, including keys, wallets, and magnetic cards such as ATM and credit cards. In addition, they may be asked to change into a hospital gown or other suitable garment. Finally, they may be asked to remove any eye shadow they may be wearing, because eye shadow sometimes contains metallic substances.

If research devices are being used that are not part of the MRI scanner, such as button response boxes, or equipment that monitors physiological processes, there is a small risk that this equipment or wires attached to this equipment might become hot. Please report any heating/burning sensation immediately. Your child will be encouraged to signal to have the scan stopped at any time if this occurs.

During the scan itself, your child will lie on a table that slides into a horizontal tube slightly wider than your body. They will be asked to lie still, but they will be able to hear and speak to the MRI personnel/research staff. Some people experience anxiety, panic, or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to your child, please tell the researchers before they have the scan. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If they feel uncomfortable for any reason before or during the procedure, we want them to tell the researchers. If for any reason during the procedure they want to stop, they may do so at any time.

The MRI scanner used for this study has been approved for clinical use by the FDA. However, the investigator may use different radiofrequency pulses or gradients, in which case the MRI may not be considered FDA-approved. Also, some of the operation settings for ordinary clinical circumstances being used to perform scans at the CMU-Pitt Bridge Center are not approved by the FDA. Nevertheless, there are no known significant risks with this procedure at this time since the radiofrequency magnetic fields and magnetic fields, at the strengths used, are felt to be without harm. There are conservative federal guidelines for radiofrequency magnetic field exposure and our examinations fall within those guidelines.
FOR WOMEN: The safety of MR imaging during pregnancy has not been proved. If your child is, or might be, pregnant, they cannot take part in this study.

Holding of ADHD medications
If your child takes ADHD medication, we will ask you to withhold their medication while they participate in the study for a few days before they start the sleep changes weeks and during

that week. That will be for a little over a week. Withholding ADHD medication during this time could worsen their ADHD symptoms. For example, your child may have a hard time paying attention in school or controlling their impulses. The study team will be checking in with you during these periods. If at any time, you feel they need to resume their medications, please have them do so and inform the study team. You may wish to discuss this with your child's physician.

Other survey risks
Some of the questions from the interviews and questionnaires may be upsetting to you or your child. You or your child can refuse to answer any questions they don't want to. They can also stop the testing at any time.

Detecting mental health issues
The surveys we do may detect a mental health problem, such as suicidality, intent to harm others, or drug abuse. If previously unreported abuse is discovered, you and/or your child will be further evaluated and steps will be taken to ensure their safety (e.g., creating a safety plan, providing referrals).
If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence you or your child's willingness to continue, this new information will be discussed with you.

Benefits
Your child is not likely to experience benefits from the interview procedures or self-report measures, aside from an increased awareness of their sleep patterns and eating behaviors; however, we hope that the information we get from this study may help children with sleep or eating problems in the future.

4. NEW INFORMATION

We will tell you about any new information that we learn that may cause you to change your mind about staying in the study.

5. CONFIDENTIALITY

The study team takes steps to keep your child's information safe. Specifically, all children will be identified only by code number which will appear on documents used for evaluation for

statistical analyses. All records and information will be kept locked in the clinical research facilities. Publications of this research will not identify individual children.
We will take steps to protect the information contained in the text messages to the degree permitted by the technology being used. Some of the following steps may be taken:

- encrypting the data during transmission,
- eliminating sensitive health care information from the texts
- storing all data gathered on secure servers
- providing you with a secure device when the circumstances warrant
- we will delete data in the event of a lost or stolen device.

In addition, the National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Representatives from the following agencies may access your child's identifiable research information.

- The researcher and their support staff
- The study sponsor, the National Heart, Lung, and Blood Institute
- Authorized representatives of the University of Pittsburgh Office of Research Protection

Your child's private identifiable information may be stripped of identifiers and used for future research studies or distributed to another researcher or federal repository for research studies without additional informed consent. If your child participates in any other studies with Dr. Goldschmidt, we will retain your data with identifiers from this study for use with her other studies.

You will not be allowed to see or copy the information about your child's participation described in this form if the research study is open. You may see and copy the information when the study is completed.

Per University of Pittsburgh policy, research records for children will be maintained until at least age 25 per PA State Law. If your child participates in any other studies with Dr. Goldschmidt, we will retain your data with identifiers from this study for use with her other studies.

6. RETURN OF RESULTS

The investigators for this project are not trained to perform radiological diagnosis, and the MRI scans performed in this study are not designed to find abnormalities. The investigators and University of Pittsburgh are not responsible for failure to find existing abnormalities in your child's MRI scans. However, on occasion the investigator may notice an MRI image that seems abnormal. When this occurs, the investigator will inform you and recommend that you consult with your child's primary care physician. The decision whether to proceed with further examination or treatment lies solely with you and your physician. Because the images collected in this study do not comprise a proper clinical MRI study, these images will not be made available for diagnostic purposes.

7. CLINICAL TRIAL REGISTRY

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. law. This Website will not include information that can identify your child. At most, the Website will include a summary of the results. You can search this Website at any time.

8. COSTS

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your child's usual medical care. Some of the services your child will receive are being performed only because your child is participating in this research study. These 'research only' services include the MRI scans. These services will be paid for by the study and will not be billed to you/your child or your health insurance company. If you believe you have received a bill for a research-related procedure, contact the study team and the UPMC office that sent the bill.

9. PAYMENTS

Will I be paid for participating? The overall compensation looks like this:

Visit 1 Zoom (hybrid-virtual or on site)	$50

Week 1 Sleep change, sleep tracking, surveys, mealtime recordings, and food recalls (exact breakdown below)	Up to about $91.20
Week 1 Post-practice week visit	$25
Week 2 Sleep change, sleep tracking, surveys, **mealtime recordings,** and food recalls	Up to about $93.20
Week 2MRI visit	$50 (child must complete to be paid)
Week 3 Rest week	Up to $7
Week 4 Sleep change, sleep tracking, surveys, mealtime recordings, and food recalls	Up to about $98.20
Week 5 MRI Visit (2nd)	$50 (child must complete to be paid)
TOTAL AMOUNT (for all study activities and visits)	**About $465**

Breakdown by Activity:
On the weeks where your child does phone surveys, food recalls, mealtime recordings, and tracks their sleep, they can be paid for each of these activities.

Your child will earn 74 cents for each survey they complete.

Weekdays =	4 surveys every day	$0.74 per survey
Weekends =	5 surveys every day	
TOTAL AMOUNT	**90 surveys over 3 weeks**	**$66.60** possible

There are bonuses for doing other activities, too.

Bonus for completing mealtime recordings (maximum of 3 meals and 3 snacks per day)	**$126** **(per 21 days, with $1.00 per rating)**
Bonus for calling/texting the study line to report bedtime & wake time	$63 (per 21 days, with $3.00 per day)
Bonus for wearing Acti-watch and reporting bedtime & wake time during “rest” week	$7 (per 7 days, with $1.00 per day)
Food recalls	$9

	(per 9 possible recalls, with $1.00 per recall)

There are bonuses too, for completing surveys.

Bonus for at least 70% of surveys completed	
Week 1	$3.00
Week 2	$5.00
Week 3	$10.00

Your child will be compensated at the end of every week during which they participate in the study. Compensation will be withheld each week, however, until study materials from the previous week, including the Acti-watch, loaner scales, stadiometers, and iPads, etc., are returned to the research team. The final compensation will be withheld until all borrowed study materials, including your child's loaner smart phone, are returned to the research team. Please remember to bring all borrowed materials with you to each study visit.

Your child will be paid on a reloadable debit card. Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a "Form 1099 – Miscellaneous" with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

10. COMPENSATION FOR INJURY

This study does not include any treatment or intervention; therefore, a research related injury/illness is unlikely to occur. If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

There is no coverage for emergency treatment of injuries at the MRI facility.

11. RIGHT TO WITHDRAW

You have the right to refuse to sign this form and not allow your child to participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any UPMC health care site. If you do not sign, your child will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to have your child quit the study after signing this form, no new information will be collected about your child unless you give us permission to do so. However, the researchers may continue to use information that was collected before you removed your child from the study to complete analysis and reports of this research. If you decide to have your child quit the study please tell Andrea Goldschmidt (goldscha@pitt.edu; 412-647-3089) or another member of the study team (BITElab@upmc.edu; 412-586-9066).

By signing this consent, I give the researchers my permission to audio record the interviews. Audio recordings will be kept for at least seven years after the conclusion of the study. The research team will have access to the audio recordings to ensure consistent interview processes.

For copyright reasons, the cognitive test will not be recorded. Further, we ask that you and/or your child not audio or video record any portion of the cognitive test.
I AGREE THAT I WILL NOT AUDIO/VIDEO RECORD THE COGNITIVE TEST. Initial the box with your answer.

_____ YES _____ NO

Contact for Future Studies: Your child's participation in **any research** is completely voluntary and you/ your child should feel no pressure to have them participate in another research study. **Please check and initial one** of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about my child participating in other research projects studying sleep, eating behaviors, and/or overweight/obesity. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator.

_____ ☐ No, I do not want to be contacted about my child participating in other research projects. **Do not** give my contact information to the staff of any other research studies.

In the future, we might ask participants to undergo additional procedures; namely, wearing a continuous glucose monitor and blood draws to assess glucose levels. Although we are **not** asking participants to undergo either at this time, your feedback will help us determine if this is feasible for future participants.

Q. Would your child be willing to undergo two 2-hour blood draws to assess their glucose levels on the morning of each of their MRI visits? Extra compensation would be provided.

_____ ☐ Yes _____ ☐ No

Q. Would your child be willing to wear a continuous glucose monitor (a tiny senor inserted under the skin, usually worn on the belly or arm) for each of the sleep restriction and extension weeks? Extra compensation would be provided.

_____ ☐ Yes _____ ☐ No

PARENTAL PERMISSION

I have read this informed consent form. The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any part of this research study at any time. Any future questions will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be answered by a listed investigator.
I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.
A copy of this consent form will be given to me/my child.

_____
Printed name of Child participant

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for their participation in this research study and provide my authorization for the use of their medical records.

By signing below, I give my permission for my child to participate in this research study and for the described uses and releases of information.

_____ _____

Print name of Parent or Guardian Relationship to Participant (Child)

_____ _____

Signature of Parent or Guardian Date (MM/DD/YEAR)

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Print name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date (MM/DD/YEAR)

CHILD ASSENT

This research has been explained to me, and I agree to participate.

Signature of Child-Subject_____ Date_____

VERIFICATION OF EXPLANATION

I certify that I have carefully explained the purpose and nature of this research to (name of child) in age appropriate language. They have had an opportunity to discuss it with me in detail. I have answered all their questions and they provided affirmative agreement (i.e., assent) to participate in this research.

_____ _____

Signature of Person Obtaining Assent Date (MM/DD/YEAR)

Role in Research Study _____ Date