Research Consent Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital,

Newport Hospital, and Gateway HealthCare

403919 _____

Committee#

_____

Name of Study Participant

Title of Research Study: Project REST

Principal Investigator: Andrea Goldschmidt, Ph.D.

Your child is being asked 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 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.

If you decide to allow your child to be in the study, you will be asked to sign this consent which states that the study has been explained, that your questions have been answered, and that you agree to have your child participate. If your child is 8 years or older, the "assent" (agreement) of your child will be obtained by the researcher before your child may participate in this study. Your child must sign the assent form. You will be given a copy of the signed consent form to keep.

STUDY KEY INFORMATION

1. What is the purpose of the research?

We are interested in understanding more about thinking processes in children, and how these may relate to their sleep and eating behaviors in real-time. We want to better

understand these processes so we can help children develop better skills in these areas to improve their eating behaviors.

2. What is experimental/new in this study?

This study is incorporating new research methods to obtain information about thoughts, feelings, and behaviors in children as they occur in daily life. Multiple methods of data-collection will be used to strengthen the quality of our findings through corroborating data. These methods include MRI analysis, self-report questionnaires, smartphone application surveys, dietician-led dietary assessments, and actigraph data.

3. What do I have to do in this research?

This study entails 4 in-person visits (including the one today), and 3 weeks of "tracking" over the next month. During these "tracking" weeks, your child will be asked to complete food recalls, monitor their sleep with an actigraph watch ("acti-watch"), and respond to short questionnaires throughout the day on a study-provided smartphone. Your child will not be asked to respond to questionnaires during the school day if it is prohibited by you or your child's school policy. Your child will be asked to sleep 1.5 hours longer every day for one week, and 1.5 hours shorter every day for one week, separated by a "rest" week, in which they will not partake in any study activities. In-person visits will be used to assess height/weight, report any problems or concerns regarding study activities, and administer questionnaires. At two of these in-person visits, your child will be asked to complete a 40-minute MRI scan.

4. What could go wrong?

Risks are minimal in this study. Your child may incur injuries or exhibit mood changes due to fatigue/sleepiness during the sleep manipulation weeks. During the MRI scans, your child might become bored or anxious while laying still for long periods of time. Your child may also become bored or frustrated when completing cognitive tasks and questionnaires.

5. What are the benefits?

Your child will likely not receive any direct benefit from the study, aside from an increased awareness of their sleep patterns and eating behaviors.

6. Other things I should know about this research?

Other possible risks include the remote possibility that the information would be released outside of the research setting, which could be upsetting for you. However, strong measures are taken to ensure that all information remains confidential. Specifically, all participants 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 participants.

7. If I don't want to take part in this research what are my other choices?

Participation is voluntary, and your child is not required to complete any study activities that you do not want to. Your child is welcome to withdraw from the study at any time; however, compensation will not be received for incomplete visits.

- Please carefully read this form, additional detail about each item just described is found below
- Please listen to the study team explain the study and this form to you
- Please ask questions about anything that is not clear

1. Nature and Purpose of the Study

Your child is being asked to take part in a research project because we are interested in understanding more about thinking processes in children, and how this may relate to their sleep and eating behaviors. We want to better understand this process so we may in the future help children develop better skills in these areas to improve their eating behaviors.

We expect to enroll 120 children into this study. The study is sponsored by the National Heart, Lung, and Blood Institute and the Weight Control and Diabetes Research Center.

2. Explanation of Procedures: If you agree that your child can take part in this study, your child will be asked to…
    1. Complete an **assessment visit** at the Weight Control and Diabetes Research Center, which will take approximately 2 hours. You and your child will receive a detailed study explanation, provide informed consent, complete study questionnaires, and be trained in how to complete cognitive tasks and questionnaires using a Web-based application (app) loaded onto a personal or study-loaned smartphone. You and your child will both have your height and weight measured and complete assessments of eating behaviors, cognitive functioning, and psychiatric symptoms. We would like to record part of the assessment visit for training purposes, but you can decline to have it recorded and still have your child participate in the study.

I GIVE THE RESEARCHERS PERMISSION TO AUDIO/VIDEORECORD THE INTERVIEWS WITH MY CHILD

☐ YES ☐ NO

_____ _____ _____
Signature of parent/guardian* Date and Time when signed

You will be given the opportunity to review the questionnaires before they are administered to your child, and to withdraw your consent for your child to complete any or all of the questionnaires if you choose. In addition, you and/or your child will be asked to complete a questionnaire which addresses how physically developed your child has become, in terms of genital (penis, testicle, or labial) growth, and the emergence and growth of hair around the genitals. This is called Tanner staging, allowing the doctor and the researchers to understand at what point in physical growth towards an adult body a child or adolescent has reached.

Your child will be given a $50 gift card (to their choice of either Target or Walmart) for completing today's visit in exchange for their time and effort. At the end of today's visit, your child will be asked to either download an application (app) onto their personal smartphone, or borrow a study smartphone to have access to this app. A member of the research team will teach your child how to use the app and respond to signals from it. Over the next month, your child will complete 3 weeks of tracking and 1 week of rest. During tracking weeks, your child will be asked to complete questionnaires and tasks on the smartphone app throughout the day. The app will signal them 3- 5 semi-random times throughout the day, and before bedtime. They will be asked to complete the given tasks or questionnaires within 45 minutes of receiving the signal. We will also ask your child to complete the tasks or questionnaires each time they eat.

We are aware that some study procedures may distract participants during the school day, and we will work with your family to minimize impact on school activities. If your child's school's policy prohibits any cell phone use, we ask that you comply with those policies and leave the phone at home during school hours. No app signals will be sent during school hours, and even if your child's school has no prohibition against cell phone usage, we ask that your child turn the phone on "silent" mode during school hours and only complete recordings during non-academic time. Regardless of school policy, if you do not feel comfortable having your child bring the cell phone to school, you can still participate in the study and instruct your child to leave the phone at home on school days.

On 3 random days each tracking week (two weekdays and one weekend day), your child will also receive a call from a dietician who will ask them questions about their eating. If able, you will be asked to be present for these phone calls to assist your child in recalling their meals. Your child will be asked to take pictures of their meals and snacks during tracking weeks to guide these conversations with the dietician. If your child's school's cell phone policy allows, we ask that your child takes pictures of their meals/snacks during the school day. If your child packs their school

lunch/snacks, they will have the opportunity to upload pictures of their packed meals/snacks prior to the school day, as it is being packed.

____ I give my child permission to use their cell phone at school to take pictures of their meals/snacks, in accordance with his/her school policy.

_____ I do not give my child permission to use their cell phone at school to take pictures of their meals/snacks.

_____ _____

Signature of parent or guardian Date

During the 3 tracking weeks, your child will be asked to wear an "acti-watch" device that will track their sleeping. The acti-watch will be worn on the wrist and has a similar design as a standard smart watch (e.g., Apple watch). They will be instructed on how to use the acti-watch to signal when they go to bed and when they wake up. The acti-watch will be worn 24 hours a day, including in the shower and during physical activity. The only exceptions for taking the acti-watch off is if your child will be in water (e.g., a swimming pool, bath) for more than 30 minutes, or if your child plays a heavy contact sport (e.g., football, wrestling).

2. Over the next week (Week 1), your child will be asked to wear the acti-watch, take pictures of their meals/snacks, complete 3 phone calls with a dietician, and complete tasks and questionnaires on their phone. This will be a **practice tracking week** for them to get used to the study. At the end of this practice week, you and your child will return to the center to exchange their acti-watch for a new one, and report any problems they might have had in the first week. This **second visit** will take no more than 30 minutes. Your child will receive a $25 gift card (to either Target or Walmart) at the end of this visit.

3. During Week 2 (a **tracking week**) of the study, we will ask your child to either increase the time that they usually sleep for by 1.5 hours every day, or decrease the time that they usually sleep for by 1.5 hours every day. They will be asked to wear their acti-watch, take pictures of their meals/snacks, complete 3 phone calls with a dietician, and complete tasks and questionnaires on their phone during this week. We will also be calling or texting you and your child each day to check in about their sleep patterns and compliance to EMA signals. At the end of the week, you and your child will come back for a **third visit** to exchange their acti-watch for a new one, and report any problems they might have had in the past week. At this visit, your child will also be asked to complete a 40-minute MRI scan. This visit will take place on

Brown University's campus at the MRI Research Facility building (185 Meeting St., Providence, RI, 02912).

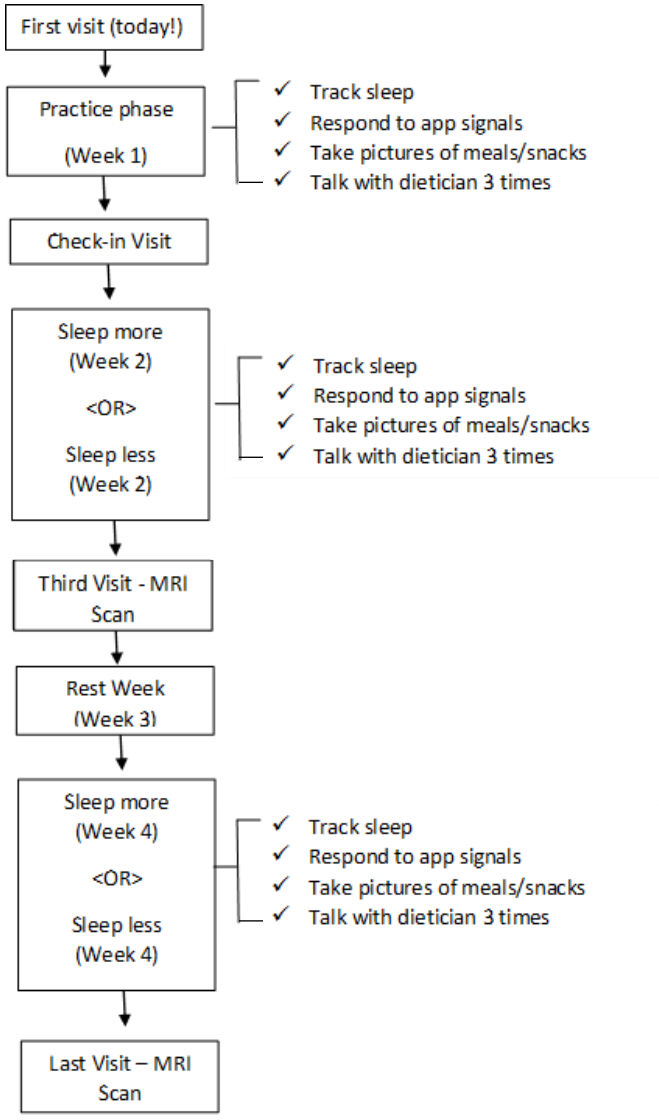
An MRI scanner uses a magnet and radio waves to take pictures of your child's brain. Your child will need to lie still for the scanner for up to an hour. Being in the MRI scanner will not be painful for your child, but some children get antsy or nervous being in the scanner, and some children become anxious or claustrophobic from lying in an enclosed space. Someone will be in a room close by while they are in the scanner, and your child will be able to tell them if s/he wants to come out. Your child will have to remove any metal items they are wearing or have on, like jewelry, cell phones, or coins. They also need to make sure they don't wear any clothes with metal zips, fasteners, buttons, belts or buckles. Make sure to tell someone if your child has an artificial limb or joint, a pacemaker, or screws or plates in their body from a previous surgery. This is because the magnet in the MRI scanner is very strong so if it comes in contact with any metal it could be dangerous for your child. You will be asked to complete an additional consent form which describes the risks and benefits of MRI procedures in greater detail. Your child will receive a $50 gift card at the end of the third visit.

4. Week 3 of the study will be a **rest week**, in which your child will not be asked to complete any study activities. They will not receive signals from the smartphone app; they will not receive phone calls from the dietician or be asked to take pictures of their meals/snacks; and they will not be asked to wear their acti-watch.

5. Week 4 will be a **tracking week**, in which your child will be asked to complete tasks and questionnaires on their phone, wear their acti-watch, and take pictures of their meals/snacks. They will also receive 3 phone calls from a dietician, plus daily phone or text check-ins with the research team. During this week, your child will be asked to either increase the time that they usually sleep for by 1.5 hours every day, or decrease the time that they usually sleep for by 1.5 hours every day. If they were asked to decrease their sleep in Week 2, they will now be asked to increase their sleep; if they were asked to increase they sleep in Week 2, they will now be asked to decrease their sleep.

6. At the end of Week 4, you and your child will come back to the clinic for a **final visit** to have their weight measured and follow-up questionnaires completed. Your child will also complete a second MRI scan, in which they will be asked to lie inside the scanner for about 40 minutes. Your child will return all study materials (e. g., acti-watch, smartphone) at this final visit, receive $75 for his or her participation.

Here is a chart to visually summarize what will occur over the next 4 weeks of the study:



We think you will be in the study for about 5 weeks, starting from the time of the phone screen, until you finish the 3 tracking weeks and all 4 visits. Today's visit will take about 2 hours, the second visit will take about 30 minutes, the third visit will take about 1.5 hours, and the final visit will take about 1.5 hours. We will try to schedule your visits at a time that is convenient for you.

Your child will receive up to $200 (in gifts cards to either Target or Walmart) for completing all study visits ($50 for the today's visit, $25 for the post practice-week visit, $50 for the first MRI visit, and $75 for the second MRI visit/final study visit). At MRI scan visits, your child must complete the scan in order to receive the compensation for that visit.

Your child will also receive additional monetary compensation for each EMA recording they complete, as well as each food recall completed and mealtime picture taken. Your child will receive 3 EMA prompts on weekdays and 5 EMA prompts on weekends, for a total of 75 prompts over 3 separate weeks of assessment (x $1.00 per each recording = $75). They can also receive an additional $6 per day for completing mealtime recordings, assuming a maximum of 3 meals and 3 snacks per day at $1.00 per self-initiated rating (x 21 days = $126). Finally, your child will receive $1.00 for each completed food recall (x 9 possible recalls over 3 weeks = $9). Thus, assuming perfect compliance, your child can earn up to $410 for completing all required portions of the protocol over the entire 1-month study. Cash or a giftcard will be given to your child at each follow-up visit for each EMA prompt, mealtime picture, and food recall they completed in the previous week.

If you remove your child from the study, it would still be useful for us to know how your child does over the next 6-months. We would appreciate if you would permit us to get follow-up information about your child's health from their doctor or medical record.

____ If I withdraw my child from the study, you have my permission to collect information about my child's health from their doctor or medical record.

_____ I do not give my permission for you to continue to collect information about my child if I stop their participation in the study.

_____ _____

Signature of parent or guardian Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to have your child quit the study please tell Andrea Goldschmidt (andrea.goldschmidt@lifespan.org; 401-793-8251).

Costs for participating in this study

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 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.

Contact Information:

For questions about the study or concerns, please contact the researcher (Andrea Goldschmidt, Ph.D.) at (401) 793-8251 or andrea.goldschmidt@lifespan.org.

3. Discomforts and Risks

The risks of study participation are considered very minimal given that the investigation is observational in nature. Any risks typically associated with data transmission via smartphone will be minimized via electronic safeguards such as secure servers and encryption of data as described below. Your child may have difficulties concentrating at school or incur injuries during daily activities during the sleep restriction phase of the study due to fatigue or daytime sleepiness. Your child may run the risk of interrupting their school schedules or other activities when attempting to complete ambulatory assessments on their smartphone device, but will be instructed not to complete recordings when doing so would be detrimental to safety (e.g., while crossing the street). Your child may become distressed while completing psychological assessments. Your child may become bored or frustrated during completion of cognitive tasks. Some children may become bored or uncomfortable (e.g., from acoustic noise) during the fMRI portion of the study. 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 you or they wish, ask to have the evaluation stopped at any time, or contact the investigator or research staff at (401) 793-8962 for further assistance.

This study is neither designed nor intended to detect health problems in your child. The MRI scans that your child will undergo do not substitute for an appropriate medical examination by a qualified health care provider. If you suspect that your child might be suffering from injury or illness, including any injury involving the head or brain, you should not rely on this study as a way to determine whether or not your child is well.

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 Brown University are not responsible for failure to find existing abnormalities in your child 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. The investigators and Brown University are not responsible for any examination or treatment that you undertake based upon these findings.

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.

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. 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.

If any mental health related problem is detected, such as suicidality, intent to harm others, or drug abuse, or 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). Reports of physical or sexual abuse will be reported to state authorities as mandated by law.

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.

4. 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.

5. Refusal/Withdrawal

It is up to you whether you want your child to be in the study. You are not required to enroll your child or have them participate. If you decide you want your child to participate, you can always change your mind and remove them from the study at any time. If you decide not to have your child be in the study, or if you remove them later, your child will still be able to get the health care services they would normally get. If you enroll your child but later the researcher or your child's doctor feels being in the study is no longer good for your child, they may choose to take your child out of the study before it is over. If new information becomes available that might change your mind about whether you want your child to stay in the study the researcher will share this information with you as soon as possible.

6. Medical Treatment/Payment in Case of Injury

This study does not include any treatment or intervention; therefore, a research related injury/illness is unlikely to occur.

7. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you or your child have any complaints about your child's participation in this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6897.

8. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your child's research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your child's information to someone outside of Lifespan) their health information for research purposes. If you sign this form you agree to have your child be in this research study and you permit the use and disclosure of your child's health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw your child from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, your child will stop taking part in the study and no new information will be collected about them. However, if you cancel your permission, it will not apply to actions already taken or information already collected about your child by the hospital or the researchers before you canceled your permission

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor: National Heart, Lung, and Blood Institute
- Doctors, nurses, laboratories and others who provide services to your child or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your child's health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your child's health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your child's information.

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 Lifespan 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 (as described in Section 6), no new information will be collected about your child unless you gave us permission to do so. However, the hospital or 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.

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.

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.

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.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT MY CHILD TO TAKE PART IN THIS RESEARCH STUDY.

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. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp. DO NOT sign this document after this expiration date.

If the expiration date is blank, this document does not expire.

The Researcher is required to provide a copy of this consent to you.

_____	_____	_____
Signature of Parent or Guardian	Date (MM/DD/YEAR)	Time when signed

_____
Print name of Child participant

_____	_____	_____
Signature of researcher or designate	Date (MM/DD/YEAR)	Time when signed

☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**

A witness must be present for the entire consent process in the following situations (please check the appropriate box):

☐ The individual cannot read or has visual impairments that limit their ability to read and this consent document was read to the participant or legal representative,

☐ The individual is not English speaking, and through an interpreter, this consent document was presented orally to the participant or legal representative and this document serves as the summary for such consent. In addition, a short form of the consent was provided to the study participant in the individual's language.

I confirm that the information in this consent form was accurately explained to the participant or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

Signature of Witness /Interpreter	Date (MM/DD/YEAR)	Time when signed

Printed Name of Witness/Interpreter