Study Name: Project THINK: Trajectories of Health, Ingestive Behaviors, and Neurocognition in Kids

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY
University of Pittsburgh, UPMC Western Psychiatric Institute & Clinic

Study Title:
Project THINK: Trajectories of Health, Ingestive behaviors, and Neurocognition in Kids

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Source of Support:
This study is receiving funding from the National Institute of Diabetes and Digestive and Kidney Diseases.

Study Key Information:
You and your child are 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 you and your child. Taking part in this study is completely voluntary. Even if you decide to participate and 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 participate and to have your child participate in the research.

Due to COVID-19, you and your child might be reading this form in your home, on a research website called "REDCap", or in-person at our research center. If you decide to participate and 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 you and your child's questions have been answered, and that you agree to participate and to have your child participate. If your child is 8 years old or older, the "assent" (agreement) of your child will be obtained by the researcher before your child may participate in this study. The assent agreement is located at the end of this form. Your child must sign the assent agreement. You will be given a copy of the signed consent form to keep.

A. What is the purpose of the research?

We are interested in understanding more about thinking processes in children, and how these may relate to children's weight and eating behaviors. This is not a treatment study, but it will help us better understand the relationship between children's thinking and their eating, so that we can develop ways to help children better regulate their eating.

B. What is experimental/new in this study?

This study will last for two years, during which your child is likely to be starting puberty. Puberty marks physical, emotional, and cognitive changes. We are particularly interested in how changes in children's thinking and feeling during this time may relate to their eating behaviors. We will be using brain imaging techniques, as well as questionnaires, interviews, and thinking activities as part of our study.

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

There are up to 9 visits at five time points (including the one today, if you and your child are reading this at an in-person visit):

- Visits 1/2: Baseline: Full assessments lasting ~3 hours split between 2 visits
- Visit 3: 6 months: Condensed assessments lasting ~1 hour
- Visits 4/5: 12 months: Full assessments lasting ~3 hours, split between 2 visits
- Visit 6: 18 months: Condensed assessments lasting ~1 hour
- Visit 7: 18 months: fMRI group only ~90-120 min
- Visits 8/9: 24 months: Full assessments lasting ~3 hours, split between 2 visits

You and your child may attend these visits either in-person or hybrid-virtually via a HIPAA-compliant Zoom or Teams link. At these visits, you and your child will be asked to complete questionnaires. You and your child will also both give height/weight measurements. Your child will also be asked to do some activities so we can understand how they think and discuss their eating habits with a member of the research team. Some of these activities cannot be completed virtually; thus, your child will need to come in-person to complete these, even if the rest of the visit is completed virtually/remotely.

Participants will be randomly assigned (like the flip of a coin) into an MRI group or a non-MRI group. Those in the MRI group will be asked to complete two 40-minute fMRI scans. These fMRI scans will occur at baseline (i.e., within the next few weeks) and at the 18-month follow-up. You and your child must consent to randomization in order to participate in this research study.

D. What could go wrong?

Risks are considered very minimal in this study. In the main part of the study, the primary risk is that you and your child may become bored or frustrated when completing cognitive tasks and questionnaires. During the fMRI scans, children might become bored or anxious with the loud noises and while laying still for long periods of time. There is also the risk of breach of confidentiality.

E. What are the benefits?

This is not a treatment study, so your child will likely not receive any benefit from the study. We hope the information from this study will help us learn how to better help children with their eating behaviors in the future.

F. Other things I should know about this research?

This is not a treatment study for weight control.

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

Participation is 100% voluntary, and you and your child are not required to complete any study activities that you or they do not want to. You and your child are 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 :

You and your child are being asked to take part in a research project because we are interested in understanding more about children's thinking skills, and how they may relate to their weight and eating behaviors. We want to better understand the relationship between children's thinking and their eating, so that we can develop ways to help children better regulate their eating.

We expect to enroll 180 children and a parent (360 total participants) into this study. The study is sponsored by the National Institutes of Health.

2. Explanation of Procedures:

If you agree that to participate and to have your child take part in this study, you and your child will be asked to:

1. Complete a **baseline** assessment at Bellefield Towers (Location: 100 N Bellefield Ave, Pittsburgh, PA 15213) or hybrid-virtually via Zoom/Teams, which will take approximately 3 hours. This assessment will be split between two visits, unless your child is capable and willing to complete it in one sitting. If you are reading this consent form at the research center, this is your baseline assessment. For families that attend in-person visits, all members of the family and study staff present must wear a face mask at all times. Family members will have their temperature taken at the door and will be asked COVID-19 screening questions prior to entry. Study staff will sit 6-feet away from the family for the majority of the visit, and all study materials will be sanitized before and after the visit. You and your child will receive a detailed study explanation, provide informed consent, and complete study questionnaires. Both you and your child will have your height and weight measured and complete assessments of eating behaviors, cognitive functioning, and mental health. If you choose to complete this visit virtually, a member of the study staff will drop off a scale and stadiometer at your house for you to take your and your child's height and weight. Study staff will also drop off an iPad and laptop with cognitive tasks pre-loaded for your child to complete. If you decide to participate virtually, your child will still need to come to our Center to complete cognitive tasks that cannot be done remotely. If you and your child do not feel comfortable coming to a shortened in-person visit, you will be put on a waitlist and enrolled at a later date when you feel safer/more comfortable coming in person.

Whether in person or hybrid-virtually, we would like to record the interview with your child on their eating behaviors for training purposes, but you can decline to have it recorded. You, the parent, will not be recorded at any point during this study.

If you complete the first visit virtually, your child will be given a cognitive test over Zoom or Teams with study staff. 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. During this study, Dr. Goldschmidt and her research team will collect information about you and your child for the purposes of this research. This includes your name, your address, phone number, e-mail address, assigned sex at birth, and your child's age and date of birth. We will also measure and record height and weight of you and your child, and collect information about your child's psychological functioning, such as eating behavior and thinking skills. This information will be used to determine study eligibility, and to understand more about brain

functioning and thinking skills in children, and how this might be related to their eating and weight.

At the end of the baseline visit, we will randomly assign your child to one of two groups: an fMRI scan group or a non-fMRI scan group. This assignment is based on your child's age, assigned sex at birth, and height/weight, to ensure that the two groups are similar in composition. There is a 50/50 chance your child will be assigned to the fMRI group. Participants that are randomized to the fMRI group will be asked to complete fMRI scans at baseline and at the 18-month follow-up visit. fMRI scans will take place at the BRIDGE Center (Location: 1st Floor of the Mellon Institute, 301 S Bellefield Ave, Pittsburgh, PA 15213).

An MRI scanner uses a magnet and radio waves to take pictures of your child's brain. Your child will need to lie very still for the scanner for up to an hour. Being in the fMRI 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 they want 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 fMRI scanner is very strong so if it comes in contact with any metal it could be dangerous for your child. Your child will also be asked to refrain from eating at least 2 hours prior to a scan.

2. All participants will be asked to attend **follow-up assessments at 6-, 12-, 18-, and 24-months** post-baseline. Full-battery follow-up assessments (12- and 24-months) will take about 3 hours to complete and can be split across two visits. Half-battery follow-up assessments (6- and 18-months) will take about 1 hour to complete and will be done in one visit. Participants in the fMRI group will attend an additional fMRI scan visit (~1.5 hours) at the 18-month assessment. At these visits, the research team will take height/weight measurements of you and your child, and you and your child will be asked to complete questionnaires. Your child will also be asked to complete a few cognitive tasks and discuss their eating habits with a member of the research team. Participants will be seen at Bellefield Towers for all follow-up visits. If COVID-related concerns remain present at the time of the follow-up(s), you will have the option to complete the(se) follow-up visit(s) hybrid-virtually/remotely. If you choose to complete follow-up visits virtually, study material will be dropped off at your house and study staff with conduct interview portions over Zoom or Teams; however, you and your child will still need to attend a shortened in-person visit to complete tasks that cannot be done virtually/remotely.

You and your child will be in the study for a little over 2 years, starting from the time of the phone screen, until you finish the 24-month follow-up. We would like your permission to stay in touch with you after the 2 years of follow-up, in case we have additional studies that would allow us to assess you and your child beyond the timeline of the current study. At the present time there is no plan to administer any assessments beyond the 24-month follow-up; we just want to contact you to make sure we have accurate contact information and keep you posted on the study's progress.

Data Reuse

If you recently participated in Project REST, 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.

3. Study Risks:

The risks of study participation are considered very minimal given that the investigation is observational in nature. Your child may become bored or frustrated during completion of cognitive tasks. 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 wish, ask to have the evaluation stopped at any time, or contact the researcher listed on the first page of this document for further assistance.

fMRI scans are generally considered to be safe as no radiation is emitted; however, accidents and injuries can occur. Such adverse events are extremely rare if appropriate safety precautions are followed. Because the fMRI machine exposes the body to a very strong magnetic force, 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 an fMRI scan, a researcher or technician will ask whether or not their body contains any metallic medical devices or

equipment, including 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 and the researcher or technician will also complete a checklist that addresses issues of fMRI safety.

fMRI scans are also potentially dangerous for anyone wearing any metal objects, including jewelry, watches, hair holders, eyeglasses or metal on clothing, as well as eye shadow, which sometimes contains metallic substances. Your child 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.

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 fMRI 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.

If research devices are being used that are not part of the fMRI 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.

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 fMRI during pregnancy has not been proved. If your child is, or might be, pregnant, they cannot take part in this study.

CAUTION: This study is neither designed nor intended to detect health problems in participants. The fMRI 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, they should not rely on this study as a way to determine whether or not you are well.

The investigators for this project are not trained to perform radiological diagnosis, and the fMRI 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 fMRI scans. However, on occasion the investigator may notice an fMRI 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 University of Pittsburgh 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 fMRI study, these images will not be made available for diagnostic purposes.

In this study, 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. UPMC takes your and your child's confidentiality seriously and will take steps to protect the information contained in the text messages to the degree permitted by the technology being used. Depending on the nature of the study, 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, and/or remote data deletion in the event of a lost or stolen device.

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, 412-585-9081, as opposed to texting information to our study staff.

However, 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. 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 or your child's 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.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

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.

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. Information obtained could be subject to subpoena, as questionnaires will assess underage drinking and alcohol use.

4. Study Benefits:

This is not a treatment study, so you or your child will likely not receive any benefit from the study. We hope the information from this study will help us learn better how to help children with their eating behaviors in the future.

5. Confidentiality:

Any information about you or your child obtained from this research will be kept as confidential (private) as possible. All records related to you and your child's involvement in this research study will be stored in a locked file cabinet and/or in a password protected electronic database that will be accessible to the investigators and their staff. You and your child's identity on these records will be indicated by your subject identification number rather than by your name, and the information linking your subject identification number with your identity will be kept separate from the research records. You and your child will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

In addition to the investigators listed and their research staff, the following individuals may have access to your information related to you and your child's participation in this research study:

- Authorized representatives of the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections may review you and your child's identifiable research information for purposes of monitoring the conduct of this research study.
- If investigators learn that you, your child, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to you or your child's identifiable information to provide services and addressing billing and operational issues.

At some point, you and your child's information may be de-identified and used by other researchers for future research studies. If this happens, we will not contact you for additional consent. In addition, per University of Pittsburgh data retention policy, research records will be maintained for 5 years past the age of majority (age 25 per PA State Law) after study participation ends. 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.

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 and your child. The researchers may not disclose information that may identify you or your child, even under a court order or subpoena, unless you give your permission to release this information. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you or your child 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 child's 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 you or your child's medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented your child to in this informed consent document. The Certificate does not stop you or your child from voluntarily releasing information about themselves or your child's involvement in this research. If others obtain your written consent to receive research information about your child, then the researchers may not use the Certificate to withhold that information.

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 you or your child. At most, the Website will include a summary of the results. You can search this Website at any time.

6. Access to Study Results:

You and your child will not receive any study results, as the testing is being done purely for research purposes.

7. 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. 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 interviews, questionnaires, fMRI scans, and cognitive tasks. These services will be paid for by the study and will not be billed to you/your child or your health insurance company.

8. Payments:

Your family will receive up to $475 ($550 if in fMRI group) for completing all study visits:

- Baseline I: $50
- Baseline II (assessment visit for non-fMRI group, fMRI visit for fMRI group): $75
- 6-month: $50
- 12-month I: $50
- 12-month II: $75
- 18-month: $50
- 18-month scan (fMRI group only): $75
- 24-month I: $50
- 24-month II: $75

All compensation is taxable income to the participant 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.

9. Compensation in Case of Injury:

There is no compensation available if you are injured. You do not waive any rights by signing this form.

10. Refusal/Withdrawal:

It is up to you whether you want to participate and want your child to be in the study. You are not required to enroll your child or have them participate. If you decide you do not want you and your child to participate, you can always change your mind and leave 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 and your child want to stay in the study the researcher will share this information with you as soon as possible.

If you and your child decide to quit the study after signing this form, no new information will be collected about you and your child unless you gave us permission to do so. However, the researchers may continue to use information that was collected before you and your child quit the study to complete analysis and reports of this research.

11. Rights and Complaints:

Signing this form does not take away any of your lawful rights. If you or your child have any further questions about this research study, you or your child may contact the investigators

listed at the beginning of this consent form. If you or your child have any complaints about 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 Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh, at 1-866-212-2668.

12. SIGNATURES:

PARENTAL PERMISSION

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 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.

Printed Name of Child-Subject_____

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 my participation in this research study and also their participation in this research study. A copy of this consent form will be given to me/my child.

Parent's or Guardian's Name (Print)_____

Relationship to Participant (Child)_____

Parent or Guardian Signature_____ Date_____

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.

Name of Person Obtaining Consent (Print)_____

Role in Research Study_____

Signature of Person Obtaining Consent_____

Date_____

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 the 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_____