Lifespan Affiliate Site where research will be conducted

☒ Rhode Island Hospital	☐ The Miriam Hospital
☐ Bradley Hospital	☐ Newport Hospital
	☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

014018
Committee #

_____
Name of Study volunteer

Project TEACH: The Eating, Affect, and Cognitive Health Study

You and your child are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to allow your child to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you and your child will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you and your child.

If you decide to allow your child to be in the study, you will be asked to sign an agreement which states that the study has been explained, that your questions have been answered, and that you agree to have your child participate. You will be given a copy of this form to keep.

Federal and Lifespan institution rules require that if your child is 8 years or older, the "assent" (agreement) of your child be obtained by the researcher before your child may participate in this study. Your child must sign the consent form as well. You will be given a copy of the signed consent form to keep.

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 thinking processes in children, and how this may relate to their eating behaviors. We want to better understand this process so we can help children develop better skills in these areas to improve their eating behaviors.

   We expect to enroll 50 subjects into this study. The study is sponsored by the National Institute of Health (NIH) and the Weight Control and Diabetes Research Center.

2. Explanation of Procedures

Participation will involve a screening conversation via telephone and mail to determine study eligibility. You have already completed this screening. If you and your child are eligible, you are now being asked to sign this consent form. This consent form and assent form for children will be explained to you by a member of the research team. Should you wish to participate, you and your child will be asked to sign these documents indicating your willingness to participate and complete an in-person interview and several questionnaires to further determine eligibility.

If your child is eligible and you have agreed to participate, you will be asked to stay at the Weight Control and Diabetes Research Center for approximately 2 hours. You 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 have their height and weight measured and complete assessments of eating behaviors, cognitive functioning, and psychiatric comorbidities. We would like to record the interview for training purposes, but you can decline to have them recorded.

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

□ YES □ NO

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

_____ _____ _____
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 or your child will be asked to complete a questionnaire which addresses how physically developed your child has become, in terms of 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.

Eligible children will be asked to complete questionnaires and cognitive tasks on their personal smartphone or a study-loaned smartphone over the following 15 days. Your child will be prompted 3-5 times a day randomly to complete these questionnaires or tasks; however, these prompts will not interfere with the school day. The research team will work with each participant's school schedule to ensure prompts are not timed during their specific school hours. On 3 randomly selected days, your child will also be asked to complete a dietary recall. For these recalls, a trained and registered dietician will call your child and ask about their eating. Two of these dietary recalls will occur during weekdays, and one will occur on the weekend.

At the end of the 15-day assessment period, you will be asked to return to the Weight Control & Diabetes Research Center to have you and your child's weight measured, receive cash compensation, return any study-loaned smartphone, and complete repeated assessments of eating behavior to assess potential changes.

We think you will be in the study for about 4 weeks, starting from the time we spoke to you on the phone, until you finish the 15-day assessment period and in-person follow-up visit. Each of these in-person visits will take about 2 hours. We will try to schedule your visits close together so it's easier for you.

Eligible participants will receive up to $100 for completion of study procedures ($50 for the intake assessment, and $50 for completion of the 2-week protocol) plus additional incentives for timely responses to random signals and dietary recalls (e.g., $1 for each survey and dietary recall completed). Participants have the potential to earn a maximum of $153, assuming perfect compliance to all study visits, surveys, and dietary recalls. Any money your child earns for completing surveys and dietary recalls during the assessment period will be given to them at the follow-up visit.

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.

Contact Information:
Andrea Goldschmidt, Ph.D., (401-793-8251; 196 Richmond St., Providence, RI, 02903) will be available to answer questions for research study volunteers about the study or any concerns about side effects/problems.

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 run the risk of interrupting their routines or activities when attempting to complete cognitive tasks and record eating episodes 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).

Some of the questions from the interviews and questionnaires may be upsetting to you or your child. You can refuse to answer any questions you wish, ask to have the evaluation stopped at any time, or contact the investigator or research staff at (401) 793-8962 for further assistance.

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.

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

4. Benefits

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit children in the future or aid in our understanding of cognitive processes in children who have eating and/or weight problems.

5. Alternative Therapies

Since treatment is not being offered, there are no alternative therapies. You and your child may choose not to participate. The decision whether or not you wish to participate in this study will not affect your care at Lifespan.

6. 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 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 on the researcher or your 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.

Taking part in this study is voluntary. If you choose not to participate in this study, your care at Lifespan will not be affected.

You may choose not to participate at any time during the study. Leaving the study will not affect your care at Lifespan.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Andrea Goldschmidt, Ph.D., in writing at the address on the first page. Andrea Goldschmidt may still use your information that was collected prior to your written notice.

If you remove your child from the study, it would still be useful for us to know how your child does over the next 2 years. We would appreciate if you would permit us to get follow-up information about your child's health from their doctor or medical record.

I GIVE THE RESEARCHERS PERMISSION TO OBTAIN FOLLOW-UP INFORMATION, SHOULD I DECIDE NOT TO PARTCIPATE ANY FURTHER

□ YES □ NO

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

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

Andrea Goldschmidt, Ph.D., may decide to take you out of the study without your consent if:

- Your child is unable to meet the requirements of the study;
- Your child's medical condition changes;
- New information becomes available that indicates that participation in this study is not in your child's best interest; or
- If the study is stopped, or the sponsor chooses to end the study. This may happen at any time, for reasons unrelated to healthcare.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If your child is injured by a medical treatment or procedure they would have received even if they were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If your child does experience a research injury, Lifespan or the study doctor can arrange medical treatment for them. Such treatment will be paid for as described below.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, Lifespan will provide such treatment at no cost to you. You must notify Andrea Goldschmidt as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you

think that you have suffered a research related injury, you must let Andrea Goldschmidt know right away.

If you have insurance and you or your child has a research injury that is not covered by the study, it is possible that some or all of the cost of treating your child could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. 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 those studies, you may contact Janice Muratori, anonymously if you wish, in the Lifespan Office of Research Administration, telephone number (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.
You and 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. In particular, 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 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, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you 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, the National Institute of Health;
- Doctors, nurses, laboratories and others who provide services to you 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, and 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 you or your child's treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you and 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 them 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.

For more detail about privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

FUTURE RESEARCH
It is possible that your child may be eligible for another research study in the future. The researchers are requesting your permission to contact you to find out if you are interested in having your child participate in any future studies. Please place your initials next to one of the boxes below to tell the study team whether or not you want to be contacted about future research studies.

_____ I DO want to be contacted about future studies.
(Initials)

_____ I DO NOT want to be contacted about future studies.
(Initials)

Parent/Guardian Initials _____

SIGNATURE

I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, AND I GIVE PERMISSION FOR MY CHILD TO PARTICIPATE IN THIS RESEARCH STUDY.

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/guardian* Date and Time when signed

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

I AGREE TO PARTICIPATE IN THIS STUDY

_____ _____
Signature of study volunteer (child)* Date

_____
Age of study volunteer (child)

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT ABOVE BY THE PARENT/GUARDIAN OR AUTHORIZED REPRESENTATIVE

_____ _____
Signature of witness (required if consent presented orally or at the request of the IRB) Date

_____ _____
Signature of Translator Date

Parent/Guardian Initials _____

IF STUDY VOLUNTEER IS UNABLE TO SIGN OR EXCEPTION TO ASSENT IS SOUGHT, PLEASE EXPLAIN:

_____

_____

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE PARENTS AND STUDY VOLUNTEER, THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

_____ _____ _____

Signature of researcher or designate Date and Time when signed

* If signed by agent other than parent and study volunteer, please explain below.

_____

_____