CONSENT TO TAKE PART IN RESEARCH

Dartmouth College
Jennifer A. Emond, PhD & Diane Gilbert-Diamond, ScD

Introduction: **You are being asked to take part in a research study. Taking part in research is voluntary.**

You and your child are being asked to take part in this study because your child meets the age requirement for the study and is interested in participating in the study.

Your and your child's decision whether or not to take part will not influence your and your child's future medical care, job status, academic standing, etc. Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

The goal of our study is to understand how a child's genetics and family environment may influence their growth and development.

What is required to participate?

There are no special requirements to participate in this study. This study is open to anyone who meets the study eligibility criteria and who is able and willing to complete all study activities.

Will you benefit from taking part in this study?

You and your child will not personally benefit from being in this research study. We hope to gather information that may help people in the future.

What does this study involve?

The study requires six visits to our office over a period of 2 ½ years. The first visit will be when your child is approximately 2 ½ years old. There will then be a visit every six months until your child is 5 years old. Your child will wear an activity monitor, like a FitBit, on an elastic belt before each visit. You will also write down all of the food and drink your child consumed over 3 days at each visit time point (using a paper diary we give you) and complete an online survey. Then at each visit, your child will play age-appropriate computer games and will be provided with snack foods and water. We will measure your and your child's weight and height at the office visit, as well as your child's growth based on skinfold measurements (more details are below). We will also collect a saliva sample from your child at the first study visit for genetic analysis. Each office visit may last up to one hour. More details on each study activity are below the table.

Table 1. Brief summary of the study activities. There are a total of 6 study visits, every 6 months. The same parent/guardian is asked to complete all of the parent/guardian activities throughout the study.

	Child activity	Parent/ guardian activity
At each visit time point (material will be mailed to the parent)		
Wear a physical activity monitor for 7 days	✓	--
Write down all foods and drinks consumed by the child for 3 days	--	✓
Online survey	--	✓
At the office visit (1.5 hour)		
Play computer games	✓	--
Be given snack foods	✓	--
Watch an age-appropriate video	✓	--
Collect body measurements (e.g., height, weight)	✓	✓
Collect a saliva sample (at the first visit only)	✓	--

Physical activity monitor: Your child will wear a physical activity monitor, like a FitBit, on their waist for 7 days before each study visit. The monitor is placed on a comfortable elastic belt. We ask that you write down when your child wears the device and when he/she removes it. We will provide you with a paper document to write those details down. We will mail you the activity monitor before each study visit.

Food diary: You will also complete a diary to write down all foods and drinks your child consumes over 3 days at each visit time point. We will give you a paper booklet with instructions for how to do that, and a study team member will discuss those instructions with you. We will give you information for childcare providers about the diary if needed. We will mail you the diary at each study visit time point.

Online surveys: You will also complete an online survey before each visit. Each survey will ask about your and your child's media use, sleep habits, and eating habits as well as your habits for how you feed your child. The survey will also collect information on your household structure and socio-demographic factors like age, race, ethnicity, and household income.

Computer games: Some of the computer games include eye-tracking to measure where your child is looking when playing the games. The eye tracker is a high-resolution camera mounted to a computer monitor to measure where a person's eyes are looking. It is non-invasive and does not require any equipment to be placed on the head, or on or around the eyes. The monitor does not save video when tracking the eyes. Children who wear glasses can play these games with their glasses on.

Body measurements: We will collect your and your child's height, weight, and body fat measurements at each study visit. We will measure your child's waist circumference using a measuring tape. We will also measure how thick your child's skin is at different locations on his/her body: at his/her right tricep, behind the right shoulder and just above the right hip. These measurements are taken using an instrument called a caliper that can measure the thickness of skin when it is slightly compressed.

Saliva sample: We will collect a saliva sample from your child at the first study visit for genetic analyses using a small sponge that will be used to gently wipe the inner cheek and gumline of your child's mouth. You will not receive a copy of your child's genetic data.

What are the options if you do not want to take part in this study?
The alternative is not to take part in this study.

If you take part in this study, what activities will be done only for research purposes?
All the procedures, tests, and activities described in this consent form are being done only for research purposes.

What are the risks involved with taking part in this study?

- This study is a low-risk study.

- There are no risks associated with your child wearing the physical activity monitor device other than potential discomfort when wearing the belt.

- There are no risks associated with having your child's eye movement measured while playing computer games.

- Children with food allergies could experience adverse reactions to the food served at the study visit. In order to prevent allergic reactions, *please inform us of any food allergies your child has*. Children with severe food allergies may not take part in this study. A study team member has reviewed potential food allergies with you during the screening interview. **Notify the study team member now if you have any questions about a potential food allergy:** media.and.health@dartmouth.edu.

- Your child may experience slight discomfort when we measure skinfold thickness because we will compress his/her skin. We will stop if your child is experiencing moderate to severe discomfort or does not want to continue with the skinfold measurements.

- There is the risk that the privacy and confidentiality of your own and your child's study data, including your child's genetic data, could be compromised. This is a risk for any research study. **We take that risk extremely seriously and have multiple steps in place to ensure that the risk is extremely low**. See the next section for details.

How will your privacy be protected?

We are careful to protect the identities of every person in this study. We keep all study information secure and confidential.

We save all study data in an encrypted database on a secure Dartmouth server that is password-protected. All collected data will be de-identified by removing any personal information from the data set and using a random number to refer to study participants. Personal identifying information and study data are saved on separate computer servers, and only the principal investigators and the research team members who directly interact with study participants have access to the information that could re-identify a study participant's data.

Saliva samples and samples of isolated DNA will never be labeled with participant identifiers and will only be labeled with randomly generated ID numbers. Only the principal investigator and research team members who directly contact the participants will have access to the information needed to re-identify a participant's genetic sample. Genetic data will only be used for IRB-approved research and cell samples, isolated DNA, and genetic data will be destroyed when no longer needed for the aims of this study. The genetic data that is uploaded to the NIH database dbGAP, per NIH guidelines, will be completely de-identified.

Any paper files will be stored in a locked file cabinet in a secure office that is locked after hours. When study data are no longer needed, electronic data will be permanently deleted from the database and paper files will be securely shredded and destroyed.

Parents and children can withdraw their data from the study at any time by contacting Dr. Jennifer Emond at 1-603-646-5709 or Jennifer.A.Emond@Dartmouth.edu.

The information collected for this study will be used only for purposes of the research as stated earlier in this form. Please note that the HIPAA Privacy Rule does not recognize as valid any authorization for the use or disclosure of Protected Health Information (PHI) for future, unspecified research projects. An authorization is permitted, however, for the initial compilation of information in a data repository for future research use. Each research project using the repository data requires an additional authorization or waiver of authorization.

Who may use or see your and your child's health information?

By signing this form, you allow the research team to use your and your child's health and health behavior information. The identifiable health information collected for this study may be used by researchers or officials, with IRB approval, from:

- Dartmouth College
- Dartmouth Health

By signing this form, you also allow IRB-approved collaborators from other institutions access to your and your child's de-identified health information for IRB-approved research purposes.

Some of the information used in this study including names, addresses and dates of birth, called Protected Health Information ("PHI"), is protected by federal privacy laws. By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires notification so you are aware *if your* PHI is disclosed to others, it may no longer be protected by federal privacy laws.

No publication or public presentation about the research described above will reveal your or your child's identity without another authorization from you.

Identifiable data collected for this study will be used for research purposes which are determined to be reasonable and in line with expectations by a review committee.

Your permission to have us use your and your child's health information for this study will not end until the study is completed. During this study, you and others who take part in the study will not have access to the study data.

This research is covered by a Certificate of Confidentiality from the NIH. The researchers with this Certificate may not disclose or use information or documents that may identify you or your child in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect and harm to self or others.

<u>What if you decide not to give permission to use and share your personal health information?</u>

If you do not allow use of your health information for this study, you may not take part in this study. If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

Will you be paid to take part in this study?

Yes. You will be compensated up to $1,000 for participating in this study based on the following:

Study visit	Child age	Study activities	Compensation
1 ($120 total)	~2.5 years old	Study visit & online survey	$40
		Physical activity monitor	$30
		Food diary	$50
2 ($130 total)	~3.0 years old	Study visit & online survey	$50
		Physical activity monitor	$30
		Food diary	$50
3 ($140 total)	~3.5 years old	Study visit & online survey	$60
		Physical activity monitor	$30
		Food diary	$50
4 ($185 total)	~4.0 years old	Study visit & online survey	$70
		Physical activity monitor	$40
		Food diary	$75
5 ($195 total)	~4.5 years old	Study visit & online survey	$80
		Physical activity monitor	$40
		Food diary	$75
6 ($230 total)	~5.0 years old	Study visit & online survey	$90
		Physical activity monitor	$40
		Food diary	$100

We will also provide participants travelling from more than 15 miles away with mileage compensation ($10) so that fuel costs are not a deterrent for participation.

All compensation will be in the form of electronic gift cards. Compensation will be prorated as needed based on the level of participant.

Other important items you should know:

Leaving the study: You may choose to stop taking part in this study at any time for any reason. If you decide to stop taking part, it will have no effect on your and your child's future medical care, job status, academic standing, etc.

New Information: New information related to this research will be made known to you when it becomes available. This may affect your decision to stay in this study.

Funding: This study is funded by a research grant awarded to Jennifer A. Emond and Diane Gilbert-Diamond from the National Institutes of Health (R01DK136698). Dr. Emond and Dr. Gilbert-Diamond are employed by Dartmouth College.

Number of people in this study: We expect 240 children to enroll in this study.

Whom should you call with questions about this study?

If you have any questions about this study or need to report a study-related concern including injuries, please call the director for this study: Dr. Jennifer A. Emond at 1-603-646-5709 during Monday-Friday, 8:30 AM – 5:00 pm or email at Jennifer.A.Emond@Dartmouth.edu. Contact your physician or call 911 for any urgent health-related concerns.

If you have questions, concerns, complaints, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-6482 during Monday-Friday, 8:30 AM – 5:00 PM.

CONSENT

- I have read the above information about the Study and have been given time to ask questions.
- I agree to have my child and myself take part in this study.
- I agree to accompany my child for each study visit and to complete the online surveys at each visit, to the best of my ability.
- I acknowledge I may be provided with a given a copy of this signed consent form upon request at any time.

SIGNATURE OPTIONS

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Parent /or Legal Guardian's Signature Date PRINTED NAME

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Researcher or Designee Signature Date PRINTED NAME