Official Title	Multicenter Pilot Project to test the Healthy Parents and Children Enhancement (H-PACE) Program
NCT Number	NCT06548074
Document Type	Informed Consent Form
Document Date	1/16/2025

Consent to take part in a research study:

Multicenter Pilot Project to test the Healthy Parents and Children Enhancement (H-PACE) Program

Principal Investigator:	Jason Mendoza, MD, MPH	Fred Hutchinson Cancer Center	(206) 667-6601
Program Administrator:	Elizabeth Carosso	Fred Hutchinson Cancer Center	(206) 667-2716
Community Project Manager:	Genoveva Ibarra	Fred Hutchinson Cancer Center	(509) 837-6359

Important things to know about this study.

You and your child are invited to take part in a research study.

The focus of this study, called H-PACE, is to learn if the H-PACE program helps improve kids' behaviors and beliefs about active and healthy living.

If you agree to join this study, we will ask you to complete two surveys and participate in home activities that follow the H-PACE program your child will be learning at the before or after school program.

You do not have to join this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits for saying no or dropping out.

Below is a complete description of this study. Please read this description. You can ask any questions to help you decide whether to join the study.

We would like you to join this research study.

We are doing a research study to learn whether the H-PACE program helps improve kids' behaviors and beliefs about active and healthy living.

You and your child are being asked to participate in this study because your child attends one of the schools that offers the H-PACE Program as a before or after school option for kids and is enrolled in third, fourth, or fifth grade.

The H-PACE program will take place at your child's school and is completely free. Only children in the third, fourth and fifth grades attending the before or after school program are eligible to participate in the H-PACE program.

In this program, your child will participate in lessons and activities that encourage daily, healthy lifestyle behaviors (for example, eating 5 or more servings of fruits and vegetables, spending 2 hours or less on-screen time, 1 hour of physical activity, 0 sugary drinks, 10 hours of sleep).

Children will meet two times per week before or after school for 12 weeks. Each H-PACE session will last 60 minutes. Parents are asked to complete two surveys, participate in home activities, and have the option to join a Facebook group of other parents participating in this study. Before the program starts, and again at the end of the program (weeks 11-12) study staff will show your child how to place an activity meter around their waist using a belt or a clip. This small electronic device, about the size of a pager, will provide minute-by-minute estimates of your child's overall physical activity. Your child will wear the activity meter all day, including while asleep, for seven days. The only exception is during baths or swimming, since the meter is not waterproof. After this 7-day period, study staff will collect the activity device from your child at the before or after school program. The meter does not track or record locations, only physical activity.

We will enroll up to 38 parents and their children (76 total) at two different elementary schools. We hope the information we learn will help people embrace an active and healthy lifestyle in the future.

If you and your child join the study, we will ask you and your child to participate in the following activities:

Research Activities	**Location**	**How much time it will take**
Child Activities		
Have his or her height and weight measured	Child's school site	10-15 minutes
Wear an activity meter for 7 days in a row	Child's school site & Home	7 Days each time at 2 times throughout the study
Take a survey about lifestyle behaviors	Child's school site	10-15 minutes
Participate in the H-PACE curriculum	Child's school site	12 weeks
Parent Activities		
Take a survey about yourself, your child, and your household	Home	Approximately 30 minutes at 2 times throughout the study
Participate in home activities that follow HPACE curriculum (i.e. craft projects, family dinners, reading or listening to music)	Home	Weekly

You will also have the option of joining a private Facebook group with other parents in the study. The focus of this group will be sharing ideas and receiving support from other parents for making changes related to healthy living for their children.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits for saying no or dropping out.
If you leave the study, the information you have already provided cannot be removed from the study records.

What are the benefits?
The potential benefit of participating in this study is improving healthy lifestyle behaviors. Children may also learn how to include healthy lifestyle behaviors as part of their normal daily lives.

What are the risks?
The potential risks of participating could include:

- Embarrassment from having weight measured.
- Potential injuries while doing physical activities.
- Others could potentially learn about your choices or beliefs about healthy lifestyle choices.

In addition to the standard practices described below to protect the information provided by you, we will also limit access to the Facebook sharing site to the research team and participants who are part of the study and have accepted the Facebook friend request. However, please be aware that Facebook's policies are subject to change at any time.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information
Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Researchers involved with this study.
- The study sponsor and their agents.
- Fred Hutchinson Cancer Center
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be disclosed if required by law. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you.

At most, the Web site will include a summary of the results. You can search this Web site at any time.

At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. The Certificate may not last the duration of the research. Talk to the study staff if you have questions about this.

We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if they believe that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Will you pay me to be in this study?
If you participate in this study, you will receive:

- $20 gift card after completing the survey at the beginning of the study
- $20 gift card after completing the final survey at the end of the study period.
- In addition, we will provide a $20 gift card after your child wears the activity meter at the start of the intervention, and $40 after wearing the activity meter at the end of the study period.

How much will this study cost me?
There is NO cost to participate in this study.

Will you contact me in the future?
We will not contact you in the future.

What will my information be used for?
Your information (even if made anonymous) will not be used for any research other than this study.

Confidentiality
We will take careful steps to keep your information confidential in a way that no names and other personal information (e.g., email address) will appear in any publications or reports. All collected data will only be reported as a summary. Data in digital form will be keyed on an external hard drive on password protected computers. Individual

information will be protected in all data resulting from this study. We will keep one master list that will contain email addresses for linking data sources. Once data collection is complete, analyses will be performed on de-identified data sets. All data will be destroyed three years after completion of the study. No data will be collected from participants who choose to 'opt out' during the research process; their data will be immediately destroyed.

Other information

If you have questions or concerns about this study, you may talk to a member of the study team anytime. If you have questions or complaints about this study, please call Dr. Jason Mendoza MD at (206) 667-6601. If you have questions about your rights as a research participant, call the Director of the Fred Hutch Institutional Review Office at 206-667-5900 or email irodirector@fredhutch.org.

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol: RG1124059
Current consent version date: 8.06.2024
Previous consent version date: N/A
Copies to: