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

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Investigator Statement:

I have read Protocol RG#1124059 entitled "Multicenter Pilot Project to test the Healthy Parents and Children Enhancement (H-PACE) Program" ("Protocol"), version date 05/09/2024.

I agree to carry out my responsibilities in accordance with the Protocol, applicable laws and regulations (including 21 CFR Part 312), Good Clinical Practice: Consolidated Guidance (ICH-E6), and applicable policies of The Fred Hutch/University of Washington/Seattle Children's Cancer Consortium.

Fred Hutch P. Investigator: Jason Mendoza MD, MPH

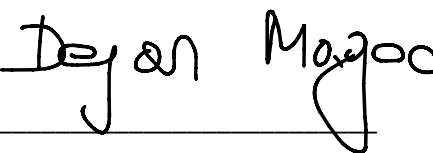
NMSU Investigator: Dejan Magoč,
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Signature: _____



Date: 5/9/2024

Signature: _____



Date: _____

9/9/2024

PROTOCOL SYNOPSIS

Protocol Title	Multicenter Pilot Project to test the Healthy Parents and Children Enhancement (H-PACE) Program
Protocol Number (RG #)	RG#1124059
Funding Agency or Sponsor	National Institutes of Health, National Cancer Institute
Study Type	Prevention
Study Objectives	Aim 1: Test the feasibility of the H-PACE program research protocol. Aim 2: Pilot test the H-PACE program for improving lifestyle behaviors (i.e., PA, fruit and vegetable intake, screen time, sleep) that impact childhood obesity. Aim 2 are exploratory objectives.
Primary Endpoints	Measure feasibility of program, including recruitment, attendance, and completion of assessment activities. Measure preliminary efficacy of H-PACE on moderate to vigorous physical activity levels via accelerometers
Exploratory Endpoints	Exploratory Objectives include fruit and vegetable intake, screen time, sugary drink intake, and sleep measured via self-reported surveys. We will also measure potential mediators of these behaviors, including self-efficacy, self-esteem, and the level of readiness to change relevant to lifestyle behaviors via self-reported surveys.
Study Design	Behavioral Intervention
Population	Elementary school children, 8-11 years old, and their parent/guardian, who is 18 or older. Specifically, children enrolled in a before or after school programs in selected public schools in Las Cruces, New Mexico, and Sunnyside, Washington.
Intervention	The intervention is a curriculum consisting of three parts: 1 – Educational component, 2 – Physical Activity component, and 3 - Snack component. The educational component includes 30-minute lessons on the importance of physical activity, consuming fruits and vegetables, limited screen time and sleep, followed by fun and entertaining games and activities.
Intervention Groups	All children will receive the intervention H-PACE before or after school program
Study Schedule	The intervention is conducted over a 12-week period, twice per week, 1 hour each day.
Number of Participants	68 parent-child pairs
Estimated Study Duration (months)	3 years
Duration of Participation (months)	14-15 weeks (2–3-week baseline assessment + 12 week intervention)

ABBREVIATIONS

5-2-1-0+10	Five or more servings of fruits and vegetables, two hours or less of recreational screen time, one hour of physical activity, zero sugary drinks, ten hours of sleep
BMI	Body Mass Index
CI	Confidence interval
CTMS	Clinical Trial Management System
DSMC	Data and Safety Monitoring Committee
DSMP	Data and Safety Monitoring Plan
H-PACE	Healthy Parents and Children Enhancement (H-PACE) Program
ICF	Informed Consent Form
IRB	Institutional Review Board
LAR	Legally authorized representative
NMSU	New Mexico State University
PA	Physical Activity
PI	Principal Investigator
SRC	Scientific Review Committee

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1.0 INTRODUCTION TO THE PROTOCOL

1.1 Introduction and Scientific Rationale

In New Mexico (NM), 15.2% of children between the ages of 6-15 are obese, ranking NM 23rd among all U.S. states.¹ Obesity prevalence also increases with age. In 2018, only 13% of NM children ages 2-4 years were obese compared with 32% of adults 18 years of age and older. Likewise for Washington (WA) in 2016, 12% of children ages 2-4 years were obese compared to 29% of adults.

Proper nutrition and physical activity (PA) are essential parts of overall health. Together, they can decrease the risk of developing obesity as well as related diseases such as diabetes, heart disease, stroke, and several types of cancer.^{6,7} Since childhood obesity strongly tracks into adulthood, obesity and related obesogenic behaviors among children greatly increase the risk of obesity and cancer in adulthood.^{8,9} Studies have shown a strong association between higher body mass index (BMI) during childhood and adolescence and increased risk for several malignancies in adulthood, including leukemia, Hodgkin's disease, colorectal cancer, and breast cancer.³ Moreover, higher childhood BMI is independently associated with increased overall cancer mortality.⁴ A high percentage of Americans, however, do not practice healthy eating habits and are not sufficiently physically active.⁵ Indeed, only 51.5% of Americans attain the weekly levels of recommended PA and 26% engage in no leisure-time PA.^{5,10} This trend is also true for school-age children, where approximately 75% of those between the ages 6-15 do not meet the PA guidelines of 60 minutes of moderate-to-vigorous PA per day and 21.8% do not participate in 60 minutes of PA on at least one day a week.⁵ Moreover, screen time (e.g., television, video games, cell phones) has contributed to the epidemic of sedentary behavior and physical inactivity. For instance, 22% of children ages 10-17 report watching television three or more hours/day, and 47.7% report using computers and other electronic devices for recreational purposes three or more hours/day.⁵

1.2 Evidence to Date

To address the prevalence of obesity and related diseases, programs focusing on increasing opportunities for active living and healthy eating are necessary. Multi-component school-based obesity prevention programs have demonstrated increases in PA and improvement in dietary habits; however, most afterschool programs are short term; evidence is needed to confirm long-term effects. Moreover, programs that involve parents have shown to be more successful in helping children choose healthier behaviors. Unfortunately, due to technological advancement, opportunities for children to be active in schools have become more limited in modern society. Furthermore, the coronavirus pandemic and social distancing have a negative impact on already low participation in PA.^{11,12} To address the issues related to low levels of PA and other health related behaviors, there is a need for community-based programs that are sustainable in order to have a lasting impact on young children living in the local community.

The proposed feasibility study, Healthy Parents and Children Enhancement (H-PACE) program, is based on the 5-2-1-0+10, a national childhood obesity prevention campaign designed to help families, schools, communities, and physicians to raise awareness of nutritional and PA daily guidelines.¹³ Similar to the 5-2-1-0+10 initiative, the H-PACE will encourage daily lifestyle behaviors (five or more servings of fruits and vegetables, two hours or less of recreational screen time, one hour of PA, zero sugary drinks, ten hours of sleep) that impact childhood obesity. The H-PACE program is grounded in Social Cognitive Theory.^{14,15} This theory posits that learning occurs in a social context with a dynamic and reciprocal interaction of the person, environment, and behavior. It is expected that implementing the H-PACE program through an existing before or after school program in Las Cruces, NM and a new partnership in Sunnyside, WA among children 8-11 years of age (third through fifth grade) will be feasible and demonstrate clinically important changes in improving children's lifestyle behaviors.

1.3 Study Intervention/Activities

This **behavioral intervention** is a 12-week educational program, Healthy Parents and Children Enhancement (H-PACE) program. The program consists of three parts: 1 – educational component, 2 - PA component, and 3 - snack component. The educational component includes 30-minute lessons on physical activity, fruits and

vegetables and sleep, followed by fun and entertaining games and activities. The PA component (30-minutes) is composed of a variety of enjoyable activities including warm-up, main activities (e.g., walk/run/jog and aerobic fun games), and cool-down. The snack component is designed to introduce children to tasty and healthy foods and to teach children the skills to enable them to select and prepare healthy snack foods at school and at home. Snack education lessons will emphasize the benefits of fruit and vegetable intake, and include a discussion of food composition (e.g., fat content, sugar, sodium). Once a week, children will be involved in the preparation of healthy snack foods at home with parents by taking home fruit and vegetable boxes with recipes for family-based engaging activities.

1.4 Risks/Benefits

Participation in this pilot project poses no more risk than what would be encountered in regular physical activity and health-related behavior studies. Participants may feel fatigued after engaging in moderate to vigorous physical activity. Participants will be reminded and recommended that they can take extra breaks to stay hydrated during the sessions and take breaks whenever needed. Potential discomfort involved with the physical activity program include soreness, fatigue, and physical discomfort. All of these potential discomforts will be verbally addressed with the participants and parents. Participants will be advised to take breaks or stop the activity program if at any point they feel fatigued or experience physical discomfort. Participants will also be encouraged to stay hydrated throughout the physical activity program.

Children and parents may experience some benefits from participation. Parents and children will be provided information on healthy lifestyle choices.

Risks also include the potential for disclosure of information reported on surveys. Prior to conducting study analyses, all identifiable participant information will be removed to ensure confidentiality and anonymity. For more information on data management and securing participant confidentiality, refer to Sections **Error!** **Reference source not found.** and **Error! Reference source not found.**

2.0 OVERVIEW OF STUDY DESIGN

2.1 Study Design

Information regarding the H-PACE curriculum and research study will be shared with parents by sending flyers through existing take-home packet process and by posting information throughout the schools' bulletin boards. Schools may also invite study staff to share information about the study at parent meetings. The recruitment materials will have study staff contact information. Interested parents will contact study team via provided contact information to request more information and, if interested, complete parent consent and child assent process. Parent consent and child assent process can be completed in person or by sending documents in take-home packets to and from the school via child.

The general purpose, procedural details, and all safety concerns and possible risks involved with the project will be verbally described and explained to the participants by bilingual/bicultural study staff before they read and sign the consent form. Informed consent, assessments and assent forms will be provided in English and Spanish for parents and children. In addition, the documentation will be verbally described in the participants' preferred language. Participants will be verbally assured that they will not be penalized in any way if they decline to participate or if they choose to discontinue their participation in the study for any reason.

Each parent will be asked to 1 - complete a baseline assessment (self-administered 20–30-minute questionnaire), 2 - join a voluntary, private, and hidden Facebook group. This group will offer the highest level of restrictions on visibility and accessibility, being accessible only by invitation. Within this platform, a virtual peer support group will be established, serving as a space where parents can access study-related information and

exchange strategies, discuss challenges, and celebrate successes and 3 - complete a post-program assessment (self-administered 20–30-minute questionnaire).

Each child will be asked to 1 - Complete a baseline assessment (self-administered 30-minute questionnaire), 2 - Wear an accelerometer for 7 days at baseline (prior to 12-week H-PACE program) 3 - Participate in the 12-week before/after school H-PACE Program, which includes weekly educational lessons, physical activity, and health snacks, 4 - Wear an accelerometer for 7 days in week 11-12, and 5 - Complete a post-program assessment (self-administered, 30-minute questionnaire).

2.2 Study Objectives and Endpoints

Primary Objective(s)	Endpoints
Test the feasibility of the H-PACE program research protocol	- Recruit 136 participants (68 parents and 68 children) parent-child pairs - Greater than 75% of children meet each of the following two “success” metrics: - Children attend >75% of program sessions. - Children complete >80% of assessment activities Time frame: 14-15 weeks
Exploratory Objectives	
Pilot test the H-PACE program for improving lifestyle behaviors (i.e., PA, fruit and vegetable intake, screen time, sleep).	

3.0 INCLUSION AND RECRUITMENT

The PI and study team at each site will meet with school district leadership to discuss study and select which schools will participate in this study. Both PIs have experience conducting school-based interventions in their respective areas of Las Cruces, NM and Sunnyside, WA. These districts largely serve low-income Hispanic students. However, all 3rd - 5th grade children at the intervention sites will be encouraged and eligible to participate in the proposed H-PACE before/after school program initiative regardless of their ethnic background. Considering that Las Cruces, NM has an approximately 50% Hispanic demographic, and Sunnyside, WA is predominantly Hispanic, with approximately 81% identifying as such, predominantly of Mexican descent, coupled with the trend of younger generations comprising an even greater proportion of Latinos, particularly within lower-income schools, it is expected that approximately 85% of program participants will identify as Hispanic. Nonetheless, it is imperative to emphasize that there is no exclusionary criterion based on race or ethnicity for participation in the program.

3.1 Eligibility of Women

Participants from various ethnic backgrounds at the targeted schools' sites will be recruited to participate in the current proposal. We expect that for the child participants, ~50% will be girls. With respect to the parents/guardians enrolled into the study, we expect that 95% of parent/guardian participants will be women.

3.2 Eligibility of Minority Groups

Individuals of any sex, gender, race, or ethnicity are eligible for this study.

3.3 Recruitment of Minority Groups

Individuals of any race and ethnicity are eligible for this study. Individuals of any sex/gender, including those who do not identify as binary or those with a gender different than that assigned at birth, are eligible for this study. The study recruitment strategy aims to achieve representation of minority groups that reflects the demographics of the population in the two study site areas.

3.4 Inclusion Across the Lifespan

Participants must be young children in 3rd-5th grade at selected elementary school sites. Thus, it is anticipated that children between the ages of 8-11 years will make up the majority of child research participants in the study. The child's parent/guardian is also invited to participate as programs that involve parents have shown to be more successful in helping children choose healthier behaviors.

Children in 3rd – 5th grade and their parent/guardian (≥ 18 years of age) are eligible for this study. The study population is restricted to this specific age group based on prior studies indicating that children under eight years old struggle with attention and adherence to physical activity (PA) programming.^{20,21} Furthermore, behaviors related to health, such as physical activity, healthy eating, and sleep, which are learned during childhood, tend to persist into adolescence and adulthood.¹² Therefore, targeting young children in this study aims to combat the national issue of declining physical activity and health-related behaviors among youth.

3.5 Study Population

Given that Las Cruces, NM is nearly 50% Hispanic and Sunnyside, WA is predominantly Latino (81%) with majority being of Mexican descent and given that younger generations have even higher proportions of Latinos and are overrepresented in the lower income schools, it is anticipated that 85% of participants will be Hispanic. However, there is no exclusion of participants based on race/ethnicity. Thus, participants from various ethnic backgrounds at the targeted schools' sites will be recruited to participate in the current proposal. We expect that for the child participants, ~50% will be girls. With respect to the parents/guardians enrolled into the study, we expect that 95% of parent/guardian participants will be women due to our experience recruiting for similar studies involving elementary school children and their parents.

Projected Target Accrual
ETHNIC AND SEX* DISTRIBUTION CHART

TARGETED / PLANNED ACCRUAL			
Ethnic Category	Study Target (Sex assigned at birth)		
	Females	Males	Total
Hispanic / Latinx	84	34	118
Not Hispanic / Latinx	13	5	18
All Participants	97	39	136
Racial Categories	Study Target		

American Indian / Alaska Native			
Asian			
Native Hawaiian / Other Pacific Islander			
Black / African American			
White	97	39	136
More Than One Race			
All Participants	97	39	136

* The Consortium acknowledges that the sex/gender categories in this table do not constitute the full spectrum of gender identities that are relevant in our society, nor necessarily encompass identities that may be of interest in specific research projects.

4.0 PARTICIPANT ELIGIBILITY

The study will involve 68 parent-child pairs. That is 136 participants, 68 being adults and 68 being children. For analytic purposes, the child is the focus of analyses, with the parents providing ancillary data on household and social context that children cannot provide due to developmental constraints. Thus, the exploratory analyses use a sample size of 68 parent-child pairs.

Children aged 8-11 years (3rd - 5th grade) from two elementary schools in the Las Cruces Public School (LCPS) district will take part during the 2023-2024 academic year. This will be followed by participation from two elementary schools in Sunnyside, WA during the 2024-2025 academic year. All adult participants must be at least 18 years old.

4.1 Inclusion Criteria

- Children in 3rd – 5th grade, 8-11 years of age, attending the before/after school program at the selected elementary schools.
- Parents/Guardians of the eligible child, who are ≥ 18 years old.
- Fluency in English or Spanish

4.2 Exclusion Criteria

- Children who are not in 3rd – 5th grade.
- Children not attending the afterschool program at the selected elementary schools.
- Parents/Guardians of the eligible child, who are < 18 years old.

5.0 STUDY PROCEDURES

After obtaining IRB approval, the study team will recruit children in grades 3-5, ages 8-11 years, at four elementary school sites (two in NM for 2023-2024 and two in WA for 2024-2025) and one parent for each child. Participation will be open to all students in the before/after school program, however only the first 15 parent-child pairs at two NM schools and 19 parent-child pairs at two WA schools will be enrolled into the study.

*NOTE: NMSU secured IRB approval at their institution and has begun data collection. Once Fred Hutch IRB approval is secured, IRB oversight will be transferred to Fred Hutch.

Each **parent** will be asked to:

1. complete a baseline assessment (self-administered 20–30-minute questionnaire),
2. participate in a private, invitation-only Facebook group, a virtual peer support group where parents can receive study information and share strategies, challenges, and successes and
3. complete a post-program assessment (self-administered 20–30-minute questionnaire).

Each **child** will be asked to:

1. complete a baseline assessment (self-administered 30-minute questionnaire),
2. wear an accelerometer* for 7 days at baseline (prior to 12-week H-PACE program)
3. participate in the 12-week before/after school H-PACE Program, which includes weekly educational lessons, physical activity, and health snacks,
4. wear an accelerometer for 7 days in week 11-12**, and 5 - Complete a post-program assessment (self-administered, 30-minute questionnaire).

Accelerometers are activity meters or a small electronic device that the child would wear on a belt. It is about the size of a pager. The meter gives minute-by-minute estimates of how much their whole body is moving. The meter is not a tracking device and does not record where you have been.

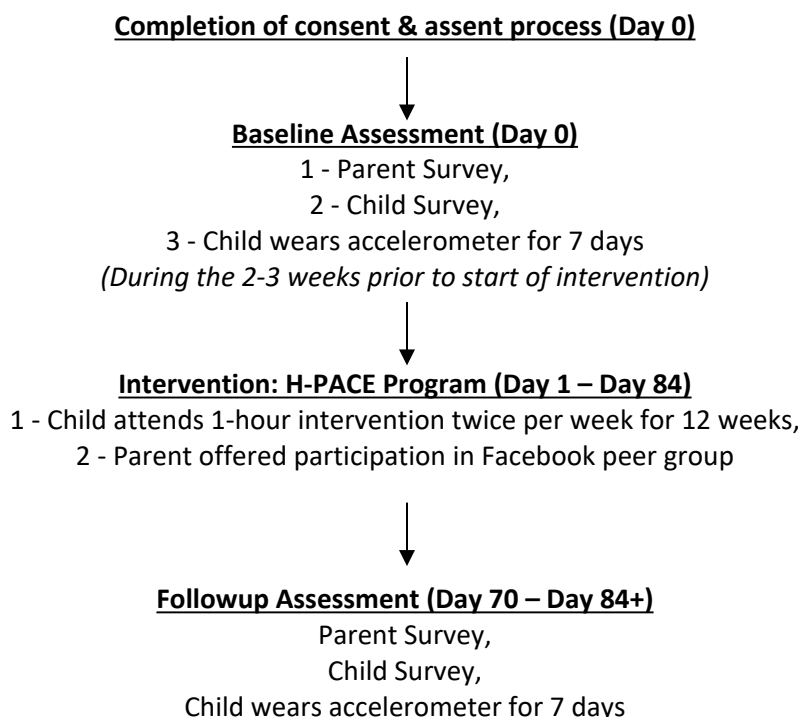
During the 12-week intervention period, children enrolled in H-PACE will participate in educational activities (30 minutes) and physical activity activities (30 minutes), for a total of 60 minutes twice per week. The educational component of H-PACE is strategically designed to empower children with the knowledge, skills, self-efficacy, and intentions necessary to make informed and healthy dietary and PA choices. This is achieved through the implementation of diverse educational strategies, including modeling, monitoring, goal setting, contracting, skill training, as well as practice and reinforcement.

Each educational session spans 30 minutes, allowing for thorough exploration of specific topics such as PA, fruit and vegetable consumption, and sleep. Following these sessions, engaging physical activities (30 minutes) are integrated to ensure enjoyment and competitiveness with other before/after school pursuits typically favored by children, such as television watching and computer gaming.

** We will assess PA during weeks 11-12, so we can obtain a measurement of the intervention week while the intervention is ongoing. It represents the optimal intervention effect, and in addition makes measurement more feasible given that the teams can visually check if kids are wearing accelerometers, as well as collect them.

5.1 Study Design

SCHEMA



5.2 Study Procedures

After obtaining IRB approval, the study team will recruit children in grades 3-5, ages 8-11 years, at four elementary school sites (two in NM for 2023-2024 and two in WA for 2024-2025) and one parent for each child. Participation will be open to all students in the before/after school program, however only the first 15 parent-child pairs at two NM schools and first 19 parent-child pairs at two WA schools will be enrolled into the study.

*NOTE: NMSU secured IRB approval at their institution and has begun data collection. Once Fred Hutch IRB approval is secured, IRB oversight will be transferred to Fred Hutch.

Each parent will be asked to 1 - complete a baseline assessment (self-administered 20–30-minute questionnaire), 2 - participate in a private, invitation-only Facebook group, a virtual peer support group where parents can receive study information and share strategies, challenges, and successes and 3 - complete a post-program assessment (self-administered 20–30-minute questionnaire).

Each child will be asked to: 1 - Complete a baseline assessment (self-administered 30-minute questionnaire), 2 - Wear an accelerometer* for 7 days at baseline (prior to 12-week H-PACE program) 3 - Participate in the 12-week before/after school H-PACE Program, which includes weekly educational lessons, physical activity, and health snacks, 4 - Wear an accelerometer for 7 days in week 11-12**, and 5 - Complete a post-program assessment (self-administered, 30-minute questionnaire).

Study staff will send reminders via text, email, or phone regarding use of accelerometers during baseline and follow-up data collection, and any study-related appointments, such as accelerometer pick up/drop off, parent survey completion, etc. These reminders will be provided no more than once a week, if needed, based on the parents' preferences. Parents can opt out of receiving these reminders at any time without any impact on their

participation in the study. The goal is to ensure that participants remain informed and supported throughout the study.

Accelerometer are activity meters or a small electronic device that the child would wear on a belt. It is about the size of a pager. Before the program starts (week 0) and at the end (weeks 11-12) of the program, the study staff will show the child how to place the accelerometer around their waist with instructions to keep it on all day even while asleep. The only exception is during baths or swimming, as the device is not waterproof. The meter gives minute-by-minute estimates of how much their whole body is moving. The meter is not a tracking device and does not record where you have been. After the 7-day period the staff will collect the device from the child during the before/after school program.

During the 12-week intervention period, children enrolled in H-PACE will participate in educational activities (30 minutes) and physical activity activities (30 minutes), for a total of 60 minutes twice per week. The educational component of H-PACE is strategically designed to empower children with the knowledge, skills, self-efficacy, and intentions necessary to make informed and healthy dietary and PA choices. This is achieved through the implementation of diverse educational strategies, including modeling, monitoring, goal setting, contracting, skill training, as well as practice and reinforcement.

Each educational session spans 30 minutes, allowing for thorough exploration of specific topics such as PA, fruit and vegetable consumption, and sleep. Following these sessions, engaging physical activities (30 minutes) are integrated to ensure enjoyment and competitiveness with other before/after school pursuits typically favored by children, such as television watching and computer gaming.

** We will assess PA during weeks 11-12, so we can obtain a measurement of the intervention week while the intervention is ongoing. It represents the optimal intervention effect, and in addition makes measurement more feasible given that the teams can visually check if kids are wearing accelerometers, as well as collect them.

5.3 End of Study Intervention

N/A

5.4 Follow-Up

At the end of the 12-week program the parent-child pair) will be asked to complete a self-administered questionnaire (approximately 30 min.) about food preferences, dietary knowledge, self-efficacy, intentions to choose healthful food options, and participation in sedentary activities and sports activities.

6.0 STUDY CALENDAR

Research Activities	Week 0	Week 1-2	Week 1-12	Week 11-12
Child Activities				
Complete Child Assent & Baseline Survey	X			
Have his or her height and weight measured	X			
Wear an activity meter* for 7 days in a row		X		
Participate in the H-PACE curriculum			X	
Complete Child Follow up Survey				X
Wear an activity meter* for 7 days in a row				X
Parent Activities				

Complete Consent & Baseline Survey	X			
Participate in home activities that follow HPACE curriculum (i.e. craft projects, family dinners, reading or listening to music)			X	
Complete Parent Follow up Survey				X

7.0 PARTICIPANT DATA COLLECTION

7.1 Demographics

Demographic data will include age, date of birth, preferred language, sex, country of birth, education level, income, and race/ethnicity.

7.2 Other Participant Evaluation(s)

The parent and child surveys will also be completed in-person with a study staff member, via take-home packet process. Hard copies will be entered in REDCap. See parent and child surveys in Appendices, Section 16. The accelerometer data will be downloaded to a secure network data folder. Once the data is copied, it will be cleared from the accelerometer.

8.0 ADVERSE EVENTS

8.1 Adverse Events and Unanticipated Problems

This is not a treatment study and does not require adverse event reporting. Unanticipated problems, including but not limited to the death of a research participant or withdrawal from the study due to an unanticipated or worsening health event or condition, will be monitored and reported to the appropriate review committees as outlined in Section 11.0: Data and Safety Monitoring Plan.

9.0 ANALYSIS PLAN

9.1 Study Design

As outlined in the Study Overview and Program Plan, we propose to test the feasibility of the H-PACE program research protocol. As an exploratory objective, we plan to assess the H-PACE program for improving lifestyle behaviors (i.e., PA, fruit and vegetable intake, screen time, sleep) using a pretest-posttest research design. Adult and child participants will complete a self-administered survey and the child will wear an accelerometer to measure activity and sleep. Both measurements will be collected before and after participation in the H-PACE program.

9.2 Sample Size and Power

A sample size of 54 provides 80% power to detect an effect size of Cohen's $d_z = 0.39$ when using a paired t-test (two-tailed) with $\alpha = .05$. We assume a maximum attrition of 10% based on previous short-term feasibility studies we have conducted in school settings.

Cohen's d_z represents the standardized mean difference effect size¹. A 2012 meta-analysis² of the effects of interventions on moderate or vigorous physical activity in children reported a pooled intervention effect of 0.16. The standardized mean differences ranged from -0.34 to 1.11 across the thirty studies included in the meta-analysis, with mean 0.26, slightly less than the standardized mean difference on which the power calculation was based.

9.3 Randomization – N/A

9.4 Primary Endpoints/Outcomes Analysis

To evaluate feasibility, we will calculate the percentage of children who attended more than 75% of program sessions and the percentage of children who completed more than 80% of assessment activities. We will use descriptive statistics to describe the study population with respect to participants and family sociodemographic. The study approach will be considered a success from a feasibility standpoint if >75% of participants meet each of the two “success” metrics.

9.5 Secondary Endpoints/Outcomes Analysis – N/A

9.6 Exploratory/Correlative Analysis

For each lifestyle behavior, we will estimate the mean difference in behavior pre- to post-intervention and provide 95% confidence intervals for the mean difference. Paired t-tests will be used to test the statistical significance of mean differences. These analyses will be followed by repeated measures linear mixed model analyses, which will adjust for covariates. This model allows for children to be nested within schools and considers child as a random effect, which accounts for within child correlations across time.

10.0 DATA MANAGEMENT/CONFIDENTIALITY

Electronic data collection forms must be completed and submitted for each participant enrolled in the study. Any changes or corrections made to in the study database must be subsequently reviewed and signed by the PI. The source documentation for the study will be the participant's REDCap survey and accelerometer results.

Only study staff with approval from the PI will have access to the participant's study records. Hard copies of signed consent, assent forms and surveys will be kept in a locked and secure filing cabinet. Electronic copies will be uploaded to REDCap for the Coordinating Center to access. Data from the accelerometers will be downloaded onto secure networks filing system. We will then upload into REDCap de-identify it and make available to the Statistician. We will keep one master list that will contain ID numbers for linking data sources. Once data collection is complete, analyses will be performed on de-identified data sets. All data will remain confidential, and no names will appear in any publication or report. Data will only be reported in aggregate form. Data will be destroyed three years after completion of the research.

11.0 DATA AND SAFETY MONITORING PLAN

The PI will oversee data and safety monitoring for this project. Weekly meetings with the study staff will be held to discuss the protocol, enrollment, and participant statuses to ensure participant safety and the validity and integrity of the study data. All staff members will attend trainings on these procedures and will be given

information on the importance of reporting any unanticipated problems immediately. The PI will examine available data to assess whether safety is compromised and report to the IRB per policy.

In addition, protocols are reviewed at least annually and as needed by the Fred Hutch Scientific Review Committee (SRC) and the Fred Hutch Institutional Review Board (IRB). The review committees evaluate accrual, adverse events, stopping rules, and adherence to the applicable data and safety monitoring plan for studies actively enrolling or treating participants. The IRB reviews the study progress and safety information to assess continued acceptability of the risk-benefit ratio for human participants. Approval of committees as applicable is necessary to continue the study.

The trial will comply with the standard guidelines set forth by these committees and other institutional, state, and federal guidelines.

12.0 INVESTIGATOR OBLIGATIONS

The PI is responsible for the conduct of the study at the site and oversight of the intervention of all study participants. The PI must assure that all study site personnel, including sub-Investigators and other study staff members, adhere to the study protocol and to all applicable regulations and guidelines regarding the study both during and after study completion.

The PI must ensure that all participants are informed of the nature of the program, its possible hazards, and their right to withdraw at any time, and each participant signs a form indicating their consent to participate prior to undergoing any study-related procedures.

13.0 ADMINISTRATIVE AND REGULATORY CONSIDERATIONS

13.1 Participant Registration

Consented subjects will be entered into the Clinical Trial Management System (CTMS, OnCore) by the Fred Hutch Coordinator. A complete, signed study consent and assent are required for registration.

Registration Instructions for New Mexico State University Coordinators:

- Upload a copy of the signed consent form and a copy of the signed assent form to REDCap study record. Subjects will not be registered without proof of signed consent and assent.
- The Fred Hutch study coordinator is responsible for entering information into the Clinical Trial Management System (CTMS, OnCore).

Signed ICFs will be stored in a secure cabinet and available for verification by monitors or regulatory agents at any time.

13.2 Documentation

The PI and study staff are responsible for maintaining a comprehensive and centralized filing system containing all study-related documentation. These files must be suitable for inspection by applicable regulatory agencies at any time and should consist of the following elements: subject files (supporting source documentation and the Informed Consent); study files (the protocol with all amendments, copies of all pre-study documentation, and all correspondence with the IRB).

13.3 Disclosure of Data/Publication

Individual participant medical information obtained as a result of this study is considered confidential and disclosure to third parties other than those noted below is prohibited. Such medical information may be given to the participant's personal physician or to other appropriate medical personnel responsible for the participant's welfare. Data generated as a result of this study are to be available for inspection on request by relevant regulatory agencies including the IRB. Participants will not be referenced by name, study ID, or any other specific identifier in publications.

13.4 Ethical Considerations

The Investigator agrees to conduct this study in accordance with IRB and local legal requirements and with the Declaration of Helsinki (1989). The Investigator will conduct all aspects of this study in accordance with all national, state, and local laws of the applicable regulatory agencies.

13.5 Informed Consent

The PI assumes the responsibility of obtaining written Informed Consent for each participant or the participant's legally authorized representative (LAR) before any study-specific procedures are performed.

Participants meeting the criteria set forth in the protocol will be offered the opportunity to participate in the study. To avoid introduction of bias, the Investigator must exercise no selectivity with regard to offering eligible participants the opportunity to participate in the study. Participants or parents/legal guardians of all candidate participants will receive a comprehensive explanation of the proposed study procedures and other factors that are part of obtaining a proper Informed Consent. The Informed Consent will inform participants that they may choose to withdraw from the study at any time, any anticipated circumstances under which the Investigator may withdraw the participant from the study regardless of the participant's consent, and the consequences of a participant's decision to withdraw from a study. Subjects may be removed from this study at any time at their discretion. Participation in this study is entirely voluntary, and participants reserve the right to withdraw their involvement at any stage without penalty or consequence. Contact information for withdrawal from the study is provided in the consent form. Participants will be given the opportunity to ask questions concerning the study, and adequate time to consider their decision to or not to participate.

Informed Consent will be documented by the use of a written Consent Form that includes all the elements required by Department of Health and Human Services (DHHS) regulations and ICH guidelines. All participant tracking information will also be stored in REDCap. Hard copies of signed consent, assent forms and surveys will be kept in a locked and secure filing cabinet. Electronic copies will be uploaded to REDCap for the Coordinating Center to access. Data from the accelerometers will be downloaded onto secure networks filing system. We will then upload into REDCap de-identify it and make available to the Statistician. We will keep one master list that will contain ID numbers for linking data sources. Once data collection is complete, analyses will be performed on de-identified data sets. All data will remain confidential, and no names will appear in any publication or report. Data will only be reported in aggregate form. Data will be destroyed three years after completion of the research.

A copy of the signed form will be offered to each participant, the original signed Consent Form will be filed within the participant's study records. The date and time of time of the Informed Consent must be recorded in the source documents. Time of Informed Consent is only required to be recorded when study activities occur on the same day as consent.

If an amendment to the protocol changes the participant participation schedule in scope or activity, or increases the potential risk to the participant, the Informed Consent Form must be amended. Any amended Informed Consent must be reviewed by Sponsor or designee (if applicable) and approved by the IRB prior to use. The revised Informed Consent Form must be used to obtain re-consent from any participants currently enrolled in

the study if the participant is affected by the amendment and must be used to document consent from any new participants enrolled after the approval date of the amendment.

13.6 Institutional Review Board

The PI will assure that an appropriately constituted IRB that complies with the requirements of Title 21 CFR Part 56 and/or Title 45 CFR Part 46 will be responsible for the initial and continuing review and approval of the clinical study. Before initiation of the study, the PI or designee will forward copies of the protocol and Consent Form to be used for the study to the IRB for its review and approval.

The PI or designee will also assure that all changes in the research activity and all unanticipated problems involving risks to human participants or others will be reported promptly to the IRB, and that no changes will be made to the protocol without IRB approval, except where necessary to eliminate apparent immediate hazards to human participants.

The PI or designee must promptly notify the IRB of any reportable event in compliance with the IRB's policies. The Investigator or designee will be responsible for submitting periodic progress reports to the IRB in compliance with the IRB's policies at intervals appropriate to the degree of participant risk involved in the study, but not less than once per year and at the completion or termination of the study.

13.7 Participant Privacy

Participants will be informed of the extent to which their confidential health information generated from this study may be used for research purposes. Following this discussion, they will be asked to sign the HIPAA authorization form and informed consent documents if applicable to the study design. The original signed document will become part of the participant's medical records or study files, as applicable. Participant will receive a copy of the signed document. The use and disclosure of protected health information will be limited to the individuals described in the informed consent document.

14.0 STOPPING THE STUDY

Subjects may be removed from this study at any time at their discretion. Participation in this study is entirely voluntary, and participants reserve the right to withdraw their involvement at any stage without penalty or consequence. Contact information for withdrawal from the study is provided in the consent form.

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16.0 APPENDICES

- Appendix A: Sample Survey Parent – English
- Appendix B: Sample Survey Parent - Spanish
- Appendix C: Sample Survey Child – English
- Appendix D: Sample Survey Child - Spanish

Appendix A – Parent Survey English

H-PACE Parent Survey

Fred Hutch IRB
Approved
1/16/2025

The following questions are about your child enrolled in the H-PACE program. Please answer questions only about this child.

What is your child's full name?

(Please include first and last name)

What is your child's date of birth?

How old is your child?

What is your child's gender?

- ☐ Boy
- ☐ Girl
- ☐ Transgender male (assigned female at birth)
- ☐ Transgender female (assigned male at birth)
- ☐ Other
- ☐ I don't know.
- ☐ Choose not to answer.

Which language does your child speak best?

- ☐ Only Spanish
- ☐ Spanish better than English
- ☐ Both equally
- ☐ English better than Spanish
- ☐ Only English
- ☐ Other language
- ☐ Choose not to answer

Do you consider your child to be Hispanic?

- ☐ Yes
- ☐ No
- ☐ Choose not to answer

What race do you consider your child to be?
(Check all that apply)

- ☐ White (includes Hispanic White, European, Caucasian)
- ☐ Asian
- ☐ Black/African American (Includes Hispanic Black, African American)
- ☐ American Indian
- ☐ Native Hawaiian
- ☐ Pacific Islander
- ☐ Alaskan Native
- ☐ Multi-Racial
- ☐ Other
- ☐ Choose not to answer.

In what country was your child born?

- ☐ United States (except Puerto Rico)
- ☐ Puerto Rico
- ☐ Mexico
- ☐ Cuba
- ☐ Dominican Republic
- ☐ Guatemala
- ☐ El Salvador
- ☐ Colombia
- ☐ Other
- ☐ Choose not to answer.

About how long has your child lived in the United States?

- ☐ Less than 1 year
- ☐ 1 year
- ☐ 2 years
- ☐ 3 years
- ☐ 4 years
- ☐ 5 years
- ☐ 6 years
- ☐ 7 years
- ☐ 8 years
- ☐ 9 years
- ☐ 10+ years
- ☐ Choose not to answer.

The following questions are about you and your household:

What is your height in feet and inches or meters?

Feet/Inches

Or

Meters

What is your weight in pounds or kilograms?

Pounds

Or

Kilograms

In what state do you currently live?

- ☐ New Mexico
- ☐ Washington

How are you related to the child above?

- ☐ Mother
- ☐ Father
- ☐ Brother or Sister
- ☐ Grandparent
- ☐ Aunt/Uncle
- ☐ Cousin
- ☐ Other relative
- ☐ Family friend
- ☐ Legal Guardian
- ☐ Other
- ☐ Choose not to answer.

What is your date of birth?

What is your gender?

- ☐ Male
- ☐ Female
- ☐ Transgender male (assigned female at birth)
- ☐ Transgender female (assigned male at birth)
- ☐ Other: _____
- ☐ I don't know.
- ☐ Choose not to answer

What is the highest grade or year you completed in school?

- ☐ 8th grade or less
- ☐ Some high school
- ☐ High school graduate or technical school
- ☐ Associate degree
- ☐ Bachelor's degree
- ☐ Completed college
- ☐ Post graduate training/degree
- ☐ Choose not to answer.

Please, think about your total household income last year. Include income earned from jobs(s) by you or any member of your household, help from a family member, the government or other agency such as: Disability, Unemployment, child support, alimony, scholarships, social security, rent, or interest earned by any member of your household. Before taxes, what was your total household income last year?

- ☐ No income
- ☐ \$20,000 or less
- ☐ \$20,000 to \$50,000
- ☐ \$40,000 to \$60,000
- ☐ \$60,000 to \$80,000
- ☐ \$80,000 to \$100,000
- ☐ \$100,000 to \$120,000
- ☐ \$120,000 or more
- ☐ Don't know.
- ☐ Prefer not to answer

Including yourself, how many people did your household income support last year?

What language do you read and speak best?

- ☐ Only Spanish
- ☐ Spanish better than English
- ☐ Both equally
- ☐ English better than
- ☐ Only English
- ☐ Other language
- ☐ Choose not to answer

Do you consider yourself to be Hispanic?

- ☐ Yes
- ☐ No
- ☐ Choose not to answer.

What race do you consider yourself to be?

(Check all that apply)

- ☐ White (includes Hispanic White, European, Caucasian)
- ☐ Asian
- ☐ Black/African American (Includes Hispanic Black, African American)
- ☐ American Indian
- ☐ Native Hawaiian
- ☐ Pacific Islander
- ☐ Alaskan Native
- ☐ Multi-Racial
- ☐ Other

In what country were you born?

- ☐ Choose not to answer.
- ☐ United States (except Puerto Rico)
- ☐ Puerto Rico
- ☐ Mexico
- ☐ Cuba
- ☐ Dominican Republic
- ☐ Guatemala
- ☐ El Salvador
- ☐ Colombia
- ☐ Other: _____
- ☐ Choose not to answer.

About how long have you lived in the United States?

- ☐ Less than 1 year
- ☐ 1 year to 4 years
- ☐ 5 to 9 years
- ☐ 10 to 14 years

- ☐ 15 or more years
- ☐ Choose not to answer.

The following questions are about your neighborhood environment: Select the best response for each option.

How often do the following occur in your neighborhood?

	Never	Sometimes	Frequently
Drug dealers or users hanging around.			
Drunks hanging around.			
Unemployed adults loitering.			
Young adults loitering.			
Gang activity.			
Disorderly or misbehaving groups of young children.			
Disorderly or misbehaving groups of teenagers			
Disorderly or misbehaving groups of adults.			

Instructions:

You will be given a set of questions. Please select the answer you think is the best in regard to your child. Your answers are confidential; there are no right or wrong answers to any of the questions. TV means shows watched on TV, computer, tablet, phone, or another screen device.

ATTITUDES

Please read each statement carefully. Select the answer that you think in best in relation to your child. There are no right or wrong answers.

How much do you agree or disagree with the following statements?

If you child had less screen time on most days, your child would:

	Agree	Disagree	Neither Agree nor Disagree.
...be healthier.			
...have less difficulty paying attention.			
...be exposed to fewer violent or aggressive programs.			
...have more energy to play.			
...have fewer problems to becoming an overweight child.			
... be exposed to fewer adult issues, like sexual situations.			
...get more physical activity.			
...think better.			
...learn better eating habits.			

...set a good example for others.			
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	Agree	Disagree	Neither Agree nor Disagree.
...be too thin.			
...make you spend less money on junk food or fast food.			
...be exposed to fewer unhealthy programs or commercials.			
...be better behaved.			
...live longer.			

POSITIVE AND NEGATIVE ANTICIPATED EMOTIONS			
Please, read each statement carefully, Select the answers that you think is the best in relation to your child. There are no right or wrong answers.			
How much do you agree or disagree with the following statements?			
If you asked your child to have less screen time and they were to do it, you would feel:			
	Agree	Disagree	Neither Agree nor Disagree.
...pleased.			
...disappointed.			
...happy.			
...proud.			
...frustrated.			
...excited.			
...concerned.			
...upset.			

If you asked your child to have less screen time and they refused, you would feel:			
	Agree	Disagree	Neither Agree nor Disagree.
...pleased.			
...disappointed.			
...happy.			
...proud.			
...frustrated.			
...excited.			
...concerned.			
...upset.			

SELF-EFFICACY

Please read each statement carefully. Select the answers that you think is the best in relation to your child. There are no right or wrong answers.

How sure are you that you can...

	Sure	Somewhat sure	Not sure
...limit your child's screen time to 2 hours or less daily.			
...offer different activities for your child instead of screen time.			
...get your child to play outside instead of screen time.			
...set specific hours when your child can have screen time.			

DESIRES

Please, read each statement carefully. Select the answers that you think is the best in relation to your child. There are no right or wrong answers.

Do you agree or disagree with the following statements:

	Agree	Disagree	Neither Agree nor Disagree.
I want my child to have less screen time.			
I want to restrict the amount of screen time my child can have.			

Think about everything your child ate or drank last week. Remember what your child had for breakfast, lunch, dinner, after school, while watching TV, at bedtime, and on the weekend.

How many days last week did your child eat or drink it?

Glasses of milk.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ 1 glass
- ☐ 2 glasses
- ☐ 3+ glasses

What kind of milk did your child drink?

- ☐ Whole milk
- ☐ Reduced fat 2%
- ☐ Low fat 1%
- ☐ Non-fat milk
- ☐ Chocolate milk
- ☐ Soy milk
- ☐ Lactaid milk
- ☐ Don't know

Real fruit juice, like orange juice, or Mexican fruit drinks like licuados.

(Do not include soda).

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ 1 glass
- ☐ 2 glasses
- ☐ 3+ glasses

Drinks like Coke or 7-Up, Sunny Delight, Hawaiian Punch,
or aguas frescas (DO NOT include diet soda)

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ 1 bottle
- ☐ 2 bottles
- ☐ 3+ bottles

Apples, bananas, oranges.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ 1/2
- ☐ 1
- ☐ 2

Any other fruit, like strawberries, grapes.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ A little
- ☐ Some
- ☐ A lot

Lettuce salad

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ A little
- ☐ Some
- ☐ A lot

Tomatoes, including on salad

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day

- ☐ ¼ tomato
- ☐ ½ tomato
- ☐ 1 tomato

How much in one day?

- ☐ A little
- ☐ Some
- ☐ A lot

Other vegetables like corn, carrots, greens, broccoli.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week

- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ A little
- ☐ Some
- ☐ A lot

Vegetable soup, tomato soup, any soup or stew with vegetables in it.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ A little
- ☐ Some
- ☐ A lot

Hamburgers, cheeseburgers.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ 1 small
- ☐ 1 large
- ☐ 2 large

Hot dogs, corn dogs, or sausage.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ 1
- ☐ 2
- ☐ 3

Pizza or pizza pockets.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ A little
- ☐ Some
- ☐ A lot

Fish, fish sticks or sandwiches, tuna, shrimp.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ A little
- ☐ Some
- ☐ A lot

Candy, candy bars.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ Mini
- ☐ Small
- ☐ Large

Cookies, donuts, cakes like Ho-Hos.

- ☐ None last week
- ☐ 1 day last week
- ☐ 2 days last week
- ☐ 3-4 days last week
- ☐ 5-6 days last week
- ☐ Every day last week.

How much in one day?

- ☐ A little
- ☐ Some
- ☐ A lot

Appendix B – Parent Survey Spanish

H-PACE Encuesta para Padres

Las siguientes preguntas son sobre su hijo(a) inscrito(a) en el programa de H-PACE. Por favor, responda solo sobre este(a) hijo(a).

¿Cuál es el nombre completo de su hijo(a)?

(Por favor, incluya nombre y apellido)

¿Cuál es la fecha de nacimiento de su hijo(a)?
(mes/día/año)

¿Qué edad tiene su hijo(a)?

¿Cuál es el género de su hijo(a)?

- ☐ Niño
- ☐ Niña
- ☐ Niño transgénero (asignado mujer al nacer)
- ☐ Niña transgénero (asignado hombre al nacer)
- ☐ Otro
- ☐ No sé.

¿Qué idioma habla mejor su hijo(a)?

- ☐ Solo español
- ☐ Español mejor que inglés
- ☐ Ambos por igual
- ☐ Inglés mejor que español
- ☐ Solo inglés
- ☐ Otro idioma

¿Considera usted que su hijo(a) es hispano(a)?

- ☐ Sí
- ☐ No
- ☐ Prefiero no contestar.

¿Qué raza considera usted que es su hijo(a)?
(Marque todas las que apliquen)

- ☐ Blanco (incluye Blanco Hispano, Europeo, Caucásico)
- ☐ Asiático
- ☐ Negro/Afro-Americano (incluye Hispano, Negro, Afroamericano)
- ☐ Indio Americano
- ☐ Nativo Hawaiano
- ☐ Isleño del Pacífico
- ☐ Nativo de Alaska
- ☐ Multiracial
- ☐ Otro
- ☐ Prefiero no contestar.

¿En qué país nació su hijo(a)?

- ☐ Estados Unidos (excepto Puerto Rico)
- ☐ Puerto Rico
- ☐ México
- ☐ Cuba
- ☐ República Dominicana
- ☐ Guatemala
- ☐ El Salvador
- ☐ Colombia
- ☐ Otro
- ☐ Prefiero no contestar.

¿Hace cuántos años que su hijo(a) vive en Estados Unidos?

- ☐ Menos de 1 año
- ☐ 1 año
- ☐ 2 años
- ☐ 3 años
- ☐ 4 años
- ☐ 5 años
- ☐ 6 años
- ☐ 7 años
- ☐ 8 años
- ☐ 9 años
- ☐ 10+ años
- ☐ Prefiero no contestar.

Las siguientes preguntas son sobre usted y su hogar:

¿Cuál es altura en pies y pulgadas o en metros?

- ☐ _____
Pies/pulgadas
- ☐ _____
Metros
- ☐ No sé.

¿Cuánto pesa en libras o kilogramos?

- ☐ _____
Libras
- ☐ _____
Kilogramos
- ☐ No sé

¿En cuál estado vive actualmente?

- ☐ New Mexico
- ☐ Washington

¿Cuál es su parentesco con el niño/la niña?

- ☐ Mamá
- ☐ Papá
- ☐ Hermano(a)
- ☐ Abuelo(a)
- ☐ Tío(a)
- ☐ Primo(a)
- ☐ Otro familiar
- ☐ Amigo(a) de la familia
- ☐ Tutor/Guardián legal
- ☐ Otro
- ☐ Prefiero no contestar.

¿Cuál es su fecha de nacimiento?
(mes/día/año)

¿Cuál es su género?

- ☐ Hombre
- ☐ Mujer
- ☐ Hombre transgénero (asignado mujer al nacer)
- ☐ Mujer transgénero (asignado hombre al nacer)
- ☐ Otro
- ☐ No sé.
- ☐ Prefiero no contestar

¿Cuál es el nivel o año escolar más alto que usted completó?

- ☐ Escuela secundaria/Enseñanza Media (equivalente a 7º al 9º grado) o menos.
- ☐ Algo de Preparatoria o Bachillerato (equivalente a 10º al 12º grado)
- ☐ Graduado de Preparatoria o Bachillerato o GED.
- ☐ Algo de universidad o escuela técnica.
- ☐ Graduado de Escuela técnica o Grado de asociado (Associate Degree)
- ☐ Licenciatura o completó la universidad
- ☐ Postgrado
- ☐ Prefiero no contestar.

Piense acerca de su ingreso familiar durante el año pasado. Incluya el salario de trabajo(s) que usted o algún miembro de su hogar haya ganado, también incluya ayuda económica que le dieron familiares, el gobierno u otras agencias de ayuda tales como: pensión por incapacidad (“disability”), pago por desempleo (“unemployment”), manutención de niños (“child support”), pensión que se le paga a un exesposo, o exesposa, becas, seguro social, renta, interés que algún miembro de su familia haya ganado.

¿Cuál fue la entrada económica de su familia durante el año pasado antes de la deducción de impuestos?

¿Cuántas personas mantuvo su ingreso familiar del año pasado, incluyéndose a usted?

- ☐ Ningún ingreso
- ☐ \$20,000 o menos
- ☐ \$20,000 o \$40,000
- ☐ \$40,000 o \$60,000
- ☐ \$60,000 o \$80,000
- ☐ \$80,000 o \$100,000
- ☐ \$100,000 o \$120,000
- ☐ \$120,000 o más
- ☐ No sé
- ☐ Prefiero no contestar

¿Qué idioma habla y lee mejor usted?

- ☐ Solamente español
- ☐ Español mejor que inglés
- ☐ Ambos igual
- ☐ Inglés mejor que español
- ☐ Solamente inglés
- ☐ Otro idioma
- ☐ Prefiero no contestar

¿Se considera usted hispano(a)?

- ☐ Sí
- ☐ No
- ☐ Prefiero no contestar

¿Qué raza se considera usted?

(Marque todos los que apliquen)

- ☐ Blanco (incluye Blanco Hispano, Europeo, Caucásico)
- ☐ Asiático
- ☐ Negro/Afroamericano (incluye Hispano Negro, Afroamericano)
- ☐ Indio Americano
- ☐ Nativo Hawaiano
- ☐ Isleño del Pacífico
- ☐ Nativo de Alaska
- ☐ Multirracial
- ☐ Otro
- ☐ Prefiero no contestar

¿En qué país nació usted?

- ☐ Estados Unidos, excepto Puerto Rico
- ☐ Puerto Rico
- ☐ México
- ☐ Cuba
- ☐ República Dominicana
- ☐ Guatemala
- ☐ El Salvador
- ☐ Colombia
- ☐ Otro
- ☐ Prefiero no contestar

¿Cuántos años ha vivido usted en los Estados Unidos?

0

- ☐ Menos de 1 año
- ☐ 1 a 4 años
- ☐ 5 a 9 años
- ☐ 10 a 14 años
- ☐ 15 años o más
- ☐ Prefiero no contestar

Las siguientes preguntas son sobre su vecindad o barrio: Escoja la respuesta más apropiada.
¿Qué tan seguido ocurre lo siguiente en su vecindario?

	Nunca	Raramente	Frecuentemente
Hay traficantes de drogas o personas que usan drogas			
Borrachos vagan en el área			
Adultos desempleados vagan en el área			
Jóvenes vagan en el área			
Actividades de gangas/pandillas			
Grupos de niños que se portan mal			
Grupos de jóvenes que se portan mal			
Grupos de adultos que se portan mal			

Instrucciones:

A usted se le dará un conjunto de preguntas.

Por favor escoja la respuesta que usted piense es más apropiada con respecto a su hijo(a).

Sus respuestas son confidenciales; no hay respuestas correctas o incorrectas a ninguna de las preguntas.

Aparatos electrónicos significa programas vistos en la televisión, computadora, tableta, teléfono y otro dispositivo de pantalla.

ACTITUDES

Por favor lea cada una de las frases detenidamente. Seleccione la respuesta que usted piensa es la más apropiadas en relación con su hijo(a). No hay respuestas correctas ni incorrectas.

¿Qué tanto está usted en acuerdo o desacuerdo con las siguientes frases?

Si su hijo(a) pasara menos tiempo viendo o usando los aparatos electrónicos la mayoría de los días, entonces él/ella:

	De acuerdo	En desacuerdo	Ninguno de los dos
... sería más saludable.			
... tendría menos dificultad en poner atención.			
... estaría expuesto(a) a menos programas violentos o agresivos.			
... tendría más energía para jugar.			
... tendría menos problemas con convertirse en un niño(a) con sobrepeso.			
... estaría expuesto(a) a menos temas de adultos, así como situaciones sexuales.			
... haría más actividad física.			
... pensaría mejor.			
... aprendería mejores hábitos de alimentación.			
... pondría un buen ejemplo para otros.			

	De acuerdo	En desacuerdo	Ninguno de los dos
... estaría muy delgado(a).			
... lo/la haría a usted gastar menos dinero en comida chatarra o comida rápida.			
... estaría expuesto(a) a menos programas o comerciales no saludables.			
... se portaría mejor.			
... viviría más tiempo.			

EMOCIONES ANTICIPADAS (NEGATIVAS O POSITIVAS)

Por favor lea cada una de las frases detenidamente. Seleccione las respuestas que usted piensa más apropiadas en relación con su hijo(a). No hay respuestas correctas ni incorrectas.

¿Qué tanto está usted de acuerdo o en desacuerdo de sentirse de la manera indicada en con respecto a la situación descrita?

Si usted le pidiera a su hijo(a) que pasara menos tiempo con los aparatos electrónicos y él/ella lo hiciera, usted se sentiría:

	De acuerdo	En desacuerdo	Ninguno de los dos
... complacido(a).			
... decepcionado(a).			
... contento(a).			
...orgullosa(a).			
...frustrado(a).			
...emocionado(a).			
...preocupado(a).			
...molesto(a).			

Si usted le pidiera a su hijo(a) que pasara menos tiempo con los aparatos electrónicos y él/ella no lo hiciera, usted se sentiría:

	De acuerdo	En desacuerdo	Ninguno de los dos
... complacido(a).			
... decepcionado(a).			
... contento(a).			
...orgullosa(a).			
...frustrado(a).			
...emocionado(a).			
...preocupado(a).			
...molesto(a).			

EFICACIA PROPIA

Por favor lea cada una de las frases detenidamente. Seleccione las respuestas que usted piensa más apropiadas en relación con su hijo(a). No hay respuestas correctas ni incorrectas.

Qué tan seguro(a) está usted de que puede...

	Seguro(a)	Casi seguro(a)	No estoy seguro(a)
...limitar la cantidad de tiempo que su hijo(a) ve o usa los aparatos electrónicos a 2 horas o menos diariamente.			
...ofrecer diferentes actividades para su hijo(a) hacer en vez de ver o usar los aparatos electrónicos.			
...hacer que su hijo(a) juegue afuera en vez de ver o usar los aparatos electrónicos.			
...establecer horas específicas en que su hijo(a) pueda ver o usar los aparatos electrónicos.			

DESEOS/ANHELOS

Por favor lea cada una de las frases detenidamente. Seleccione las respuestas que usted piensa más apropiadas en relación con su hijo(a). No hay respuestas correctas ni incorrectas.

¿Está usted de acuerdo o en desacuerdo con las siguientes frases?:

	De acuerdo	En desacuerdo	Ninguno de los dos
Yo quiero que mi hijo(a) vea o use menos los aparatos electrónicos.			
Yo quiero limitar la cantidad de tiempo que mi hijo(a) pasa viendo o usando los aparatos electrónicos.			

Piense acerca de todo lo que su niño/a comió o bebió la semana pasada. Recuerde lo que su niño/a tuvo en el desayuno, al almuerzo, la cena, después de la escuela, mientras vio la televisión, a la hora acostarse, y en el fin de semana.

¿Cuántos días de la semana pasada su niño/a lo comió o bebió?

Vasos de leche.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ 1 vaso
- ☐ 2 vasos
- ☐ 3+ vasos

¿Qué tipo de leche bebió su hijo(a)?

- ☐ Leche entera
- ☐ Grasa reducida 2%
- ☐ Bajo en grasa 1%
- ☐ Leche descremada
- ☐ Leche con chocolate
- ☐ Leche de soja
- ☐ Leche sin lactosa (Lactaid)
- ☐ No sé

Jugo natural de fruta, como jugo de naranja, o bebidas de fruta mexicanas como licuados

(NO incluya sodas)

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ 1 vaso
- ☐ 2 vasos
- ☐ 3+ vasos

Refrescos como Coke, 7-up, Sunny Delight, Hawaiian Punch, o aguas frescas

(NO incluya refrescos dietéticos)

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ 1 botella
- ☐ 2 botellas
- ☐ 3+ botellas

Manzanas, plátanos, o naranjas.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ 1/2
- ☐ 1
- ☐ 2

Cualquier otra fruta, como fresas, uvas.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Un poco
- ☐ Algo
- ☐ Mucho

Ensalada de lechuga

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Un poco
- ☐ Algo
- ☐ Mucho

Tomates, incluyendo en ensaladas.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ ¼ tomate
- ☐ ½ tomate
- ☐ 1 tomate

Ejotes o guisantes/chicharos

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Un poco
- ☐ Algo
- ☐ Mucho

Otras verduras como elote, zanahoria, hojas verdes o brócoli.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Un poco
- ☐ Algo
- ☐ Mucho

Sopa de vegetales, sopa de tomate, cualquier sopa o guiso de vegetales.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Un poco
- ☐ Algo
- ☐ Mucho

Hamburguesas, hamburguesas de queso

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ 1 pequeña
- ☐ 1 grande
- ☐ 2 grande

Hot dogs, corn dogs, or salchicha.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ 1
- ☐ 2
- ☐ 3

Pizza o Pizza Pockets.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Un poco
- ☐ Algo
- ☐ Mucho

Pescado, palitos de pescado o sándwiches, atún o camarones.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Un poco
- ☐ Algo
- ☐ Mucho

Dulces o golosinas

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Mini
- ☐ Pequeño(a)
- ☐ Grande

Galletas, donas, pasteles como Ho-Hos.

- ☐ Nunca la semana pasada
- ☐ 1 día de la semana pasada
- ☐ 2 días de la semana pasada
- ☐ 3-4 días de la semana pasada
- ☐ 5-6 días de la semana pasada
- ☐ Todos los días de la semana pasada

¿Cuánto en un día?

- ☐ Un poco
- ☐ Algo
- ☐ Mucho

Appendix C – Child Survey English

H-PACE - Survey Kids

What is your name?

(Please include first and last name)

What is your date of birth?

What is your height in feet and inches or meters?

Feet/Inches

Or

Meters

What is your weight in pounds or kilograms?

Pounds

Or

Kilograms

We want to know how you are doing! Please take a moment to answer these questions. Mark the response that best describes your current situation.

How many servings of fruits and vegetables do you have a day?

One serving is: 1/2 cup of fresh or frozen (the size of a fruit cup) of vegetables, 1 cup of leafy greens (a small salad), or a piece of fruit the size of a tennis ball.

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ More than 5

How many times a week do you eat breakfast?

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

On a school day, do you eat breakfast at home or at school?

- ☐ Most of the time at home
- ☐ Most of the time at school
- ☐ Sometimes at home and sometimes at school
- ☐ I don't eat breakfast.

On a school day, do you eat lunch at school (from the school cafeteria) or bring lunch from home?

- ☐ Most of the time from the school cafeteria
- ☐ Most of the time bring from home.
- ☐ Sometimes from the school cafeteria and sometimes at school.
- ☐ I don't eat lunch.

How many hours of screen time do you have each day?
Don't include schoolwork.

- ☐ Less than 1
- ☐ Less than 2
- ☐ 2-3
- ☐ 4-5
- ☐ 5 and more
- ☐ TV only
- ☐ Tablet or smartphone only
- ☐ Both TV and tablet/smartphone

Do you have a TV or keep a tablet or smartphone in your bedroom?

How many hours do you sleep each night?

- ☐ 5 or less
- ☐ 6-7
- ☐ 8-9
- ☐ 10 or more

How many minutes each day do you spend being active? This means you are breathing harder, and your heart is beating faster.

- ☐ 30 or less
- ☐ 60-90
- ☐ 90-120
- ☐ 120 or more

What are two things you would like to change now?
Please, mark only 2.

- ☐ Eat more fruits and vegetables.
- ☐ Eat with your family more often.
- ☐ Eat less fast food/takeout.
- ☐ Drink less soda, juice, or punch.
- ☐ Drink more water,
- ☐ Be more active- get more exercise.
- ☐ Spend less time watching TV or using a tablet/smartphone.
- ☐ Get more sleep.

H-PACE – Encuesta para Niños

¿Cómo te llamas?

(Por favor incluye tu nombre y apellido)

¿Cuál es tu fecha de nacimiento?
(Mes/Día/Año)

¿Cuál es tu estatura en pies/pulgadas o metros?

Pies/Pulgadas

Metros

¿Cuál es tu peso en libras o kilogramos?

Libras

Kilogramos

¡Queremos saber cómo estás! Por favor, tómate un momento para responder estas preguntas. Marca la respuesta que mejor describa tu situación actual

¿Cuántas porciones de frutas y verduras comes al día?

Una porción es: 1/2 taza de fruta fresca o congelada (el tamaño de un vaso de fruta/ "fruit cup"), 1 taza de verduras de hojas verdes (una ensalada pequeña) o una pieza de fruta del tamaño de una pelota de tenis.

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ Más de 5

¿Cuántas veces a la semana desayunas?

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

En un día escolar, ¿desayunas en casa o en la escuela?

- ☐ La mayor parte del tiempo en casa
- ☐ La mayor parte del tiempo en la escuela
- ☐ A veces en casa y a veces en la escuela.
- ☐ No desayuno

En un día escolar, ¿almuerzas en la escuela (comida de cafetería de la escuela) o traes el almuerzo de la casa?

- ☐ La mayor parte del tiempo de la cafetería de la escuela
- ☐ La mayor parte del tiempo lo traigo de casa
- ☐ A veces de la cafetería y a veces de casa
- ☐ No almuerzo

¿Cuántas horas al día pasas frente a una pantalla?

No incluyas el trabajo escolar.

¿Tienes una tele o mantienes una tableta o un celular en tu cuarto?

- ☐ Menos de 1
- ☐ Menos de 2
- ☐ 2-3
- ☐ 4-5
- ☐ 5 o más
- ☐ Sólo tele
- ☐ Sólo tableta o celular
- ☐ Ambos tele y tableta/celular

¿Cuántas horas duermes cada noche?

- ☐ 5 o menos
- ☐ 6-7
- ☐ 8-9
- ☐ 10 o más

¿Cuántos minutos al día pasas activo?

Esto significa que respiras más fuerte y tu corazón late más rápido.

- ☐ 30 o menos
- ☐ 30-60
- ☐ 60-90
- ☐ 90-120
- ☐ 120 o más

¿Cuáles son dos cosas que te gustaría cambiar ahora?

Por favor marca solo 2.

- ☐ Comer más frutas y vegetales
 - ☐ Comer con tu familia más seguido
 - ☐ Comer menos comida rápida/comida para llevar
 - ☐ Tomar menos gaseosas, jugos o ponches.
 - ☐ Tomar más agua
 - ☐ Ser más activo - hacer más ejercicio
 - ☐ Pasar menos tiempo viendo tele o usando una tableta/celular
 - ☐ Dormir mas
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