Title of Study: Health4Kids (H4K) Intervention Trial for Hispanic Families

Consent to be part of a Research Study
The University of Texas Health Science Center at San Antonio (UTHSCSA)
To be conducted at
University of Texas Health Science Center at San Antonio,
University Health System (UHS)

Information about this form

You and your child may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child, please note that in the sections that follow the word "you" refers to your child.

This form gives you important information about the study. You will be asked to sign in more than one place in this document.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is **Deborah Parra-Medina, Ph.D.** of the Dept. of Epidemiology and Biostatistics at the University of Texas Health Science Center at San Antonio.

Research Partner
This research is being conducted in partnership with the University Health System (UHS).

Study Sponsor:
National Institute of Child Health and Human Development (National Institutes of Health), a federal agency that promotes scientific research, is funding this study. This organization is providing money to the University of Texas Health Science Center at San Antonio so that the researchers can conduct the study.

Purpose of this study – "Why is this study being done?"

Improving children's diet and physical activity habits may improve their overall health and mental well-being. Researchers hope to determine the best ways to help children and their families develop lasting healthy habits.

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to participate in this study because your child is Hispanic, 6-11 years old, meets height and weight criteria, and lives with you full-time. Your participation in the study will last for 12 months. This study will enroll 230 study participant (child-parent/guardian) pairs.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this one-year study, you will attend 4 visits with your doctor and 7 visits with research staff for assessments. **We will combine your assessment with research staff and doctor visits whenever possible.**

	Month 0 (Baseline)*	Month 1**	Month 6*	Month 12*
Assessments with Research Staff*	2 visits	1 visit	2 visits	2 visits
Doctor Visits	1 visit	1 visit	1 visit	1 visit

* Research staff will ask you to stop by a UHS lab to get your child's blood drawn.

**The assessment immediately following the Month 1 doctor visit is very brief and includes only body measurements for parent and child.

Assessments with Research Staff

Assessments at Month 0 (baseline), Month 6, and Month 12 occur in 2 parts and take place over 2 weeks:

- Part 1 (1st week): Child receives activity monitor.
- Part 2 (2nd week): Research staff checks the monitor. If the monitor did not measure enough days of wear then the child will be asked to wear the monitor for another week.
- *[Only if necessary]* Part 3 (3rd week) – This will only be scheduled if your child is asked to wear the monitor for another week.

Parent and child:

Questionnaires will ask about your family's health and well-being, background information (such as your age, education level, language(s) you read and speak), foods your family eats, and physical activities your family does.
Body measurements, such as height, weight, and waist circumference, will be measured for both the child and the parent/guardian at each of the 4 assessments.

Child only:

The **fitness test** is a 3-minute step test to assess the child's physical fitness.
An **activity monitor** will be worn by your child every day for one week to measure activity.
Approximately one (1) teaspoon of **blood** will be drawn to measure fasting glucose, insulin, and cholesterol.

Assignment to Study Groups

After completing baseline assessments and meeting with your doctor, you will be assigned to one of two study groups.

You may not choose your group.

You will be assigned to **Group A** or **Group B** by chance (like flipping a coin).

These groups will receive the same benefits and incentives and do the same assessments and doctor visits.

The main difference between the groups is the amount of contact with the health educator as described below.

<u>Group A</u>:

You will receive brief counseling with your doctor and a folder with information about improving diet and physical activity in order to stay healthy.

You will receive a text message from the study at least once each week about keeping your family healthy.

Group B:

In addition to brief counseling with your doctor, information about improving diet and physical activity in order to stay healthy, and text messages, you will receive the following from a health educator:

30-minute face-to-face introductory session with a health educator.

Eight (8) 20-minute phone calls during the first 6 months to discuss healthy eating and healthy lifestyle tips, discuss your progress, and answer any questions you may have.

Note: All calls will be recorded for quality control purposes. We will not identify you on these recordings.

Monthly newsletters.

Fitness tracking device and activity tracking log.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

Risks – "What are the risks of participation in the research?"

Researchers designed this study to learn how well the Health4Kids program works for families.

Risks and side effects related to the **Health4Kids Intervention** include those which are:
Less likely and not serious (5 to 20 subjects out of 100),

- You may have an injury that affects your tendons, bones, ligaments, or muscles while taking part in physical activity. The majority of these injuries are minor and temporary (e.g., muscle pulls/strains, minor stress fractures, tendonitis, sprains, etc.). However, there is a low risk of permanent injury. We recommend that you reduce or temporarily stop your physical activity and see your doctor if the injury persists.

Risks and side effects related to the **fitness test** include those which are:
Less likely and not serious (5 to 20 subjects out of 100),

- Fatigue during step test
- Leg muscle soreness afterward.

Risks related to the assessments (surveys) include those which are:
Less likely and not serious (5-20 subjects out of 100),

- You may feel uncomfortable about some of the questions asked during assessments

Risks related to the **blood draws** include those which are:
Likely and not serious (5 to 20 subjects out of 100),

- Pain and bruising from the needle stick.

Every precaution will be taken to minimize your risk including loss of privacy and physical harm. To protect your privacy, in any publications resulting from this research, no names or other identifying information will be noted unless specific written permission has been obtained from you. For more information about risks and side effects, ask one of the researchers or study staff.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctor. See the section "Contact Information" for phone numbers and additional information.

If you are injured as a result of the research procedures, your injury will be treated. You will be responsible for any charges. We have no plans to give you money if you are injured. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

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Benefits – "How could you or others benefit from your taking part in this study?"

We hope that you will learn about healthy eating and how to be more physically active. There is no guarantee or promise that you will receive benefit from this study. We hope the information learned from this study will benefit other people in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you. Your other choices may include: Being active on your own without being in the study, or asking your doctor for dietary and activity alternatives.

Payments – Will there be any payments for participation?

You will receive gift cards and a child-appropriate gift upon completing each assessment:.

Assessment	Child incentive	Parent incentive
Month 0 (2 parts)_	Gifts valued up to $10	$40 in gift cards
1 month		$20 in gift cards
6 months (2 parts)_	Gifts valued up to $10	$60 in gift cards
12 months (2 parts)	Gifts valued up to $10	$80 in gift cards

If you complete all assessments, you will receive a total payment of $230 in gift cards and gifts, combined.

Costs – Will taking part in this study cost anything?

There is no cost for you to participate in the study.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study. More information concerning confidentiality is described in the "Authorization to Use and Disclose Protected Health Information as part of a Research Study."

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Laura Esparza can be reached at 210-562-6514

If primary is not available, contact:
Deborah Parra-Medina, PhD can be reached at 210-562-6521

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

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Research Consent Signature Section

If you agree to participate in this research, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction.

Parent (Guardian) Participant Signature Section

- You have voluntarily decided to take part in this research study.

Printed Name of Parent/Guardian	Signature of Subject	Date	Time AM PM
Printed Name of Witness	Signature of Witness	Date	Time AM PM

☐ *Check if consent obtained from an individual who can understand & comprehend English but is physically unable to talk or write. Have witness initial below.*
Declaration of witness: I was present for the entire consent process. _____ ←(initials of witness)

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

☐ Consent was obtained from this individual who can understand & comprehend English but is physically unable to talk or write.
The method used for communication with the subject was: _____. The specific means by which the subject communicated agreement to participate was:_____

Child Signature Section

You are voluntarily giving your consent for your child to participate in this study because you believe he/she would want to take part if able to make the decision and you believe it is in his/her best interest.

Printed Name of Child	Signature of **Child**, indicating Assent, if Age 7 or Older (If incapable of signing, person obtaining consent should initial here)	Date	Time AM PM
Printed Name of Person Consenting for Subject (Parent/Guardian)	Signature of Person Giving Consent ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time AM PM
Printed Name of Witness	Witness Signature	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Authorization to Use and Disclose Protected Health Information as part of a Research Study

This section describes the use of your health information. If you agree to allow the researcher to use your private information, you will be asked to sign at the end of this section.

Confidentiality – Will your health information be protected?

Research policies require that private information about you be protected. This is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: results from laboratory testing, insurance information, medical history and demographic information such as age, gender, and language preference.

We will get this information by asking you and looking at your clinic chart.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the sponsor of the study
- the members of the local research team
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Health Science Center at San Antonio, South Texas and University Health System (UHS).

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax.

The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use a special number instead of your name to identify your health information. When we report study results in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Deborah Parra-Medina, PhD, 7411 John Smith Drive, Suite 1000, San Antonio, Texas 78229. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. You will only have access to your PHI until the end of the study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

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Authorization Signature Section

If you agree to the use of your protected health information in this research, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction about the collection, use and sharing of your protected health information.

Parent (Guardian) Participant Signature Section

You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject (Parent/Guardian)	Signature of Subject	Date	Time AM PM
Printed Name of Witness	Signature of Witness	Date	Time AM PM
Printed Name of Person Obtaining Authorization	Signature of Person Obtaining Authorization	Date	Time AM PM

Surrogate Signature Section:

You authorize the collection, use and sharing of another person's protected health information as described in this form.

Printed Name of Subject (Child)

Printed Name of Person Signing for Subject	Signature of Person Signing ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time AM PM
Printed Name of Witness	Witness Signature	Date	Time AM PM
Printed Name of Person Obtaining Authorization	Signature of Person Obtaining Authorization	Date	Time AM PM