

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Summertime: Kids in Motion

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This is a research study about children's sleep and health-related behaviors in Mexican American children. The study research staff from UCSF Department of Epidemiology and Biostatistics will explain this study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Dr. Suzanna Martinez at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: The purpose of this study is to learn more about how children spend their time, including sleep habits, eating patterns and activities, in Mexican American children.

You and your child are being asked to take part in this study because you are the mother of a Mexican/Mexican American child who is 8-10 years old.

Study Procedures: If you choose to be in this study, your child will be in a three-week study. You will be asked about your family's sleep habits, your eating habits, your neighborhood where you live, and questions about you such as your age, where you were born. Your child will be asked about your family's habits about sleep and food, and physical activity, and will be asked to wear an activity monitor. Your child will also be asked to sleep normally for the first week, and then sleep less than 8 hours one week for four consecutive days, and more than 10 hours another week for 4 consecutive days

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Uncomfortable interview questions
- Height and weight measurements
- Feeling drowsy, tired or moody on the days that your child is asked to get less sleep

We will tell you more about these risks and other risks of taking part in the study later in this consent form. There may also be risks that we do not know about.

Possible Benefits: There will be no direct benefit to you from participating in this study.

Your Other Options: You do not have to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You and your child are being asked to take part in this study because you are the mother of a Mexican/Mexican American child who is 8-10 years old.

Why is this study being done?

The purpose of this study is to learn more about how children spend their time, including sleep habits, eating patterns and activities, in Mexican American children.

- **Who pays for this study?** The sponsor of the study is the National Heart, Lung, and Blood Institute.

How many people will take part in this study?

The study will enroll 40 families.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

- The interviewer/visitor will interview you and your child for about an hour in your home. You will be asked about your family's sleep habits, your eating habits, your neighborhood where you live, and questions about you such as your age, where you were born. Your child will be asked about your family's habits about sleep and food, and physical activity.
- The interviewer/visitor will show you an activity monitor for your child to use, and explain how to use it. Your child will be asked to wear the activity monitor on 4 full days (Tuesday-Friday) for three straight weeks.
- On the 1st week (Tuesday-Friday), your child will be asked to keep a usual sleep schedule.
- On the 2nd week (Tuesday-Friday), your child will be asked to sleep for at least 10 hours a night or for less than 8 hours a night.
- On the 3rd week (Tuesday-Friday), your child will follow the opposite sleep schedule.
- The interviewer/visitor will measure you and your child's height, weight, waist, and hip.

- The interviewer/visitor will help you set a sleep schedule for the 2nd and 3rd week. You will also be sent text messages or phone calls each day to remind you of your child's sleep schedule.

The interviewer/visitor will make 3 more visits to your home on Fridays or Saturdays for the next 3 weeks. The following procedures will occur at *the following visits*:

- The interviewer/visitor will interview you and your child for about 20 minutes each about what your child ate.
- The interviewer/visitor will check the activity monitor, and pick it up on the last visit

You and your child will be asked to complete an activity monitor log and a sleep and food diary. All these study procedures will be done at your home. You will be reminded to complete the diary in text messages or phone calls.

How long will I be in the study?

You will be asked to in the study for three weeks.

Can I stop being in the study?

Taking part in this study is your choice and completely voluntary. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you can refuse to answer any questions, and you may leave the study at any time. Also, the study researcher may stop you or your child from taking part in this study at anytime if they believe it is in your best interest or if the study is stopped. No matter what decision you make, there will be no penalty to you in any way.

What side effects or risks can I expect from being in the study?

- Some of the interview questions may make you or your child uncomfortable or upset, but you and your child are free to decline to answer any questions you or your child do not wish to answer.
- Having your height and weight and other measures taken may make you or your child uncomfortable, but you and your child are free to decline to have these measures taken.
- Wearing the activity monitor may be slightly uncomfortable for your child while sleeping.
- On the days that your child is asked to sleep less than 8 hours, it is possible that he/she may feel drowsy, tired or moody.
- You may want to monitor your child's mood and behavior. The study team will be monitoring your child's sleep and will discuss with you how to proceed if your child is having too much drowsiness.

You or your child can decide to stop at any time. Just tell the study researcher or interviewer/visitor right away if you or your child wishes to stop being in the study.

Are there benefits to taking part in the study?

There will be no direct benefit to you/your child from participating in this study. However, the information that you and your child provide may help health professionals learn more about children's time spent sleeping, eating, and in activities.

What other choices do I have if I do not take part in this study?

You may choose either to take part or not to take part in the study. No matter what decision you make, there will be no penalty to you in any way

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your or your child's personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name, your child's name, and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

Are there any costs to me for taking part in this study?

There will be no costs to you/your child as a result of taking part in this research.

Will I be paid for taking part in this study?

In return for your time and effort, each participating family will be paid \$25 for taking part in for week one and \$25 for week two, and \$40 for week three, in the form of a gift card. Gift cards will be provided after completion of each week that you and your family participates.

What happens if I am injured because I took part in this study?

It is important that you tell the study investigator, Dr. Suzanna Martinez, if you feel that you have been injured because of taking part in this study at (415) 476-2300.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at (415) 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

Any study-related questions, problems, or complaints should be directed to the investigator responsible for the study at the UC Nutrition Policy Institute, Dr. Suzanna Martinez at (415) 476-2300.

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.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at (415) 476-1814.

ASSENT AND CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate, and provide voluntarily consent to you and your child's participation, you should sign below:

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION

I have explained the study to _____ (*print name of child here*) in language he/she can understand, and the child has agreed to be in the study.

Date

Signature of Person Conducting Assent Discussion

Name of Person Conducting Assent Discussion (*print*)