

**STUDY TITLE:** In-home obesity prevention to reach infants through maternal and social transmission

**PRINCIPAL INVESTIGATORS:** Kayla de la Haye, PhD, and Sarah-Jeanne Salvy, PhD

## **EXPERIMENTAL SUBJECT'S BILL OF RIGHTS**

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

### **CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:**

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Signature: \_\_\_\_\_  
(Research Participant)

Signature: \_\_\_\_\_  
(Parent or Legally Authorized Representative)

If signed by other than the research participant, indicate relationship: \_\_\_\_\_

## **INFORMED CONSENT & PARENTAL PERMISSION**

**TITLE:** In-home obesity prevention to reach infants through maternal and social transmission

**PRINCIPAL INVESTIGATORS:** Kayla de la Haye, PhD, and Sarah-Jeanne Salvy, PhD

**DEPARTMENT:** Department of Preventive Medicine, University of Southern California

**TELEPHONE NUMBER:** 323-442-8228

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***In this form, “you” also means “your child.”***

We invite you to take part in a study. This form will give you information about the study and what will happen in the study. Take as much time as you need to read this form. You may want to discuss it with your family, friends, or with the staff from Antelope Valley Partners for Health (AVPH) or Children’s Bureau. If you do not understand parts of this form, please ask questions. If you decide to participate with your child, you will be asked to sign this consent form.

This research study is sponsored by the Eunice Kennedy Shriver National Institute for Child Health and Human Development at the National Institutes of Health. They provide money to cover the costs of conducting this study.

### **WHY IS THIS STUDY BEING DONE?**

The goal of this study is to provide a program that we call “Healthy Habits” that is a part of your home visitation program. We hope to understand if the program helps families start habits for healthy eating and physical activity. You and your child are invited to participate because you have been part of a home visitation program. About 300 families will take part in the study.

### **WHAT IS INVOLVED IN THE STUDY?**

If you decide to participate in our study, you will be *randomly assigned*, like flipping a coin, to one of two groups. This means that you will have an equal chance of being in either study group. The two possible study groups are: (1) the *standard home visitation program*, or (2) the *standard home visitation program + the Healthy Habits program*.

If you are in the “standard home visit program”, you will continue to get the same home visit program without changes.

If you are in the “standard home visit + the Healthy Habits program,” you will get the healthy eating and physical activity module AND the standard home visit program for the next 12 months. It will take about 15 minutes of your one-hour home visit to review the Healthy Habits program.

### Standard Home Visit Program

- AVPH and Children’s Bureau use the Healthy Families America program for their standard home visit program. This is the program that you and your baby are already involved in. If you have any questions about this standard program, please ask your AVPH / Children’s Bureau home visitor.

### Healthy Habits Program

- Home visitors will deliver the Healthy Habits program as part of their home visits. You will learn about:
  - Healthy eating and foods for you and your child/children
  - How to change the kinds of food that are in your home to so your family can eat more healthy foods
  - Cooking cultural food with healthy ingredients
  - Making healthy choices that work with your budget
  - Fun and easy ways to increase your physical activity and be active with your kids
  - Free and safe physical activities in your neighborhood that work with what your family likes, and your schedule
- Healthy Habits also has group activities. For these activities, families in the study will get together in your neighborhood to learn about family health and well-being. The activities will take place once every two weeks at AVPH and include:
  - Cooking classes with other parents. These classes will teach you how to cook healthy meals with the foods you have, and how to prepare healthy meals ahead of time for the week. Parents will be able to share what they learn with other parents.
  - Walking groups where you will meet up with other families from your community to walk and be active in safe places in your neighborhood.

### Assessments

- Surveys - All families in either study group will be asked to complete surveys three (3) times: the first is at the start of the study (month 0), the second after 6 months, and the third after 12 months. There will be extra short surveys in between, to help us keep track of Healthy Habits. AVPH staff will visit your home to ask you the survey questions.
  - *Intake survey (Assessment 1, 2, and 3).* You will complete a survey that asks questions about your life and current situation, such as age, education, income

- level, whether or not you receive support from WIC, race and ethnicity, family history, childhood experiences, and relevant medical history and health behavior patterns for you and your child.
- *Diet and activity assessment (Assessment 1, 2, and 3)*. We will ask you about the types and amounts of food that you and your child have eaten, and will ask about you and your child's physical activity. We will ask you about how often you do these behaviors, and if they are habits.
  - *Feeding style and food security (Assessment 1, 2 and 3)*. You will complete a few short questionnaires about how you feed your child, and how much your family can afford healthy foods.
  - *Social support questionnaire (Assessment 1, 2 and 3)*. You will complete a questionnaire about the close people in your life, your relationships with these people, and how much these people help and support your families' health and wellbeing.
  - *Healthy foods and activities in your home (Assessment 1, 2, and 3)*. The AVPH staff that is doing the survey will go through a check list of healthy foods and equipment for activities that are in your home.
- Blood draws - During the first and last assessment (*Assessment 1 and 3*), we will ask you for a small amount of blood. We will do the blood draw at AVPH. A qualified nurse will draw blood from a vein in your arm. We will draw 2 small tubes of blood, which is less than a tablespoon. We will test the blood for blood sugar, fat in the blood, and hormones that are linked with fat tissue

During the last assessment (Assessment 3 only), a qualified nurse will also take a small blood sample from your child by doing a standard fingerprick procedure to test for blood sugar.

- Other assessments:
  - Blood pressure - We will check your blood pressure (*Assessment 1 and 3 only*).
  - Measure height, weight, and waist circumference (*Assessment 1, 2, and 3*) - At your house, we will collect weight, height/length, and waist measurements from you and your child. This should take about 10-15 minutes. Your Home Visitor will also take some extra weight measurements, for you and your child, every 3 months.
  - Interviews and Focus groups – You *may* be invited to take part in an interview and/or focus group during the study. This will be a 30 minute to one-hour discussion of your thoughts and opinions about Healthy Habits.

We will review your records held by AVPH or Children's Bureau to get information on your infant's weight and length at birth. We will also gather information from your home visitation

program that are routinely measured such as child immunizations, parent-child interaction, and child development.

A chart is provided at the end of this form to summarize what will happen during the study.

### **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

Possible risks and discomforts you could experience during this study include:

- Some of the questions may make you feel uneasy or embarrassed. You may choose to skip any surveys or questions that make you uncomfortable.
- Blood draws on both you and your child may be uncomfortable, and carry a small risk of fainting, bleeding, bruising, and rarely, infection. If you have any questions about the blood draw, please let the nurse know, and they will work with you to reduce discomfort. You may also choose not to complete the blood draws.
- There is a small risk that people who are not connected with this study will learn your identity or your personal information. We will use a survey ID, instead of your name and personal information. All private information will be kept in a locked cabinet behind a locked door. Any private information on computers will be kept behind our University secure firewalls for protection.
- If our staff feel that you may be under distress or might need additional help, they will work with AVPH or Children's Bureau and offer you referrals to doctors.
- There are no known risks or discomforts for participating in the Healthy Habits program. Our trained staff have made the program to meet national dietary guidelines.

### **WILL YOUR INFORMATION BE KEPT PRIVATE?**

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The University of Southern California's Institutional Review Board (IRB) may review your records. The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants.

Only the research team will see data from our study. All computer files with participant personal information will be password-protected. Forms with personal information will be kept confidential and stored in a locked cabinet. We may publish the results from this study in journals or present it at meetings. If we do, we will report results from all participants and we will not use your name. Your identity will be coded and your personal information will be kept private. All data will be kept in a locked room for five years after the study ends.

There are some exceptions to confidentiality. These would be, for example, when the information is subpoenaed for police investigations or court proceedings, such as, if we suspect that your life or the life of others is endangered, or in cases of suspected child abuse.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US 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.

You will be asked to sign a separate HIPAA Authorization for Research form authorizing the access, use, creation, and disclosure of your health information. This is in addition to the medical release forms that AVPH and Children's Bureau will ask you to sign.

### **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?**

You may not receive any direct benefit from taking part in this study. However, it is also possible that you may gain skills and abilities that help your family to have healthy habits. You may also feel good about helping to develop a health program for families like yours.

### **WHAT OTHER OPTIONS ARE THERE?**

You may choose not to take part in the study. If you decide not to participate, you will still receive the standard home visitation program but no data or assessments will be collected for this study.

### **ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?**

You will receive a \$30.00 gift card for completing the first assessment (survey + blood draw); a \$20.00 gift card for completing the 6-month assessment (survey only); and a \$30.00 gift card for completing the final 12-month assessment (survey + blood draw). If you complete all of these assessments, you will receive a total of \$80.00 in gift cards. You will receive a gift card for each of these assessment sessions that you complete, even if you are not able to complete **all** of the assessments or if you do decide not to complete the entire study.

### **WHAT ARE THE COSTS?**

There is no cost to you for taking part in this study.

### **WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?**

During the study, we may learn new things about the risks or benefits of being in the study. If we do, we will share this information with you. You can always change your mind about being in the study at any time.

**WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?**

Your decision to participate in the study is voluntary. Your decision whether or not to be in this study does not affect your care in the home visitation program. You are not giving up any legal claims or rights. If you **do** decide to participate in this study, you are free to change your mind and stop being in the study at any time.

**CAN YOU BE REMOVED FROM THE STUDY?**

You may be removed from this study without your consent for any of these reasons: (1) You do not follow the programs' instructions; (2) We feel that the study is harmful to you or your child; or (3) The sponsor closes the study. If this happens, the study team will discuss other options with you. If you were removed from our study, this would not change the services provided to you by AVPH or Children's Bureau.

**WHO DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?**

You can contact *Kayla de la Haye, PhD* at 323-442-8228 or *Aimee Fata (Project Coordinator)* at 310-423-2034 with any questions, concerns, or complaints about the research or your participation in this study. If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-442-0114 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Fax: 323-224-8389 or email at [irb@usc.edu](mailto:irb@usc.edu)).

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the USC Institutional Review Board at 1640 Marengo Street, Suite 700, Los Angeles, CA 90033.

***You will be given a copy of this consent form.***

**AGREEMENT:**

*I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing for me and my child to take part in this study.*

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<b>Name of Parent Participant</b>	<b>Signature</b>	<b>Date Signed</b>
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**Name of Child**

*\*\*\* If mother is less than 18 years old, also complete the information below:*

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<b>Name of Parent/ Legal Guardian</b>	<b>Signature</b>	<b>Legal Relationship</b>	<b>Date Signed</b>
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I have personally explained the research to the participant using non-technical language. I have answered all the participant's questions. I believe that she understands the information described and freely consents to participate.

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<b>Name of Person Obtaining Informed Consent</b>	<b>Signature</b>	<b>Date Signed</b>
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*\*\*\*A witness is required when: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form. If no witness is needed, leave this signature line blank.*

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<b>Name of Witness***</b>	<b>Signature</b>	<b>Date Signed</b>
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Assessment number	Assessment 1	Assessment 2	Assessment 3
Time of visit (in months)	month 1	month 6	month 12
<b>Information we will collect about you:</b>			
Intake questionnaire: age, race, education, income, child experiences, & medical, health behavior, and family history	X	X	X
Diet and activity assessment (for you and your child)	X	X	X
Feeding style and food security questionnaire	X	X	X
Social support and social network questionnaire	X	X	X
Height, weight, and waist circumference	X	X	X
Vitals and blood draw	X		X
<b>Information we will collect about your child:</b>			
Height/length, weight, and waist circumference	X	X	X
Blood draw (finger prick)			X
<b>Estimated time for the Assessment:</b>	<b>3 hours</b>	<b>2 hours</b>	<b>2.5 hours</b>