TEXAS
The University of Texas at Austin

Consent and Parental Permission to Participate in Research

Basic Study Information

Title of the Project: Project Sueño: Sleep & Understanding Early Nutrition in Obesity
Principal Investigator: Megan Gray, MD, MPH, FAAP
Study Sponsor: American Diabetes Association

Invitation to be Part of a Research Study

You are invited to complete a screening questionnaire to see if you and your baby are eligible to participate in the Project Sueño research study. This consent form will also help you choose whether or not to be randomly assigned to one of three groups in the Project Sueño study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- The purpose of the Project Sueño study is to investigate if community-based programs influence infant feeding, sleep practices, and growth among Latino infants and toddlers.
- To participate, you must be:
  - At least 18 years old
  - Latino ethnicity
  - Mother to a baby that is less than 2 months of age
  - Your baby should also be: full term at birth, a single baby (not a twin or triplet), have no major health problems, and a patient at CommUnityCare.
- If you choose to participate you will be asked to complete a screening questionnaire that should take about 10 to 15 minutes to complete. This screening questionnaire will confirm your eligibility to participate in the Project Sueño study. If you are eligible to participate in the Project Sueño study, you may be asked to:
  - Participate in one of three groups: a standard care group, a Centering Parenting group, or a Texting group.
  - Complete additional questionnaires asking about you and your baby.
  - Record your and your baby's activity using wearable devices.
- For this form, you will also be asked to agree to be randomly assigned to one of the three Project Sueño study groups.
- We will also ask you to permit us to gather information from your baby's medical records when they are 2-, 6-, 12-, 18-, and 24-months old.
- The risks involved are not greater than everyday life or a normal doctor's appointment, which may include a risk of a breach in confidentiality.
- There are no direct benefits to you or your baby from completing this screening questionnaire.
- Taking part in this study is voluntary. You do not have to participate and you can stop at any time.

More detailed information about the screening questionnaire, randomization and medical record requests may be described later in this form. More details about the Project Sueño study and the group you will be assigned to are described in a different form, if you are determined eligible.
Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

The purpose of the Project Sueño study is to understand how mothers think and feel about feeding their babies and putting them to sleep, understand more about programs that can support mothers taking care of babies, and how professionals can be most helpful in helping mothers make decisions about their baby's feeding and sleeping.

What will happen if you and your child take part in this study?

- If you agree to participate, you will be asked to complete a questionnaire that will ask about your background, health, and how you are feeling. The questionnaire may also ask about your baby's background, health, sleeping habits, and feeding.
- If your answers show that you qualify for the study and you agree to take part in the Project Sueño study, you will be randomly assigned into one of three groups: a standard care group, a Centering Parenting group, or a Texting group. By signing this consent, you are agreeing to be randomly assigned to participate in any of these groups. Group assignment is random. This means that you cannot choose your group, and the study staff cannot choose your group either. If you are eligible to participate, you will be informed of your group assignment before your baby's 2-month appointment. We will ask you to consent to participate in your assigned study group in a separate form.
- We also seek your permission to use your baby's information for the study. We will go over the section of this form that will allow us to store and use some of your baby's medical records. When you sign this form after our explanation, you permit us to have access to this information. We will obtain the following information from the medical chart:
    - Your baby's date of birth and dates they had appointments at CommUnityCare.
    - Your baby's length, weight, head circumference, thigh and arm circumferences when they are 2-, 6-, 12-, 18-, and 24-months old.
    - Your responses to developmental assessments of your baby delivered by CommUnityCare.

How long will you and your child be in this study and how many people will be in the study?

Participation in this screening questionnaire should only take 10 to 15 minutes to complete. We will collect information from your baby's medical record until they are 24-months old.
160 mother-baby pairs will be asked to completed the screening questionnaire.

What risks and discomforts might you or your child experience from being in this study?

The risks involved are not greater than everyday life or a normal doctor's appointment. Some of the questions may address sensitive topics. If you do not wish to answer a question, you may skip it and go on to the next question. Some questions may make you angry, emotionally upset, or stressed-out now or at a later time. If this occurs, the study team may refer you to your health care provider, provide you with some resources, or you can contact any of the following organizations for help:

- Mental Health Helpline: call 1-800-662-4357 or visit https://www.samhsa.gov/find-help/national-helpline
- Suicide Prevention Lifeline: call 9-8-8 or visit https://988lifeline.org/

If you experience discomfort or distress that is related to a personal concern that came from participating in this study, we will be happy to discuss your experience with you using the study team contact information below. If your distress continues, we can refer you to supportive resources depending on the nature of your concern.
There may also be a risk of a breach in confidentiality. To avoid this, we will protect your and your baby's information as much as possible as described below.

How could you and your child benefit from this study?

There may be no direct benefits you or your baby might experience from completing this questionnaire. Possible benefits of the Project Sueño study include learning more about baby development and learning about important healthy feeding, eating, and sleeping habits through education and materials provided by the study team. We believe that the information from this study will help families make healthy decisions in their everyday lives. The results of this project also will be important for creating programs to help parents and families develop healthy sleeping and eating habits for their infants and toddlers.

What will happen to the samples and/or data we collect from you and your child?

We will collect data from the questionnaire you will be asked to complete. We will also collect data from your baby's well child appointments. These data will be de-identified and grouped together so no one will be able to identify you or your baby. De-identified data sets will be retained indefinitely and analyzed by approved members of the study team, and may also be shared with the following data repositories to help other researchers learn more about eating and sleep in infants:

- The National Sleep Research Resource: https://sleepdata.org/
- The National Children's Study Archive: https://www.nichd.nih.gov/research/supported/NCS
- The Harvard Dataverse: https://dataverse.harvard.edu/

The results of this study may also be published or presented at a scientific meeting.
A description of this study will be available on http://ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you or your baby. At most, the website will include a summary of the results. You can search this website at any time.
We will also collect information that can identify you (like your name, your baby's name, your contact information). This information will be stored separately from study data and will only be available to approved members of the study team. We will keep this information indefinitely so we may contact you for future research studies, but will protect your information as much as possible as described below.

How will we protect your and your child's information?

Your name, your baby's name, and any other information that can directly identify you or your baby will be stored separately from the data collected for the study**.** Your and your baby's privacy and confidentiality will be protected by stripping all identifying information from the final dataset. No one will know your confidential responses to the questionnaire. You and your baby will be assigned a random code number. For all data collected, this code number will be used and not your name, your baby's name, or any other identifying information about you or your baby. Investigators who oversee the analyses for this project and who work with the data will not have access to your name, your baby's name, or other identifying information about you or your baby. The research will only be reported in aggregate form, so individuals will not be identifiable from any research report. All data will be stored in locked cabinets or secure files to which only authorized research personnel to have access. If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you and your baby will be protected to the extent permitted by law. Your and your baby's research records will not be released without your consent unless required by law or court order. Information about you and your baby may be given to the following organizations:

- The study sponsor and/or representative of the sponsor
- Representatives of UT Austin and the UT Austin Institutional Review Board
- Other collaborating organizations: CommUnityCare

If you agree, we plan on sharing your and your baby's de-identified data with other researchers. Those researchers in turn may share your and your baby's de-identified data with additional researchers. Future research studies may be similar to this study or may be very different. The data shared with other researchers will not include information that can directly identify you or your baby. Researchers will not contact you for additional permission to use this information. We also plan to publish the results of this study. To protect your and your baby's privacy, we will not include any information that could directly identify you or your baby.

Under certain situations, we may break confidentiality. If during the study we learn about child abuse or neglect, we will report this information to the appropriate authorities including the police and/or the Texas Department of Family and Protective Services.

What will happen to the information we collect about you and your child after the study is over?

We will keep your and your baby's research data indefinitely to use for future research analyses. Your name, your baby's name, and other information that can directly identify you or your baby will be kept securely indefinitely and stored separately from the research data collected as part of the project.

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What if we learn something about your or your child's health that you did not know?

As part of this study, we may learn medically relevant information about you or your baby. If we learn something that you and your doctor did not know, we will contact you to refer you or your baby to your doctor to receive treatment. Any follow-up medical appointments will be billed to you and/or your insurance.

How will your child's health information be used and shared during the study?

As part of this research study, we will ask you to share identifiable health information about your baby with us and/or permit us to access existing information from your baby's healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?
The following types of information may be used for the conduct of this research:

	☐ Complete health record	
☐ Information about sexually transmitted diseases	☐ Diagnosis & treatment codes	☐ Discharge summary
☒ History and physical exam	☐ Consultation reports	☒ Progress notes
☐ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	☐ Information about mental health
☐ Other physical or mental health information (specify):		

Where will you get my baby's records?
For this study, we will obtain records from the following healthcare providers:

- CommUnityCare

Who will use or share protected health information about my baby?
The covered entities listed above are required by law to protect your baby's identifiable health information. By signing this document, you authorize them to use and/or share your baby's health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Study Staff
- Institutional Review Boards
- Government/Health Agencies
- American Diabetes Association
- Research Collaborators
- Others as Required by Law

If your baby's health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my baby's protected health information expire?
We will retain information from your baby's medical records indefinitely. As described previously, we will protect your baby's privacy and confidentiality by stripping all identifying information from the data to be analyzed. Any information that can directly identify you or your baby will be kept securely and stored separately from the research data collected as part of the project. If you later decide that you do not want to share your baby's medical information any longer, please contact the study team in writing to withdraw your authorization. Contact information for the study team can be found at the end of this form.

What happens if I say no?
You do not have to sign this consent form. Your decision to not sign this form will not affect any other treatment, health care, enrollment in health plans, or eligibility for benefits other than those indicated as part of this research study.

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How will we compensate you and your child for being part of the study?

You will receive a $10 payment for your participation in this screening questionnaire. Payment will be with cash, gift card, or Tango card.

What are the costs to you and your child to be part of the study?

There are no costs to complete this screening questionnaire.

What other choices do you and your child have if you do not take part in this study?

You may choose not to take part in this study.

Your and Your Child's Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your or your baby's relationship with The University of Texas at Austin, CommUnityCare, your baby's doctor or healthcare provider, etc. You and your baby will not lose any benefits or rights you already had if you decide not to participate. You do not have to answer any questions you do not want to answer. You may change your mind and withdraw from this study and/or take back the right to use your baby's protected health information at any time. However, even if you withdraw or take back permission, the researchers may still use or disclose information they have already collected about you and your baby for this study. To take back permission, you must write to the Principal Investigator.

Contact Information for the Study Team

If you have any questions about this research, you may contact:
Megan Gray, MD, MPH, FAAP
Phone: 512-495-3002
Email: megan.gray@austin.utexas.edu
Address: 1400 Barbara Jordan Blvd., Austin, TX 78723

Contact Information for Questions about Your and Your Child's Rights as Research Participants

If you have questions about your and your baby's rights as research participants, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:
The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu
Please reference the protocol number found at the top of this document.

Your Consent

Consent for randomization:

☐ I understand that before I can participate in the Project Sueño study I will be randomly assigned to one of three study groups.

Consent for data repositories:

☐ I GIVE permission to share my de-identified, aggregate data with other researchers, including the data repositories listed earlier in this form.

☐ I DO NOT GIVE permission to share my de-identified, aggregate data with other researchers, including the data repositories listed earlier in this form.

Consent for future contact:

The University of Texas at Austin

☐ I GIVE permission to securely store my name and contact information for future research purposes.

☐ I DO NOT GIVE permission to store my name and contact information for future research purposes.

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.
I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date

Parental Permission

Consent for data repositories:

☐ I GIVE permission to share my child's de-identified, aggregate data with other researchers, including the data repositories listed earlier in this form.

☐ I DO NOT GIVE permission to share my child's de-identified, aggregate data with other researchers, including the data repositories listed earlier in this form.

Signature:
By signing this document, you are agreeing to your child's participation in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.
I understand what the study is about and my questions so far have been answered. I agree that my child to take part in this study.

_____
Printed Subject Name

_____
Printed Legally Authorized Representative Name and Relationship to Subject

_____
Signature Date