PARTICIPANT CONSENT FORM
OKLAHOMA STATE UNIVERSITY

PROJECT TITLE: Sleep and Mother Baby Regulation (SLMBR)

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This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision.

Why Have I Been Asked To Participate In This Study?
You are being asked to take part in this study because you are over the age of 18 and are currently pregnant.

Why Is This Study Being Done?
The purpose of this study is to learn more about the risk factors that affect the emotional health of women during pregnancy and following childbirth. We want to understand how harmful childhood experiences and problems sleeping affect women's immune system and emotional health, and how well babies sleep.

How Many People Will Take Part In The Study?
About 80 mothers and their babies will take part in this study through other research projects going on at OSU-Stillwater and OSU-Tulsa.

What Is Involved In The Study?
All pregnant women 18 years and over who participate in the HATCH project or the DADIO project will be provided recruitment information about the study, and asked for permission to be contacted by research staff. Women can also contact us directly through our website if they are interested in participating.

1. Surveys

Enrollment: When you are approximately 29 weeks pregnant, you will be asked to take a survey. It will take about 45 minutes or less to do the survey. You will be asked questions about:

A. Yourself, your neighborhood, and your family: There are questions about who you live with, where you grew up, and what your family was like growing up, including things that were positive and negative.

B. Your feelings and behaviors: There are questions about your feelings and emotional health, stressful experiences, sleep patterns, and sleep problems.

6 weeks postpartum: About 6 weeks, or 2 months, after you give birth, we will schedule a visit with you that can take place on the OSU-Tulsa campus, the OSU-Stillwater campus, or your home depending on where you live. At the appointment we will ask you complete a survey. The survey will take 30 minutes or less. You will be asked about:

A. Your recent sleep patterns: There are questions about how you've been sleeping since giving birth and about any problems you've been having sleeping.

B. Your feelings and behaviors: There are questions about your feelings and emotional health, and stressful experiences.

C. Your baby's health and sleep patterns: There are questions about how your baby has been eating and sleeping, and any problems he or she may be having.

16 weeks postpartum: About 16 weeks, or 4 months, after you give birth, we will schedule an appointment for a visit. We will ask you to complete another survey. The survey will take 30 minutes or less. You will be asked about:

A. Your recent sleep patterns: There are questions about how you've been sleeping since giving birth and about any problems you've been having sleeping.

B. Your feelings and behaviors: There are questions about your feelings and emotional health, and stressful experiences.

C. Your baby's health and sleep patterns: There are questions about how your baby has been eating and sleeping, and any problems he or she may be having.

2. Sleep Diaries

Enrollment: When you are about 30 weeks pregnant, you will be shown how to complete a sleep diary, and asked to track your sleep every day for 4 days.

16 weeks postpartum: At about 16 weeks after your baby is born, we will review how to complete a sleep diary for yourself, and show you how to complete a sleep diary for your baby. You will be asked to track your sleep and your baby's sleep every day for the following 4 days.

3. Blood Draw

6 weeks postpartum: At the visit, we will collect up to 12ml or about 2.5 teaspoons of blood drawn from your arm. We are interested in your blood because there are tests that we can run to look for indicators of the effects of stress on your body, which can affect your sleep, your mood, and your baby's health.

These blood samples will be retained at minimum 5 years and at maximum 20 years in a biobank in order to potentially measure additional biomarkers as technology and funding become available to do so.

No identifying information will be tied to your blood samples; it will be known to the research team only by an identification number. Biobanks store samples of biological material collected from many people. The storage allows us to preserve the samples for use in future research. Samples will not contain any identifying information, like your name or address.

4. Other Data

A. We ask you about your height and weight at enrollment, and we will measure your and your baby's height and weight at the 6 week and 16 week visits.

B. With your permission, we will access data you already provided to researchers in the HATCH or DADIO studies. We also ask your permission to share the data we collect in this study with those researchers. We work together with the researchers leading those studies to understand different parts of women's health during pregnancy and following childbirth. We want to respect your time and participation in our studies, and so we share data so that you don't have to answer the same questions again and again.

Specifically, we will access available data about your health history, delivery and birth complications, harmful childhood experiences, interpersonal violence, stress hormones and immune system function, and information about how you feed, change, and talk to your baby. The data files will <u>not</u> contain any identifying information, like your name or address.

How Long Will I Be In The Study?
We think that you will be in the study for 5 to 6 months. There may be some anticipated reasons that your participation will be stopped by the investigator, even though you said you wanted to participate.

You can stop participating in this study at any time without any penalty. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

What Are The Risks of The Study?
The risk for you is small. It is possible that you may become upset or uncomfortable filling out the questionnaires or during the blood draw. If you become uncomfortable or too upset, you can stop the activity. Drawing blood from a vein may cause a small amount of pain or soreness and temporary bruising or swelling at the spot where the blood is drawn. Rarely, a minor infection may result from this procedure.

Are There Benefits to Taking Part in The Study?
If you agree to participate in this study, there will be no direct benefit to you. If you are interested, our team will provide you with a summary of your sleep patterns and your baby's sleep patterns. Some of our survey questions may lead you to reflect on your health, and the health of your baby. We hope that the information learned from this study will benefit other moms and their babies in the future, however no benefit is guaranteed.

What Are the Costs?
There is no cost to you if you participate in this study.

Will I Be Paid For Participating in This Study?
Yes. At enrollment, we will make sure you still have your reloadable debit card from the other research projects, and if not, we will provide you a new one. When you finish each part of the study, money will be loaded onto your research debit card.

If you participate in all parts of the study, you will receive a total of $110. Here is the list of payments:

Enrollment:
$10 for completing the survey
$20 for completing the sleep diary ($5 for each day completed).

6 weeks postpartum:
$30 for completing a short survey and blood draw.

16 weeks postpartum:
$10 for completing the survey.
$20 for completing a sleep diary for you ($5 for each day completed).
$20 for completing a sleep diary for your baby ($5 for each day completed).

Bonus Drawing:
If you complete all four days/nights of the sleep diary, you will be entered in a drawing for a chance to win $25. We will hold a drawing every 8 weeks for those who completed the diary in that time period. You will be notified by email if you are our winner.

What About Confidentiality?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

There are organizations outside OSU that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food & Drug Administration and other regulatory agencies, and the OSU Institutional Review Board may also inspect and/or copy your research records for these purposes.

Research records will be securely stored on a password-protected, encrypted server and/or locked file cabinets in a locked office, and only researchers and individuals responsible for research oversight will have access to the records. Your blood sample will be stored in a secure biobank. In addition, your name and contact information will never be connected to your survey or biological data, and will only be linked through an ID number. The file linking your name and contact information and your ID number will be stored on password protected computer separate from your other data.

The reason for keeping your contact information is so that we can contact you again over the 26 weeks you are participating in the study. Once all data has been collected and coded, the link from your name to your ID number will be destroyed.

Confidentiality will be maintained except under certain situations as required by law. For example, current Oklahoma law requires that any child abuse (including sexual abuse, physical abuse, or neglect) of a minor must be reported to state officials. In addition, if a person reports that he/she intends to harm him/herself or others, legal and professional standards require that the individual must be kept from harm, even if confidentiality must be broken.

What Are My Rights As a Participant?
Taking part in this study is voluntary. You may choose not to participate. If you refuse to participate, there will be no penalty or loss of benefits to which you are otherwise entitled. If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

We will contact you with any important findings from the research that may affect your health, welfare, or willingness to continue your participation in this study. Also, we would like to contact you in the future regarding other studies that you might qualify for. Your decision about whether or not to participate in future studies will not affect your participation in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

Whom Do I Call If I have Questions or Problems?
If you have any questions about this research project, you may contact:
Dr. Lucia Ciciolla (405) 744-8067, lucia.ciciolla@okstate.edu) in the Psychology Department at Oklahoma State University, 116 N Murray Hall, Stillwater, OK 74078

If you have questions about your rights as a volunteer in this research project, contact:
Dr. Hugh Crethar, IRB Chair, 223 Scott Hall, Stillwater, OK 74078, 405-744-3377 or irb@okstate.edu.

Signature:
By marking your initials on each line, you are agreeing to participate in the specific parts of the research study under the conditions described in this document. You have not given up any of

your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

_____ Your initials here indicate your permission to access data you already provided to researchers in the HATCH or DADIO studies, and to share data collected in this study with them.

_____ Your initials here indicate your consent to respond to survey questions about yourself and track your sleep.

_____ Your initials here indicate your consent to have your height and weight measured.

_____ Your initials here indicate your permission to draw and store your blood.

_____ Your initials here indicate your consent to respond to survey questions about your baby and track your baby's sleep.

_____ Your initials here indicate your consent to have your baby's height and weight measured.

_____ Your initials here indicate your consent to be contacted for future studies.

I have been fully informed about the procedures listed here. I am aware of what I will be asked to do and of the benefits of my participation. I sign this consent form freely and voluntarily. A copy of this form will be given to me. I hereby give permission for my participation in this study.

PARTICIPANT SIGNATURE (age ≥18)	Printed Name	Date
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date