University of Idaho
Research Study Consent Form

Study Title: Effects of maternal stress on human milk composition and subsequent infant outcomes

Researchers:
Principal Investigator: Yimin Chen, PhD, RD; University of Idaho
Co-investigator: Laura Holyoke, PhD; University of Idaho
Co-investigator: Brian Scottoline, MD, PhD; Oregon Health & Science University
Co-investigator: David Dallas, PhD; Oregon State University
Co-investigator: Brook Lang, MD; Kootenai Health

What is the purpose of this study?

The purpose of the research is to assess whether an 8-week mindfulness intervention will beneficially affect the mental well-being of preterm infant mothers, their human milk composition, and infant health. You are being asked to participate because you are over 18 years of age and a mother of preterm infant (<36 weeks gestation). About 500 people will take part in this research.

What will I be asked to do if I am in this study?

If you agree to take part in this study, you will be asked to provide saliva, urine, and human milk samples at the time of project entry, 4 weeks (mid-point), and 8 weeks (end of participation) after providing informed consent. At the same time points, you will also be asked to complete two separate questionnaires: Perceived Stress Scale (PSS; 14 questions) and Self-Compassion Scale-Short Form (SCS-SF; 12 questions). At the same time points, the following infant non-invasive samples will be collected: saliva, urine, and stool. These will be used to assess infant metabolism and immune responses. Taking part in the study will take about no more than an hour at the above time points, and some brief optional daily activities (<15 minutes), and four video conferencing (not recorded) with the Certified Mindfulness Facilitator, if you are in the intervention group. We will tell you about any new information that may affect your willingness to continue participation in this research.

All participating mothers will be asked to complete the Perceived Stress Scale (PSS; 14 questions) and Self-Compassion Scale-Short Form (SCS-SF; 12 questions). The purpose of these questionnaire is to determine whether degrees of stress and self-compassion influence human milk composition. During research project participation, you can stop at any time if the questionnaires cause discomfort. Below include a couple of sample questions from each questionnaire.

Perceived Stress Scale (PSS):

- In the last month, how often have you felt that you were unable to control the important things in your life?

Never	Almost Never	Sometimes	Fairly Often	Very Often
0	1	2	3	4

- In the last month, how often have you found that you could not cope with all the things that you had to do?

Never	Almost Never	Sometimes	Fairly Often	Very Often
0	1	2	3	4

Self-Compassion Scale-Short Form (SCS-SF):

- When something painful happens I try to take a balanced view of the situation.

Almost Never				Almost Always
1	2	3	4	5

- When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.

Almost Never				Almost Always
1	2	3	4	5

All participating mothers will be randomly assigned to either control or intervention group. If you are assigned to the intervention group, you will participate in four group video conferences with the Certified Mindfulness Facilitator. You may choose to not turn on your video camera during these group conferences. And these group conferences will not be recorded.

Are there any benefits to me if I am in this study?

The potential benefits to you from being in this study include improvement in mental well-being. Additionally, you may help others in the future if the results from this research leads to practice change mental health care for mothers of preterm infants.

Are there any risks to me if I am in this study?

The risks or discomforts of participating in this research include increased emotional experience triggered by your participation. If this happens, please let the researcher(s) know and seek professional counseling. You are free to dropout from the research project at any time; your participation is voluntary. The anticipated benefits from this research is very impactful for future clinical practice changes to support mothers of preterm infants. There are no funds available for compensation for study related injuries (we do not anticipate any physical injuries related to research participation).

Will my information be kept private?

The data for this study will be kept confidential to the extent allowed by federal and state law. Under certain circumstances, information that identifies you may be released for

internal (Institutional Review Board) and external (funding agency: National Institute of Health) reviews of this project. All data will be collected and entered directly in a secure and encrypted research database without personal identifiers. All the body fluid samples will also be collected in containers without personal identifiers. Only research staff directly involved in this study will have access to the de-identified data.
The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. Information or biospecimens collected during this study may be used for future research studies or distributed to other researchers for future research studies without your additional permission. Any identifiers will be removed so that the information or samples cannot be linked back to you. If you do not agree to this, you may choose to not join the study. In order to withdraw your previously collected data from the study you must contact the Principal Investigator Yimin Chen, PhD, RD or Co-investigator Brian Scottoline, MD, PHD (if you are in OHSU) or Co-investigator Brook Lang, MD (if you are in Kootenai Health).

Are there any costs or payments for being in this study?

There will be no costs associated with participation in this research study. The study also does not have funding to provide compensation for participation. You will not receive payment or any other form of compensation for taking part in this study.

Who can answer questions about this research?

If you have questions about this study or the information in this form, please contact the research team at: Yimin Chen, PhD, RD; 875 Perimeter Drive, MS 3183, Moscow, ID 83844-3183; yiminc@uidaho.edu. If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the University of Idaho Institutional Review Board at (208) 885-6340, or e-mail irb@uidaho.edu, or regular mail at: 875 Perimeter Drive MS 3010, Moscow, ID 83844-3010.

The University of Idaho Institutional Review Board has approved this project.

What are my rights as a research study volunteer?

Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time. You will be given a copy of the consent form for your records. In order to withdraw your previously collected data from the study you must contact the Principal Investigator Yimin Chen, PhD, RD or Co-investigator Brian Scottoline, MD, PHD (if you are in OHSU) or Co-investigator Brook Lang, MD (if you are in Kootenai Health).

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.
- You are giving your voluntary consent to take part in the study.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent