

## LETTER OF INFORMED CONSENT

IRB # 1-20-0574 | Valid until 2.24.2030

### **TITLE: Investigating the causes and correlates of maternal health during the perinatal period**

#### **RESEARCHERS**

Carmen Hové, MA, PhD candidate

Amy Boddy, PhD

#### **PURPOSE**

You are being asked to participate in a research study on maternal postpartum health conducted by Carmen Hove and Amy Boddy at the University of California, Santa Barbara (in collaboration with the University of Washington). Because so much of the previous research on the postpartum period has focused on infant outcomes, there is a lot we still don't know about *maternal* immune function, health, and disease risk during the postpartum period – and we'd like to change that! **The purpose of this study is to (1) determine how maternal immune function changes across the postpartum period and (2) investigate how these shifts map on to other key factors, including hormone levels, sleep quality, physical and mental wellbeing, and infant feeding method.** If you decide to participate, you'll be asked to provide two saliva samples (and optional blood samples) and complete an online questionnaire – all from your own home. Participation is completely voluntary.

#### **PROCEDURES**

**In light of COVID-19, this study is designed so that you can participate entirely from the comfort of your own home.** If you decide to participate, you will choose your preferred 24-hour collection period from a list of possible dates. If you aren't available on any of the pre-selected dates, researchers will reach out to find a time that works. If you're currently pregnant, we will schedule your data collection after you deliver. Once your collection period is scheduled, you will be mailed a home-collection kit with detailed instructions on safe and proper use. When your collection period begins, you'll be asked to (1) provide two "passive drool" saliva samples, once before bedtime on the first day and again the following morning, (2) keep a simple record of when and how you fed your infant over the course of the day, and (3) complete a final online questionnaire. We'll also ask you to provide two finger-prick blood spot samples, but this is optional. Saliva and blood samples will be used to measure your hormone levels and immune status. Once you've completed your collection period, a researcher will pick up your samples via curbside pickup. **In total, your participation will span a single 24-hour period, with saliva and optional blood samples each taking ~15 minutes and the final questionnaire requiring about 20 minutes.** We expect that roughly 100 individuals will participate in this research and that the study will take about 6 months to complete. **Once we are done analyzing samples, we will send you your salivary cytokine levels (IL-6, IL-8, TNF-a, IL-1B), C-reactive protein concentration, and hormone profile (estradiol, progesterone, and cortisol) via email. Since we will measure both evening and morning levels of each of the biomarkers, you'll be able to see how much each changed across time.** As researchers, we can only provide these data for your own interest. By themselves, these results should NOT be used to diagnose, prevent, or treat any underlying disease or impairment. You'll need to talk directly with your healthcare provider if you want to learn more about the possible clinical relevance of your research results.

#### **RISKS**

Physical: If you opt into the blood collection portion of this study, you may experience some discomfort during each finger prick. You may continue to feel slight discomfort at the site of the prick for one or two days following the procedure, and there is a very slight risk of infection. Participation in this study poses a small risk of exposure to SARS-CoV-2, the virus that causes COVID-19. We minimize risk of exposure by (1) safely and hygienically preparing all home-collection materials, (2) shipping kits early so that you can leave them unopened for several days before your collection period begins, (3) providing clear instructions

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for safe use of all home-collection materials, (4) providing safe disposal of used finger-prick devices (if you opt-in to the blood collection portion), and (4) conducting contactless/physically distanced curbside pickup. Researchers will always observe best-practices, including use of appropriate PPE (protective personal equipment) while packing your home-collection kit and conducting curbside pickup.

Emotional: You may find some questions included on the questionnaire to be personal or upsetting. For example, the survey contains questions regarding birth complications and depressive symptoms. If you feel uncomfortable answering any of these questions, you can skip them or quit the survey. Please note that as researchers we are not qualified to provide counseling services, so we aren't able to follow up with you after this study. If you feel upset after completing the study or find that some questions or aspects of the study triggered distress, talking with a qualified clinician may help. If you would like assistance, please contact the Perinatal Support Washington "Warm Line" at 1-888-404-7763. In the case of an emergency please call 911. Information on both national and local resources will also be included at the end of the questionnaire.

Security: Anytime you share information online there are risks of hacking or interception. While we can't completely eliminate this risk, we minimize risk as much as possible by using Qualtrics (a gold-standard secure server) to collect, store, and transmit survey data. Your identifying information (e.g. name, address, phone number) will be kept on a single master file stored on a secure server, which only the investigators will be able to access. At the end of the study, this master file will be permanently destroyed. All electronic devices used to analyze your data will be encrypted and password protected. When communicating with you over email, researchers will only use their official UC Santa Barbara encrypted email accounts to further ensure digital security.

### CONFIDENTIALITY

In scientific research, there is always a chance your data could be seen by someone who shouldn't have access. We'll minimize this risk in the following ways.

- **Your data will be identified with a randomly coded participant identification number (PID), rather than your name.** This includes both survey data and biological data.
- Your fully de-identified saliva samples will be sent to a third-party laboratory, where they will be analyzed for immune markers and hormone levels. Any remaining sample will be discarded.
- Your fully de-identified blood samples will be stored and analyzed for immune markers in a keycard protected laboratory at the University of Washington. The only people who will have access to these de-identified samples will be approved researchers. Remaining samples will be destroyed after 3 years.
- The investigators, and ONLY the investigators, will be able to *temporarily* link your data, PID, and contact information via the master file (described under Security section above) so that we can send you your individual research results. As soon as you receive your study results, this link will be immediately and permanently destroyed.
- While your data may be used in future research studies without additional consent, it will be fully de-identified. No one will be able to link your data back to you.
- Biospecimens (e.g. saliva, blood) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. All data will be fully de-identified. You will not share in any commercial value or profit derived from the use of your bio-specimens and/or information obtained from them.

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### **COSTS/PAYMENTS**

Other than a total time commitment of approximately 1.5 hours over a 24-hour time period, there are no costs to participation. Compensation will be offered in the form of a \$40 Amazon or Visa gift card (or \$50, if you opt into the blood collection component). Gift cards will be emailed to you after you complete your sample collections and the questionnaire. Please keep in mind that while responses to certain questions on the final questionnaire (e.g. time of day you took your saliva samples) are required in order to maintain study integrity, you are free to skip any other questions that you do not want to answer (e.g. history of miscarriages, ethnicity). Skipping such questions will have no impact on compensation.

### **EMERGENCY CARE AND TREATMENT FOR INJURY**

Although it extremely unlikely that you will suffer any injury, given the minimal risks associated with this research, if you are injured as a direct result of research procedures, you will receive reasonably necessary medical treatment at no cost. The University of California does not provide any other form of compensation for injury.

### **RIGHT TO REFUSE OR WITHDRAW**

You may refuse to participate, and you may also change your mind about being in the study and quit after the study has started.

### **QUESTIONS**

If you have any questions about this research project or if you think you may have been injured as a result of your participation, please contact Carmen Hové at (360) 621-3508 / [carmenhove@ucsb.edu](mailto:carmenhove@ucsb.edu) or Amy Boddy at (805) 893-2456 / [amyboddy@ucsb.edu](mailto:amyboddy@ucsb.edu). If you have any questions regarding your rights and participation as a human research subject, please contact the Human Subjects Committee at (805) 893-3807 / [hsc@research.ucsb.edu](mailto:hsc@research.ucsb.edu). You can also write to the University of California, Human Subjects Committee, Office of Research, Santa Barbara, CA 93106-2050.

### **PARTICIPATION IN RESEARCH IS VOLUNTARY**

Selecting "I consent" below will indicate that you have decided to participate as a research subject in the study described in the Letter of Informed Consent. If you do not want to participate, simply select "I do not consent" to exit this survey.

I consent

I do not consent