UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Pregnancy co**R**onav**I**rus **O**utcomes **R**eg**I**s**T**r**Y** (PRIORITY)

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This is a medical research study. The study coordinator will explain the study to you. This study is being conducted by researchers from the Department of Obstetrics, Gynecology, and Reproductive Sciences at UCSF and they are available to answer questions about the study as well.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask the study doctor.

You are being asked to take part in this study because you are a pregnant woman or a recently pregnant woman who is under investigator for Coronavirus (COVID-19) or has been diagnosed with COVID-19.

Why is this study being done?

The purpose of this study is to collect health information, including the course and outcome of pregnancy, among pregnant/postpartum women under investigation for COVID-19 or who have been diagnosed with (COVID-19). The goal of the study is to better understand how pregnant/postpartum women are effected by COVID-19 including what their symptoms are, how long they last, and how COVID-19 may impact their pregnancy and/or delivery.

This study is supported by the UCSF Department of Obstetrics, Gynecology, and Reproductive Sciences.

How many people will take part in this study?

About 2000 people will take part in this study.

What will happen if I take part in this research study?

Enrollment (Baseline):

- The study will be discussed with you, and you will be asked to review and verbally agree to participate in the study.
- You will complete questionnaires online or on paper about your medical and pregnancy history, current medication, symptoms, mood, questions about smoking history, marijuana

use, alcohol use, illegal drug use, and care experiences including racial and ethnic discrimination.
- You will be asked to complete a medical records release form for you and your baby so we can obtain a report of your COVID-19 investigation and your infant's well-baby visits. Medical records are kept confidential. Before we request any medical records, you must sign an Authorization for Release of Health Information which will specify which records will be released. You may still participate in the study if you do not agree to the release of medical records.

The questionnaires will take about 30 minutes to complete.

Follow-up: Once a week for 4 weeks

After you enroll and complete the initial baseline questionnaires, study staff from UCSF will contact you by phone, mail, text message, or email to complete a brief questionnaire about your health status. This contact will occur once a week for 4 weeks after enrollment.

These questionnaires will take about 10 minutes to complete.

Follow-up: 8-Week Visit

Study staff at UCSF will contact you by phone, mail, text message or email to complete questionnaires about your health and medical status, mode, and your baby's health, about 8 weeks after enrollment.

These questionnaires will take about 15 minutes to complete.

Follow-up: Month 6 Visit

Study staff at UCSF will contact you by phone, mail, text message or email to complete questionnaires about your health and medical status, mood, and your baby's health, about 6 months after enrollment.

These questionnaires will take about 15 minutes to complete.

Final Visit: Month 12 Visit

Study staff at UCSF will contact you by phone, mail, text message or email to complete questionnaires about your health and medical status, mood, and your baby's health, about 12 months after enrollment.

These questionnaires will take about 15 minutes to complete.

How long will I be in the study?

Participation in the study will last about 12 months. There will be 8 times that we contact you to complete questionnaires (enrollment, then once a week for 4 weeks, 8 Weeks, 6 months, and 12

months). All together, the total time it may take to complete all of the questionnaires over the year is 1 hour 55 minutes.

It is important for us to keep in contact with you so we can understand the long-term impact of COVID-19 on pregnant/postpartum women. The questionnaires can be completed electronically through our website, on paper and mailed to our office, or over the phone.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study staff if you are thinking about stopping or decide to stop. The study doctor may stop you from taking part in this study at any time if she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

There are minimal risks for participants in this study which include:

- *Anxiety while completing study questionnaires:* Some of the questions you will be asked may cause you to feel uncomfortable or cause you anxiety. You may skip any questions that you do not feel comfortable answering.

- *Confidentiality:* Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your name will not be used in any published reports about this study.

Are there benefits to taking part in the study?

There is no direct benefit to you from participating in this study. However, we hope that the information gained from the study will help researchers understand the impact of COVID-19 on the health and well-being of pregnant women.

What other choices do I have if I do not take part in this study?

You may elect not to participate in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Information gathered directly from you by the researchers and through review of the medical record will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- The Center for Disease Control

Are there any costs to me for taking part in this study?

You will not be charged for any of the study activities.

If you opt to receive your surveys via text message, standard messaging and data rates may apply. You may opt out of this service.

Will I be paid for taking part in this study?

In return for your time and effort you will be paid up to $80 in electronic or plastic gift cards for taking part in this study. When you complete the initial questionnaires at Enrollment, at Week 8, at Month 6, and at Month 12 visits you will receive $20 in gift cards. A gift card will be emailed or mailed to you 1-2 weeks after each visit.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to the study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor, Vanessa Jacoby, MD at 415-514-8299.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.