

**UNIVERSITY OF WASHINGTON
CONSENT FORM TO STUDY COVID-19 IN PREGNANT WOMEN**

Immune Response to Infections in Pregnant and Non-Pregnant Women and Men

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24-hour emergency telephone number: 206-598-6190 (University of Washington paging operator, please page the chief obstetric resident on call)

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

We are trying to find out how the virus that causes the infectious disease, called COVID-19, might cause problems in pregnancy such as preterm labor and more severe disease in the mother. The purpose of this study is to investigate the mother's and newborn's immune response to understand differences between women with COVID-19 in pregnancy and healthy women. We would like to obtain blood from you, cord blood from the placenta after the delivery, amniotic fluid and pieces of the placenta (the "afterbirth"). We will use your samples to study how the immune system in the mother, placenta and newborn responds to the virus causing COVID-19. If we decide to use your samples for a purpose not described in this application we will ask the IRB for approval to do so.

STUDY PROCEDURES

If you agree to be a part of the study we will do the following procedures. Your doctor or obstetrical care provider will likely recommend that you have a blood draw several times during your pregnancy.

- 1) We would like to take 4 teaspoons of blood from you up to 3 times on different days prior to delivery of your infant. It will take about 30 more seconds during your blood draw. It is likely that we can do this at the time of other blood draws requested by your doctor. If it is not possible to have your blood drawn with a medically indicated draw, we would like to draw your blood just for the study, which will take about 3 minutes.
- 2) We would like to collect extra blood (up to 8 teaspoons) from the umbilical cord after delivery. This blood is usually thrown away.
- 3) We would like to collect 4 teaspoons of amniotic fluid if cesarean section is performed as part of your regular care at the time of your delivery.

- 4) We would like to obtain small pieces of your placenta (afterbirth). The placenta is usually thrown away.
- 5) After your delivery, we would like to draw 4 teaspoons of your blood from a vein in your arm after your delivery, at a time convenient for you. This will take about 5 minutes.
- 6) We will review your medical record and your baby's medical record and gather information such as medical history, lab results, information about surgeries, treatment, and how you and your baby have done after the birth.
- 7) We would also like you to fill out two short questionnaires. One is about your health and the other one is about your race and ethnicity. This will take about 5 minutes. All information we get will be confidential. You may refuse to answer any question.

We will also collect DNA (from your blood) and test it to see if we can discover how the way genes make proteins might make someone susceptible to having more severe COVID-19 disease or related pregnancy complications. Since these results are not clinically relevant to you, we will not give you the results.

We may want to contact you in the future to ask about the health of your baby. Please indicate below whether or not you give your permission to be contacted in the future.

RISKS, STRESS, OR DISCOMFORT

Some people feel that being in a study and providing samples is an invasion of their privacy. We will address concerns about your privacy in the "Other Information" section of this consent form. The insertion of the needle to draw blood may cause temporary discomfort and a bruise may form where the needle enters the vein. Rarely, an infection may develop. Removing 8 teaspoons of cord blood from the placenta after delivery will take 3-5 seconds and causes no risk to your baby. Taking some pieces from the placenta after it is delivered and collecting some amniotic fluid creates no risk for you or your infant.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You may choose to participate in the study or not to participate in the study. Your decision will not affect your medical care. You do not have to be in the study to receive the medical care that you need.

BENEFITS OF THE STUDY

You and your baby will not benefit from this study. We hope that this study will help us provide better care for mothers and babies who are born premature.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the National Institutes of Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

Information about you is confidential. We will label your samples and the information about you with a number, not your name. We will keep your name, address, telephone number, and other information that might identify you separate from your sample. The link between your study ID and your identifiers will be kept by the University of Washington researchers indefinitely. Dr. Adams Waldorf will have access to your identifiable data while a link exists. If we publish the results of this study, we will not use your name. Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is possible that unauthorized persons might discover that you are in this study, or might obtain information about you.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You will not be charged for the extra testing on the samples collected. You will be compensated as a thank you for the time you spend completing the sampling procedures. Specifically, for each visit we will give you \$25 for a blood draw or \$10 if the blood draw is only from the umbilical cord after delivery.

The National Institute of Health requires that information regarding your race and ethnicity be collected. You will be given a form to complete; however, your response is strictly voluntary. The information will not be linked to your name or medical records. If you want to withdraw your samples from use please contact Dr. Kristina Adams Waldorf at (206) 543-5555.

RESEARCH-RELATED INJURY

If you think you have an injury or illness related to this study, contact Dr. Kristina Adams Waldorf right away at 206-543-5555. The study staff will treat you or refer you for treatment. The University of Washington will pay up to \$10,000 to treat injury or illness caused by the study. No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form.

Printed name of study staff obtaining consent	Signature	Date
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Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

By signing this consent, I give my permission for the following specimens to be collected:

Prior to delivery:

- 1) Up to four blood draws of up to 4 teaspoons of my blood on separate days

During delivery or immediately following:

- 2) 4 teaspoons of amniotic fluid if a cesarean section is performed as a standard part of my care
- 3) Pieces of the Placenta (afterbirth)
- 4) Up to 8 teaspoons of umbilical cord blood

After Delivery:

- 5) One blood draw of up to 4 teaspoons of my blood

Also, we would like to contact you within 5 years after the date on this form to ask you about your health and your baby's health.

I understand that providing my address and phone number is my choice and not required to participate in this study.

Telephone: _____

Address: _____

Email Address: _____

Printed name of subject

Signature of subject

Date

Copies to: Researcher and Subject