UNIVERSITY OF WASHINGTON
CONSENT FORM: VACCINE IMMUNE RESPONSE IN PREGNANCY
PREGNANT ADULTS

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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 immune response to vaccines differs in pregnant women and non-pregnant adult women. The purpose of this study is to investigate the mother's immune response to understand differences between women who receive a particular vaccine in pregnancy and healthy women. We are interested in studying immune responses to the COVID-19, seasonal influenza and TdAP vaccines. Additionally, we are interested in how immune responses might differ between currently available COVID-19 vaccines. We would like to obtain blood from you, cord blood from the placenta after the delivery, and amniotic fluid. We will use your samples to study how the immune system in the mother, placenta and newborn responds to the vaccines in pregnancy. 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.

1) We would like to take 2 teaspoons of blood from you up to 5 times on different days relative to your vaccination. If this is for a COVID-19 vaccine, the days are relative to the **first** vaccine.
    a. Visit 1: within two months **before** your vaccine
    b. Visit 2: Day 1 (1 day after your vaccine)
    c. Visit 3: Day 3 (3 days after your vaccine)
    d. Visit 4: Day 10 (10 days after your vaccine)
    e. Visit 5: Day 21 (21 days after your vaccine)

2) We would like to collect extra blood (up to 8 teaspoons) from the umbilical cord after delivery if you are delivering at UW Medicine. This blood is usually thrown away.
3) We would like to collect 2 teaspoons of amniotic fluid if a cesarean section delivery is performed as a standard part of your care and if you are delivering at UW Medicine.
4) 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.
5) We would also like you to fill out short questionnaires about respiratory symptoms and whether or not you've previously been diagnosed with COVID-19 or influenza. This will take less than 5 minutes. All information we get will be confidential. You may refuse to answer any question.

We will also collect RNA (from your blood) and test it to see if we can discover how cells respond individually to vaccination. Since these results are not clinically relevant to you, we will not give you the results.

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. Dizziness and fainting may occur following a blood draw. 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. Collecting some amniotic fluid at the time of a Cesarean section 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 receiving novel vaccines.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from a gift fund at the University of Washington.

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.

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 for a total of up to $125.

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.

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 or call collect at (206) 221-5940. 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 five blood draws (up to 2 teaspoons) of my blood on separate days

During delivery or immediately following:

2) 2 teaspoons of amniotic fluid if a cesarean section is performed as a standard part of my care if I am delivering at UW Medicine
3) Up to 8 teaspoons of umbilical cord blood if I am delivering at UW Medicine

Also, we would like permission to contact you for up to 5 years to ask you or your baby to participate in new research.

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