

For the Use of Patient Health Information for Research

Program Title: Immune Responses to Infections in Pregnant and Non-Pregnant Women and Men
Lead researcher: Kristina Adams - Waldorf
Institution of lead researcher: University of Washington

A. Purpose of this form

The purpose of this form is to give your permission to the research team to obtain and use your/your baby's patient health information. Your/your baby's patient information will be used by the program named above.

State and federal privacy laws protect your/your baby's patient information. These laws say that, in most cases, your health care provider can release your/your baby's identifiable patient information to the research team only if you give permission by signing this form.

You do not have to sign this permission form. If you do not, we will not collect any information about you or your baby. Your decision to not sign this permission will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

B. The patient information that will be obtained and used

"Patient information" means the health information in your/your baby's medical or other healthcare records. It also includes information in your/your baby's records that can identify you/your baby. For example, it can include your/your baby's name, address, phone number, birthdate, and medical record number.

1. Location of patient information

By signing this form you are giving permission to the following organization(s) to disclose your/your baby's patient information for this follow up program.

- UW Medicine (includes University of Washington Medical Center & Clinics; Harborview Medical Center & Clinics; UW Medicine Neighborhood Clinics; University of Washington Sports Medicine Clinic; UW Medicine Eastside Specialty Center; Hall Health Primary Care Center; University of Washington Physicians)

2. Patient information that will be released for research use

This permission is for the health care provided to you and your baby from the start of your pregnancy until 5 years from your delivery date.

The specific information that will be released and used for this follow up program is described below:

- Date of birth (or age)
- Date of last menstrual period
- Expected date of delivery
- Any maternal risk factors
- Contraception

- Medical history of previous pregnancies
- Current medications
- Prenatal test results
- Course and outcome of pregnancy
- Characteristics of the baby
- Medical History/treatment
- Laboratory/diagnostic tests
- Radiology Records
- Consultations
- Hospital Discharge Summary

C. How your/your baby's patient information will be used

1. Who may receive your/your baby's patient information

- The sponsor of this research. "Sponsor" means any persons or companies that are: working for or with the sponsor, or are owned by the sponsor
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Institutional oversight review offices at the research site, the UW, or state
- Other researchers who may use your/your baby's information for future research studies

2. Why your/your baby's patient information will be used and/or given to others

- To do the research
- To study the results, and
- To see if the research was done right

If the results of this study are made public, information that identifies you/your baby will not be used.

The researcher will use your/your baby's patient information only in the ways that are described in the follow-up program consent form that you sign and as described in the HIPAA Authorization here.

You can ask questions about what the research team will do with your/your baby's information and how they will protect it.

The privacy laws do not always require the receiver of your/your baby's information to keep your/your baby's information confidential. After your/your baby's information has been given to others, there is a risk that it could be shared without your permission.

You have the right to obtain your/your baby's patient information in your/your baby's healthcare record. The study procedures do not include a plan to share the research results, though you may be able to request them through the Washington State Public Records Request system after the study is done.

D. Expiration

This permission for the researchers to obtain your/your baby's patient information ends when 10 years after the date of delivery.

E. Canceling your permission

You may change your mind at any time. To take back your permission, you must send your **written** request to:

Dr. Kristina Adams - Waldorf
University of Washington
Box 356460
Seattle, WA 98195

If you take back your permission, the research team may still keep and use any patient information about you/your baby that they already have. But they can't obtain more health information about you/your baby for this program unless it is required by a federal agency that is monitoring the research.

Changing your mind will not affect any other treatment, payment, health care, enrollment in health plans or eligibility for benefits.

F. Giving permission

I have read this HIPAA Authorization form describing how my/my baby's patient information will be used. I have had a chance to ask questions about the use of my/my baby's patient information and I have received answers to my questions. I agree to the use of my/my baby's patient information for this program.

Printed Name of Program Subject

Birthdate

Signature of Program Subject

Date of signature

You will receive a copy of this signed form. Please keep it with your personal records.