

MAGEE-WOMENS HOSPITAL
of the University of Pittsburgh Medical Center
OB/GYN/RS Department

CONSENT TO PARTICIPATE IN A RESEARCH REGISTRY

TITLE: Magee-Womens Hospital Research Registry for Women and Infants Health

PRINCIPAL INVESTIGATOR: Judith Balk, MD, MPH
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CO-INVESTIGATORS:

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Magee-Womens Hospital Medical Staff (A complete, current listing is available upon request).

What is the purpose of this research registry?

We are asking for your permission to put information about you and/or, your baby, in a Women and Infants Health Research Registry. This research registry will allow us to look at medical charts to learn about diseases that particularly affect women and infants. It will also be used to find patients, such as you, who may want to take part in research studies on women and infants health.

Who is being asked to participate?

Patients 18 years of age or older who come to Magee-Womens Hospital (MWH) or go to a provider affiliated with MWH are being asked to participate in this research registry for Women and Infants Health. Patients under the age of 18 are being asked for permission to enroll their babies in this research registry.

What will my participation involve?

If you agree to participate in this research registry, your and/or your baby's Magee and associated physicians medical charts may be looked at by researchers to see if you qualify to take part in research studies. You may then be contacted by a researcher who will talk to you about a specific study. If you sign up now for the research registry, you still can refuse to take part in any research study that these people talk to you about. And if you decide to take part in any research study, you will have to sign a separate permission form for that study. By agreeing to participate in the research registry, you also agree to let investigators include your / your baby's current and/or future medical record information in research. Your baby's participation in this registry will end when your baby turns one year old.



Who will know about my participation?

Records pertaining to your and/or your baby's participation in this research registry will be kept by the Magee Health Medical Records Department, and will be available only to Magee researchers. A current, complete listing of these individuals will be provided to you upon your written request. All information about your and/or your baby's hospital treatment will be handled in a confidential (private) manner consistent with other hospital medical records. You will not be specifically identified in any publication of research results.

Who will have access to my and/or my baby's identifiable medical record information contained in the research registry?

In addition to the investigators, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review information contained within the research registry to ensure that the research registry adequately protects your confidentiality. Also, in unusual cases, your research records may be released in response to an order from a court of law.

For how long will my and/or my baby's medical record information continue to be placed in the research registry and used for research purposes?

We will continue to include your medical record information in the research registry indefinitely unless you take back your permission for participation in the research registry. Your baby's participation ends when your baby turns one year old.

Is my participation voluntary?

Your participation in the research registry is completely voluntary. Whether or not you provide your permission for participation in this research registry will have no affect on you and/or your baby's current or future medical care at MWH or related health care provider.

May I withdraw, at a future date, my consent for participation?

If you change your mind, you can withdraw from the research registry at any time. There will then be no additional collection of your medical record information and no further use for the research purposes described above. Once you notify that you are withdrawing your permission, any researchers who have been given your name or contact information will be notified not to contact you or to access your medical records. However, any research use of your medical record information before the date that you withdraw your permission will not be destroyed. To withdraw, you need to write a letter to the Principal Investigator listed above which says that you wish to withdraw. Withdrawing from this research registry will not change your and/or your baby's care and benefits at MWH.



What are the possible risks of my participation?

Only approved investigators associated with the research registry and their research staff will see personal information about you or your baby that is contained within the research registry. However, there is a possible risk that information about your health and that of your baby might become known to individuals other than research registry investigators.

What are the possible benefits of my participation?

There are no anticipated benefits; however, a possible benefit is that you may be informed of future research for which you are and/or your baby may be eligible.

Will I be paid for my participation?

You will not receive any money for participating in this research registry.

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VOLUNTARY CONSENT:

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research registry, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh, (1-866-212-2668).

I AM 18 YEARS OF AGE OR OLDER AND I CONSENT TO ENROLL:

- Myself** _____
Printed Name of Mother
Mother Date of Birth

- My Baby** _____
Printed Name of Baby

I understand that as a minor the above stated child is not allowed to participate in research without my consent. By signing this form, I agree to my and my infant's participation in this research study. A copy of this consent form will be given to me.

Signature of Mother for Herself and Baby

Date

I AM UNDER THE AGE OF 18 AND I CONSENT TO ENROLL MY BABY:

Printed Name of Mother

Mother Date of Birth

Printed Name of Baby

I understand that as a minor the above stated child is not allowed to participate in research without my consent. By signing this form, I agree to my baby's participation in this research study. A copy of this consent form will be given to me.

Signature of Mother for Baby

Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of the Women and Infants Health Research Registry to the above-named individual, and I have discussed the possible risks and potential benefits of participation in this Research Registry. Any questions the individual has about this Research Registry have been answered, and the physicians and research staff associated with Women and Infants Health will be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

