Sample only; cannot be used without Board approval.

PREGNANT PARTNER INFORMATION RELEASE FORM
For Research Purposes

TITLE:

PROTOCOL NO.:
WIRB® Protocol #

SPONSOR:

INVESTIGATOR:

STUDY-RELATED PHONE NUMBER(S):

Purpose of this Release Form

You became pregnant while your male partner (the biological father of your baby) was taking part in a research study.

With this release form, we are asking for your permission to collect medical information about your pregnancy, its outcome, and if appropriate, the birth and health of your baby. We want to see if the study drug(s) your partner was given have any effect on your pregnancy and/or the health of your baby.

This release form may contain words that you do not understand. Please ask the research study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this release form to think about or discuss with family or friends before making your decision about the collection of your pregnancy information.

If you agree to this collection, we will collect information about your pregnancy, the outcome of your pregnancy, and if appropriate, the birth and the health of your baby. We will give you a signed and dated copy of this release form to keep for your records.

Risks to You

The risk to you from allowing us to collect this information is possible loss of confidentiality of your/your baby's medical records information.

Benefits to You

You will not receive any direct benefit from allowing the collection of information about your pregnancy and its outcome. But what we learn from your information might lead to better understanding of the effect on pregnant women and their unborn babies who are exposed to the study drug taken by the baby's father during a research study.

Costs to You

There will be no cost to you for allowing us to collect this information about your pregnancy.

The regular medical care costs related to your pregnancy and the birth and care of your baby will be billed to you and/or your health insurance in the usual way.

Your Alternative

Your alternative is to not allow us to collect and use this information for research purposes.

Your Decision is Voluntary

Your decision to allow us to collect and use information about your pregnancy and the birth and health of your baby is completely voluntary. If you decide to allow us to collect this information, you can change your mind at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide not to allow the collection and use of the information, this will not affect medical care for either you or your baby.

Authorization to Use and Disclose Information for Data Collection Purposes

This section of the release form is called an "authorization." It describes the information that we will collect, why we will collect it, and with whom we will share it.

What information about you and your baby might be used and given to others?

The research study doctor will get personal and medical information about your pregnancy and the birth and health of your baby.

Who might use and give out information about you and your baby?

The research study doctor and the study staff.

Who else might get this information?

The sponsor of the research study. "Sponsor" means any people and companies that

- are working for the sponsor,
- are working with the sponsor, or
- are owned by the sponsor.

Your information might also be seen by

- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- [site specific]
- the Western Institutional Review Board® (WIRB®)

Why will your/your baby's information be used and/or given to others?

Your/your baby's information might be used by the research study doctor or others

- to see if the study drug affects you and your baby
- to make sure the research was done right

If the results of the research study are made public, information that could identify you or your baby will not be used.

What if you decide not to give permission (authorization) to use and give out (disclose) your/your baby's information?

Your information and/or your baby's information will not be collected or included in the research study.

Can you review or copy your/your baby's information?

Yes.

Can you withdraw or revoke (cancel) your permission?

Yes, but this permission will not stop automatically.

You can withdraw your permission to use and disclose your/your baby's health information at any time. You do this by writing to the research study doctor.

When you withdraw your permission, no new information that identifies you or your baby will be collected. Information that has already been collected for the research study might still be used and given to others.

Is your/your baby's health information protected after it has been given to others?

There is a risk that your health information and your baby's health information will be given to others without your permission.

If You Have Questions

You can contact the research study doctor, [site specific], at [site specific] for any of the following reasons:

- you have questions about the collection of your/your baby's information or you have questions about the research study that your baby's father is in
- you think you or your baby have a problem related either to the collection of your information or to the research study
- you have questions, concerns, or complaints to report about the collection of your/your baby's information

If you have questions about your/your baby's rights or if you have questions, concerns, or complaints about the research study your male partner is in, you can contact

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research studies.

WIRB will not be able to answer some questions, but you can contact WIRB if the research study staff cannot be reached or if you want to talk to someone other than the research staff.

Do not sign this release form unless you have had a chance to ask questions and you have received satisfactory answers to all your questions.

If you agree to the collection of information about your pregnancy and the birth and health of your baby, you will receive a signed and dated copy of this release form for your records.

Pregnant Partner Signature

I have read the information in this release form (or someone read it to me).

I have had an opportunity to discuss the collection of this information with the research study doctor or research staff. My questions have been answered to my satisfaction.

I agree to allow the collection of information about my pregnancy and the birth and health of my baby.

I authorize the use and disclosure of my information and my baby's information to the parties listed in the authorization section of this release form for the purposes described.

Consent and Assent Instructions:
Consent: Pregnant partners able to provide consent must sign on the line below
Consent is provided by the Legally Authorized Representative for pregnant partners unable to consent
Assent (for individuals who require a Legally Authorized Representative):
Complete the assent signature block below, as applicable.

Pregnant Partner's Printed Name _____

_____ _____
Signature of Pregnant Partner Date
(completed by the pregnant partner herself)

OR

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Pregnant Partner's Legally Authorized Representative or Relationship to Pregnant Partner

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

ASSENT SIGNATURES, For pregnant partners with a Legally Authorized Representative:

Assent:

For pregnant partners who have a legally authorized representative, I confirm that:

- I have explained the information in this consent form to the extent compatible with the individual's understanding, and the individual has agreed to the collection of the medical information outlined above.

OR

- The individual is not able to assent due to lack of mental capacity.

_____ _____

Signature of Person Conducting Assent Discussion Date

10-07-2014 version