**PREGNANT PARTNER INFORMATION FORM**

**Title:**

**Protocol no.:**

**Sponsor:**

**Investigator:**

**Study-related**

**Phone number(s):**

**Purpose of this Form**

You became pregnant while your partner was taking part in a research study. Your partner has received an investigational drug (a drug not approved by the Food and Drug Administration). It is recommended that you promptly report this to the health provider taking care of you during your pregnancy. Your pregnancy care provider can contact the study doctor to receive appropriate medical information about the investigational drug.

There is not a lot of human data (information) about the possible risk to you or your baby. The sponsor of the research study is asking for your permission to collect medical information about your pregnancy, its outcome, and if appropriate, the birth and health of your baby. This form may contain words that you do not understand. Please ask the 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 form to think about or discuss with family or friends before making your decision about the collection of your pregnancy information.

If you agree, your partner’s study team or the sponsor [Name of sponsor] of the study will collect your health information.

If you agree to permit collection of information about your pregnancy and, if appropriate, the health of your baby, you will be asked to sign an authorization (release of information) form that will be provided by the study team, your pregnancy care provider, primary care doctor, and/or your baby’s pediatrician. It describes the information that will be collected and with whom it will be shared.

**Risks to You**

The risk to you from allowing the collection of this information is possible loss of confidentiality of your/your baby’s medical records information. Every effort will be made to protect the confidentiality of this information but this cannot be guaranteed.

**Benefits to You**

You will not receive any direct benefit from allowing the collection of information about your pregnancy and its outcome. Your information might lead to a better understanding of the effect the investigational drug has on sperm and the outcomes of pregnancy.

**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 Decision is Voluntary**

Your decision to allow the collection and use of information about your pregnancy and, if appropriate, the birth and health of your baby is completely voluntary. If you decide to allow the collection of 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. Your decision will also not affect your partner and their ability to continue to participate in the study.

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.

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

The study doctor or sponsor will get personal and medical information about your pregnancy and, if appropriate, the birth and health of your baby.

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

* The study doctor and the study staff.
* The sponsor of the 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

• The Duke University Health System Institutional Review Board (IRB)

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

Your/your baby’s information might be used by the study sponsor or others to see if the study drug has affected you and your baby. If the information results in a publication, information that could identify you or your baby will not be used. This information will be kept by the sponsor indefinitely.

**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.

**Can you review or copy your/your baby’s information?**

Yes.

**Can you withdraw or revoke (cancel) your permission?**

Yes.

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

Their address is (insert whichever appropriate, *mailing/email address of PI*)

When you withdraw your permission, no new information that identifies you or your baby will be collected. Information that has already been collected will still be used and given to others as described above.

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

Not necessarily. There is a risk that your health information and your baby’s health information provided to those above may be further disclosed to other individuals and groups. In that event, the information may no longer be protected by federal privacy laws.

Although health information collected as part of a study is usually protected, in some cases information can be obtained by law enforcement under applicable law.

**If You Have Questions**

You can contact the 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 study that your partner is in

• you think you or your baby have a problem related either to the collection of your information or to the study

• you have questions, concerns, or problems to report about the collection of your/your baby’s information

Contact Dr. (PI’s Name) at (PI’s Number with Area Code)during regular business hours and at (PI’s 24-hour Number with Area Code) after hours and on weekends and holidays.

For questions about your rights, or to discuss problems, concerns or suggestions related to the collection of your protected health information for this study, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

Do not sign the 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 the release form for your records.

**Pregnant Partner Signature**

“I have read the information in this information form (or someone read it to me) and the DUHS [or other entity] authorization (release of information) form.

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.”

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Printed name of Pregnant Partner

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Signature of Pregnant Partner Date Time