**Please note that instructional text is yellow highlighted.**

**All instructional text should be removed prior to submission to WCG IRB.**

PREGNANT PARTNER INFORMATION RELEASE FORM

For Research Purposes

**Title:** Title from first page of protocol/study plan

**Protocol No.:** Sponsor’s protocol number

WCG IRB Protocol #[will be assigned after submission to WCG]

**Sponsor:** Name

**Investigator:** Name

 Address

 City, Province, Postal Code

**STUDY-RELATED**

**PHONE NUMBER(S):** Number

 Number (24 hours)

 [A 24-hour phone number is required] (for studies that are more than minimal risk)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

**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, 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, your provincial health plan, and/or your health insurance in the usual way.

You will not receive any money for allowing collection of your/your baby’s health information. The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

**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 otherwise 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.

**Confidentiality and the Collection, Use and Disclosure of Your Personal Information**

This section of the release form tells you about your/your baby’s privacy rights. If you sign this form, you will be giving your permission for the collection, use and disclosure of your/your baby’s personal information for the purposes of this study.

**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.

**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.

For the purposes set out above, the study doctor and study staff may share and disclose information about you/your baby to the sponsor. "Sponsor" includes any persons or companies contracted by the sponsor to have access to the research information during and after the study. The information will be given to Health Canada. It may also be given to the U.S. Food and Drug Administration (FDA) and governmental agencies in other countries where the study drug may be considered for approval. Information, including your/your baby’s medical records, which identifies you/your baby and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

* the sponsor, including anyone working for or with the sponsor, or owned by the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

* Health Canada;
* the FDA;
* governmental agencies in other countries; and
* WCG IRB.

There may be other circumstances where your/your baby’s information may be disclosed if required by law or for your/your baby’s benefit in the event of an emergency.

You have access rights to your/your baby’s personal information and the possibility to correct your/your baby’s personal information according to local law and procedures. You can discuss this with your study doctor. You may take away your permission to collect, use and share information about you/your baby at any time by providing reasonable notice to the study doctor. If you do this, no new information about you/your baby will be gathered after that date. However, the information about you/your baby that has already been gathered may still be used and given to others as described in this form.

Information collected about you/your baby will be kept as a part of the data for the research study in which your partner is a participant. The research study data will be kept for 15 years as required by Health Canada.

**If You Have Questions**

You can contact the research study doctor or study team at the number(s) listed in this document 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.

This research is being overseen by WCG IRB, the Research Ethics Board (REB) for this study. An REB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

* You have questions, concerns, or complaints that are not being answered by the research team.
* You are not getting answers from the research team.
* You cannot reach the research team.
* You want to talk to someone else about the research.
* You have questions about your rights as a research participant.

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.

You have not waived any of your rights to legal recourse, including if you or your baby are harmed as a result of the research, by participating in this research.

**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.

 Signature of pregnant partner or adult participant’s legally Date

 authorized representative

 Printed name of participant Date

 (not required if participant personally provided consent)

 Signature of person obtaining consent Date