**Pregnancy Follow-Up Consent Form**

TITLE

Protocol #

Sponsor:

Investigator: [First, Last name], MD

University of Kansas Medical Center

913-588-xxxxx

You are being asked to sign this consent form because:

• You recently became pregnant while participating in the above-named study within XX days after the last dose of the study treatment \_\_\_\_\_\_\_\_\_\_\_\_.

**Or**

• Your partner received the study treatment\_\_\_\_\_\_\_\_, as part of a clinical study, and you became pregnant within XX days of his last dose of the study treatment.

Since you became pregnant while you (or your partner) were participating in the main study, the sponsor would like to collect information about your pregnancy. Providing this information is entirely voluntary. This form describes the possible risks and benefits as well as information for safety monitoring of your pregnancy. Please read it carefully and ask as many questions as you need to, before deciding about this research. You can ask questions now or anytime during the study.

You will be informed of any new information that might cause you to change your mind about participating.

**Why am I being asked to take part in this safety monitoring activity?**

You are being asked to take part in this safety monitoring activity because you recently became pregnant while you (or your partner) were participating in the main treatment study receiving the study treatment \_\_\_\_\_\_\_\_\_\_\_ (or within XX days of the last dose of\_\_\_\_\_\_\_\_\_\_\_\_).

The risks to you or your baby are not known. Therefore, the study sponsor, [Sponsor], would like to collect information about you and your newborn baby to [*Please adjust bullets below as applicable to your study*]:

• Determine if there is any risk to the mother or baby from the mother’s use of the study drug.

**OR**

• Determine if there is any risk to the mother or baby from the father’s use of the

study drug since you became pregnant.

The purpose of this form is to inform you of how your (and your baby’s) personal health information may be used or given to others so that you can decide whether to permit the use and disclosure (sharing) of your (and your baby’s) health information for the purposes stated in this form. It is important that any symptoms are reported promptly to the doctor monitoring your pregnancy, regardless of whether or not you think these changes are related to the study treatment, \_\_\_\_\_\_\_\_\_\_\_.

**What will I be asked to do?**

We would like to collect as much information as possible to help determine if there is any risk to you, or the baby. The researchers would like to follow you and your baby’s clinical course during the pregnancy and up until delivery. Researchers will ask questions and record information about:

• The outcome of the pregnancy, including spontaneous or voluntary termination

(miscarriage or abortion).

• Details of the birth and the presence or absence of:

* any birth defects, congenital abnormalities, or maternal and/or newborn complications.

**What are the possible risks or discomforts?**

There are no medical risks associated with the collection of information about your pregnancy. The main risk of this safety monitoring activity is the possible loss of confidentiality of your, and/or your baby’s medical record information.

There may be pregnancy risks associated with the study treatment that are not yet known.

**Are there benefits to being in this safety monitoring activity?**

You will not benefit from this safety monitoring. Researchers hope that the information that may be useful for other patients who may become pregnant while on this research study.

**Will it cost anything to be in the safety monitoring activity?**

You will not be charged for being in the safety monitoring activity. If you and/or your baby have any medical expenses at KUMC related to your pregnancy, delivery, or the care of your baby before or after the baby’s birth, they will be billed to you or your medical

/hospital insurance and/or third party provider.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the study sponsor) and KUMC will not be responsible for any costs related to your pregnancy, delivery, or the care of your baby before or after the baby’s birth.

**Will I get paid to participate in the safety monitoring activity?**

There is no payment for this safety monitoring activity.

**Will the researchers get paid for doing the safety monitoring activity?**

The institution (KUMC Research Institute, Inc.) will receive payments from the sponsor, [Sponsor]**,** for conducting this study. Payments will be used for research purposes only.

**What happens if I get hurt or sick during in the safety monitoring activity?**

If you or your baby gets hurt or sick during the safety monitoring activity, then neither [Sponsor] nor KUMC will pay any money to you, or pay your medical bills. You or your insurance or government program will be responsible for paying any bills to treat any illness or injury if you or your baby gets hurt or sick during this safety monitoring activity.

Payments will not be offered for other expenses (such as time off work, lost wages, childcare, etc.). You do not give up any legal rights by signing this form. If you think you have been harmed as a result of this research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

**Do I have to be in the safety monitoring activity?**

Your agreement in providing your and your baby’s health information is voluntary. You can choose whether or not to sign this form. Even if you decide not to join the safety monitoring activity, you can still come to KUMC for services and treatment which would be billed to you or your medical /hospital insurance and/or third party provider in the ordinary manner.

If you are the partner of a study participant, your partner can continue participating in the study even if you decide not to participate in the safety monitoring activity.

**What other choices do I have?**

This is not a treatment study. You can choose not to be in the safety monitoring activity.

**How will my privacy be protected?**

The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name and that of your baby will not be used in any publication or presentation about the study. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you are not a patient of The University of Kansas Medical Center, you might be required to complete additional paperwork in order to obtain your medical records. If you decide not to sign the form, your information will not be collected and you cannot be in the safety monitoring activity.

**Add the required HIPAA Authorization language in the remainder of this section if protected health information is being used or created for the project.**

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the safety monitoring activity.

The researchers will only use and share information that is needed for the safety monitoring activity. To do the safety monitoring activity, they will collect health information from the safety monitoring activities and from your medical record.Your health care providers may release your private health information to Dr. [PI name] and the research team. The team may use any and all of your information needed for the safety monitoring activity. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this safety monitoring activity and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

The research team will share your safety monitoring activity data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

* Federal agencies that oversee human research (if a study audit is performed)

**Remove any of bulleted list below that does not apply:**

* Study partners, including [identify partnering institutions]
* [Funding source/sponsor]
* Business partners of the sponsor
* Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
* The FDA and similar groups in foreign countries [This bullet can be removed for studies that do not involve FDA-regulated products.]
* Other groups that help manage or provide services to support the study
* Ethics committees that review the study for other locations

Your permission to use and share your (or your baby’s) health information will not expire unless you cancel it. To cancel your permission, please write to [PI Name]. The mailing address is [PI Name], University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you (or your baby) unless they need information about a side effect of [the study drug, device, treatment]. They are permitted to use and share information that was gathered before they received your cancellation.

**Can I stop being in the safety monitoring activity?**

You may stop being in the safety monitoring activity at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC or health benefits.

You have the right to cancel your permission for researchers to use your (or your baby’s) health information. If you want to cancel your permission, please write to you Dr. [Principal Investigator] at Dr. [Principal Investigator], 3901 Rainbow Boulevard, Kansas City, KS, 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of the study drug. They may use and share information that was gathered before they received your cancellation.

**Who can I talk to about the safety monitoring?**

You can ask questions at any time about the use and sharing of your and your baby’s information. Before you sign this form, [Principal Investigator], MD, or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you

have any further questions about your rights and the use of sharing of your and/or your baby’s information, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

**Consent**

[*Principal Investigator*] or the research team has given you information about this research safety monitoring activity. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this safety monitoring activity.

By signing this form, you say that you freely and voluntarily authorize participation in this research safety monitoring activity. You agree that you can be contacted by the study doctor and be asked about the pregnancy, the birth and health of your baby. You have read the information and had your questions answered. ***You will be given a signed copy of the consent form to keep for your records.***

Print Participant’s Name

Signature of Participant Time Date

Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date