

**PREGNANT PARTNER CONSENT FORM and AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION**

**STUDY TITLE**

Principal Investigator:

Contact Phone number(s):

Instructions:

* Use this ICF template if;
  + Investigator and/or sponsor want to collect data from pregnant partner of study subject only for monitoring outcomes.
* Use the standard BioMed ICF template to create an ICF for pregnant partners if;
  + Investigator and/or sponsor want to collect information from pregnant partner of study patient for research purposes (e.g., the pregnant partner will be enrolled as a research subject).
* In both cases:
  + The partner consent form to be used should be included with the initial submission to the IRB.
  + Study staff must have initial permission from study subject before approaching the pregnant partner.

**PURPOSE OF THIS FORM**

Researchers at The University of Toledo have been informed that you became pregnant while your male partner (the biological father of your baby) 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 your doctor.

Since there is not a lot of human data 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. Please review this form carefully and ask any questions before you make a decision about whether or not you want to authorize the sponsor to collect this information. Your authorization is completely voluntary. 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 will collect your health information and provide it to the sponsor. We will give you a signed and dated copy of this form to keep for your records.

If you agree to permit collection of information about your pregnancy and the health of your baby, you will be asked to sign the authorization (release of information) at the end of this form that will allow the study team to collect information from your obstetrician, primary care doctor, and/or by your baby’s pediatrician. This form describes the information that will be collected and with whom it will be shared.

**RISKS AND DISCOMFORT YOU MAY EXPERIENCE**

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.

**POSSIBLE BENEFITS TO YOU**

You will not receive any direct benefit from allowing the collection of information about your pregnancy and its outcome. But what is learned from your information might lead to a 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. We cannot and do not guarantee or promise that you will receive any benefits from participating.

**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 by your regular health care providers in the usual way.

# **PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART**

# If you decide to allow your information to be collected, you will not receive any compensation for doing so.

# **PAYMENT OR OTHER COMPENSATION TO THE RESEARCH SITE *(Include this section only if applicable)***

# The University of Toledo is receiving money or other benefits from the sponsor of this research as reimbursement for conducting the research.

# **CONFIDENTIALITY - (USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION)**

# We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. By authorizing us to collect information about your pregnancy, you give to The University of Toledo (UT), the Principal Investigator and all personnel associated with this research study your permission to use or disclose the health information that we collect. We will use this information for the purpose of collecting information that might help us and the sponsor understand more about the potential risks to unborn children whose fathers were receiving the investigational product in our research study.

The information that we will use or disclose includes personal and medical information about your pregnancy and the birth and health of your baby. Data collected may be transferred to representatives of the Sponsor’s businesses and consultants or regulatory authorities outside of your country. Names and addresses will be removed from any information about you or your baby that leaves UT and will be replaced by a unique number linked to your partner’s trial number so that you or your baby cannot be identified from the information. We may use this information ourselves, or we may disclose or provide access to the information to the following as part of the research study:

* The Sponsor (sponsor name) and their representatives
* The U.S. Food and Drug Administration (FDA)
* Department of Health and Human Services (DHHS) agencies
* Governmental agencies in other countries
* The University of Toledo
* The University of Toledo Institutional Review Boards
* The University of Toledo Research and Sponsored Programs

Under some circumstances, the Institutional Review Board, or the Research and Sponsored Programs of the University of Toledo or their designees may review your information for compliance audits. We may also disclose your protected health information when required by law, or in response to judicial orders.

The University of Toledo is required by law to protect the privacy of your health information, and to use or disclose the information we obtain about you in connection with this research study only as authorized by you in this form. However, the information we disclose with your permission may no longer be protected by privacy laws. This means your information could be used and re-disclosed by the persons we give it to without your permission.

You have the right to revoke (cancel) the permission you have given to us to use or disclose your protected health information at any time by giving written notice to [PI name and address]. However, a cancellation will not apply if we have acted with your permission, for example, information that already has been used or disclosed prior to the cancellation. Also, a cancellation will not prevent us from continuing to use and disclose information that was obtained prior to the cancellation. Your permission for us to use and disclose your/your child’s protected health information will expire when your child reaches age 18, unless you cancel it sooner.

If you choose to cancel your permission, this will not impact your partner’s standing in the research study in any way.

A more complete statement of University of Toledo’s Privacy Practices is set forth in its Joint Notice of Privacy Practices. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the University of Toledo’s Privacy Officer at 419-383-6933.

For questions about your rights, or to discuss problems, concerns or suggestions related to the collection of your protected health information, contact the University of Toledo Biomedical [Cancer (if applicable)] Institutional Review Board at 419-383-6796.

**YOUR DECISION IS VOLUNTARY**

Your decision to allow the collection and use of information about your pregnancy and 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 his ability to continue to participate in the study. If you decide not to participate or to discontinue participation, your decision will not affect your future relations with the University of Toledo or The University of Toledo Medical Center.

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.

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| **OFFER TO ANSWER QUESTIONS** Before you sign this form, please ask any questions on any aspect of this form that is unclear to you. You may take as much time as necessary to think it over. If you have questions at any time, including but not limited to questions, concerns or problems about the collection of your/your baby’s information, or if you think you or your baby have a problem related either to the collection of your information or to the study, you may contact Dr. [PI CONTACT INFO]  If you have questions beyond those answered by the research team, please feel free to contact the Chairperson of the University of Toledo Biomedical [Cancer (if applicable)] Institutional Review Board at 419-383-6796. | | | | | |
| **SIGNATURE SECTION** **(Please read carefully)** | | | | | |
| **BY SIGNING THIS DOCUMENT YOU AUTHORIZE US TO USE OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION AS DESCRIBED IN THIS FORM.** | | | | | |
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| The date you sign this document, that is, today’s date, MUST fall between the dates indicated on the approval stamp affixed to the bottom of each page. These dates indicate that this form is valid when you enroll in the study but do not reflect how long you may participate in the study*.* Each page of this Consent/Authorization Form is stamped to indicate the form’s validity as approved by the UT Biomedical [Cancer (if applicable)] Institutional Review Board (IRB).  ***“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.”***   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | Name of Pregnant Partner (please print) |  | Signature of Pregnant Partner or  Person Authorized to Consent |  | Date |  | |  |  |  |  |  | a.m. | | Relationship to the Pregnant Partner (Healthcare Power of Attorney authority or Legal Guardian) | | |  | Time | p.m. | |  |  |  |  |  |  | | Name of Person Obtaining Consent (please print) |  | Signature of Person Obtaining Consent |  | Date |  | | **YOU WILL BE GIVEN A SIGNED COPY OF THIS FORM TO KEEP.** | | | | | | | | | | | |