**Pregnant Partner**

**Informed Consent Form**

|  |  |
| --- | --- |
| **Title of Study:** | Insert Title of Research StudyInsert Study Number |
| **Principal Investigator:** | Name of the Principal InvestigatorDepartment of Principal InvestigatorApplicable NYU School or CollegeAddressPhone Number |
| **Emergency Contact:** | Insert Emergency Contact Insert Phone Number/Pager, etc. |

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects.” These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed and dated by you for you to keep.

1. What is the purpose of this study?

Your partner was treated with an experimental drug called, *[name of drug / therapy]*.

During the course of your partner’s treatment with the drug or during *[number of months]* months after stopping treatment, you became pregnant.

As the risk to you and to your baby are unknown, we would like to collect information about you and your baby for drug safety purposes. The purpose of this form is to inform you of how you 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 you and your baby’s health information for the purposes stated in this form.

1. How long will I be in the study?

Your participation will last until *[the time after birth when data will no longer be collected]*.

1. What will I be asked to do in the study?

The type of information we wish to obtain includes: general information about your pregnancy and your baby, including gender and weight; information about the pregnancy and birth itself, including complications; and information about the health of your baby. This information is collected routinely during pregnancy, at childbirth, and during routine care of your baby*.* We would like to collect information about your baby’s health until age *[age of baby]*.

No additional monitoring beyond the collection of standard pre- and post-natal care data is planned to be done as part of this research. Information about you and your baby will be obtained from your/your baby’s medical records held by your/your baby’s health care provider and her/his institution.

1. What are the possible risks or discomforts?

This study only involves the collection of information recorded as part of your and your baby’s standard medical care. There is a small risk of a breach of confidentiality if people not connected with this study learn your/your baby’s identity or personal information.

1. What if new information becomes available?

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

1. What are the possible benefits of the study?

There will be no benefit to you or your baby by allowing this collection of information. However, information obtained from your participation in this study may help other people in the future by providing information about the effects of the study drug on pregnancy and the baby resulting from that pregnancy.

1. What other choices do I have if I do not participate?

This is not a treatment study for you. Your alternative is to not agree to provide health information about

your pregnancy and your baby.

1. Will I be paid for being in this study?

You will not be paid for participating in this study and the study will not cover any costs related to your pregnancy, delivery, or care of your baby.

1. Will I have to pay for anything?

You will not have any costs for providing your and your baby’s health information in this research study.

This research will not cover any costs related to your pregnancy, delivery, or care of your baby. You and/or your health insurance will be billed for the costs of medical care related to your pregnancy, delivery, and care of your baby. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

1. When is the study over? Can I leave the study before it ends?

Your participation is limited to the time you are pregnant and until about *[the time after birth when data will no longer be collected]* after the birth of your baby. If you decide to provide this information, you are free to stop at any time. Doing this will not interfere with you or your baby’s future care or loss of benefits you and your baby are entitled to.

1. How will you protect my/my baby’s confidentiality?

Your/your baby’s medical information is protected health information, or “PHI,” and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your/your baby’s research record as well as information in your/your baby’s medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your/your baby’s medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you/your baby receive, and so that other members of the NYU Langone Health community who may treat you/your baby have access to important information about your/your baby’s health.

You have a right to access information in your/your baby’s medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

1. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you/your baby and relates to your/your baby’s past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your/your baby’s health information with others in connection with this study, in other words, for purposes of this research, including conducting and overseeing the study.

Your/your baby’s treatment outside of this study, payment for your/your baby’s health care, and your/your baby’s health care benefits will not be affected even if you do not authorize the use and disclosure of your /your baby’s information for this study.

**What information may be used or shared with others in connection with this study?**

All information in your/your baby’s research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your/your baby’s medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your/your baby’s physical examinations, laboratory tests, procedures, questionnaires, and diaries.

**Who may use and share information in connection with this study?**

The following individuals may use, share, or receive your/your baby’s information for this research study:

* The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
* The study sponsor: *[sponsor name]*
* Governmental agencies responsible for research oversight (e.g., the U.S. Food and Drug Administration, or FDA).
* Health care providers, including your/your baby’s doctors and others who provide services to you/your baby in connection with this study, and laboratories or other individuals who analyze your/your baby’s health information in connection with this study.
* Other study sites involved in the research

Your/your baby’s information may be re-disclosed or used for other purposes if the person who receives your/your baby’s information is not required by law to protect the privacy of the information.

**What if I do not want to give permission to use and share my/my baby’s information for this study?**

Signing this form is voluntary. You do not have to give us permission to use and share your/your baby’s information, but if you do not, you/your baby will not be able to participate in this study.

**Can I change my mind and withdraw permission to use or share my/my baby’s information?**

Yes, you may withdraw or take back your permission to use and share your/your baby’s health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the Principal Investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you/your baby will not be able to stay in this study.

**How long may my/my baby’s information be used or shared?**

Your permission to use or share your/your baby’s personal health information for this study will never expire unless you withdraw it.

1. The Institutional Review Board (IRB) and how it protects you/your baby

The IRB reviews all human research studies—including this study. The IRB follows federal government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health’s IRB is made up of doctors, nurses, non-scientists, and people from the community.

1. Who can I call with questions, or if I’m concerned about my rights as a research subject?

If you have questions, concerns, or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at 212-263-4110.

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov/), as required by U.S. law. This website will not include information that can identify you/your baby. At most, the website will include a summary of the results. You can search this website at any time.

|  |
| --- |
| **When you sign this form**, you are agreeing to take part in this research study/have your baby take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer/volunteer your baby.  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Subject (Print) |  | Signature of Subject |  | Date |
|  |  |  |  |  |
| Name of Person Obtaining Consent (Print) |  | Signature of Person Obtaining Consent |  | Date |

**Witness to Consent of Non-English Speaking Subjects Using the “Short Form” in Subject’s Spoken Language**

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Witness (Print) |  | Signature of Witness |  | Date |

**Witness to Consent of a Subject Who Cannot Read or Write**

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

[ ]  Subject making his/her own “X” above in the subject signature line

[ ]  Subject showed approval for participation in another way; describe:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Witness (Print) |  | Signature of Witness |  | Date |