***Note (REMOVE THIS TEXT BEFORE SUBMITTING):***

* *Note: this template can be used in paper form or made into an e-consent document.*
* *Grey boxes with black text in brackets are to be completed.*
* *Red, italicized text in brackets is help text and/or a prompt for information that also must be included.*
* Orange text is optional, sample wording.
* *Do NOT delete the paragraph headings.*
* *Edit this document to reflect your activity and relevant IRB requirements.*
* ***This form is only to be used for pregnant partners who are considered non-subjects.***
* *With the guidance language removed, this template has the following readability scores:*
	+ *Flesch Reading Ease: 58.7*
	+ *Flesch-Kincaid Grade Level: 8.5*

# **Pregnant Partner Consent**

**[Title of Project]**

**[Version date]**

Please read this form or have this form read to you. Take your time to make your decision. Make sure we explain the information to you. Ask us any questions. You may also want to talk about participation with your doctor and family, loved ones, or friends. The choice to join, or not, is yours. If you decide to join, please sign and date this form.

## **Why am I being contacted?**

You partner has joined a research study to test whether a drug called  [drug name]  can  [drug purpose] . While in the study, your partner was asked to use birth control because the effects of  [drug name]  on pregnancy and the growing baby are not known. Your partner has told us that you became pregnant while he was in the study. You are being asked to give your medical information to  [PI name]  and  [study sponsor] .

We are asking for your permission to contact your doctor for information about your pregnancy. The information your doctor gives us will help  [study sponsor]  study the effects of  [study drug] . It will also help us send reports to the Food and Drug Administration or other Regulatory Authorities as required by law.

**What will I be asked to do?** We will collect medical information about you and your baby during your pregnancy. We will also follow the health of your child 30 days after giving birth for any important medical issues.

**What are the risks?**  [Detail any known risk of harm that the participant may experience including physical, psychological, social, economic, legal, or unknown risks. Any risks listed in the protocol must be addressed in the consent form. Include likelihood (e.g., likely, rare), magnitude/seriousness (e.g., mild, severe) and temporary or permanent, and side effects that may be temporary, irreversible, long-term, or life threatening.] . There is a risk of stress, emotional pain, inconvenience, and possible loss of privacy and confidentiality.

**Can sharing my information help me?** Sharing your and your child’s health information will not help you. Allowing  [PI name]  or  [study sponsor]  access to your medical records may help us better understand the effects of  [study drug]  during pregnancy.

**Can sharing my information benefit the researchers or WCM/NYP?**

*[Include any language required by the Conflict-of-Interest Committee]*

**Do I have other choices?**  [Explain other choices participants have if participants have any, including other research studies etc. If not state, Not sharing my information.]

**How will my information be used and protected?** We will collect health information about you during your pregnancy.  [Discuss steps that you will take to ensure confidentiality, e.g. where will data be stored, who will have access to the data, how will data be transferred, to whom and where, when will data be de-identified, security of storage, when and how data will be destroyed] . We will take steps to protect all of your personal information, but we cannot promise confidentiality of all of your information. Your personal information may be disclosed if required by law.

Your name will not be used in any reports about this study. *[Revise the last sentence if you intend to use names or other identifiers in publications.]* The WCM researchers for this project, the WCM Institutional Review Board (IRB), the Office of Human Research Protection (OHRP), Department of Health and Human Services (DHHS), *[National Institutes of Health (NIH), Food and Drug Administration (FDA) and/or their representatives, {Name of Sponsor/Commercial Entity} and/or their representatives, Data Safety Monitoring Board, an independent group of experts,]* may access your records.

By signing this consent form, you give permission to access your health information.

There are no plans to destroy your information collected for this study. *OR* Your information collected for the study will be destroyed  [indicate when] .

*[If the research includes a Certificate of Confidentiality, include the following. If not, please remove.]*

This study has a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information that may identify you in any action or suit unless you say it is okay. They also cannot provide information as evidence unless you have agreed.  This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know.  The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.  The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop releases required by the federal Food and Drug Administration (FDA).  The Certificate also does not stop your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or other people not connected with the research.  The Certificate of Confidentiality does not stop you from choosing to release information about your participation in this study. It also does not stop you from having access to your own information.

**How will the researchers share my information?** *[One of the following statements is required:]*

*[If there will be no secondary future research with or without identifiers:]*

Your information collected for this study will not be used or shared for future research studies, even if we remove information that identifies you like your name or date of birth.

OR

*[If there will be secondary future research without identifiers:]*

All information that identifies you (e.g., your name, date of birth) will be removed from the information collected in this study. After we remove all identifiers, your information may be used for future research studies or shared with other researchers without your permission. You will not get the results of these studies. You will not receive financial benefit from future research with your information.

**Will I be paid?** You will not be paid.

**Do I have to share my information? Can I stop?** It is your decision whether to share your information or not. You have the right to choose not to share your information or to stop your participation at any time. Your decision to share your information or stop participating will not affect your regular care nor your relationship with Weill Cornell Medicine, your doctors, or other employees. *[If applicable, discuss the process for participants to withdraw once the project has begun.]*

You will be told about new information that may affect your health, wellbeing, or willingness to participate.

**What are the costs?** You or your insurance company will be charged for your usual medical care.  [Study sponsor]  will pay for the costs of collecting your information. There is no cost to you for sharing your information.

**What if I have questions?**

If you have any questions, please contact:

 [Researcher's name]

 [Department]

 [Address]

 [Phone]

 [Email address]

If you have questions about your rights or if you have a compliant, please contact the WCM Institutional Review Board (IRB) at:

WCM IRB, (646) 962-8200, irb@med.cornell.edu

Website: https://research.weill.cornell.edu/irb

**HIPAA Authorization for Use and Disclosure of Your Protected Health Information**

We will be collecting health information about you and sharing it with others as part of this study. This information is “protected” because it identifies you.

**Protected Health Information (PHI)**

By signing this Consent Document, you are allowing the following people to use or release your protected health information for this study:  [list all people or class of people (i.e. researchers and their staff) that will access PHI or you can also create a document to give participants that lists these people]

This information may include:  [list PHI, e.g. results of physical exams, medical history, body mass index, sensitive diagnoses if applicable, etc.] . We will use this information to:  [include the purpose and describe each use of the requested information] . The health information listed above may be used by and/or released to:  [name or class of persons involved in research; i.e. researchers and their staff] .

In addition to the people listed in this form, there is a chance that your health information may be shared outside of the research study and no longer be protected by federal privacy laws. Examples of this include releases to law enforcement, legal proceedings, health oversight activities and public health measures.

**Right to Withdraw Your Authorization**

Your permission for the use and release of your health information for this project will not expire unless you cancel it. Your health information will be used or released as long as it is needed for this project. However, you can stop your permission at any time by contacting the WCM Privacy Office in writing. To do this, please send a letter to:

Privacy Office

1300 York Avenue, Box 303

New York, NY 10065

Email: privacy@med.cornell.edu

If you have questions, please call (646) 962-6930.

The research team does not have to destroy or retrieve any of your health information that has already been used or shared.

If you have questions about the privacy practices of the institution, you can request a Notice of Privacy Practices from your doctor.

**Refusal to Sign**

If you choose not to sign this consent form and give permission for the use and release of your protected health information, you information will not be shared. Your decision to sign this consent form or stop participating will not affect your regular care, benefits, nor your relationship with Weill Cornell Medicine, your doctors, or other employees.

**Signature**

I agree to share my information with the researchers. My questions have been answered. I will get a signed copy of this form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Name of Adult Participant Signature of Adult Participant Date

**Legally Authorized Representative**

I am making a decision on behalf of the participant who signed above whether to share his/her/their health information. My questions have been answered. I will get a signed copy of this form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of legally authorized representative (LAR) or healthcare proxy |  | Print Name and relationship to participant (when appropriate) |  | Date |

**Witness to Consent of Participants Who Cannot Read or Write**

I confirm that the consent form was presented orally to the participant in the participant’s own language, the participant was given the opportunity to ask questions, and the participant has communicated consent to participate:

* Making his/her mark above
* Other means; Indicate here: \_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of witness for adults unable to read or write |  |  |  | Date |

#### **Participant Medical Record Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

#### **Researcher Signature** (to be completed at time of informed consent)

I confirm that the content of this informed consent form was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­\_\_\_\_\_\_\_

Name of Research Team Member Signature of Research Team Member Date