**LSUHSC-NO PREGNANT PARTNER CONSENT FORM TEMPLATE**

**Instructions for Using the Template**

* Specific instructions for completing the form are in **blue** or **red** text. In general, **blue** text references required information. **Red** text references information that may or may not be applicable to your study or is otherwise optional.
* In each section, **black** text is suggested language. While not mandatory, we highly recommend using this language to maintain consistency across consent forms. This text is optimized for readability and grade-level comprehension using the tools described below.
* Insert the LSUHSC IRB # for the study and your consent version date in the header. Consent forms must have the IRB #, a version date, and page numbers.
* Before you submit your consent document to the IRB, delete the instruction pages.Delete all **blue,** **red** and yellow-highlighted text before finalizing the document. The font color of the finished consent document should be black. The finished document should reflect what you will give to the subject.
* As much as possible, write in common, everyday language that can be understood by a participant with an 8th to 10th grade education, similar to the style used in popular news magazines and newspapers.
	+ Use active voice rather than passive voice whenever possible.
	+ Use short, simple sentences and short paragraphs.
	+ Avoid medical and scientific jargon.

**DELETE THE INSTRUCTION PAGES FROM THE CONSENT FORM PRIOR TO SUBMITTING TO THE IRB**

Louisiana State University Health Sciences Center - New Orleans

Pregnant Partner Consent

**STUDY TITLE:**

**PRINCIPAL INVESTIGATOR:**

**EMERGENCY CONTACT:**

**STUDY SPONSOR:**

1. Invitation to be Part of a Research Study

The research team is asking you to be in this study because [describe in one sentence why the potential participant qualifies for this study]. **Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this consent form will help you decide if you want to participate. Before deciding:

* You can discuss this study with friends and family.
* You can also discuss it with your health care doctor or request a second opinion.
* If you have any questions, you can ask the researchers for more information before deciding to participate.
* Even if you choose to participate, you can decide to stop participating at any time.

In this consent form, “you” always refers to the participant. If you are a legally authorized representative, please remember that “you” refers to the study participant.

2. Why is this study being done?

Your partner will be or has been taking part in a research study called [study title]. Some of the drugs that your partner is taking for the research may move into semen. The effects of your partner’s study medications on pregnancy and the developing fetus (baby still in the womb) are currently not known or not fully understood. For this reason, the researchers would like to follow your pregnancy and birth to collect medical information try to find out if the study medications have any effect on your pregnancy and the health of your baby.

3. What will happen if I take part in this study?

If you agree to sign this consent form, the researchers will review and collect medical information relating to your pregnancy, the delivery of your baby, and the health of your baby at least at [list ages when information will be collected] for any important medical issues.

 4. What are the risks of taking part in this study?

There is a possible risk of loss of confidentiality of your and your baby’s medical record information by allowing the collection of this information. Every effort will be made to protect the confidentiality of this information but this cannot be guaranteed.

5. Are there any benefits to participating in this study?

**Possible benefits to you**

There are no direct benefits to you or your baby for providing information related to your pregnancy.

**Possible benefits to others or society**

This information may help researchers understand the potential effects that study medications may have on pregnancy and developing babies.

6. How will my information be kept confidential?

The researchers will protect your information by [briefly describe how the study staff will keep research data secure and identify who may access the data]. We will make every effort to maintain your privacy but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.

The following people or groups may review your study records for purposes such as quality control or safety:

* The study sponsor and/or representative of the sponsor [delete if there is no sponsor]
* Representatives of LSUHSC-NO and the LSUHSC-NO Institutional Review Board
* Other collaborating organizations [list other orgs or delete if not applicable]
* Officials of the Department of Health and Human Services or the Federal Food and Drug Administration [FDA may be deleted if this is not an FDA regulated study]
* Authorized government officials of foreign countries where this study also is taking place. [Replace “foreign countries” with names of specific countries if the study is being conducted in only a few such countries; delete if not applicable]
* Other organizations or agencies if required by law.

The results of the study may be released to the funding agency [provide the name of the funding agency, if known]. If any publications and/or presentations result from this study, they will not identify you by name.

7. Will there be any costs to me for taking part in this study?

There will be no cost to you for allowing the researchers to collect this information about your pregnancy, delivery, or baby. 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 in the usual way.

8. Will I be paid or for taking part in this study?

**INSTRUCTIONS:** Choose one of the following statements to include in this section.

You will not receive any type of payment for taking part in this study.

**[OR]**

You will receive [nature and total amount of incentive/compensation] for your participation in this study. Payments will occur [explain disbursement/conditions of payment; include circumstances, if any, where partial payment or no payment may occur; payments must be in equal amounts at each visit throughout the course of the study]. You will be responsible for any taxes assessed on the compensation.

The study team will release your name, address, social security number and amount of payment to Accounting Services. If the total payment for your participation in research is greater than $600 in a year, Accounting Services will report this amount to the Internal Revenue Service as income as required by law.

9. Who can I contact if I have questions about this study?

**The research team:**

You may contact the following individuals with any questions or concerns about the research or your participation in this study.

|  |  |
| --- | --- |
| **Principal Investigator**Name:      Address:      Phone #:      24-Hour Phone #:       | **Co-Investigator**Name:      Address:      Phone #:      Research Injury Phone #:       |

**Office of the Chancellor, LSU Health Sciences Center - New Orleans:**

You may contact the Office of the Chancellor by phone at (504) 568-4801, if

* you have questions about your rights while taking part in this study, or
* you have any concerns or suggestions, and
* want to talk to someone other than the researchers about the study.

[Include the following paragraphs if this is an applicable clinical trial of a drug, device, biologic or other product regulated by the FDA; otherwise delete.]

**Public information about this study:**

*ClinicalTrials.gov* is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available at [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The National Clinical Trials number for this study is NCT     .

10. What will happen if I cannot complete the study?

There are several reasons why you may not complete the study.

The researchers or the study sponsor might decide to stop the study at any time.

The researchers may end your participation in this study, without your permission, for a number of reasons.

You also may decide on your own to stop participating in the study. If you are thinking about withdrawing, let the researcher know. The researcher will inform you of any significant new findings during the study that may impact your willingness to continue participation.

Information collected about you up to the point of withdrawal will remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

11. Your Participation in this Study is Voluntary

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason or no reason at all. No matter what you decide, there will be no penalty to you and you will not lose any services, benefits or rights you would normally have.

Add the following if the potential participant may be a LSUHSC-NO student or faculty/staff member; otherwise delete this paragraph.

If you are a LSUHSC-NO student or faculty/staff member, you may choose not to be in the study or to stop being in the study before it is over at any time. Your decision will not affect your grades or job status at LSUHSC-NO. You will not be offered or receive any special consideration if you take part in this research study.

12. Your Consent

By signing this document, I acknowledge or am aware that:

* The researcher(s) discussed the study with me and answered all my questions.
* I will receive a copy of the consent form.
* I do not waive any of my legal rights by signing this consent document.
* I can contact the study team or the Chancellor’s Office using the contact information provided above if I have any questions or concerns after signing the consent form.

**Signature of Pregnant Partner:**

*I agree to take part in this study.*

Participant Signature Printed Name Date

**INSTRUCTIONS:** Include this signature block when you anticipate enrolling adult subjects who cannot read. **Otherwise, delete.**

**Signature of Reader & Witness to Consent of Subjects Who Cannot Read:**

*The study subject has indicated to me that he/she is unable to read. 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 for participation by completing the signature line above.*

Reader Signature Printed Name Date

Witness Signature Printed Name Date

**Signature of Person Obtaining Consent:**

*I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.*

Signature of Person Obtaining Consent Printed Name Date

Time