

## Pregnancy/Pregnant Partner Consent Disclosure

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### Sample Only (revised 11/14/19) – Cannot be used without IRB Approval

**[TAKE NOTE:**

- *If you are gathering information about a **pregnant participant**, you may describe the data collection procedures for the pregnant participant and infant in the main consent form template. However, if you are gathering information about a **pregnant partner** and infant, you must use this template to create a separate consent form to be signed by the pregnant partner.*
- *This abbreviated consent form may only be submitted to the IRB if you are requesting an alteration of informed consent for the pregnant partner in the Form 1 IRB electronic application. Also, remember that if you are collecting individually identifiable health information protected under HIPAA, you must request a waiver of the subject authorization for the HIPAA requirements in the Form 1 IRB electronic application.*
- *If your study is industry-sponsored, and this sponsor prefers the use of a full consent form for the pregnant partner, download the full pregnant partner consent form from the IRB website:  
<http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php> .*
- *If the protocol requires collecting identifiable information about the newborn infant after delivery for any amount of time after birth, then the infants are research subjects too. This means that the number of research subjects you provide in your IRB study application must account for the total number of: subjects who will participate in the main study, potential pregnant partner subjects, AND potential infant subjects.*
- *Be sure to use the UTHSC header and to insert a 'preparation date' on the document.]*

1. Provide the title of the research study at the top of the page.
2. Specifically state, “You are being given the opportunity to participate in this observational pregnancy research study. You became pregnant while you or your partner were taking part in the research study named above. The research study is/was testing the experimental [*drug, device, vaccine*] named [*X*].”
3. State what effects, if any, are known on the developing fetus.

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Subject Initials \_\_\_\_\_  
[*OR*]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

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The effects of [X] are not known on the developing fetus (unborn baby) in humans at this time. The [drug, device, vaccine] [X] that you/your partner is or has been taking may cause problems in your pregnancy or birth defects in the unborn infant you are carrying.

4. Indicate who is performing the research (i.e., the Principal Investigator's name), and provide a phone number, indicating that they should contact you (or name the designee) "if you have questions about this observational pregnancy research study."
5. State the purpose of the observational pregnancy research study in lay terms. For example: The purpose of this pregnancy research study is to provide information about your pregnancy [add if applicable: and about your infant after delivery] to the study sponsor [X] (the company that provided the [drug, device, vaccine]) OR [name of institution or federal funding agency] OR study doctor.
6. Explain the research procedures in lay terms and how long the subject's participation will be including whether the participation will last up until the delivery and/or past the delivery date. For example:

Medical information will be collected about your progress, the outcome of your pregnancy, and [add if applicable: about your infant's health after delivery] from you and your infant's doctors. This includes information such as:

- Your medical history including known history of hereditary diseases
- Previous pregnancy(ies) history and outcomes
- Details about your current pregnancy including date of conception and date of delivery
- Medications used during pregnancy
- Results of any tests taken prior to birth
- Details of any events or assessments that you have during or after birth
- Details of any complications during the pregnancy
- The progress and outcome of your pregnancy
- [add if applicable:] Health information about your infant after delivery

If you agree to provide information, your involvement in the study will last throughout your pregnancy until the delivery of your infant [or edit as applicable: until your infant is one year old].

You [add if applicable: or your infant] will not be asked to undergo any additional tests for research purposes.

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7. List any foreseeable risks. These might include tiring from answering questions; being uncomfortable when answering sensitive questions; the subject's private, identifiable information being seen by people not involved in the research; etc. If there are no foreseeable risks, this should be clearly stated. For example:

There is a risk that your [add if applicable: or your infant's] private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your [add if applicable: or your infant's] confidential information. You may be asked questions about your pregnancy that make you feel uncomfortable. You are not required to answer these questions if you do not want to do so.

The research may involve risks to you or to the embryo or fetus, which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

8. If there will be no direct benefits to subjects, this should be clearly stated. Further, explain the anticipated benefits for society (i.e., what knowledge could be gained?). For example:

There is no direct benefit to you [add if applicable: or your infant] for allowing your health information to be collected. However, this information will help doctors better understand the effects of [X] on the course of pregnancy and in human infants who may have been exposed to [X].

9. Specifically state, "Your participation is voluntary and if you choose to not participate or to stop participating at any time, your decision will not result in a penalty or affect your rights."

In addition, if you will be recruiting potential subjects who are students, residents, or fellows (of UT/any school associated with this research) and/or employees (of UT/any institution/agency associated with this research), include the following statement(s):

"If you are a student of [school name], participating or not participating in this study will in no way influence your grade in any course. If you are a resident or fellow of [school name], participating or not participating in this study will in no way influence your academic standing. If you are an employee of [name of

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*institution/agency*], participating or not participating in this study will not affect your employment status.”

10. Explain how you will maintain the confidentiality of the data.
11. Specifically state,  
“You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at <http://www.uthsc.edu/research/compliance/irb/> if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.”
12. If you are conducting a clinical trial with (i.e., administering for research purposes and evaluating) a drug, biologic, and/or device, the following sentences must be included:

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US 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.

### **FUTURE CONTACT:**

*[Include this section and EDIT the following paragraph if you wish to retain subjects' contact information (and PHI) in order to contact them in the future regarding participation in other studies- you must also indicate this in your application.]*

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order to contact you in the future and tell you about other studies in which you might be eligible to participate.

Put your initials on one of the lines below:

\_\_\_\_\_ We CAN keep your contact information and health information [*add if applicable:* , as well as your infant’s health information,] to ask you about participating in future studies.

\_\_\_\_\_ We MAY NOT keep your contact information and health information [*add if applicable:* , or your infant’s health information,] to ask you about participating in future studies.

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*[Include this section and EDIT the following paragraph if you wish to attempt to find subjects lost to follow up- you must also indicate this in your application.]*

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- Certified mail will be sent to you requesting that you call us.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.
- *[list any other ways that you stated in your application]*

Put your initials on one of the lines below:

\_\_\_\_\_ We CAN attempt to find/contact you in the above ways.

\_\_\_\_\_ We MAY NOT attempt to find/contact you in the above ways.

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Subject Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

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### CONSENT OF SUBJECT/PREGNANT PARTNER:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

\_\_\_\_\_  
Signature of Research Subject (18 years +)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Adult Research Subject

***[If you are utilizing a Legally Authorized Representative for an incompetent adult subject, then the following 3 lines must be included here, above the Person Obtaining Consent lines:]***

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Legally Authorized Representative

\_\_\_\_\_  
Relationship of Legally Authorized Representative

***[If the research study involves the collection of identifiable information about the infant upon or past the date of delivery, then the 3 following lines must be included here, above the Person Obtaining Consent lines:]***

\_\_\_\_\_  
Printed Name of Infant if known

\_\_\_\_\_  
Signature of Parent/Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
***[Insert Preparation Date]***

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\_\_\_\_\_  
**Printed Name of Parent/Legal Guardian**

**Check Relationship to Minor:**

- Parent**  
 **Court-Appointed Legal Guardian**

\_\_\_\_\_  
**Signature of Person Obtaining Consent**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**

\_\_\_\_\_  
**Printed Name of Person Obtaining Consent**

In my judgment, the subject [*or legally authorized representative*] has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

\_\_\_\_\_  
**Signature of Investigator**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**

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[*Insert Preparation Date*]