## Who should use this Pregnant Partner Consent form?

This document should be used by investigators or study teams when developing a pregnant partner consent form for Investigator- initiated studies or when the central IRB does not have a pregnant partner consent form.

## How do I use this form?

Please fill in the required information in the blue highlighted areas. Next, remove all highlights and brackets. Remove any sections, indicated by blue font, that are not applicable.

## Do I submit this form the IRB for review?

Yes. Please upload this form into iStar 24.7 after a participant’s partner is reported as pregnant via an amendment.

# **Pregnant Partner Consent Form**

Study Title:

Principal Investigator:

Department:

24 – Hour Phone:

## **Why am I receiving this consent form?**

You are receiving this consent form because the biological father of your child is (or was) participating in a clinical study which uses [insert name of drug here].

## **What is this study about?**

We hope to learn about your pregnancy and the birth and health of your child. We do not know the risk to you or the fetus/child from [insert name of drug here]. We hope to learn more through this data collection.

## **Why am I being asked to be in this study?**

You are being asked to participate in this study because the biological father of your child is (or was) participating in a clinical study [Insert name of study here] which uses [insert name of drug here], which is not approved by the United States Food and Drug Administration (FDA) for the use in patients with [insert name of disease/condition here].

## **What will I have to do in this study?**

You will be asked to provide information about your pregnancy and your health during your pregnancy. We may also want to know about the health of your fetus or child.

## **Will I get any kinds of study treatments or drugs in this study?**

No. We are only collecting data from your medical records or asking you questions.

## **Will you collect data about my fetus or child?**

Yes. [Describe what data will be collected and how e.g., medical records here, phone calls, surveys, etc].

## **What type of information are you going to collect about me?**

We will gather medical information related to [insert name of drug here] and your pregnancy and the birth and health of your child. We will collect [insert type of information that the study team will collect here]. We will review the medical records relating to your pregnancy, or your fetus, or child to determine if there are any health problems.

## **Do I have to have additional tests done to me by my doctor/obstetrician (OB) to be in this study?**

No. You will not be asked to have any additional tests or procedures.

## **Are there any physical risks to me or my fetus/child by taking part in this study?**

No. There is no physical risk in collecting information about you or your fetus or child in this study. The study does not require that you take any medication.

## **Is there a possibility that my information could be shared by accident?**

Yes. There is a risk that your confidential medical information could be shared by accident. To prevent this from happening the study team has strict procedures that they follow. The HIPPA Authorization form will describe in detail the procedures to protect information.

## **What is HIPAA Authorization?**

HIPAA is a Federal Law that provides additional protections of your medical records and related information. You will be asked to sign a separate HIPAA form to authorize access, use, creation, and disclosure of your health information.

## **Are you going to share what you learn about me or my fetus or child from this study with other doctors or researchers?**

Yes. We may share this information. We will not share your name or, if applicable, the name of your child. Any data we share will be sent securely to the other researchers. We may need to share safety information with regulatory authorities like the FDA. If we do, your name will not be used.

## **What happens with the information you collect?**

We may write a paper for a scientific publication about the data we collect in this study. We may present the information at a professional meeting. If we share the data from this study, other doctors and researchers may present the information at a professional meeting or write a paper. No identifying information will ever be shared.

## **What is the benefit for me to be in this study?**

There is *no direct benefit* for you or your fetus or child to participate in this study. The information collected may help us understand the effects of exposure to the study drugs to pregnant people and their fetus/child.

## **Do I have to have to be in this study?**

No. You do not have to participate in this study. You can withdraw your permission to collect and disclose your/your baby’s health information at any time [indicate withdrawal procedures] and whether information already collected will/will not be used.

## **If I decide to be in this study, do I have to answer every question?**

No. You only answer the questions you want to answer.

## **Do I get paid for being in this study?**

No. You will not be paid for being in this study.

## **Are there any costs for me to be in this study?**

No. There are no costs to be in this study.

## **Will I get reimbursed for my pregnancy expenses?**

No. Your regular medical care for your pregnancy is your responsibility. The birth of your child, and care of your baby will be billed to you and/or your health insurance in the usual way.

## **Who is paying for this study?**

[Insert name of sponsor here] is sponsoring this study.

## **What happens if you find out information that could be important to me about [insert name of drug here], will you tell me?**

Yes. Any important information that is discovered during the study and could make a difference about you or your fetus or child’s health will be provided to you.

## **Who do I call if I have any questions?**

[Insert study contact name (PI/Co-PI/Coordinator, phone, email here].

## **Who has reviewed this research?**

This research has been reviewed by the USC Institutional Review Board (IRB). This is a board of experts that reviews and monitors research studies. The IRB is responsible for your rights as a research participant.

## **What do I do if I have a complaint about this study?**

Contact the IRB at (323) 442-0114 or by email at hrpp@usc.edu.

**Statement of Consent**

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant Signature Date Signed

(and Time\*)

**Legally Authorized Representative** Delete if not applicable.

Name of Legally Authorized Signature Date Signed

Representative (and Time**\***)

Person Obtaining Consent

I have personally explained the research to the participant and/or the participant’s legally authorized representative using non-technical language. I have answered all the participant’s questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent Signature Date & Time Signed

Witness Delete if not applicable.

A Witness is Required When: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form.   
If no witness is needed, leave this signature line blank.

Name of Witness Signature Date Signed

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. By indicating below, I am agreeing to take part in this study.

\_\_\_\_\_\_YES, I agree to participate in the study.