**SAMPLE**

**PARTNER - PREGNANCY LETTER OF INFORMATION**

*Study title*

**Note from the HSREB:** Participation in studies involving drugs or devices which may affect the foetus or newborn baby requires that any resultant pregnancy during the study, or a specified time after participation in a study, requires that the pregnancy is followed – this is always on a voluntary basis. The details and wording outlined below refer to the biological parents, i.e. the individuals whose reproductive system produced the baby.

**LOCAL STUDY DOCTOR**: *Name and affiliation and contact*

Sponsor Information and geographical location

**INTRODUCTION**

You are receiving this letter because you have become pregnant while your partner is taking part in this study.

Your partner is participating in a research study involving the use of drugs or treatments which may harm a foetus (unborn child). He had been advised not to father a child during the time he is taking the drugs or treatments and for a period of XXXX after. This letter is to inform you that there may be risks to a foetus fathered by your partner.

We are asking you to voluntarily provide us with information concerning your pregnancy and its outcome. Only information, relating to your current pregnancy and the outcome of the pregnancy, will be collected and/or analyzed [As a reminder Western’s HSREB will only allow for collection of data related to the current pregnancy as it pertains to the participant’s inclusion in the study. Do not state, that past medical records including abortions, miscarriages, etc. will be collected from the pregnant partner]. You may provide this information yourself or give permission to your health care provider to release it directly to your partner’s study doctor. The purpose of collecting this information is to determine how the drug or treatment may affect the foetus.

**VOLUNTARY PARTICIPATION**

Your agreement to provide information on your pregnancy and its outcome is voluntary. You may refuse to provide this information, refuse to answer any questions or withdraw your consent for data collection at any time with no effect on the care of your partner who is participating in this [drug/medical device] study. Should you decide to withdraw your consent for data collection on your pregnancy and its outcome, we will no longer request information from you or your health care provider, however information collected prior to your withdrawal of consent may continue to be used in future analyses of the safety of the drug or treatment.

**CONFIDENTIALITY & PRIVACY ISSUES**

The study in which your partner is enrolled is sponsored by *Sponsor [insert name]*. The de-identified information about your pregnancy and its outcome will be forwarded to the sponsor or companies working on behalf of the sponsor, where it will be analyzed and stored on their safety database. The sponsor may then be required to forward the information to health authorities worldwide, and the information may also be used in reports for scientific presentations or publications. The results may also be used for future safety assessments.

All information collected regarding your pregnancy and the outcome of your pregnancy will be kept confidential to the limit allowed by law. The information will not be given to your partner. The data will be coded to hide your identity and the identity of your baby. In particular, your name and other identifying information will not be sent to the sponsor of the study. If the results of the trial are published, your identity and that of your baby will remain confidential.

We will do our best to protect your confidentiality however, representatives of Sponsor, regulatory agencies such Health Canada and the U.S Food and Drug Administration (FDA), Western University’s Health Sciences Research Ethics Board, and Lawson Quality Assurance and Education Program (if applicable) may need to examine your identifiable information and/or your original medical records to verify the information and monitor the conduct of the study. In these cases, they will see your name and the name of your baby.

**RISKS**

There are no known risks to providing this information other than those mentioned above. However, when it comes to data there is always the risk of a privacy breach.

**BENEFITS**

It is unlikely that you will benefit directly by providing this information, however it may provide important safety information to the company that makes this drug.

**CONTACT INFORMATION**

If you have any questions about the study and data collection you may contact the study doctor XXXXX at XXXXX

**If this study does not require Lawson oversight:**

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics (519) 661-3036, 1-844-720-9816, email: ethics@uwo.ca.  The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential.

***Or***

**If this is a study that requires Lawson oversight:**

The Letter of Information should include the following language for St. Joseph’s Health Care London as a contact outside of the research team:

If you have any questions/concerns about your rights as a research participant or the conduct of this study, please contact: St. Joseph’s Health Care London Patient Relations Consultant at 519-646-6100 ext. 64727

The Letter of Information should include the following language London Health Science Centre as a contact outside of the research team:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036.

Please keep this letter for your records.

**PARTNER - PREGNANCY CONSENT FORM**

(To Be Signed In the Event of a Pregnancy)

Study Title

Local Study Doctor

Local Study Doctor Contact Information

|  |
| --- |
|  |
| Name of Study Participant (Patient) |

I have read the Partner Pregnancy Letter of Information. All questions have been answered to my satisfaction. I will receive a copy of this signed and dated consent form.

Please pick one of the following options:

|  |  |
| --- | --- |
| **Consent for informing the Pregnancy Healthcare Provider** | **Pregnant Partner initials** |
| **YES,** I agree that my Pregnancy Healthcare Provider may be contacted for information about my participation in these follow-ups. Information will be limited to my current pregnancy. |   |
| **NO,** I do not want my Pregnancy Healthcare Provider contacted for information about my participation in these follow-ups. I agree to provide the information directly to my partner’s study doctor.  |   |

Name of Pregnancy Healthcare Provider (if applicable):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact Information of Pregnancy Healthcare Provider:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A copy of this signed informed consent form may be provided to your Pregnancy Healthcare Provider (e.g., GP, gynecologist, midwife) by your partner’s study doctor, if you agree.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Female Partner’s Name |  | Signature |  | Date Signed |

I have explained to the female partner named above (and/or her substitute decision maker), the reasons why it is necessary to collect data regarding the current pregnancy and its outcome. A copy of this signed and dated informed consent form will be provided with a copy of this signed and dated informed consent form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Person Obtaining consent |  | Signature |  | Date Signed |