**SAMPLE**

**FEMALE PARTNER - PRELIMINARY LETTER OF INFORMATION**

*Study title*

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

**INTRODUCTION**

Your partner is participating in a research study involving the use of drugs or treatments which may harm a foetus (unborn child). He has 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 the foetus should you become pregnant with your partner. You and your partner should use an effective birth control method such as barrier method (condoms, diaphragm); oral, injectable, or implant birth control; or abstinence to avoid becoming pregnant. If you do become pregnant it is important to inform your partner’s study doctor as soon as possible.

If you become pregnant while your partner is taking part in this study; we will ask you to voluntarily provide us with information concerning your pregnancy and its outcome. You will receive another letter explaining the request and a consent form to sign. Only information, relating to your pregnancy and the outcome of the pregnancy, will be collected and/or analyzed. 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 have affected the foetus.

**VOLUNTARY PARTICIPATION**

Your agreement to provide information on your pregnancy and its outcome is voluntary. You do not have to make a decision about whether or not you want to provide this information at this time. 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 the clinical trial. Should you decide to withdraw your consent for data collection regarding your pregnancy and its outcome, we would 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 information about your pregnancy and its outcome would be forwarded to the sponsor or companies working on behalf of the sponsor, where it would be analyzed and stored in their safety database. The sponsor may also 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 with regard to your pregnancy and the outcome of your pregnancy would be kept confidential to the limit allowed by law. The information would not be given to your partner. The data would be coded to hide your identity and the identity of your baby. Specifically, your name and other identifying information would not be sent to the sponsor of the study. If the results of the trial are published, your identity and that of your baby would remain confidential.

Representatives of Sponsor, regulatory agencies such Health Canada and the U.S Food and Drug Administration (FDA), and Western University’s Health Sciences Research Ethics Board may need to examine your original medical records to verify the information and monitor the conduct of the study. In these cases, they would see your name and the name of your baby, but no identifying information would be attached to any information collected from your records.

**RISKS**

There are no known risks to providing this information other than those mentioned above.

**BENEFITS**

It is unlikely that you would benefit directly by providing us with this information however it might 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 or access the online form at: <https://apps.lhsc.on.ca/?q=forms/patient-relations-contact-form>.

Please keep this letter for your records.