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**ADDENDUM TO INFORMED CONSENT FORM
Pregnant Partner/Spouse Informed Consent Form**

RESEARCH PROTOCOL TITLE:

PROTOCOL NO.:

SPONSOR: GlaxoSmithKline

INVESTIGATOR: Dr. X

TELEPHONE:

PARTNER'S SUBJECT NUMBER:

INTRODUCTION

The purpose of this consent form is to explain why GlaxoSmithKline (GSK) would like to follow the progress of your pregnancy. The information provided in this form will help you decide if you would like to take part in providing information about your pregnancy. Please ask Dr. X or the study coordinator to explain any words or information you do not understand.

PURPOSE FOR COLLECTING THIS INFORMATION

Your partner has been participating in a research study to test whether an experimental drug called [study drug] can reduce the time to progression of his prostate cancer. This study compares [study drug] with a placebo (an inactive substance). Your partner received [study drug] or placebo based on a 50-50 chance (like flipping a coin).

Your partner was told to use birth control while he was enrolled in the study because the effects of [study drug] on pregnancy and the developing foetus are not known or are not fully understood at this time.

You are being asked to provide information to GSK and Dr. X because your partner has reported that you became pregnant while he was enrolled in this study.

What is known is that [study drug] decreases the level of a hormone which is important for the development of genitals in an unborn male foetus (unborn baby). It is therefore possible that male offspring of women exposed to the study medication during pregnancy may be born with abnormal male genitalia. There may be other risks to the foetus that are unforeseeable. For this reason, GlaxoSmithKline would like to collect some information on your pregnancy.

Dr. X will be paid by GSK for collecting this pregnancy information.

RISKS AND DISCOMFORT

There are no medical risks to you associated with collecting information about your pregnancy.

As described above, there is a risk that [study drug] may affect the foetus if a woman is exposed to [study drug] during pregnancy. You should be careful to avoid exposure to the study medication, including broken capsules because [study drug] can be absorbed through the skin.

PROCEDURE

GlaxoSmithKline has asked Dr. X to collect information from you on your pregnancy to help better understand the effects of exposure to [study drug] during pregnancy.

You (as a pregnant partner) are being asked to provide information concerning your pregnancy (specify exactly what health information will be gathered). You will be followed to determine the outcome of your pregnancy (e.g., live birth) and for up to 6 - 8 weeks following delivery of your child to confirm that he or she is healthy (state specific health indicators that will be used). Any premature termination of the pregnancy will also be reported.

VOLUNTARY PARTICIPATION

Your participation is entirely voluntary. You may refuse at any time. You may decide not to take part or you may decide to take part and then change your mind. Refusal to participate will not result in any penalty or loss of benefits to which you or your partner are otherwise entitled. If you decide to withdraw after providing some information, GSK will only keep your information collected up to that point. (provide a rationale for keeping already collected data if the pregnant partner withdraws consent)

BENEFITS

There will be no direct benefit to you by allowing Dr. X or GSK to follow the progress of your pregnancy. However, you may help scientists better understand the effects of exposure to [study drug] during pregnancy.

CONFIDENTIALITY OF RECORDS

Your partner has been assigned a subject number when he entered the study. Researchers use this number to keep track of samples and information. To protect your privacy, any information collected about your pregnancy will not be linked to your name or your partner's name and will only be recorded using this subject number that has been assigned to your partner. Your partner's study doctor and his or her study staff will keep the link between your partner's subject number and your name. Your child's name will not be collected.

GSK or those working with GSK (for example other researchers) will be the only persons working with your pregnancy information. Any pregnancy information collected will be stored securely (for how long?). GSK will require anyone who works with your information to agree to hold it in confidence.

By agreeing to take part in this research, you will allow information related to your pregnancy to be seen by people involved in [study drug] research. These people include GSK, people working with GSK on this research, research ethics boards (REBs), and regulatory authorities, such as the FDA and Health Canada.

Your study-related information and any research results will be put on a computer and stored in electronic databases. International regulations for information on computers will be followed. Your pregnancy information could be sent to other researchers working with GSK and to other GSK sites around the world. Relevant laws on processing personal information will be followed. It is possible that your anonymized information, if stored outside of Canada may be accessed without your knowledge or consent by governments, in compliance with foreign laws.

EMERGENCY CONTACT

If you have questions about this study or if you wish to withdraw from providing any additional information concerning your pregnancy, please contact Dr. X or the study coordinator at the phone number listed on page one of this form.

RESEARCH ETHICS BOARD CONTACT

For questions or concerns regarding your rights as a research subject or the ethical review of this project, you may contact the Vancouver Island Health Authority Research Ethics Office at **250-370-8620**.

CONSENT

A copy of this Informed Consent Form (signed and dated) will be given to you or your legal representative

My signature below indicates that:

1. I have read this form and that the study has been explained to me.
2. I have had the opportunity to ask questions and I am satisfied with the answers and explanations that have been provided.
3. I have been given the time and opportunity to read the information carefully, to discuss it with others and to decide whether or not to take part in this research.
4. I voluntarily agree to provide the requested information.
5. I do not waive any of my legal rights.

Subject (Pregnant Partner) Name (please print)

Subject (Pregnant Partner) Signature

Date

Name of Person Obtaining Consent*

Signature of Person Obtaining Consent*

Date

Investigator Name (please print)

Investigator Signature

Date

* If different than investigator