[Insert letterhead]

Pregnancy Follow-up Consent

TITLE:

PROTOCOL TITLE:

STUDY DOCTORS: **Phone number:**

SPONSOR:

Introduction

You have been invited to take part in a research study. Taking part in this study is voluntary. You may choose to take part or you may choose not to take part in this study. You also may change your mind at any time. **If applicable include**: If you decide to stop participating in the study, the researcher/study doctor will discuss other options with you. Whatever you choose it will not affect your usual care and you will not lose any benefits to which you are entitled.

This consent form has important information to help you make your choice. It may use words that you do not understand. Please ask the study doctor to explain anything that you do not understand. It is important that you have as much information as you need and that all your questions are answered. Please take as much time as you need to think about your decision to participate or not, and ask questions about anything that is not clear. You may find it helpful to discuss it with your friends and family. The study staff will tell you about the study timelines for making your decision.

1. **Why am I being asked to join this pregnancy follow-up?** Please choose from the 2 options below or edit as necessary.

You are being invited to take part in this follow-up because you recently took part in the above named study and became pregnant while receiving the study drug.

OR

You are being invited to take part in this follow-up because when you became pregnant, your partner was receiving (or had recently finished receiving) a study drug as part of a clinical trial.

We are asking your permission to collect information about your pregnancy and the birth and health of your baby, for research purposes.

2. **What is the purpose of the pregnancy follow-up?**

The sponsor would like to collect this information to learn more about the study drug and to see if there is any risk to the mother or baby during pregnancy.

If you agree to sign this consent form you will be contacted by the study doctor and be asked about your pregnancy and the birth and health of the baby. This information will be passed on to the Sponsor, [name of sponsor].

3. **How long will I be in the pregnancy-follow-up?**
If you agree to take part in this follow-up, your involvement will last until [please specify time frame (e.g. the end of the pregnancy (for example, when the baby is born), after the end of the pregnancy, for 6 months, etc.)].

4. **What will happen if I take part in the pregnancy follow-up?**
Please describe what the participant will be expected to do and what information will be collected from their/their baby's health record.
Example for pregnant partner:
We are asking for your permission to collect the following information from your health record:
Age
Medical History
Complications associated with pregnancy (if applicable)
Date of delivery
Health of your child
We will contact you to ask you questions relating to your health and the health of your child. You may be asked questions that are personal; you can refuse to answer these if you wish.

5. **Are there risks to the pregnancy follow-up?**
We do not anticipate that the collection of this information will involve any added physical risks to you.

Interviews/Questionnaires: During the questionnaires and/or the interview, you may become uncomfortable or experience some anxiety, emotional and/or psychological distress due to the nature of the questions. You can skip questions, take a break or stop answering at any time. The following resources are available for you to contact for psychological support:
If applicable include, If your responses indicate that there is a serious risk of harm to yourself or others, confidentiality will be broken in order to protect you or another person. If we feel that you need urgent care as result of participating in this research study we will intervene according to routine clinical care practices.

Confidentiality risk (for all studies):
Despite protections being in place, there is a risk of unintentional release of information. Researchers will make every attempt to protect your privacy.

Researchers do not know what effects the study drug used in the main clinical trial may have on a fetus (unborn child).

6. **If I decide to take part in this study, can I stop later?**
Note: requiring a written notification is not acceptable. It is the study team's responsibility to document the request. Verbal notification is sufficient. Parents/patients should not be asked to go through the additional burden of writing a letter for documentation purposes.

It is your choice to take part in this study, participation is voluntary. You can change your mind at any time during the research study. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you will receive. If you decide to leave the study, you can contact your researcher/study doctor. You have the right to request the destruction of your information collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

7. What about new information?

You will be told, in a timely manner, about new information that may affect your or your child's health, welfare, or willingness to stay in this follow-up study.

8. What are my rights when participating in a research study?
Edit as required

You have the right to receive all information that could help you make a decision about participating in this study, in a timely manner. You also have the right to ask questions about this study at any time and to have them answered to your satisfaction.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You have the right to be informed of the results of this study once the entire study is complete

You will be given a copy of this signed and dated consent form prior to participating in this study.

9. What about my privacy and confidentiality?

Edit as applicable for your study

Protecting your privacy is an important part of this study. If you decide to participate in this study, the [researchers/study staff] will collect and use information from your/your child's [health/medical] records. They will only collect and use the information they need for this study.

The personal health information or personal information collected about you /your child will have all directly identifiable information removed (i.e., name, MCP) and replaced with a code or with a "study number". There will be a master list linking the code numbers to names. The study doctor is responsible for keeping it separate from the samples and personal health information. If applicable, This link will not

be available to the [Sponsor/Funding agency/Coordinating centre].

Study information collected during the study will kept at this site and stored in a secure, locked place that only the study staff will be able to access. After the study closes, study information will kept as long as required by law, which could be xx years or more. This information will be stored [name the appropriate location]. [Name the appropriate person/role] is the person responsible for keeping it secure.

Study information sent to the sponsor, and companies working for the sponsor, will be stored in a secure central database. When the results of this study are published or presented at scientific meetings, your/your child's name and other personal information will not be used in the publication.

All information that identifies you/your child will be kept confidential, and to the extent permitted by applicable laws, will not be disclosed or made publicly available, except as described in this consent document. Every effort to protect your/your child's privacy will be made. Even though the risk of identifying you/your child from the study data is very small, it can never be completely eliminated. If there is a breach of privacy resulting from your/your child's participation in this study you will be notified.

If data will be sent outside of Canada:
Your/your child's study information will be sent outside of Canada so there is a possible increase in the risk of identifying you/your child from the study data because the laws in other countries dealing with protection of information may not be as strict as in Canada. However, all study data that are transferred outside of Canada will have your/your child's directly identifying personal information removed (such as name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are agreeing to the disclosure of your/your child's coded information to organizations located outside of Canada.

If email will be used for study purposes (e.g., distribution of questionnaires, etc.), please add:
Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

10. Who will see my personal information?

Edit as applicable for your study

Representatives from the following organizations may come to look at the study records and your/your child's personal health information under the supervision of the study staff to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:
Edit as needed

- Sponsor Name, the company that makes the (product) and its representatives and partner companies;
- Representatives of the Health Research Ethics Board

- Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada, and (if applicable) other regulatory bodies such as the United States Food and Drug Administration (FDA).

We may continue to review your/your child's health records that you have consented for the study to access for a period of time after your last study visit in order to check that the information we collected is correct.

Your access to records

You have the right to see the information that has been collected about you/your child for this study. If you wish to do so, please contact the study doctor.

11. Will it cost me anything?

Please edit as applicable

You will not be paid for taking part in this pregnancy follow-up. Taking part in this follow-up may result in added costs to you, for example, travel, parking, meals, etc.

12. Are there other choices?

You may choose to participate or not to participate in this research. You do not have to take part in this follow-up in order to receive your usual care.

13. What are my rights?

Signing this form gives us your consent to be in this pregnancy follow-up. It tells us that you understand the information about the pregnancy follow-up. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this pregnancy follow-up still have their legal and professional responsibilities.

14. What about questions or problems?

If you have any questions about taking part in this pregnancy follow-up for research purposes, you can talk to the study doctor who is in charge of the study here at this site. That person is:

Name and telephone number of Principal Investigator

You can also talk to someone who is not involved with this study or pregnancy-follow up at all. They can tell you about your rights as a participant in a research study. This person can be reached through:

Ethics Office at 709-864-8871
Email: info@hrea.ca
Web : www.hrea.ca

Signature Page

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that I receive.
- I understand that it is my choice to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of participating in this study.
- I do not give up any of my legal rights by signing this consent form.
- I understand that all of the information collected will be kept confidential and that the results will only be used for the purposes described in this consent form.
- I allow access to health records and related personal health information as explained in this consent form.
- I understand that my family doctor [will/may] be informed of my study participation [include as applicable].
- I agree, or agree to allow the person I am responsible for, to take part in this study [include as applicable].
- [Insert any other research specific clauses that may be important to reiterate.]

Signature of participant	Printed name	Day Month Year
Signature of person authorized as substitute decision maker **[If applicable]**	Printed name	Day Month Year
Signature of person conducting the consent discussion	Name printed	Day Month Year

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant/substitute decision maker fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

Signature of Investigator Name Printed Day Month Year

Signature Page for Parent/Guardian

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse for my child/ward to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that my child/ward receives.
- I understand that it is my choice for my child/ward to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of my child/ward participating in this study.
- I do not give up any of my my child/ward's legal rights by signing this consent form.
- I understand that all of the information collected will be kept confidential and that the results will only be used for the purposes described in this consent form.
- I allow access to my child/ward's health records and related personal health information as explained in this consent form.
- I understand that my child/ward's family doctor will/may be informed of my study participation [include as applicable].
- [Insert any other research specific clauses that may be important to reiterate.]

I consent for my child/ward _____to take part in this study.

_____

Signature of parent/guardian Name printed Day Month Year

_____

Signature of person conducting the consent discussion Name printed Day Month Year

_____

Signature of witness **[If applicable]** Name printed Day Month Year

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the parent/guardian fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen for the child/ward to be in the study.

_____

Signature of Investigator Printed Name Day Month Year

To be signed by the minor participant [if appropriate]

Assent of minor participant:

I understand the purpose of this research
I understand that it is my decision to take part in this study. I can stop taking part if I chose.
I understand that taking part in this research may not help me.
I understand that there may be risks to participating in this study.

I agree that I will take part in this study

Signature of minor participant Day Month Year

Name printed Age

Participant Assistance

Complete the following declaration only if the participant is unable to read:

- The informed consent form was accurately explained to, and apparently understood by, the participant, and
- Informed consent was freely given by the participant

Signature of Impartial Witness Printed Name Day Month Year

Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows:

- The informed consent discussion was interpreted by an interpreter and
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

Interpreter Declaration and Signature:
By signing the consent form I attest that I provided a faithful interpretation for any discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

Signature of Interpreter Printed Name Day Month Year