**PREGNANT PARTNER DATA RELEASE CONSENT FORM TEMPLATE**

This consent form template is intended for consent to collect medical information regarding pregnancy, birth, and infant health from a female partner impregnated by a male participant in an experimental clinical trial.

**TITLE OF STUDY**

**Principal Investigator:** Name, degrees held (if applicable)

 Institutional affiliation

 Contact Phone Number

**(Optional) Co-Investigator(s):** Name(s)

 Institutional affiliation

 Contact Phone Number(s)

**Funder/Sponsor:** Name of sponsor/funder

**INTRODUCTION AND STUDY PURPOSE**

This section should include a brief explanation of why information about pregnancy and birth outcomes are being collected.

**Sample wording:**

*You became pregnant while your partner was taking part in a research study of an experimental drug called [drug name]. A copy of the informed consent form for that study is available for your review. As the effects of [drug name] on your pregnancy and your fetus are unknown, we are asking permission to collect information relating to your pregnancy, and, if appropriate, the birth and the health of your baby. Your participation is entirely voluntary, and your decision will not impact your partner’s ability to take part in the clinical trial. If you do not wish to permit the collection of this information, you do not need to provide a reason, and you will not lose the benefit of any medical care to which you are entitled or are presently receiving.*

*Please take time to review this consent form carefully and ask any questions you would like. You may discuss the information in this consent form with your family, friends and doctor before you decide.*

**WHO IS CONDUCTING THIS STUDY?**

**Sample wording:**

*This study is being conducted/sponsored by the [name of research group, e.g. industry sponsor/granting agency].*

*The Principal Investigator [insert study personnel and/or institution] has received financial compensation from the sponsor [name the sponsor] for the work required in doing this clinical research and/or for providing advice on the design of the study/travel expenses/etc. Financial compensation to researchers for conducting the research is associated with obligations defined in a signed contractual agreement between the researchers and the sponsor. Researchers must serve the interests of the participant and also abide by their contractual obligations. For some, the payment of financial compensation to the researchers can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the Principal Investigator.*

**WHAT IS INVOLVED?**

Provide a succinct description of what type of information will be collected, and for how long. State that the participant is not being asked to do anything other than consent to the release of data for this study, and that no additional tests or procedures are involved. Specify whether past pregnancy history will be collected.

**Sample wording:**

*If you agree, information about your pregnancy, birth, and baby’s health will be collected from you, your doctor, and/or your medical records, such as:*

* *[list of information].*

*This information will be collected throughout your pregnancy until the delivery, with a follow up period of [specify time, e.g., six months]. You will not be asked to anything other than provide permission for the collection of this information, and there are no other research tests or procedures involved.*

**WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?**

This section should explain that the participant can decide to stop participating in the study at any time and without any penalty and without providing any explanation of their reasons for doing so. It should also indicate what will happen to their data collected up to the point of withdrawal.

**Sample wording for research that is regulated by Health Canada or US FDA:**

*You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, all information about you collected up to the point of your withdrawal will be retained for analysis in order to protect the integrity of the research, which may benefit future research participants and patients. However, no further information will be collected.*

**Sample wording for research NOT regulated by Health Canada or US FDA:**

*You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information about you already collected. 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.*

*If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn, for example, where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let your study doctor know.*

**WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?**

**Required Wording:**

*Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the Fraser Health Research Ethics Board**for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.*

Describe how the participant’s identity and potentially identifiable information will be protected, including the de-identification procedures.

**Sample Wording:**

*You will be assigned a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a participant in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.*

Disclose whether the information collected will be sent outside of Canada.

 **Required wording (If applicable):**

*Any study related data, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries, [insert (for e.g.) the Patriot Act in the United States] dealing with protection of information may not be as strict as in Canada. However, all study related data that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your information [and/or samples], to organizations located outside of Canada.*

* *[Insert organization/s]*

**WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A PARTICIPANT DURING THE STUDY?**

**Required wording:**

*By signing this consent form, you are not giving up any of your legal rights.*

*If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Fraser Health REB co-Chairs by calling 604-587-4681. You may discuss these rights with one of the co-chairs of the Fraser Health REB.*

**CONSENT TO PARTICIPATE**

This section of the consent form should start on a new page with the title of the study on that page. It should be clear in this section that the consent form is not a contract and as such that the participant does not give up any legal rights by signing it.

The participant is signing the form to indicate that he/she has read, understood and appreciates the information concerning the study. As such use the first person pronoun (“I”) for this section.

It is helpful if the signature page includes a checklist of the issues most critical to making an informed decision. Ensure that the checklist fits on the page with the signatures of the participants. The signatures should never be on a separate page by themselves.

**Sample Check List:**

* *I have had the opportunity to ask questions about the information provided in this consent form and have had satisfactory responses to my questions.*
* *I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time.*
* *I understand that I am not waiving any of my legal rights as a result of signing this consent form (required for all consent forms).*
* *I have read this form and I freely consent to participate in this study.*
* *I have been told that I will receive a dated and signed copy of this form.*

**SIGNATURES**

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Participant signature Printed name of participant Date

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Signature of person administering Printed name of person Date

consent administering consent

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Investigator Signature Printed name Date