**Pregnancy Data Collection Information Sheet and Consent Form**

**Study title:**

Study Doctor: Phone:

Research Coordinator: Phone:

**Introduction**

You are being asked to read this information because you have become pregnant during or shortly after taking part in a clinical study OR because you are the partner of someone who was taking part in a clinical study and you are now pregnant. The study involved an experimental drug for the treatment of XXX. As the risks to you or to your baby from being exposed to this study drug are unknown, the study sponsor would like to collect as much information as possible about you and the outcome of your pregnancy.

Before you make a decision one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

**What information is needed?**

If you agree to allow us to collect information about your pregnancy, after signing the consent form, a member of the study staff will collect information from your medical records. This may include information related to your health, the approximate date of conception, the course of the pregnancy, any medical treatments that you received, details about your delivery and the health of your child after birth.

**What are the benefits to me?**

You will receive no benefits or payment for taking part in this follow-up research. This follow-up research will not cover any costs related to your pregnancy, delivery or care of your child. Your participation will help provide more information about the experimental drug that may benefit others in the future.

**What are the risks to me?**

There are no risks associated with this data collection. Your only involvement in the study will be to answer questions and provide health information to us.

**What are your rights?**

You do not have to agree to participate in the pregnancy follow-up. Allowing us to collect this information is completely voluntary. If you do not agree, this will also not affect your ability to be in the study or your partner’s ability to be in the clinical study (as applicable). If you sign this form agreeing to allow your data to be collected, you can still choose to change your mind at any time and without giving a reason. If you change your mind, please tell your doctor so no new information will be collected or shared with the study sponsor, but information already collected will need to be kept.

**What will happen with my information?**

This part of the research involves the collection of health information about you and your baby. This information will be collected to send to the Sponsor of the study. It will be used by the Sponsor to ensure that information about the study drug and its effect on pregnancy is collected.

Any data that we collect will be coded before it is sent to the Sponsor. This means that your name will be replaced with a code and only the local researcher will be able to link that code to you personally. No data that includes your name or anything that can identify you will be released outside of the study doctor’s office or published by the Sponsor or the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private.

The researchers may need to look at your personal health records held by health care providers that you are seeing for your pregnancy (i.e. your family doctor or obstetrician). Any personal health information that we get from these records will be only what is outlined in this consent form.

It is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from the study sponsor, representatives of the sponsor, the University of Alberta’s Research Ethics Board or Auditors, Health Canada, and/or other foreign regulatory agencies, but only while they are physically here at the study site.

By signing this consent form you are saying it is okay for the researchers to collect, use and disclose information about you from your personal health records as described above.

All of the data collected about your pregnancy and its outcome will be kept by the Sponsor for a period of at least 25 years after the end of the main study.

**Who should you contact for more information?**

For more information, please contact: Dr. XXXXX at 780-XXX-XXXX.

If you have any concerns about the conduct of this research or your rights, you may contact the Research Ethics Office at 780-492-2615. This office is independent of the study investigators.

**How do I indicate my agreement?**

By signing below, you understand:

* That you have read the above information and have had anything that you do not understand explained to you to your satisfaction.
* That you are agreeing to allow your data to be collected as part of a research study.
* That you may withdraw your consent at any time.
* That you do not waive your legal rights by providing this consent
* That the legal and professional obligations of the investigators and involved institutions are not changed by your agreement to allow your data to be collected as part of this study.

**SIGNATURE OF STUDY PARTICIPANT**

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Signature of Participant

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Name of Participant Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

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Signature of Person Obtaining Consent

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Name of Person Obtaining Consent Date

**SIGNATURE OF THE WITNESS**

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Signature of Witness

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Name of Witness Date

A signed copy of this consent form has been given to you to keep for your records and reference.