CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA
AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY

Research Study Information and Consent Form

STUDY TITLE: Pregnancy Reference Intervals for Safe Medicine (PRISM)

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1. BACKGROUND & INVITATION

A healthy start to a baby's life relies on a safe and healthy labour and delivery. Serious medical concerns can arise during labour and delivery which affect health of the mother and the child. Laboratory tests (blood tests) help to diagnose these conditions. Doctors compare the results of a patient's blood test to what is expected in 'healthy' people, however information regarding what is considered healthy in pregnant women is lacking. This study hopes to determine the 'normal range' for a number of blood tests in healthy women near the time of labour to help doctors to diagnose medical concerns of women during this important time.

You are invited to take part in this study because you are pregnant and are expected to deliver at BC Women's Hospital.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is completely voluntary. You have the right to refuse to participate in this study. If you decide to participate now, you may still choose to withdraw from the study at a later date without any negative consequences to medical care, education, or other services to which you are entitled or are presently receiving. If you do not wish to participate, you do not have to provide any reason.

If you wish to take part in this study, you will be asked to sign this form. Please take time to read the information carefully and to discuss it with your family, friends, and doctor before you decide.

3. WHO IS CONDUCTING THE STUDY?

The study is being conducted by researchers at the Children's and Women's Health Centre of BC and at the University of British Columbia.

4. WHAT IS THE PURPOSE OF THE STUDY?

Blood samples will be collected for this project to help determine the reference ranges (normal ranges) of blood tests specifically for women in labour. We hope it will fill in gaps that currently exist in pregnancy care and may improve diagnosis and treatment of women across Canada.

5. WHO CAN PARTICIPATE IN THIS STUDY?

You may participate in this study if you are

- Between 19 and 45 years of age
- Pregnant with no prior health problems
- Have not smoked during pregnancy
- Having a healthy, uncomplicated, low-risk, singleton pregnancy
- Delivering your child at BC Women's Health Centre.

No other conditions need to be met to take part in this study.

You may have been invited to donate your cord blood to Canadian Blood Services (CBS). You may participate in this study without any impact to your CBS donation.

6. WHO SHOULD NOT PARTICIPATE IN THIS STUDY?

If you have any known health condition, are taking medication, smoke or use other substances, have a complicated or high-risk pregnancy or your doctor has told you of any abnormality in your pregnancy, you might not be eligible to participate. Study personnel will be able to determine your eligibility if you are unsure.

7. WHAT DOES THE STUDY INVOLVE?

Approximately 300 women will take part in this study. If you agree to take part, we will ask you some questions about your health and personal history including your age and any

conditions which might affect your health status (e.g., substance use history, diabetes, high blood pressure). We will also ask for information about your ethnicity (race) since some laboratory normal ranges are known to be different for some ethnicities in non-pregnant populations. This questionnaire will take about 10 minutes of your time.

Based on your answers, review of your medical information, and/or study enrolment numbers at the time you deliver, you may not be eligible to continue in the study. If this is the case, we may not collect blood from you for the study. We may also not collect blood from you if you give birth before the 37th week of pregnancy.

If you are considered eligible for the study when you are at the hospital around the time of labour and delivery, we will collect approximately 20mls (4 teaspoons) of blood from you. This can be collected during an early stage of labour so that you will not be interrupted close to delivery. If your doctor or midwife requests a blood test to help with your care during labour, or an I.V. (intravenous) device is started for you, we will make every effort to collect your sample for the study at the same time, so that an additional needle poke is not required. Blood may not be collected if there are no staff available to collect samples when you are admitted to hospital or if sample collection will interfere with your care.

We will review medical records to collect information about your pregnancy, delivery and your health after giving birth.

If an adequate blood sample is collected from you for the study, or if results from blood tests ordered by your care provider are sufficient, we may also contact you by email or phone within 1 month after your delivery to ask if you had any health problems afterwards which might be relevant (e.g., an infection).

The total time required to take part in this study is approximately 30 to 40 minutes, including the time to read and sign this form and ask questions. No additional visits to your doctor are required for the study. Your participation in this study will not affect your care or your baby's care in any way.

8. WHAT ARE MY RESPONSIBILITIES?

You will be asked to answer a brief questionnaire about your medical history, family history and diet. You will also be asked to provide a blood sample. Other information required for this study is already collected as part of clinical care. If you agree to participate in the study, we will review your medical records to obtain this information. There are no other responsibilities for you to participate in this study.

9. WHAT ARE THE POTENTIAL RISKS AND/OR DISCOMFORTS OF PARTICIPATING?

Blood drawing may cause some discomfort, bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or there may be swelling in the area. Rarely, fainting or a local infection at the puncture site may occur.

Blood specimens will be collected when you are admitted to hospital around the time of labour and delivery. A study team member and blood collector may interact with you during this time.

10. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

Blood test results obtained in this study will be used for research only and will not be available to your physician or midwife. Neither you nor your child will directly benefit from participating in the study. However, we hope that the results of the study will be useful for the medical care of pregnant women in the future.

11. WHAT ARE THE ALTERNATIVES TO THE STUDY PARTICIPATION?

Participating in this study is completely voluntary. You may choose not to participate in this study or to withdraw yourself from participation in the study at anytime without providing a reason for your decision. It will not influence the availabilty or quality of the present or future health care you receive.

12. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

You may withdraw from this study at any time without giving any reason. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data and/or samples will not be able to be withdrawn, for example, where the data and/or sample 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 and/or samples, please let the study team know.

13. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. However, research records and medical records identifying you may be inspected in the presence of the Investigator or her designate and by members of the Children's and Women's Hospital Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be removed or released without your consent unless required by law.

The date and time of delivery will be collected in the study database in order that we can measure the amount of time between your blood collection and delivery. Since age can affect some blood test results, we will also collect your birthdate so that we have a precise measure of your age. This is the only personal identifying information that will be collected in the study database. This information will not be shared with individuals outside of the study team. You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include a Personal Health Number, SIN, name, etc.). This number will be used on all research-related information collected about you during the course of this study, so that your identity 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. A list that matches your name to the unique identifier that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also give you the right of access to the information about you if it is still identifiable, and if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the study team.

14. WHAT HAPPENS IN CASE OF RESEARCH RELATED INJURIES?

By signing this form, you do not give up any of your legal rights and you do not release the study team, participating institutions, or anyone else from their legal and professional duties.

15. WHAT WILL THE STUDY COST ME?

There will be no cost to you for participating in the study.

16. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or would like further information about this study, you can contact Dr. Vilte Barakauskas at 604-875-2345, ext 7649 or Dr. Benjamin Jung at 604-875-2345, x2453.

17. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A PARTICIPANT?

If you have any questions or concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

FUTURE RESEARCH

It is possible that your samples may not be suitable for this study (for example if you develop an infection shortly after delivery), or there may be a portion of your sample leftover after study testing. You may choose to donate these specimens, along with your medical information, to the BC Children's Hospital Biobank for use in future research. If you are interested in participating in the Biobank, a separate consent form will be provided. If you are not interested in participating in the Biobank, your leftover samples will be destroyed at the end of this study.

You may also choose to hear about other research opportunities available to you in the future.

Please indicate your choice below as to how you wish to have your samples and contact information handled.

FUTURE USE OF SAMPLES

I wish to have my samples and medical information deposited in the BC Children's Hospital BioBank for use in future research. (Separate consent process required).

❑ **YES** ❑ **NO**

CONTACT FOR FUTURE STUDIES:

If you would like to hear about other research projects in the future, please mark the "yes". This does not mean that you will have to take part in a new study, just that we will let you know about it. If you do not want to hear about new studies, please mark "no".

❑ **YES** ❑ **NO**

CONSENT TO PARTICIPATE

My signature on this consent form means:

- I have read and understood the participant information and consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate in this study at any time without changing in any way the quality of care that I receive.
- I authorize access to my medical history, medical records and blood sample, as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that this study will provide no specific benefit to myself or my child.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

Participant's Signature	Printed name	Date

Email Address: _____

Signature of person obtaining consent	Printed name	Date

Language of translation (if applicable): _____

Signature of translator	Printed name	Date