EPIC (Epigenetics of Placenta In Complications of pregnancy)
Participant Information and Consent Form

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INVITATION:
You are being invited to participate in this study because of one or more of the following:

a. You received an abnormal Maternal Serum Screen (MSS) results with a PAPP-A lower than 0.15 MoM **and**/**or** an hCG greater than 4.0 MoM **and**/**or** AFP greater than 2.5 MoM **and**/**or** inhibin A greater than 3.0 MoM
b. **Y**our fetus was found to be small on ultrasound **or** your doctor thinks your fetus may have intrauterine growth restriction (IUGR)
c. You h**ave a pregnancy affected by** preeclampsia **and**/**or** chromosome trisomy.

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

If you wish to participate in this study, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

BACKGROUND:
Pregnancy complications such as low birth weight or maternal high blood pressure (preeclampsia) can result from abnormal development of the placenta. Women who have an abnormal Maternal Serum Screen (MSS) are at a slightly elevated risk for these complications in their pregnancy, however most go on to have a normal term birth. The causes of low birth weight, preeclampsia, or abnormal MSS are mostly unknown.

One possible explanation for these complications is that the placenta does not function as well as it should to feed and support the baby. We are trying to understand if there are genetic or other molecular changes in the placenta that affect how the cells in the placenta function.

An example of one such change involves chemical modifications to the DNA in the cells, called DNA methylation. DNA methylation is a type of epigenetic change, that is, it does not change the sequence of the DNA code (the material our genes and chromosomes are made of) but can affect how genes are turned on and off in the cell.

PURPOSE:
Our aim is to determine whether or not genetic differences or other changes that may affect how genes are turned on and off, such as DNA methylation, are related to abnormal outcomes associated with unexplained abnormal MSS, poor fetal growth, or preeclampsia. We also hope to determine the impact of an abnormal MSS on maternal mental health and possible environmental factors that affect DNA methylation or gene expression. We hope to develop prenatal screens that predict risks accurately by studying the placenta.

WHAT THE STUDY INVOLVES:
PART1: Review of prenatal & birth records, placenta (and/or products of conception) sample, brief questionnaire and a blood sample from you. Cells from the placenta (and/or products of conception) will be tested for genetic and epigenetic changes. Four 4mL tubes (~ 3 teaspoons) of your blood will be drawn and collected for genetic studies of DNA and analyses of chemicals. Participation in PART 1 will require about 20 mins

PART 2 OPTIONAL: After the birth of your baby a sample of your baby's cells from the inside of the cheek may be obtained using a swab to compare methylation differences to the placenta.

POSSIBLE HARMS & DISCOMFORTS:
There may be some discomfort associated with the placement of the needle for blood withdrawal and occasionally bruising, swelling, feeling faint or dizzy and/or the rare chance an infection may result. There are no anticipated risks to you or your baby from obtaining a cheek swab or completing the EPDS.

BENEFITS:
Participation in this study may help to further our understanding of prenatal screening, placental development and function, and causes of poor fetal growth and maternal complications of pregnancy. There is no direct benefit to the individual from participating in this study.

REMUNERATION:
You will not be paid for your participation in this research study. We will provide you with a gift card to reimburse you for some of your hospital expenses when providing a blood sample.

WITHDRAWING CONSENT:
Your participation in this research is entirely voluntary. If you decide to enter the study and later decide to withdraw, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected. If you wish for your stored blood, placenta samples/data to be destroyed upon your withdrawal, you may contact the principal investigator of the study, at 604.875.3015. The investigator may decide to discontinue the study at any time, or withdraw you from the study at any time. If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study and up to the time of withdrawal will be retained for analysis. In the event that we receive a sample from you without consent and are unable to contact you to obtain consent, we will assume implied consent.

CONFIDENTIALITY:

Your confidentiality will be respected. Research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate, Health Canada, and the UBC Research Ethics Boards for the purpose of monitoring the research. No information or records that disclose your identity will be released or 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. We will be collecting date of birth as it is important to calculate maternal age for these studies.

You will be assigned a unique study number as a subject 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 subject in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate (research coordinator, lab manager, lab technician). 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.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the Robinson lab and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request.

Samples received will be de-identified (your name is removed) and coded with a unique study number upon receipt. The list that matches your name to the unique study number is in a password protected electronic file. The electronic file is kept on the lab server only accessible with an authorized computer login and password.

Your de-identified samples and DNA will be stored in Dr. Robinson's laboratory at the BC Children's Hospital Research Institute (BCCHR; formerly CFRI). The de-identified samples labelled with the unique study code will be stored until it is used entirely or until such DNA is withdrawn. The laboratory is in a secure building accessible only by photo key card. De-identified DNA samples will be studied at the BCCHR. Should your de-identified sample be requested by an outside investigator in collaboration with Dr. Robinson, she will obtain the proper ethics approval prior to sharing the de-identified sample. At no point will any identifiable data associated with the de-identified sample be sent to outside investigators. Your de-identified DNA sample will not be sold and will not be used for commercial purposes.

Any data or samples, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries *[for example, the Patriot Act in the United States]* dealing with protection of information may not be as strict as in Canada. However all data and or samples, that might be transferred outside of Canada will be re-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 possible transfer of your information and samples, to organizations located outside of Canada. Dr. Robinson will obtain the proper ethics approval prior to transfer of data or samples outside of Canada.

Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else. Your rights to privacy are also protected by the *Freedom of Information and Protection of Privacy Act of British Columbia.* This Act outlines rules for the collection, protection, and retention of your personal information by public bodies, such as the University of British Columbia and its affiliated teaching hospitals. Further details about this Act are available upon request.

CONSENT TO PARTICIPATE

If you have any questions about your participation in this study contact the Robinson Lab at 604.875.3015. If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

· *I have read and understood the subject information and consent form.*
· *I have had sufficient time to consider the information provided and to ask for advice if necessary.*
· *I have had the opportunity 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 result will only be used for scientific objectives.*
· *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 without effecting my participation in the main study and without changing in any way the quality of care that I receive.*
• *I authorize access to my health record and samples 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 there is no guarantee that this study will provide any benefits to me*
· *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.*

Please check boxes below.

□ PART 1 – Placenta (and/or products of conception), Blood
□ PART 2 – Infant Cheek Swab

□ A member of Dr. Robinson's research team may contact me in the future for follow-up or further research related to this study.
□ A member of Dr. Robinson's research team may contact me in the future to ask if I am interested in participating in other research studies not described in this form.

I consent to participate in this study.

Print name of subject		Signature	Date
Print name of person obtaining consent	Study Role	Signature	Date