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INVITATION:
You have been invited to participate in this research study because you have had a pregnancy diagnosed with a mole, partial mole, molar-like changes, placental mesenchymal dysplasia (and/or associated findings such as chorioangiomas and hemangiomas) or a triploid fetus

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
Your pregnancy has been diagnosed as having an abnormality of placental development. Various "epigenetic" and "genetic" changes can affect placental development. Epigenetic errors affect how genes turn on and off, in other words the activity of our genes. Epigenetic errors do not change the sequence of the DNA code (the material our genes and chromosomes are made of) whereas genetic changes often do. We are interested in genes that control placental development. One indirect measure of this epigenetic on/off switch for genes involves a chemical modification to the DNA. This chemical modification is termed DNA methylation.

These epigenetic and genetic changes include increased or decreased gene activity, having too many chromosomes or an inappropriate balance between the maternal and paternal contribution of genetic material. In some cases, however, the direct link between abnormal placental development and the epigenetic and genetic findings is not clear.

We are interested in identifying the epigenetic and genetic changes specific to those identified in triploid pregnancies, complete hydatidiform moles (CHM) , partial hydatidiform moles, molar-like changes, placental mesenchymal dysplasia (PMD), sometimes referred to as 'pseudo-moles'. We are also interested in the clinical findings associated with PMDs such as chorioangiomas and hemangiomas. The abnormalities described above generally result from an excess of paternal compared to maternal contribution to the placenta, but the exact defects critical for these outcomes are not clear.

PURPOSE:
The purpose of this research proposal is to improve our understanding of the cause of abnormal placental development characteristic of molar findings. We will use epigenetic and genetic analysis to try and determine the underlying defect in the abnormal cells. If possible we will also compare the placental (and associated findings such as chorioangiomas and hemangiomas) DNA to the fetus/child's, mother's and father's DNA.

WHAT THE STUDY INVOLVES:
Participation involves release of medical/health records related to the placenta/fetal diagnosis or associated findings on your child (pathology report on the placenta, ultrasound reports, Medical Genetics/Obstetric consult notes); donation of the placenta/fetal tissues and or tissues from your child that have been collected by pathology that can provide DNA; and four tubes (approximately 2 teaspoons) of blood from each parent for epigenetic and genetic studies of whole chromosomes and DNA. The total amount of time needed is approximately 20 minutes. Each participant (parents and child if applicable) is to receive their own consent form.

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 is the potential for identifying an underlying genetic change associated with clinical features. There may be psychological harm associated with identification of a genetic change that cannot be reversed, treated or cured. Disclosure of genetic or tissue marker research data could result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. The chance that research data would be released is estimated to be small. All counseling will reside with the original health care provider that requests the study.

RESULTS:
Participants will not generally be provided with results from these epigenetic and genetic studies. However results will be provided to a participant's referring health care provider when requested to confirm anatomic pathology findings of the placenta/fetus or child or for reproductive health counselling. We do not have an estimated turn around time for the results as this study is unfunded and completed on a volunteer basis by lab personnel. When results are provided, the counselling regarding results will reside with the original health care professional who requested the study. Results will only be provided to the requesting health care provider. The health care provider will contact you to inform you that the results are available. It is up to the health care provider to determine whether results will be provided by an in person appointment or whether a phone appointment is sufficient. No information regarding paternity will be provided.

BENEFITS
Participation in this study may help to further our understanding of pregnancy loss, pregnancy complications, and susceptibility to molar pregnancies in certain women.

REMUNERATION
There will be no payment for your participation in this research study.

WITHDRAWING CONSENT: Your participation in this research is entirely voluntary. If you decide to enter the study and later decide to withdraw at any time in the future, 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 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.

CONFIDENTIALITY:
In Canada genetic information as a form of personal information is protected legally by privacy and discrimination Acts. Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, 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 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. The medical records allow us to verify the results we derive from the analyses We will be collecting personal identifiers such as year and month of birth because many genetic factors are associated with age and prevent sample mis-handling.

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 co-ordinator, 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. 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 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.

Your de-identified samples and DNA will be stored in Dr. Robinson's laboratory at the Child & Family Research Institute (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 CFRI. De-identified samples may be sent to other co-investigators on this study for analysis, but the sample/DNA will not be used for any purposes other than those outlined in this consent. At no point will any identifiable data associated with the de-identified sample be sent to outside investigators. Your de-identified samples 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.

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT PARTICIPATION IN THIS STUDY?

If you have any questions about your participation in this study contact the Robinson Lab at 604.875.3015.

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

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).

CONSENT TO PARTICIPATE:

· *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.*

□ 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 regarding future research and for general information.

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