Principal Investigator: Wendy P. Robinson, PhD, UBC Dept. of Medical Genetics.
Contact number: Study coordinator (604-875-3015) or Dr. Wendy Robinson (604-875-3229),

BACKGROUND

The Robinson Lab focuses on how epigenetic and chromosomal changes relate to reproductive health. Epigenetics is the study of how genes are turned on and off. We specifically focus on the epigenetic mechanism known as methylation. Methylation is the addition of a methyl group to the DNA. It is the presence or absence of the methyl group that turns genes on or off. The activation or deactivation of specific genes can affect reproductive health. Chromosomes are the structures our DNA forms. Normally an individual has 46 chromosomes in each cell. A difference in the normal number or structure of the chromosomes can occur. Sometimes these changes are in all the cells of an individual or sometimes just some of the cells. Mosaicism is the term used to describe the occurrence of just different cells having a different number or structure to the chromosomes. We are interested in learning more about these connections between our genes and reproductive health.

AIM

It is increasingly common for researchers to invite participants in different kinds of research studies to bank samples of tissues and/or DNA for use in future research studies. Often the exact nature of these studies is not entirely known because new discoveries lead research in new and not always foreseen directions. However, samples collected for the purposes of one study may not get used completely and can sometimes be used to answer other research questions. For this reason, participants are asked to consider storing the remainder of the sample for future studies.

We invite you to bank your de-identified DNA for future related disease/birth defect research. Your participation in this part of the study is voluntary, so it is up to you to decide whether or not to take part. Before you decide, it is important for you to understand what the research involves. If you wish to participate, you will be invited to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision. Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide. Any questions concerning participation can be addressed to Dr. Robinson at the above phone number.

POSSIBLE HARMS AND DISCOMFORTS?

The possible harms and discomforts of the study mostly involve the collection of the blood sample, There may be some slight pain and discomfort when the needle is inserted into the vein and some minor bleeding, bruising, swelling or feeling faint or dizzy after it is removed. There is a very small chance that an infection could occur but all appropriate measures will be taken to prevent this and trained staff will take the blood sample.

There are also possible non-physical risks associated with taking part in this study. There is a small chance that some genetic information could result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. The chance that research data would be

released to these outside parties is estimated to be small and the results of this research will not be added to your medical records. Although there is no specific genetic data protection law in Canada, the Privacy Act and PIPEDA exist to protect personal data. Because every person's genes (DNA) are unique, there is a chance that, even when we have removed any information from your sample that could identify you, it might be possible to identify you or family members. The chances of this occurring are small since access to your DNA sample will be restricted.

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. Furthermore, your eligibility to participate in the main part of the study 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 604.875.3229. However, if your sample has already been tested at the time you withdraw, it may be impossible to withdraw the results once they have been compiled with the results of others participating in the study or if they have been published. Furthermore, if some of your sample has been shared with other researchers, it may not be possible to remove this part of the sample. In these cases of total withdrawal being impossible, your identity will still be protected and the chance of anyone knowing that you were ever involved in the study is small. 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. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

Dr. Robinson is the custodian of the list of participant names and the linking code. Dr. Robinson may provide access to the list of names and linking code to the research coordinator and lab manager. Both the research coordinator and lab manager have signed confidentiality agreements. The samples will be de-identified and coded upon receipt. The list of names 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.

No further consent will be sought from you for these future related genetic studies. Ethics approval will be sought for any additional research goals. Your de-identified DNA will be stored in Dr. Robinson's laboratory at the Child & Family Research Institute. The de-identified DNA sample labelled with the 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.

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. Dr. Robinson will ensure that the outside investigator has the proper ethics approval from their institution if samples are to be donated. Samples will only be donated if the outside investigator's research goals are in keeping with the types of research that you wish your sample to be used for, as indicated at the bottom of this form. 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.

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.

Your signature on this form signifies that you consent to banking your de-identified DNA sample (blood, placenta, fetal tissue) even after conclusion of this study. You understand that your de-identified DNA sample will be stored for future research directly related to the goals of this study (factors associated with NTD) or in keeping with the types of research that you wish your sample to be used for, as indicated at the bottom of this form. You will not be contacted for consent for future research, but ethics approval will be sought from the UBC C&W Research Ethics Boards for any future research with your tissue or DNA.

CONSENT TO PARTICIPATE

If you have any concerns 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 number 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 changing in any way the quality of care that I receive.*
- *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 (if applicable).*
- *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.*

If you check the boxes below, you agree to have your DNA sample and associated information described in this form stored (banked) for use in the following types of future studies without requiring further consent or contact from Dr. Robinson:

☐ I agree to consent for all future studies to learn about, prevent or treat health problems or birth defects. (for example, diabetes, heart disease)

☐ I agree that 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 or for clinical data clarification.

Print Subject Name:	Subject Signature:	Date:
Print name of person obtaining consent	Signature:	Date: