

Principal Investigator: Dr. W.P. Robinson, UBC Department of Medical Genetics
Child & Family Research Institute
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INVITATION:

You have been invited to bank your sample and DNA in this optional part of the research study because you or a family member have been diagnosed with a genetic condition or have an X chromosome abnormality. Each participant is to receive his/her own consent form.

AIM:

We invite you to bank your de-identified tissue/DNA for future related disease/birth defect research. The exact nature of these studies is not entirely known because new discoveries lead research in new and unforeseen directions. Sometimes samples collected for the purposes of one study may not get used completely and can be used to answer other research questions. For this reason, we ask you to consider storing the remainder of your sample for future studies. Your decision to bank your de-identified tissue/DNA 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 bank your de-identified tissue/DNA, you are still free to withdraw at any time and without giving any reasons for your decision. 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, for the main study. No additional samples are collected for the optional tissue banking. The risks associated with blood collection are outlined in the main consent.

There are also possible non-physical risks associated with banking your tissue/DNA. 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 very small and the results of this research will not be added to your medical records. Individual results from future studies will not be provided. 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. Although there is no specific genetic data protection law in Canada, the Privacy Act and Personal Information Protection and Electronic Documents Act (PIPEDA) exist to protect personal data.

WITHDRAWING CONSENT:

Your decision to bank your de-identified tissue/DNA is 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. Your eligibility to participate in the main part of the study will not be affected. If you wish for your samples/data to be destroyed upon your withdrawal, you may contact the principal investigator of the study, at 604.875.3015. 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 other participants 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 cases where total withdrawal is 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. 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.

Samples received as part of the main study are de-identified (your name is removed) and coded with a unique study number upon receipt. The unique study code assigned to your samples in the main study will be kept for any future studies. Only this number will be used on any research-related information collected about you during the course of any future 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) until the end of Dr. Robinson's appointment at UBC. 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 tissue/DNA will be studied at the CFRI.

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. Should your de-identified sample be requested by an outside investigator Dr. Robinson will ensure that the outside investigator has the proper ethics approval from their institution. Samples will only be donated if the outside investigator's research goals are in keeping with the types of research that you have 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..

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 TO CONTACT WITH QUESTIONS OR CONCERNS ABOUT 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 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*
- *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 indicate HOW you wish your DE-IDENTIFIED samples and information to be used for future studies (without requiring further consent or contact from Dr. Robinson):

- studies to learn about the X chromosome
- studies to learn about, prevent or treat all health problems and birth defects (for example, diabetes, heart disease)

Please indicate WHO you wish your DE-IDENTIFIED samples and information to be used by in future studies as indicated above:

- studies by local (ex. UBC/SFU) and national (Canadian) investigators
- studies by international investigators (ex. North American).
- studies by industry investigators.

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.

If signing for a child in your legal care, please print his/her name above

Print Name: _____ Signature: _____ Date: _____

Print name of person obtaining consent Study role Signature: Date: _____