

EPIC Study (Epigenetics of Placenta In Complications of pregnancy) Optional Tissue Banking Consent Form

UBC Department of Medical Genetics
Principal Investigator: Dr. W.P. Robinson 604-875-3229

AIM

We invite you to bank your de-identified tissue/DNA for future 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 individual results from these studies will not be provided to you. Your decision to bank your de-identified tissue/DNA is voluntary. Before you decide, it is important for you to understand what it involves. If you wish to participate, you will be invited to sign this form. If you decide to bank your de-identified tissue/DNA, you are free to withdraw at any time 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 for the main study. No additional sample is required for 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. 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 tissue/DNA sample will be restricted.

WITHDRAWING CONSENT

Your decision to bank your de-identified tissue/DNA is voluntary. If you 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 study will not be affected. If you wish for your samples/data to be destroyed, 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 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

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

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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 studies. Ethics approval will be sought for any additional research goals. Your de-identified tissue/DNA will be stored in Dr. Robinson's laboratory at the BC Children's Hospital Research Institute (BCCHR). The de-identified tissue/DNA sample labelled with the code will be stored until it is used entirely or until such tissue/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 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.

Your signature on this form signifies that you consent to banking your de-identified tissue/DNA sample (blood, placenta, fetal tissue) after conclusion of the main study. You understand that your de-identified tissue/DNA sample will be stored for future research directly related to the goals of this study (factors associated with placental function) 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 a Research Ethics Board for any future research with your tissue/DNA.

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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.*

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 placental function
- 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.

Print Subject Name: _____ Subject Signature: _____ Date: _____

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