

Epigenetics and Human Reproduction  
**Investigation of imprinting & Imprinting Disorders**  
**Optional Tissue Banking Consent Form**

**Principal Investigator:** Wendy P. Robinson, PhD UBC Department of Medical Genetics  
BC Children's Hospital Research Institute (BCCHR)

**Contact number:** Dr. Robinson: 604-8753229 Study Coord.: 604-875-3015

**Project funded by:** Canadian Institutes for Health Research

**Invitation:** In addition to the main part of the research study, you are being invited to bank your DNA for future studies on genetic research of imprinting disorders. The aim of tissue banking is to understand the causes and mechanism of imprinting and imprinting disorders. 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 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. 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 your participation can be addressed to Dr. Robinson at the above phone number.

**What are the possible harms and discomforts?** The possible harms and discomforts of the study mostly involve the collection of the tissue/blood sample for the main study. No additional sample is required for banking. The risks associated with tissue/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 DNA sample will be restricted.

**What happens if I withdraw my consent to bank tissue?** 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 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 participants in the

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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.

**How will my taking part in the tissue banking be kept confidential?** 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 that discloses your identity will be released or published without your specific consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. 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. 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 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.

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

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 DNA will be stored in Dr. Robinson's laboratory at the BC Children's Hospital Research Institute (BCCHR). 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.

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Should an outside investigator request your de-identified sample 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.

**What happens if something goes wrong?** By signing this consent form, you do not give up any of your legal rights against the sponsor, investigators, or anyone else from their legal and professional duties. 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, etc) even 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 (imprinting disorders) 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 Boards for any future research with your tissue or tissue/DNA.

**RESULTS:** Participants will not be notified of results from these future studies. In rare cases, if results are provided, the counselling regarding potential results will reside with the health care professional who requested original the study. If results are provided, they will be provided to the requesting health care provider. The health care provider will contact you to inform you that additional 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.

**Whom do I contact if I have any questions or concerns about my rights as a participant?** If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University Of British Columbia Office Of Research Services by e-mail at [RSIL@ors.ubc.ca](mailto:RSIL@ors.ubc.ca) or by phone at 604-822-8598 (Toll Free number 1-877-822-8598). Please reference the study number (H06-70085) when contacting the Complaint Line so the staff can better assist you.

**CONSENT FOR A MINOR**

☐ The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator/delegated staff are satisfied that the information contained in this consent form was explained to the child/participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/participant assents to participating in the research.

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### Participant Consent

My signature on this consent form means:

- *I have read and understood the participant information and tissue banking 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 results 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 records 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.*

**NOTE:** Each individual donating samples needs to sign this consent if they want their DNA banked.

**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):** Bank de-identified DNA for genetic studies related to genomic imprinting & its disorders:

- ☐ Future studies about imprinting disorders
- ☐ Future studies about the prevention or treatment of all health problems and birth defects.

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

- ☐ Studies by local (i.e. UBC/SFU) and national (Canadian) investigators
- ☐ Studies by international investigators (i.e. 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  
(OPTIONAL).

Printed name of participant (Person donating the sample)	Signature	Date
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Printed name of participant's Legally Acceptable Representative (Parent or legal guardian if applicable)	Signature	Date
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Print name of person obtaining consent	Signature	Date
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Print name of Principal Investigator	Signature	Date
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My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant's signature was obtained.