**SERF**
**Studies of Epignetics in Reproduction and Fertility**
**Subject & Control Consent Form**

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**Background:** A variety of environmental factors including hormones, stress, nutrition and chemical exposures have been linked to reproductive difficulties in many animals and humans, but are difficult to study. Environmental exposures may have long lasting effects on our genes by causing chemical modifications to the DNA that affect how genes work. These are called 'epigenetic' changes and affect when and how genes are turned on and off. Also as women age they are at increased risk to experience infertility or miscarriage. We hope to understand the influence of genes, environment, and maternal age on reproductive health and invite you to participate in this study.

**Aim:** We hope to identify genetic and epigenetic differences in blood or follicular fluid from women experiencing different reproductive outcomes. From these patterns we hope to provide better risk counselling and predict treatment outcomes.

**Who can participate:**

Women who fit in the following categories as a subject:

1) recurrent pregnancy loss
2) past trisomic pregnancy
3) early menopause before age 40
4) unexplained ovulatory infertility,
5) non-ovulatory infertility

Women who fit the following categories as a control:

1) successful pregnancy at age 37 or greater with no pregnancy loss
2) undergoing assisted reproduction for male-factor infertility only

**Procedure:** Four 4cc tubes (3 teaspoons) of your blood will be drawn for epigenetic and genetic studies of the chromosomes and DNA. We will measure blood levels of several hormones and nutritional factors. Participation also involves completing a contact form and a personal/family history questionnaire; only answering questions you wish to. With your consent your medical records will be reviewed for reproductive history, general health and medications. For women undergoing in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) we would obtain a sample of the remaining follicular fluid from the egg retrieval to perform the same analyses. The total amount of time needed is approximately 20-30 minutes.

**Results:** Individual results will not normally be provided. We will provide access to publications that result from this research data.

**Risks:** There may be some discomfort associated with the placement of the needle for blood withdrawal and occasionally, bruising, swelling, lightheadedness and/or fainting and/or infection may result.

**Benefits:** There is no direct benefit to you from participating in this study. Participation in this study may help further our understanding of infertility and reproductive health.

**Reimbursement:** There will be no payment/reimbursement 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 604.875.3229. 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. By law, this data cannot be destroyed.

**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 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 to 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. 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 Dr. Robinson will obtain the proper ethics approval prior to donating the 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 involve reproduction. 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.

Any study related data/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 study related data/samples, that might be transferred outside of Canada will be 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/or samples, to organizations located 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.

Your signature on this form signifies that you consent to participate in this study After reading the above information, you have been given the opportunity to discuss pertinent aspects of this research study and to ask questions and that you have also received a signed and dated copy of this consent form for your own records.

We invite you to bank your de-identified DNA sample received from this study for use in future related reproductive studies. A separate optional Tissue Banking Consent Form will be provided to you.

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.*

☐ **I provide permission for the Robinson Lab to contact me regarding this study.**

☐ **I provide permission for the Robinson Lab to contact me regarding future studies.**

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