University Health Network

CONSENT TO GENETIC TESTING THROUGH A RESEARCH STUDY

Title	Prevent Ovarian Cancer Program: Systematic identification of high-risk women for ovarian cancer prevention
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Introduction

You are being offered genetic testing as part of the research study "Prevent Ovarian Cancer Program (POCP)" at the Princess Margaret Cancer Centre. Please read this explanation about the risks and benefits before you decide if you would like to provide a blood sample. You should take as much time as you need to make your decision. You should ask the genetic counsellor or POCP staff to explain anything that you do not understand. Before you make your decision, feel free to talk about this study with anyone you wish. Please make sure that all of your questions have been answered before signing this consent form. Participation in this study is voluntary.

Background and Purpose

Up to 20-25% of women with high grade serous ovarian cancer have a hereditary type of cancer, which means that their family members may have an increased risk to develop cancer. In Ontario, genetic testing to look at the *BRCA1* and *BRCA2* genes, which are the genes most often associated with hereditary ovarian cancer, is available to any woman with a diagnosis of serous ovarian cancer regardless of her family history. Unfortunately most women with serous ovarian cancer have not had this testing done. This means that their female relatives may not know that they have an inherited risk to develop ovarian cancer. Finding women who have an increased risk to develop ovarian cancer will allow us to give them information on how they can reduce their risk.

Study Design & Procedures

- After a genetic counselling session, you will provide a blood sample for genetic testing. One tube (about one teaspoon) of blood can be collected at any *LifeLabs* laboratory.
- The genetic test will look at the *BRCA1* and *BRCA2* genes as well as a panel of 50 other genes that may have a role in the development of ovarian and/or other cancers.
- This test will be completed at the Princess Margaret Advanced Molecular Diagnostic Lab.
- The laboratory will report genetic changes that are likely to prevent the gene from working properly. These changes may increase a person's risk to develop cancer.

- When results are available, a genetic counsellor will review your test results with you. If appropriate, the genetic counsellor will send a referral to specialists for follow-up care.
- You will be provided with a copy of your test results and written information explaining them. A detailed note will also be sent to your family doctor.

Limitations of the Test

- A negative test result does not rule out hereditary cancer.
- This test will not tell you whether or not you have or will develop cancer. It may tell you if your risk of certain cancers is higher than the average Canadian woman.
- There is a small chance (less than 1%) that a mutation in the *BRCA1* or *BRCA2* genes may be missed using current technologies

Risks of Having the Test

- Providing a blood sample can cause minor discomfort. In some cases, bruising or discoloration near the site of needle insertion may occur.
- Some women who have this test may learn that they have an increased risk to develop ovarian cancer in their lifetime, which may cause increased anxiety.
- This test may provide information about genes that are still being studied and/or genes where doctors have no clear guidelines for cancer screening and prevention.
- Some individuals may receive uncertain results, which means that a change in a gene has been found, but is not clear if that change increases cancer risks or not.

Benefits of Having the Test

- This test may identify that you have an increased risk to develop ovarian and/or other cancer. Knowing this information will help you to learn and consider appropriate options for increased cancer screening and/or cancer risk reduction.
- Based on the results of your genetic test, the option of genetic testing may become available to your family members. They also can learn more about their condition and consider appropriate options such as cancer screening and/or cancer risk reduction.
- This test may help you to understand your family history of cancer.
- This test may determine that, based on available scientific data, your risk of developing ovarian cancer may be similar to that of the average Canadian woman.

The Type of Results to be Reported

This genetic test includes a panel of 52 genes that may be associated with an increased risk to develop cancer. Some genes are known to cause an increased risk of ovarian and/or other cancers and screening guidelines are available. Other genes are thought to cause an increased risk of ovarian and/or other cancer but the exact cancer risks are still being determined and screening guidelines are not yet available. Please initial beside the information that you would like to know.

You will have the option of receiving results on the following genes. Please indicate your choice on the last page of this document (consent).

A) *BRCA1* and *BRCA2* only. I understand that variant, or uncertain, results in these genes will be reported.
B) Genes that are known to increase the risk of ovarian and other cancers and where established guidelines for cancer screening are available. I understand that variant, or uncertain, results in these genes will be reported.
C) Genes that are thought to increase the risk of ovarian and other cancers but where established guidelines for cancer screening may not be available.
D) Genes that are known to increase the risks of other cancers (but not ovarian) and where established guidelines for cancer screening are available.

Confidentiality & Data Storage

The laboratory will report the test results to members of the Prevent Ovarian Cancer Program. You will be given a copy of your test results. The genetic test results will become part of your medical record and some individuals may have legal access to this information.

Sample Storage

If you agree, the laboratory may store any remaining sample(s) for future product development or research purposes. You will not receive any royalties, resultant payments, benefits or rights to products or discoveries.

Voluntary Participation

Your decision to have genetic testing is entirely voluntary. If you consent to genetic testing, but later decide that you do not wish to receive your genetic test results for any reason, stated or unstated, you may withdraw your consent for genetic testing. All results will be entered into your medical record upon completion of the genetic test so it is important that you contact the genetic counsellor immediately if you do not wish to know your genetic testing results. If you decide you no longer want your samples stored for any reason, stated or unstated, they can be destroyed at any time.

Questions About the Study

If you have any questions, concerns or would like to speak to the genetic counsellor for any reason, please leave a message for Jeanna McCauig at 1-866-330-0180 or email preventovariancancer@uhnresearch.ca. Please do not communicate private or sensitive information in email.

If you have any questions about voluntary participation, confidentiality, or questions related to the overall conduct of the study, please refer to the "Voluntary participation", "Confidentiality", or "Questions about the Study" sections of the POCP Study consent form.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Please keep one signed copy of this consent form for your records.

Consent

I would like my genetic test result to include information on the following genes: *(Please indicate with "X". You may select more than one)*

A) _____ *BRCA1* and *BRCA2* only. I understand that variant, or uncertain, results in these genes will be reported.
B) _____ Genes that are known to increase the risk of ovarian and other cancers and where established guidelines for cancer screening are available. I understand that variant, or uncertain, results in these genes will be reported.
C) _____Genes that are thought to increase the risk of ovarian and other cancers but where established guidelines for cancer screening may not be available.
D) _____Genes that are known to increase the risks of other cancers (but not ovarian) and where established guidelines for cancer screening are available.

Your genetic test results will not be shared with any family members unless we cannot contact you to provide you with your results (death or illness). In this case, your genetic test results may be disclosed to the biological relative listed below. If you decline to know your genetic test results, this relative <u>will not</u> be contacted.

Biological Relative's Name (print)	**Phone number**

This genetic test has been explained to me and any questions I had have been answered. I agree to provide a blood sample for genetic testing through the Prevent Ovarian Cancer Program.

If you do not want your sample to be stored, please initial below:

I do not want my remaining sample to be stored. Please destroy any remaining sample once the final report has been issued _____**.**

Study Participant's Name (print)	**Signature**	**Date**
Name of Person Obtaining Consent (print)	Signature	Date

My signature means that I have explained the genetic test to the participant named above. I have answered all questions.