University Health Network

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title Prevent Ovarian Cancer Program

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Introduction

You are being asked to participate in a research study at the Princess Margaret Cancer Centre. This province-wide research program is called the Prevent Ovarian Cancer Program or "POCP" for short. Your participation in the POCP will not remove or change any aspects of your current clinical care.

Please read this explanation before you decide if you would like to take part in the POCP research study. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. We are available to answer any questions that you may have. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this research study is entirely voluntary. **Additional information about this program, genetic testing, ovarian cancer, and program contact information is on our website: www.preventovariancancer.ca**

Background and Purpose

High-grade serous cancer (or "HGSC" for short) is the most common type of ovarian cancer and is almost always diagnosed when the disease has already spread throughout the body. There is no good way to screen for HGSC or to find it at an early stage. Fortunately, ovarian cancer can be prevented through surgery for women who have specific genetic changes (called "mutations") that increase her risk for getting ovarian cancer.

Women with certain genetic mutations may be more likely to develop ovarian cancer. The two most important genes known to increase a woman's risk for ovarian cancer are *BRCA1* and *BRCA2*. Genetic mutations can be passed on through families. This means that a first-degree relative – mother, sister or daughter – of a woman with ovarian cancer who has a mutation in *BRCA1*/2 has a 50% chance of having the same mutation. Mutations in *BRCA1*/2 or in other ovarian cancer risk genes can be identified through genetic testing.

One in every five (1 out of 5) women with high-grade serous cancer has a mutation in *BRCA1/2*. In the past, many women with ovarian cancer did not go for genetic testing. Because we know that an increased risk of ovarian cancer can be passed on from a first-degree relative, we also know that there may be many women who are unaware that they are at risk for ovarian cancer simply because their relative never had genetic testing.

Women with a family history of ovarian cancer may have a higher risk of developing the disease themselves. If a woman is at high risk for developing ovarian cancer, there are steps she can take to prevent the cancer from developing in the first place. A type of surgery called a *risk-reducing salpingo-oophorectomy* (RRSO) can be done to remove a woman's ovaries and fallopian tubes. Women with a *BRCA1* gene mutation have a 20-40% chance of getting ovarian cancer in their lifetime. Women with a *BRCA2* gene mutation have a 10-20% chance of getting ovarian cancer in their lifetime. Studies have shown that RRSO can reduce this risk by greater than 90%. If RRSO is performed before menopause, women with a change in *BRCA1/2* can also reduce their risk for having breast cancer by 50%.

The overall goal of the POCP is to identify women who have a high risk of getting ovarian cancer and offer them the opportunity to reduce that risk with genetic testing and risk reducing surgery. Through the POCP, genetic counselling and genetic testing will be available to 500 women living in Ontario who have a deceased first-degree relative (mother, sister or daughter) with a confirmed diagnosis of high-grade serous ovarian cancer, but who do not currently qualify for genetic testing through the Ontario Ministry of Health and Long-Term Care.

The purpose of this study is to identify women who carry mutations in *BRCA1/2* and other risk genes through genetic testing and provide the opportunity to prevent ovarian cancer by risk-reducing surgery. We will also gather information to study the emotional impact and possible barriers to genetic testing as well as the uptake of RRSO in women who are found to have an inherited risk to develop ovarian cancer.

You are being asked to participate in this program and research study because you have a deceased first-degree relative (mother, sister or daughter) diagnosed with ovarian cancer.

Study Design and Procedures

You have already created an account and username on the POCP website and provided permission to access the pathology report of your first degree relative. We have now reviewed all of your answers on the eligibility questionnaire and your family member's pathology report and have confirmed that you are eligible to participate.

If you agree to participate in this research study, you will be asked to participate in the following activities:

1. **Read, sign, and date this consent form:** After we have received your signed consent form, a member from the POCP team will call you to verify your full understanding of the material presented prior to proceeding.

2. **Complete a Contact Information Form**: Your full date of birth and Ontario Health Card number are required to create a UHN Medical Record Number (MRN). This number allows the POCP to book your genetic counselling appointments. If you already have an MRN, this information is needed to confirm that your personal information is up-to-date. Your phone number is required so that POCP staff can communicate important information with you outside of the study website.

3. **Complete a Family History Questionnaire**: The family history information will be used to create a family tree (pedigree) that will be reviewed by the clinical care team.

4. **Complete 'pre-test' genetic counselling for inherited ovarian cancer:** A genetic counsellor will give you information on the role of genetics in the development of ovarian cancer and details about genetic testing. You will be randomized to receive this information through an online voiced presentation followed by a brief phone call *or* an in-person/Telehealth appointment.

5. **Provide a blood sample for genetic testing:** Once you have completed pre-test genetic counselling, you will take your blood requisition (provided) to a local *LifeLabs* blood collection facility. Your blood sample will be sent directly from *LifeLabs* to Princess Margaret Cancer Centre, at no cost to you.

   The genetic test used in this study includes a panel of genes which may play a role in the development of cancer. Some of the genes on this panel may increase the risk of developing other types of cancer (i.e. not ovarian cancer); therefore, this genetic test may provide you with unexpected information about your cancer risks. Some of the genes on this panel are still being studied for their role in the development of ovarian and other cancers; therefore, this genetic test may not provide clear information about your cancer risks and screening guidelines may not be available. You will be given choices about the type of information you would like to learn from your genetic test.

Your genetic mutation status (once known) and other relevant health related information will also be disclosed to the clinical care team; however, your identity will not be revealed to research personnel. You can withdraw consent at any point before the genetic test if you do not want your blood sample processed. All test results will be included in your medical record once the genetic test is complete.

6. **Complete 'post-test' genetic counselling for inherited ovarian cancer:** A genetic counsellor will explain your genetic testing results over the phone. Arrangements for comprehensive post-test counselling closer to your home will be made, if necessary. You will receive a copy of your genetic test results.

7. **Complete Psychosocial questionnaires:** These brief questionnaires will assess your attitudes and knowledge of genetics and genetic testing. The questionnaires will be sent to you via email at 5 points:
   - Before you receive genetic counselling,
   - Approximately one week after your pre-test session of genetic counselling,
   - Approximately one week after you find out the results of your genetic testing,
   - Three months after genetic counselling and testing,
   - One year after genetic testing.

If you are found to have an increased risk of cancer as a result of this study, you will be referred for appropriate medical care close to your home. You will not be required to undergo any surgery as part of this study. We will record the short-term and long-term results of any prevention strategies to guide how we care for similar individuals in the future. You may be contacted and have the option to be included in future research studies based on our findings in the POCP.

Risks Related to Participating in the Study

There are no known medical risks to participating in this study. The blood sample collection for genetic testing is a safe and routine procedure that may cause only minor discomfort. In some cases, bruising or discoloration near the site of needle insertion may occur.

Measures will be taken to protect confidentiality of genetic test results; however, absolute confidentiality cannot be guaranteed and the risk of disclosure of this information is not known.

Benefits to Participating in the Study

By participating in this study, you may learn your mutation status for ovarian cancer risk genes and whether you are at a significantly higher risk of developing ovarian cancer compared to the general population. If you are found to have an inherited mutation which increases your cancer risks, the available screening and prevention options will be discussed with you. The

identification of any inherited genetic mutations in the ovarian cancer panel may also benefit family members who are eligible for genetic testing and/or for cancer screening and prevention.

The information we collect from the psychosocial questionnaires will ask about the emotional side of genetic testing. This information can help improve our understanding on the attitudes, barriers, etc. that exist for women to access and use these resources in order to prevent ovarian cancer. This may improve the genetic counselling process for ovarian cancer and prevent the development of this cancer in women who have an increased risk for having ovarian cancer.

Your feedback and experience will provide valuable information for our future province-wide research program.

Voluntary Participation

Your participation in this study is entirely voluntary. If you consent to join the study, but later decide you no longer wish to take part in it for any reason, stated or unstated, you may withdraw your consent and stop your participation.

Confidentiality

If you agree to join this study, the research team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- Name,
- Address,
- Date of birth (DD/MM/YY),
- Health card number,
- Family history of cancer,
- Genetic testing results,
- New or existing medical records, which includes the type, date and result of medical tests or procedures.

All research questionnaires will be completed online and linked to your unique username. The electronic information that is collected will be stored in a de-identified database that will be protected and remain confidential through security measures, such as encryption, secure logins, and passwords.

All information collected during the study will be kept in a locked and secure area by the study doctor for 10 years. The clinical care you receive following participation in this research study will be recorded in your medical record.

Representatives of the University Health Network including Research Ethics Board may look at the study records and at your personal health information to check that the information collected is correct and to follows proper laws and guidelines.

Information collected during this research study will be kept confidential and will not be shared with anyone outside the study team and people listed above unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

In Case You Are Harmed in the Study

If you are harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any harm that is directly a result of being in this study.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Conflict of Interest

The researchers conducting this investigation have an interest in completing this study. Their interests should not influence your decision to participate. You should not feel pressured to join this research study.

Questions about the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please leave a message for the program coordinator Nicole Ricker, or the principal investigator Dr. Marcus Bernardini at 1-866-330-0180. You may also send an email to preventovariancancer@uhnresearch.ca. Please do not communicate sensitive information in an email.

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.

You will be given a signed copy of this consent form.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

Please check one:

☐ **Yes, I agree** to be contacted for future studies related to the POCP.
☐ **No, I do not agree** to be contacted for future studies related to the POCP.

_____	_____	_____
Study Participant's Name (*print*)	**Signature**	**Date (DD/MM/YY)**

_____	_____	_____
Name of person obtaining consent (*print*)	Signature	Date (DD/MM/YY)

My signature (above) means that I have explained the study to the participant named above. I have answered all questions.