

WILL MY PRIVACY BE PROTECTED?

Yes. All personal information obtained for the study will be kept private, and every effort will be made to protect your confidentiality. NCI is required by Federal law not to reveal any information that is collected from study participants to anyone other than persons directly involved with the study. No personal identifying information will be released or published.

MAY I QUIT THE STUDY AFTER I JOIN?

Yes. Just as taking part in this study is voluntary, you may also choose to leave the study at any time.

WHO IS RESPONSIBLE FOR THIS STUDY?

This study is funded by the National Cancer Institute (NCI), and is being conducted through the cooperation of NCI's Clinical Genetics Branch and two NCI-sponsored organizations, the Gynecologic Oncology Group and the Cancer Genetics Network.

HOW CAN I JOIN THE STUDY OR LEARN MORE ABOUT IT?

Have questions or want to learn more about the study? Visit the study Web site at

<http://ovariancancer.gog199.cancer.gov>

You may join the study by calling the participating Gynecologic Oncology Group medical center nearest you. For assistance in finding the nearest center, call

1-800-225-3053

Or, you may find a list of Cancer Genetics Network screening centers at

http://hedwig.mgh.harvard.edu/test_reml/index.php

For additional brochures and general cancer information, call NCI's Cancer Information Service at

1-800-4-CANCER (1-800-422-6237)

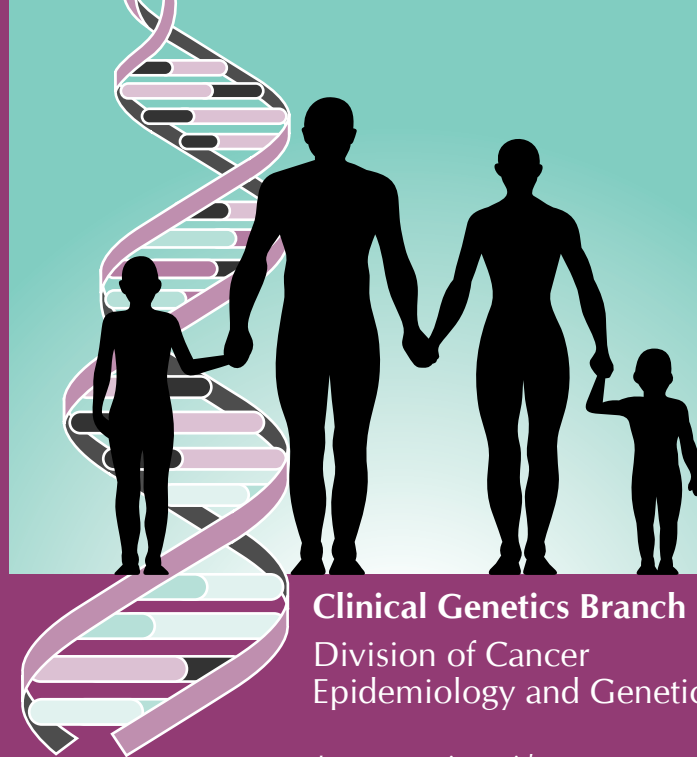
Special Note:

Women who are interested in participating in the surgical arm of this study may also be eligible to participate in another, closely-related clinical trial, called GOG 190.

NCI is sponsoring this additional ovarian cancer prevention trial to study whether a medication related to vitamin A can be used to lower your risk of ovarian cancer. Women can participate in both of these studies at the same time.

Ask your physician if this study is suitable for you. For further information, call 1-800-367-6556, or visit the following Web site:

<http://ovariancancerprevention.gog190.cancer.gov>



Clinical Genetics Branch
Division of Cancer
Epidemiology and Genetics

In cooperation with
Gynecologic Oncology Group
Cancer Genetics Network

Ovarian Cancer Prevention and Early Detection Study

By how much can surgery or
screening reduce your risk?



**NATIONAL
CANCER
INSTITUTE**

NIH Publication No. XX-XXXX
Month 2003



ASPEN #

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health • **National Cancer Institute**

ARE YOU AT HIGH RISK OF OVARIAN CANCER?

Then consider joining the Ovarian Cancer Prevention and Early Detection Study, which is looking at possible ways to help certain women:

- lower their risk of ovarian cancer
- find ovarian cancer early

ABOUT THE STUDY

The study will include women whose genes or family history may increase their risk of ovarian cancer. You have this greater risk if:

- you have a very strong family history of breast or ovarian cancer; or
- you or a close relative has a change (“mutation”) in *BRCA1* and *BRCA2*, two genes known to increase the risk of ovarian cancer.

There are two groups (or “arms”) in this study: one group is known as the “screening” arm and the other is the “surgical” arm. If you join the study, you and your primary doctor will choose which group you want to be in, after learning about the risks and benefits of each approach.

Women in this study will be followed to see by how much the surgery reduces their risk of getting cancer of the ovary, fallopian tube, or breast. The tissue removed during surgery may also be studied to see if a new method of examining the tissue after it is removed provides better information about cancer-related tissue changes.

(1) The Screening Arm

If you choose to be in the screening group, you will have your blood checked regularly to measure the body’s level of a chemical called CA-125, a substance that has been shown to be an effective monitoring tool in women who have already had ovarian cancer. This procedure is called “ROCA,” and it involves analyzing the changes in CA-125 which occur over time.

If you have an abnormal blood test result, you’ll get more tests to see if you actually have ovarian cancer.

(2) The Surgical Arm

If you choose to be in this group, you will have surgery to remove your ovaries and fallopian tubes. (Having your ovaries removed makes it impossible to have more children, so women who plan to have children will not be in this study group.)

WHO CAN JOIN?

You may be able to join this study if you are at least 30 years old, have not had ovarian cancer, and are at an increased risk of developing ovarian cancer. For the purpose of this study, you are considered at risk if:

- you or a close blood relative has a mutation in the *BRCA1* or *BRCA2* cancer gene; or
- two or more close blood relatives (mother, father, sister, brother, daughter, son, aunt, uncle, niece, nephew, grandmother, grandfather, granddaughter, grandson) have had breast or ovarian cancer; or
- at least one close blood relative has had breast or ovarian cancer, and you are of Ashkenazi Jewish descent; or
- if you have had premenopausal breast cancer (or breast cancer diagnosed prior to age 50), and you are of Ashkenazi Jewish descent.

WHAT WILL I BE ASKED TO DO?

If you join the study, you will be asked to:

Choose the study arm you prefer. You will make this choice after discussing the risks and benefits of surgery and screening with your health care providers.

Fill out forms. You will fill out forms about your personal health, your family’s medical history, and your quality of life.

Help us learn your BRCA mutation status either by providing a copy of your mutation test report or permitting the study to do research mutation testing to learn your mutation status.

Give a blood sample. Every three months you will have a small amount of blood taken from your arm for the ROCA screening blood test (CA-125).

Have an ovarian ultrasound. Each participant in the screening arm of the study will have a test called an ovarian ultrasound done once a year. Women with an abnormal ultrasound examination will be referred to a gynecologist for further evaluation.

Undergo surgery. If you are in the surgery arm, your ovaries and fallopian tubes will be removed.

Continue to get regular medical care including a routine mammograms at least once a year, by your regular health care provider.

HOW MAY I BENEFIT?

You may get these benefits from joining the study:

- Your health related to ovarian cancer will be watched closely by study staff.
- If you do get ovarian cancer, the study may help find it early, although there is no guarantee of this.
- You may help high-risk women in the future, if this study provides new information on lowering the risk of ovarian cancer or finding it early.

ARE THERE ANY RISKS TO ME?

- At the present time, there is no proven ovarian cancer screening test that has been shown to improve survival for screened women. The ROCA screening method being used in this study is new, and has not been previously tested in high-risk women. It may or may not prove to be effective.
- If you have your ovaries removed before natural menopause, you will enter menopause at an earlier than usual age. Early menopause may increase the risk of cardiovascular disease (heart attack, stroke) and bone loss or fracture due to osteoporosis (thinning of the bones). If you have this surgery, you will be told of ways to reduce these risks.