

CONSENT TO PARTICIPATE IN GOG 0212:

A Randomized Phase III Trial of Maintenance Chemotherapy Comparing 12, Monthly Cycles of Single Agent Paclitaxel or CT-2103 (IND# 70177), Versus No Treatment Until Documented Relapse in Women with Advanced Ovarian, Primary Peritoneal or Fallopian Tube Cancer Who Achieve a Complete Clinical Response to Primary Platinum/Taxane Chemotherapy
Consent Version 10/9/09

Investigators

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Study Physician _____ **Emergency Number:** _____

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

Why have I been asked to take part in this research study?

You are being asked to take part in this study because you have had surgery for ovarian cancer, primary peritoneal or fallopian tube cancer and currently have no clinical evidence of cancer after the completion of 5-6 cycles of chemotherapy.

It is up to you to decide whether or not to take part in this study. Please read this entire consent form and take your time to make your decision. We encourage you to talk to your doctor, your family and/or your friends before you decide.

Who is conducting the study?

If you decide to join this study, you will be taking part in a *clinical trial* being conducted nationally by the Gynecologic Oncology Group (GOG); an organization dedicated to clinical research in the field of gynecologic cancer. The GOG is funded by the federal government through the National Cancer Institute (NCI). Locally the Puget Sound Oncology Consortium, the Fred Hutchinson Cancer Research Center and the University of Washington are working together on this the study.

Why is this research study being done?

The standard treatment of women with advanced ovarian, primary peritoneal or fallopian cancer is surgery and chemotherapy. Standard chemotherapy for your cancer is effective, but a long-term cure is uncommon. Many patients will develop recurrent disease and need additional treatment.

Primary peritoneal and fallopian tube cancers are considered identical to ovarian cancers in terms of how they look under a microscope and how they are treated; they differ by the body site where the cancer first develops. A previously completed study showed that women with advanced ovarian cancer who had no sign of active disease after the completion of the initial 5 or 6 cycles of chemotherapy who continued to receive chemotherapy had a delay in the return of their cancer. Unfortunately, in this trial it was not possible to determine if the delay in the return of their cancer was associated with an improvement in how long they lived. Also, the question of whether the benefit of the delay in the return of their cancer was outweighed by the side effects of continuing the chemotherapy was not answered. Therefore, the standard of care for patients that do not have active disease following chemotherapy is still no further treatment.

In this study we will determine whether women with advanced ovarian, primary peritoneal or fallopian tube cancer who have no evidence of disease after the completion of initial chemotherapy live longer if they receive paclitaxel chemotherapy once a month for 12 months versus CT-2103 chemotherapy once a month for 12 months versus no further treatment until there is evidence the cancer has come back. Paclitaxel is chemotherapy drug that is standardly used to treat ovarian cancer, and is the drug used in the study noted above. CT-2103 is an experimental drug with anti-cancer activity similar to that of paclitaxel. It is possible that CT-2103 will produce similar results to that achieved with paclitaxel, but with reduced side effects.

In this study, your doctors also hope to learn how the chemotherapy treatment affects cancer behavior. Researchers will test samples of your blood and tumor if available from a previous biopsy or surgery to see which patients may respond to treatment, have side effects or have a good prognosis.

How many people will take part in the study?

About 1100 women will take part in this study.

What is involved in the study?*Before you begin the study*

To find out if you can join the study, you will need to have the following exams and medical tests. If you have had any of them recently, your doctor may decide not to repeat them.

- physical exam, which may include a pelvic exam and medical history
- blood tests
- chest x-ray
- CT scan of the abdomen or pelvis
- electrocardiogram (EKG) (a test to check your heart rhythm)

These exams and tests are part of standard good medical care even if you do not join the study. The tests may be done on an outpatient basis at your doctor's office, clinic or hospital.

Group Assignment and Treatment

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will be “randomized” into one of three study groups: Group 1, Group 2 or Group 3. Randomization means that you are put into a group by chance. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in one of the three groups. Patients in Group 1 will receive the drug CT-2103, patients in Group 2 will receive the drug paclitaxel and patients in Group 3 will receive no further treatment.

- *If you are in Group 1:* You will receive CT-2103 IV (into your vein) over 10-20 minutes once every 28 days for 12 cycles.
- *If you are in Group 2:* You will receive paclitaxel IV (into your vein) over 3 hours once every 28 days for 12 cycles.
- *If you are in Group 3:* You will not receive any further treatment unless your cancer comes back. You will have monthly exams for one year.

GROUP 1	GROUP 2	GROUP 3
CT-2103	Paclitaxel	No Treatment
<i>This drug is given into your vein over 10-20 minutes every 28 days for 12 cycles (a total of 1 year)</i>	<i>This drug is given into your vein over 3 hours every 28 days for 12 cycles (a total of 1 year)</i>	<i>Monthly exams</i>

During the Study

All aspects of this treatment will be under the close supervision of your physician and his/her medical staff. If you agree to participate in this study you will be examined at regular intervals throughout the study.

- *A history and physical exam* will be done every 4 weeks before each cycle of chemotherapy and monthly for patients in Group 3 for the first year. After the first year exams will be done every 3 months for two years and then every 6 months for 3 years
- *Blood tests* will be done 8-12 days after each cycle of chemotherapy and within 4 days of each chemotherapy treatment. All patients will have monthly CA-125 tests for the first year. After the first year will have blood tests as needed and a CA-125 will be done every 3 months during years 2-5.

Research Blood and Tissue Samples

You will be asked to undergo the following procedures that are not part of regular cancer care and are being done only because you are in this study.

- You will be asked to provide samples of your tumor (if available from a previous surgery) and six teaspoons of blood for laboratory testing that is not part of regular cancer care and is being done only because you are in this study. You

can still participate in this study if you do not give permission for your specimens to be collected and used for this optional research. For more information on this optional research please see the last three sections of this document. One section provides general information about the collection and use of specimens for research. Another section describes specific information about the use of specimens for this research study. The last section focuses on issues regarding future research.

Quality of Life Questionnaires

You will be asked to complete a questionnaire about the quality of your life. You will be asked to complete the questionnaire a total of six times, once before you go on study and 2, 4, 6, 12 and 24 months after you go on study. There are questions about how you are feeling, symptoms you may be experiencing and concerns you may have about your daily life. It will take about 5-10 minutes to complete the questionnaire each time.

How long will I be in the study?

For patients receiving chemotherapy the chemotherapy will be given over 1 year. All patients will be followed monthly for the first year. After year one you will be asked to visit your study doctor for follow-up exams every three months for two years and then every six months for three more years.

We would like to keep track of your medical condition for the rest of your life. Keeping in touch with you and checking on your condition helps us to look at the long-term effects of the study.

Can I stop being in the study?

Yes, you can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study drugs can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

You can choose to withdraw one of two ways. In the first, you can stop your study treatment, but still allow the study doctor to follow your care. In the second, you can stop your study treatment and not have any further contact with the study staff.

The study doctor may stop you from taking part in this study at any time if the study treatment does not work for your cancer, if he or she believes it is in the best interest for your health, if you do not follow the study rules, or if the study is stopped.

What are the risks of the study?

You may have side effects while on the study. Side effects will vary from person to person. Everyone taking part in the study will be carefully watched for any side effects. However, doctors do not know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medications to help lessen some of the side effects.

Many side effects go away soon after you stop taking your study drugs. In some cases, side effects may be very serious, long-lasting, may never go away or may result in hospitalization. There is also a risk of death.

You should talk with your study doctor about any side effects that you may have while taking part in the study. Whether you receive no further treatment or you receive chemotherapy your cancer may come back.

Paclitaxel (Taxol®):

Likely:

- Low white blood cell counts - this may make you more at risk for infection
- Low platelet count - this may make you bruise more easily and bleed longer if injured
- Low red blood cell count which may cause tiredness, shortness of breath or fatigue
- Mild to severe allergic reaction which may be life-threatening with hives, wheezing and low blood pressure
- Numbness and pain of the hands and feet that sometimes worsens with additional treatment and may not disappear after the drug is stopped. This may lead to difficulty walking, buttoning clothes, etc.
- Hair loss
- Muscle weakness and muscle loss
- Muscle and joint aches

Less likely, but serious:

- A slowing of the heart rate (a slow pulse is not harmful; however if you should develop any other irregularities in heart rate during treatment, an EKG and other tests may be required.)
- Irregular heartbeats
- Heart attack
- Nausea and/or vomiting
- Diarrhea
- Sores in the mouth or throat (that can lead to difficulty swallowing and dehydration)
- Fatigue
- Lightheadedness
- Headaches
- Kidney damage
- An increase in triglycerides (a blood lipid) levels which could increase risk of hardening of the arteries
- Liver damage
- Confusion; mood changes
- Skin tissue damage if some of the drug leaks from the vein while it is being given
- Changes in taste
- Irritation and swelling of the skin in an area previously treated with radiation therapy
- Rash
- Inflammation of the colon, pancreas or lungs
- Blurred vision or other changes in eyesight such as sensation of flashing lights or spots

Rare:

- Liver failure
- Swelling of the brain
- Seizures

CT-2103:**Likely:**

- Pain, tingling, and numbness in hands and feet
- Nausea
- Fatigue, weakness, lack of energy

Less likely, but serious:

- Infections
- Shortness of breath
- Low red blood count, which may cause tiredness, shortness of breath or fatigue
- Low white blood cell count, this may make you more at risk for infection
- Low platelet count, which may increase risk of bleeding
- Constipation
- Diarrhea
- Vomiting
- Fever
- Loss of appetite
- Dehydration (excessive water loss)
- Stomach pain
- Chest pain
- Joint, muscle, bone pain
- Swelling of the ankles and feet
- Cough
- Headache
- Weight loss
- Dizziness

Rare:

- Hair loss
- Itching
- Fluid around the lungs
- Increased or decreased blood pressure
- Increased or decreased blood electrolytes (changes in blood mineral levels)
- Mouth sores/ulcers
- Rash
- Increased liver enzymes

Allergic reactions during the infusion of CT-2103 have occurred infrequently (in less than 1% of patients). Symptoms of this may include nausea, vomiting, shortness of breath and a drop in blood pressure severe enough to lose consciousness and require emergency treatment. In studies so far, these reactions have occurred more often after 4 or more doses of CT-2103 chemotherapy in female patients who have had other chemotherapy in the past.

It is not known why there may be a slight increase in these patients; however, the overall numbers of patients experiencing these reactions have been small. You should stay at the clinic for at least one half hour after each study dose so that any reaction you experience may be treated right away. You may be asked to stay longer. Other unknown side effects can occur but are rare and will be monitored.

Reproductive Risks

If you are able to have children, you should not become pregnant while on this study because the drugs in this study can affect an unborn baby. You should not breastfeed a baby while on this study. If you are pregnant or breast-feeding, you cannot take part in this study. Check with your doctor about what kind of birth control methods to use and how long to use them.

Other risks

During this study you may have scans or x-rays to evaluate your cancer. There is some possible health risk from radiation exposure from these tests; however, this risk is considered small.

During the study, we will do blood and urine tests to see if the dose of some of the drugs you are receiving during your therapy should be changed or delayed. The tests will also help monitor any side effects you may have. You will not need to be hospitalized unless you have serious side effects. Some side effects may lead to decreasing the dose of the drug or stopping therapy.

Are there benefits to taking part in this study?

There may or may not be any medical benefit from taking part in this study. The study treatment may prevent or delay your cancer from coming back, but we do not know. We do know that the information from this study will help doctors learn more about this therapy in patients with ovarian, primary peritoneal and fallopian tube cancer. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Instead of taking part in this study, you can decide to have:

- Chemotherapy without being in a study
- Other experimental therapy
- No further treatment

Please talk with your doctor about these options before you enter the study.

Will my medical information be kept private?

Information about your participation in this clinical trial will be kept in your medical record and research record, including a signed copy of this consent form. If you authorize others to see your medical record, they may see a copy of this consent form.

We will do our best to make sure that the personal information in your medical records will be kept private. However, we cannot guarantee absolute privacy. Your personal information may be given out if required by law.

Medical information, including things such as your medical history, medical treatment and results of your blood tests and exams, and selected medical records will be sent to the GOG Administrative Office and the GOG Statistical and Data Center for review and analysis by physicians and other study personnel (This will include the Data Safety and Monitoring Board which reviews adverse event reports to assure patient safety). Portions of your medical information may be transmitted electronically through the Internet, but will be encrypted (scrambled) to maintain confidentiality.

Organizations that may inspect and/or copy your research records for quality assurance and data analyses are listed below. Your research records will include things such as your medical history, results of your blood tests and exams, reports from your surgery and treatment, reports of your office visits and your radiology reports.

- The Puget Sound Oncology Consortium (PSOC)
- The Fred Hutchinson Cancer Research Center (FHCRC)
- The University of Washington
- The Gynecologic Oncology Group (GOG)
- Cell Therapeutics Inc. (CTI), the company that makes CT-2103 (including CTI's representatives)
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials;
- Government agencies that may review the research to see that it is being done safely and correctly (for example, the National Cancer Institute [NCI], the Food and Drug Administration [FDA] the Office for Human Research Protections [OHRP] and the Department of Health and Human Services [DHHS])). Also, information from the Study may be given to government agencies in other countries where the study drug may be considered for approval.
- The local Institutional Review Board (a group of people who review the research study to protect your rights).

Under NCI policy, data from this Study may be provided to another researcher at some future time for use in an approved research project. If this occurs, the researcher must agree to keep individual patient information confidential.

When the research results are published or discussed in conferences, no information will be included that reveals your identity. In a few rare situations, federal or state law requires disclosure of personal information. Examples of these instances are reporting of child abuse or abuse of an elderly person.

To help us further protect your privacy, the federal government has given the GOG a Certificate of Confidentiality. With this Certificate, the researchers involved in this project cannot be forced to disclose research information that identifies you in legal actions.

You should understand that this Certificate would not change your ability to voluntarily request that research information about you be released. For example, if you request the release of your information to an insurance company, physician or other third party, GOG researchers will disclose the information requested.

What are the costs?

You and/or your health plan/insurance company will need to pay for all of the costs of treating your cancer in this study except for those described below in this section. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. You will be responsible for paying any deductibles, coinsurance, and co-payments as required under the terms of your insurance plan(s). Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment. Please talk with your doctor about any expected added costs or health insurance problems.

Cell Therapeutics Inc. (CTI), will provide CT-2103 to you at not cost. However, the charges associated with giving the drug remain your or your insurance company's responsibility. Paclitaxel is commercially available and will not be provided free for this study. The collection and testing of the research blood and tumor specimens will be done at no charge.

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him or her (name and phone number at the beginning of this form).

There is no compensation for a physical or psychological injury, which could happen as a result of this study. While medical care is available should an injury occur, the cost for such medical care will be your responsibility. No funds are available to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

The Gynecologic Oncology Group will be reviewing the data from this research throughout the study. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. You may be asked to sign another consent form in response to new information.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study or one of the other investigators listed at the beginning of this consent form.

For questions about your rights while taking part in this study, call Karen Hansen in the Institutional Review Office of the Fred Hutchinson Cancer Research Center at (206) 667-4867.

Where can I get more information?

- You may call the National Cancer Institute's (NCI's) Cancer Information Service at: 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615
- You may also visit the NCI Web site at <http://cancer.gov>
- For the NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials>
- For the NCI's general information about cancer, go to: <http://cancer.gov/cancerinfo>

You will receive a copy of this form. If you want more information about this study, ask your study doctor.

General Information about the Collection and Use of Specimens for Research

The following section of the informed consent form is about additional research studies that may be done with the research blood and tissue samples collected as part of this study. If you agree to participate in this Gynecologic Oncology Group (GOG) study, your specimens will be collected and used for the research described for this study. The next section of this document will ask you to decide whether your specimens, if still available after completion of this research study, can be used for future cancer research or for research for health problems other than cancer. You can still participate in this GOG study if you do not allow your specimens to be used for future research.

Consent for use of blood and tissue for future research

You are being asked to allow samples of your tumor removed during a previous surgery or biopsy and some of your blood to be submitted and used in research. Such bodily materials are referred to as specimens and are very important in helping doctors and scientists learn more about caring for and treating people with cancer and other diseases. The use of specimens in scientific research can also help doctors and scientists understand why some people develop cancer and others don't, and

why some people have cancers that respond or don't respond well to current therapies, and why some people have or don't have side effects to cancer therapy, for example.

The research that may be done with your specimens is not designed specifically to help you, but it may help others with cancer or other diseases in the future. Reports about research done with your specimens will not be given to you or your doctor, or be put in your health record. The research will not have an effect on your care.

When research is performed on specimens connected with clinical information about the person including the person's disease and how the person responds to treatment, for example, doctors and scientists can specifically study how to prevent, detect, treat and cure cancer and other diseases, or how to predict response to therapy, toxicities, recurrence and overall survival.

The GOG uses procedures designed to protect your privacy and confidentiality. The chance that information from your health records will be incorrectly released is very small, but you should be aware of this risk. To protect your privacy and confidentiality, the research investigators that study your specimens will never be given your name, address, phone number, Social Security number or any other personal information. In addition, your specimens will never be labeled with your name or other type of personal identifier. Your clinical specimen will be labeled with a unique series of letters and numbers. The GOG uses the unique series of letters and numbers as confidential codes to keep track of the clinical specimens, and sends research investigators specimens labeled only with these codes.

Your specimens will be used for research purposes and will not be sold. However, the research done with your specimens may help to develop new products and therapies in the future, or may be used to establish a cell line that could be patented and licensed. In any event, there are no plans to provide you with any direct financial compensation.

If you agree now that your tumor and blood specimens can be submitted and used for this research study and/or for future research, you can change your mind at any time. At that time, please contact the staff at your treating institution, typically your doctor or nurse, and tell them that you have changed your mind about allowing your specimens to be used for research. The staff at your treating institution will update the GOG regarding your wishes about using your specimens for research. If necessary, the GOG will destroy (incinerate) all of your specimens to make sure that they will no longer be used for research.

SPECIFIC INFORMATION FOR THIS RESEARCH STUDY

You are being asked to allow samples of your tumor removed during a previous surgery or biopsy and some of your blood to be submitted and used in this research study. Tumor and blood specimens will only be collected from patients who give permission to allow their specimens to be used for this research study.

The choice to let us collect your specimens and use them for this research study is up to you. No matter what you decide to do, it will not affect your care. You can still participate in this research study if you do not give permission to allow your specimens to be used for this research study.

Requirements

We are asking you for permission to have some of your tumor, if available from a previous surgery or biopsy, to be submitted and used for this research study.

We are also asking you for permission to draw a total of 6 teaspoons of blood:

- Before starting cycle 1 of treatment or within 1 week of study enrollment, 2 teaspoons of blood will be drawn into 1 tube.
- Before starting cycle 2 of treatment or 4 to 6 weeks of study enrollment, 2 teaspoons of blood will be drawn into 1 tube.
- Before, during or after treatment, two teaspoons of blood will be drawn into 1 tube.

What Will Happen To Your Tumor and Blood If You Agree

If you give permission for your tumor to be submitted and used for this research study, your health care team will send your tumor to the GOG Tissue Bank in Columbus, Ohio for storage (banking). The GOG Tissue Bank is approved by the National Cancer Institute (NCI) to store, process and distribute specimens from patients who agree to participate in the studies conducted by the GOG. The GOG Tissue Bank will be responsible for shipping tumor specimens submitted for this research study to the approved laboratories for testing.

If you give permission for your blood to be submitted and used for this research study, your health care team will use two tubes of your blood to prepare serum. Serum is the liquid part of blood after the blood is allowed to clot and both the clot and the blood cells are removed. Your health care team will then ship your serum and one tube of your blood to the GOG Tissue Bank in Columbus, Ohio for storage (banking) and processing. Staff at the GOG Tissue Bank Serum will be responsible for shipping tumor specimens submitted for this research study to the approved laboratories for testing. If you are being treated at an institution outside of the United States you will not be asked to provide these blood samples.

Laboratory testing will be carried out in specimens from women who give permission to participate in this research study. The laboratory testing will study (1) proteins that affect blood vessels and tumor cells in tumor tissue and serum and (2) single changes in DNA that may effect how drugs work and cause side effects. After the laboratory testing is finished, the results will be sent to the GOG Statistical and Data Center in Buffalo, New York for analysis.

The results from the laboratory testing will be studied to determine if testing in either tumor tissue or serum can be used to identify which patients in the future might be more or less likely to respond to the treatment or have a good prognosis. Reports of this research done on your specimens will not be given to you or your doctor, or be put in your health record.

MAKING YOUR CHOICES FOR THIS RESEARCH STUDY

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". **No matter what you decide to do, it will not affect your care. You will still be allowed to participate in this research study even if you don't want your specimens to be submitted and used for this research study.** If you have any questions, please talk to your doctor, nurse or other type of healthcare provider.

1. Do you give permission for your tumor, if available from a previous surgery or biopsy, to be submitted and used for this research study?

YES

NO

2. Do you give permission for your blood to be collected for submission and use for this research study?

YES

NO

Please sign your name after you circle your answers.

Your signature: _____ **Date:** _____

SPECIFIC INFORMATION FOR FUTURE RESEARCH

The last section of the consent will ask you to decide whether your specimens, if still available after completion of this research study, can be used for future cancer research or for research for health problems other than cancer. We will also ask your permission to use the clinical information that the GOG will collect about you as part of your participation in this research study to be utilized for future research that will use your specimens. Next, we will ask for permission to contact you in the future to participate in more research.

If you agree to allow your specimens to be used for future research, there is a chance that your specimens may be used to study changes in genetic material that are passed on in families or that are not passed on in families but are either natural changes or influenced by environment and lifestyle. These tests can focus on a section of genetic material (DNA), genetic material packaged into chromosomes or examines all of the genetic material called the whole genome. The results can then be studied to identify changes in genetic material that influence the development of diseases like cancer or the effectiveness of specific treatments including response and side effects.

The choice to let us use your specimens for future research is up to you. No matter what you decide to do, it will not affect your care. You can still participate in this GOG study if you do not allow your specimens to be used for future research.

MAKING YOUR CHOICES ABOUT FUTURE RESEARCH

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". **No matter what you decide to do, it will not affect your care.** If you have any questions, please talk to your doctor, nurse or other type of healthcare provider.

1. Do you give permission for your specimens, if still available after this research study is completed, to be used in future research to learn about, prevent, or treat cancer?

YES NO

2. Do you give permission for your specimens, if still available after this research study is completed, to be used in future research to learn about, prevent or treat health problems other than cancer (for example: diabetes, Alzheimer's disease, or heart disease)?

YES NO

3. Do you give permission for the clinical information collected by the GOG as part of your participation in this study to be used for future research that uses your specimens?

YES NO

4. Do you give permission for your specimens, if still available after this research study is completed, to be used for future research to study changes in genetic material?

YES NO

5. Do you give permission for someone from your GOG institution such as your doctor or nurse to contact you in the future to ask you to take part in more research?

YES NO

Please sign your name after you circle your answers.

Your signature: _____ **Date:** _____

Signatures

Statement of Person Conducting the Informed Consent Discussion:

I have provided an explanation of the above research program. The patient was given an opportunity to discuss the study including the procedures, risks, benefits and possible alternatives and to ask questions. A signed copy of the consent will be given to the patient.

Signature of Person Conducting the Informed
Consent Discussion

Date

Participant's Statement

I have been given a copy of all pages of this consent form. I have read the consent form or it has been read to me. This information was explained to me and my questions were answered. I agree to take part in this study.

I give permission for my medical records to be available for review and copying, for the duration of the study, to physicians and personnel for this study.

Participant's Signature

Date

Copies to: Patient
 Medical Records
 Research File