

CONSENT TO PARTICIPATE IN GOG 0213:

A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab (NSC#704865, IND #7921) Followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer  
Consent Version 6/26/09

Investigators

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**Study Doctor:** \_\_\_\_\_ **Emergency Number:** \_\_\_\_\_

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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 ovarian, fallopian tube or peritoneal primary cancer that has come back after your original treatment.

**Who is conducting the study?**

Nationally this study is being conducted by the Gynecologic Oncology Group (GOG); an organization dedicated to clinical research in the field of gynecologic cancers. Locally the Puget Sound Oncology Consortium, the Fred Hutchinson Cancer Research Center and the University of Washington are conducting the study with the GOG.

**Why is this research study being done?**

This study is being conducted for the following reasons:

- The main purpose of this study is to learn if adding bevacizumab to standard treatment with chemotherapy works better for people with ovarian, peritoneal primary and fallopian tube cancer. The study will look at time to cancer growth, survival and quality of life (wellness and physical functioning).
  - Bevacizumab is called a targeted therapy because it works by targeting a protein called vascular endothelial growth factor (VEGF) which helps new blood vessels

form. Without new blood vessels, the growth of the tumor is slowed. Previous studies with bevacizumab have produced promising results in patients with various types of cancer and it has been approved by the Food and Drug Administration (FDA). Bevacizumab is considered investigational in this study because it is still being researched and has not yet received approval from the U.S. Food and Drug Administration (FDA) for use in treating ovarian, peritoneal primary or fallopian tube cancer.

- Standard chemotherapy for patients with your type of cancer is usually carboplatin and paclitaxel. Chemotherapy is given to control the growth of the cancer and to lower the chance of it coming back. Treatment with chemotherapy has been found to be effective, but long-term cure is uncommon.
- A second purpose of this study is to determine if a second surgery to remove tumor followed by chemotherapy delays or stops the cancer from coming back.
- Another reason for doing this study is to do special tests on blood and tumor samples which should provide researchers at the GOG with information about how tumors like yours respond to treatment and predict which patients may have side effects or may do better.

### **How many people will take part in the study?**

About 660 women from different cancer treatment centers will take part in the 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. These exams, tests, and procedures are part of regular cancer care and may be done even if you do not join this study. If you have had any of them recently, your doctor may decide not to repeat them. These tests are done as an outpatient at your doctor's office, in a clinic, or in a hospital.

- History and physical examination which will include blood pressure measurement and may include pelvic examination.
- Blood tests to assess blood cell counts; liver, kidney and blood clotting function; blood mineral levels; CA-125 levels (CA-125 is a protein measured in the blood that is often elevated in patients with ovarian cancer).
- Urine test sample for urine protein level.
- Electrocardiogram (EKG)
- Chest x-ray (*not needed if you have had a chest CT or MRI*)
- CT scan or MRI of the abdomen and pelvis
- Hearing test if you have a history of hearing loss
- Pregnancy test for women of childbearing potential

*During the study:* If the exams, tests and procedures show that you can be in the study and you choose to take part, your doctor will determine if you are a good surgical candidate. If your doctor feels that you are a good candidate for surgery you will be randomized to have surgery or not, and at the same time be randomized to receive one of the two possible chemotherapy combinations (carboplatin plus paclitaxel chemotherapy or carboplatin and paclitaxel chemotherapy plus bevacizumab).

If your doctor feels that you are not a good candidate for surgery you will only be randomized to receive one of the two possible chemotherapy combinations (carboplatin plus paclitaxel chemotherapy or carboplatin and paclitaxel chemotherapy plus bevacizumab).

Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

*Summary of study treatment*

***Surgery (standard of care):*** Patients randomized to surgery will undergo standard abdominal exploration and have as much tumor as possible removed. You will sign a separate surgical consent for this procedure. Chemotherapy will start about 4-6 weeks after surgery.

***Chemotherapy Combinations:***

**Group 1:** If you are in the first group you will receive the standard treatment which is paclitaxel and carboplatin given every three weeks IV (in a vein). The study drugs will be given every 21 days (one study cycle). You will continue to receive this treatment for a total of six cycles (18 weeks) as long as your cancer does not get worse and you do not experience unacceptable side effects. If your cancer goes away while you are receiving treatment you will be given two more cycles of treatment up to a possible total of eight cycles (24 weeks). After treatment is stopped you will routine follow-up to check on your health. If your cancer comes back your doctor will discuss with you what treatment or care are best for you.

**Group 2:** If you are in the second group you will receive the standard treatment of paclitaxel and carboplatin IV with the addition of the investigational drug bevacizumab given every three weeks (IV). The study drugs will be given every 21 days (one study cycle). You will continue to receive this treatment for a total of six cycles (18 weeks) as long as your cancer does not get worse and you do not experience unacceptable side effects. If your cancer goes away while you are receiving treatment you will be given two more cycles of treatment up to a possible total of eight cycles (21 weeks). Following that, you will continue to receive bevacizumab IV every three weeks as long as your cancer does not get worse and you do not experience unacceptable side effects. After treatment is stopped you will routine follow-up to check on your health. If your cancer comes back your doctor will discuss with you what treatment or care are best for you.

Summary of Study Therapy:

<b>Part 1 (For patients that are suitable candidates for surgery)</b>	
Surgery	No Surgery
<b>Part 2 (All patients)</b>	
<p><u>Group 1</u> Paclitaxel and Carboplatin by vein every 3 weeks for up to 8 cycles</p> <p><b><i>Observation / Follow-Up</i></b></p> <p>Standard Follow-Up (every 3 months for 2 years, then every 6 months)</p>	<p><u>Group 2</u> Paclitaxel and Carboplatin <i>plus</i> Bevacizumab by vein every 3 weeks for up to 8 cycles</p> <p><b><i>Maintenance Bevacizumab</i></b></p> <p>Bevacizumab by vein every 3 weeks until disease gets worse or side effects prevent further treatment <i>then</i> Standard Follow-up (every 3 months for 2 years, then every 6 months)</p>

**During treatment on this study**

All aspects of this treatment will be under the close supervision of your study doctor and his/her medical staff. You will need the following tests and procedures done while receiving treatment on this study. The exams and tests are done to monitor side effects and to see if the treatment should be delayed or stopped. These tests are part of regular cancer care but may be done more frequently because you are on this study.

**During chemotherapy**

Patients will have the following exams and tests during study therapy. They are part of regular cancer care.

*For patients that had surgery:*

- EKG, chest x-ray and CT scan or MRI scan will be repeated prior to chemotherapy
- Examination of the surgical incision will be done to make sure there is no evidence of infection or healing problem prior to chemotherapy.

*For all patients:*

- Physical exam, including blood pressure, and review of side effects will be done before each cycle of therapy
- Weekly blood tests to check your blood counts
- Blood tests to check how well your kidneys and liver are working before every cycle
- CA-125 blood test to monitor how well the treatment is working before every cycle
- CT scan or MRI scan every 6 weeks
- If you are on a blood thinner medication, then periodic blood tests to evaluate blood clotting function will be done.

The following tests are part of regular cancer care but are being done more often because you are in this study:

- Weekly blood pressure monitoring following the first treatment of bevacizumab for at least the first cycle. When weekly monitoring is necessary, you may do this at home and provide the results to the study doctor or study nurse if you wish, as long as the study doctor feels this is safe and practical.
- Urine test to check for protein in your urine every other cycle of treatment (every 6 weeks)

The following tests are not part of regular cancer care and are being done for the purpose of this study:

- Optional blood and tissue collection for research (1-2 blood collections and samples of your tumor if left over from a previous surgery, and some of your tumor and normal tissue if left over from surgery performed as part of this study); only if you answered “yes” to the optional blood and tissue collection questions at the end of this consent form.

**During Maintenance Bevacizumab** (these tests are done more often because you are on this study)

- Prior to every course (or every 3 weeks) blood pressure measurement
- Prior to every other course (every 6 weeks) physical exam, blood tests to check your blood counts, blood tests to check how well your kidneys and liver are working, CA-125, and urine protein test
- If you are on a blood thinner medication, then periodic blood tests to evaluate blood clotting function will be done
- CT or MRI every 3 months for 2 years then every 6 months. If your cancer gets worse these tests will no longer be required

**Observation Phase/Follow-up**

- Periodic monitoring of your health status
- CT or MRI every 3 months 2 years then every 6 months. If your cancer gets worse these tests will no longer be required.

**Quality of Life Questionnaires**

We want to know how your life has been affected by cancer and its treatment. “Quality of life” looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities.

You will be asked to complete a quality of life questionnaire at the following time points:

- prior to surgery (if you are randomized to surgery)
- prior to starting chemotherapy
- prior to cycle 3 (6 weeks after starting chemotherapy)
- prior to cycle 6 (12 weeks after starting chemotherapy),
- 6 months after starting chemotherapy
- 12 months after starting chemotherapy

It takes about 10-25 minutes to fill out each questionnaire. If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

### **How long will I be in the study?**

If you are in the first group of patients you will receive up to 8 cycles of treatment over 24 weeks. If you are in the second group of patients you will continue to receive treatment as long as there is evidence that you are benefiting from the therapy and you do not have unacceptable side effects. When you stop treatment we would like to keep track of your health for 10 years.

### **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 treatment 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.

Also, 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 side effects or risks can I expect from being in the study?**

You may have side effects while on the study. Most of these are listed here; however, doctors don't know all the side effects that may happen. Side effects will vary from person to person. Everyone taking part in the study will be watched carefully for any side effects.

Side effects may be mild or very serious and may require hospitalization for management. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study therapy. In some cases, side effects can be serious, long lasting, or may never go away. *There also is a risk of death.*

You should talk to your study doctor about any side effects that you have while taking part in the study.

### **Carboplatin:**

#### **Likely:**

- Low white blood cell counts - this may make you more open to infection
- Low platelet count - this may make you bruise more easily and bleed longer if injured
- Low red blood cell count which may cause anemia, tiredness/fatigue or shortness of breath
- Fatigue
- Loss of appetite and weight loss
- Diarrhea, constipation, nausea and vomiting, and abdominal pain
- Skin rash
- Changes in taste
- Changes in electrolytes in the blood such as magnesium and potassium
- Decrease in kidney or liver function

- Hair loss

**Less likely, but serious:**

- Numbness or tingling in fingers or toes
- Ringing in the ears and hearing loss
- Allergic reactions
- Chills and fever with aches and pains
- Sores in mouth and throat (that can lead to difficulty swallowing and dehydration)
- Altered vision

**Rare, but serious:**

- Seizures
- Secondary cancers such as acute leukemia which may be fatal
- Kidney failure requiring dialysis
- Deafness
- Death

**Paclitaxel (Taxol):**

**Likely:**

- Low white blood cell counts - this may make you more open to infection
- Low platelet count - this may make you bruise more easily and bleed longer if injured
- Low red blood cell count which may cause anemia, tiredness/fatigue or shortness of breath
- 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
- Sores in the mouth or throat (that can lead to difficulty swallowing and dehydration)

**Less likely, but potentially 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
- 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, but serious:**

- Liver failure
- Swelling of the brain
- Seizures
- Death

The doctor may substitute docetaxel for paclitaxel if you experience a severe allergic reaction or severe numbness or tingling in your hands or feet to paclitaxel. Docetaxel is a similar drug to paclitaxel and has been found to be as effective in patients with ovarian and primary peritoneal cancer as paclitaxel.

**Docetaxel (Taxotere):**

**Likely:**

- Low white blood cell counts - this may make you more open to infection
- Low platelet count - this may make you bruise more easily and bleed longer if injured
- Low red blood cell count which may cause anemia, tiredness/fatigue or shortness of breath
- 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
- Shortness of breath
- Skin irritation (including hives and itching if allergic reactions)
- Low or high blood pressure
- Nausea and/or vomiting
- Diarrhea
- Mouth and throat sores
- Fatigue
- Excessive tearing of the eyes
- Chills; fever

**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.)
- Fluid retention, in the form of weight gain, poorly tolerated swelling of the legs, arms, tissues beneath the skin, sometimes fluid collections in the chest causing shortness of breath and strain on the heart, and sometimes fluid collections in the abdomen (ascites) which can cause abdominal discomfort, distention and indigestion.
- 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
- Infection and/or bleeding complications as a result of decreased blood counts

**Rare, but serious:**

- Liver failure
- Swelling of the brain
- Seizures
- Severe allergic reaction resulting in development of a rash, difficulty breathing , and low blood pressure

**Bevacizumab:****Likely**

- Mild to moderate increase in blood pressure
- Protein in urine, which can rarely lead to damage to the kidney
- Shortness of breath
- Nose bleeds
- Headache
- Loss of appetite
- Sore mouth or sore throat
- Constipation

- Fatigue
- Diarrhea
- Nausea and vomiting
- Generalized pain and pain in the abdomen (belly)

### **Less Likely**

- Mild to moderate decrease in blood pressure
- Blood clots in veins or arteries, which may be life threatening
- Mild to moderate bleeding in the tumor, stomach, intestines, vagina, or lungs
- Reactions associated with bevacizumab infusion: chills, fever, rigor
- Rash; skin ulcer, hives or welts
- Infection
- Dizziness
- Skin ulcers, hives, welts, itching
- Pain in the muscles and joints
- Chest pain
- Cough
- Nasal stuffiness, sneezing ,post nasal drip
- Wheezing
- Weight loss
- Voice changes, hoarseness, laryngitis
- Damage to the heart muscle resulting in increase heart function blood tests

### **Rare, but Serious**

- Congestive heart failure (decrease in heart function)
- Blocking of an artery by a blood clot, this can lead to a heart attack or stroke and can be life-threatening or fatal. This risk may be higher in patients receiving chemotherapy, patients over the age of 65 or patients with a history of blood clots in the arteries.
- Delay in wound healing, failure of a wound to heal or spontaneous opening of a wound including a surgical wound. You should inform your doctor if you are considering surgery.
- Development of an abnormal opening (fistula) between the large intestine and another organ, most commonly the bladder, uterus, or vagina
- Perforation of the gastrointestinal track (a tear or a hole in the gut) which may be associated with an abdominal abscess or infection. This often requires surgery to repair and can be life-threatening and fatal. You should inform your physician if you experience symptoms suggestive of bowel perforation, such as worsening or new pain in the abdomen or rectum or fever. The overall incidence of bowel perforation in patients with metastatic ovarian cancer treated with bevacizumab is about 2-4% based on several studies. However, in one of these studies for patients with metastatic ovarian cancer that has progressed after multiple chemotherapies, 5 of the 44 patients treated with bevacizumab developed bowel perforations. It is unclear at this time whether the relatively high rate of bowel perforation in this study was due to more advanced tumors, a higher number of previous therapies or other unrecognized factors in addition to bevacizumab.
- Severe allergic reactions that result in difficulty breathing or drop in blood pressure
- Serious or fatal bleeding from the tumor, brain, gut, or lungs
- Heart problems, including irregular heart beats, heart attack or heart failure, potentially serious abnormal heart rhythm.

- Reversible changes in the liver functions
- Nephrotic syndrome, a type of kidney disease caused by damage to the tiny blood vessels in the kidney
- Loss of vision in part of the visual field in one or both eyes
- Reversible Posterior Leukoencephalopathy Syndrome (RPLS) or similar leukoencephalopathy syndrome: RPLS is a medical condition related to leakiness of blood vessels in the brain and can cause confusion, blindness or vision changes, seizure and other symptoms, as well as changes in brain scans. This condition is usually reversible, but in rare cases, it can be life-threatening and may have long-term effect on brain function

Bevacizumab is an experimental drug and there is always the risk that you could experience other presently unknown side effects. You will be watched closely for any side effects and if serious side effects occur the drug will be stopped and you will be treated appropriately.

Bevacizumab may affect several organs (or parts) of your body, in addition to the possible effect it may have on your tumor. The following side effects have been seen in clinical studies and may be related to the drug: headache, protein in the urine which may indicate kidney damage, surface and deep vein blood clots and blood clots in the lungs, fever and chills, nose bleeds, high blood pressure.

In other research studies using bevacizumab along with chemotherapy drugs, patients have experienced abnormal liver function, specifically reversible, marked increases in liver enzyme levels (bilirubin and transaminase). It is unclear what causes this abnormality. It is possible that when bevacizumab is administered with chemotherapy drugs that the risk of side effects involving the liver are increased; other additional side effects may also occur when bevacizumab is given with chemotherapy drugs. However, it cannot be ruled out at this time that bevacizumab administered alone may cause these abnormalities.

A few patients have experienced “bowel perforation” and “bowel anastomotic dehiscence”. Bowel perforation occurs when an opening exists in the bowel wall allowing bowel contents to spill into the abdomen. Bowel anastomotic dehiscence is a breakdown in the surgical connection between two pieces of bowel. These events can be life-threatening. In addition, there have also been a few reports of surgical wounds healing slowly or poorly. We do not know at this time if these side effects are related to treatment with bevacizumab or if they are due to other factors such as worsening of the patient’s cancer, chemotherapy, or previous surgery or radiation.

Patients treated with bevacizumab have experienced problems with internal bleeding. Usually this has occurred at the site of specific tumors, most notably lung. In rare cases, patients with lung cancer receiving treatment with bevacizumab began spitting blood which resulted from fatal bleeding in the lungs. If you note bleeding from your gums, in your stool or urine, or you develop nosebleeds, you must inform your doctor right away. You will be monitored with blood tests if indicated by any sign of bleeding, and your treatment with bevacizumab may be stopped if any significant bleeding occurs.

Neutropenia (decrease in white blood cells) is a common side effect of chemotherapy drugs; the incidence of this event may be increase when bevacizumab is added to chemotherapy. In some clinical studies of bevacizumab plus chemotherapy, there was also an increase in neutropenia-related fever and infections, including rare incidents of infections with fatal outcomes.

You should tell your study doctor or research staff if you are considering or need surgery while being treated on this study. Since bevacizumab affects the way new blood vessels form, delayed, abnormal or incomplete healing may occur if you are taking this agent and you undergo surgery. Depending on type of wound healing complication, the recovery from these complications may take weeks to months and may require additional surgery. It is usually recommended that elective surgery be delayed in order for your body to clear this agent. However, this may not be possible based on your condition. Although little information is available to accurately determine the risk of wound complications from surgery once receiving chemotherapy and bevacizumab, it is generally considered increased above the risk assumed from surgery during chemotherapy alone. Your physician will inform you of these risks and the timing for intervention if necessary.

**Reproductive risks:** The drugs in this study can affect an unborn baby.

- You should not become pregnant while on this study and for at least 6 months after your last dose of bevacizumab. You should use birth control while on this study. You should ask about counseling and more information about preventing pregnancy. If you feel you might be pregnant you must notify your study doctor immediately. A pregnancy test may be performed.
- You should not breastfeed a baby/child while on this study and for at least 6 months after your last dose of bevacizumab.

**Radiation Risks from Diagnostic Tests:** There are some risks from the *standard* CT scans and chest x-rays used to monitor your health and tumor status in this study. These tests expose you to radiation. If you live in the US, you receive about 300 millirem of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millirem” (mrem) is a unit used to measure doses of radiation. The radiation total dose to your whole body for each CT scans and chest x-rays is about:

- Chest x-ray (2 views) - 12 mrem
- CT scan of the chest – 760 mrem
- CT scan of the abdomen – 1200 mrem
- CT scan of the pelvis – 1000 mrem

Your doctor will determine the type of scans you will have done to evaluate your disease for this study. If you have 1500 mrem, your risk of harm might be as high as 1 in 1000. If you have more procedures that expose you to radiation, your risk will go up. Risk of harm may include getting a new cancer or changes in your genes. You may need to have other x-rays or scans for your standard medical care. Your doctors will explain the risks of the other x-rays or scans.

### **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 doctors hope that the treatment may slow or stop the growth of the cancer, but the cancer may worsen despite treatment.

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?**

Your other choices may include:

- Getting treatment or care for your cancer without being in this study. This could include treatment with the combination of carboplatin and paclitaxel alone.
- Taking part in another study
- Getting no treatment and receiving supportive comfort care only

Talk with your doctor about your choices before you decide if you will take part in this 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.

We will try to keep your personal information as private as we can. We cannot guarantee absolute privacy. Your personal information may be disclosed 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, the GOG Statistical and Data Center and/or the GOG tissue bank for review and analysis by physicians and other study personnel. 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 Gynecologic Oncology Group (GOG)
- Genentech (the company that is supplying bevacizumab) and their representatives
- 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] and the Department of Health and Human Services [HHS]).
- 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 so 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.

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 some or all of the costs of treating your cancer in this study, including the cost of managing the side effects of therapy. 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).

If you are assigned to receive bevacizumab on this study, the drug bevacizumab will be provided free of charge for the study, from the Division of Cancer Treatment, and Diagnosis, NCI. However, you or your health plan will need to pay for the costs of the supplies and personnel who give you the drugs. If you should need to take the study agent much longer than is usual, it is possible that the NCI's supply of free agent could run out. If this happens, your study doctor will discuss with you how to obtain additional drug from the manufacturer and you may be asked to pay for it.

You will not be paid for taking part in this study. The institution receives payment which covers some, but not all of the cost of conducting the 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 number at the beginning of this form).

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. This study will not pay for medical treatment for any physical or psychological injury that happens as a result of this study.

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

Taking part in the 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 Data Safety Monitoring Board (DSMB), a group of experts, 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.

In the case of injury resulting from this study you do not lose any of your legal rights to seek payment by signing this form.

**Who can answer my questions about the study?**

For questions about the study or a research-related injury, contact your physician or one of the investigators at the beginning of the consent form.

For questions about your rights as a research participant, 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 about cancer and its treatment?**

- 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.

**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 procedures, including risks, benefits and possible alternatives, and to ask any additional questions. A signed copy of the consent form will be given to the patient.

\_\_\_\_\_  
Signature of Person Conducting the Informed  
Consent Discussion

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Conducting the  
Informed Consent Discussion

Participant's Statement

I have been given a copy of all 21 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 research 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

\_\_\_\_\_  
Participant's Printed Name

Copies to:            Participant  
                          Medical Records  
                          Research File

## **GENERAL INFORMATION ABOUT THE COLLECTION AND USE OF SPECIMENS FOR RESEARCH**

You are being asked to allow some of your blood to be collected and used for research. In addition, if your doctors have told you that you are eligible for the secondary surgical cytoreduction on this study you will be asked to give permission for some more of your blood to be collected and used for research and to have some of your tumor and normal tissue be collected and used for 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 therapies, 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 utilizes procedures and policies 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 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 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 clinical specimens may help to develop new products and therapies in the future, or may be used to establish a cell line or test 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 tissues and blood specimens can be submitted and used for this research study and/or for future research, your specimens will be used for research purposes only until they are used up or if you change your mind. You can change your mind at any 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 notify 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 2 teaspoons of your blood to be collected for this research study. The blood sample may be collected before or after starting treatment, or after completion of treatment. **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 and you can still participate in this research study.**

For patients randomized to undergo secondary cytoreductive surgery, you are also being asked for permission for the following additional specimens to be collected and used for this research:

- 1. Tumor tissue from your previous surgery, if available.**
- 2. Tumor and normal tissue from secondary cytoreductive surgery.** Either tumor and/or normal tissue removed during this surgical procedure.
- 3. Blood specimen drawn prior to the secondary cytoreductive surgery.** About four teaspoons of blood.

### **What Will Happen To Your Specimen(s) If You Agree**

The specimen(s) will be sent to the GOG Tissue Bank is located in Columbus Ohio. The GOG Tissue Bank is approved by the National Cancer Institute (NCI) to store, process and distribute specimens including any of your specimens submitted for this research study.

The specimens will be collected and used by different laboratories to identify or confirm biomarkers, and to measure proteins and genes.

After the laboratory testing is finished, the results will be sent to the GOG Statistical and Data Center in Buffalo, New York and studied to determine if the amount of any of these biomarkers or a specific profile can be used to identify which patients in the future might be more or less likely to recur, respond to a particular treatment or have a good prognosis (chance for long term survival), for example. These results will be used for research purposes only, and published after completion of this research study. Please ask your study doctor or research staff if you have any questions about his part of the research study.

**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 some of your tumor, that was left over from a previous surgery, to be submitted and used for this research study?

YES                      NO

2. Do you give permission for some tumor and normal tissue if removed during the secondary cytoreductive surgery performed as part of this research study to be submitted and used for this research study?

YES                      NO

3. Do you give permission for your blood to be collected for submission and used 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 examine 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 including cancer or the effectiveness of specific treatments.

**The choice to let us collect 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 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

5. 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

Please sign your name after you circle your answers.

Your signature: \_\_\_\_\_ Date: \_\_\_\_\_

Copies to: Participant  
Medical Records  
Research File