

CONSENT TO PARTICIPATE IN GOG 0187:  
Phase II Study of Paclitaxel for Ovarian Stromal Tumors as Second-Line Treatment  
Consent Version 8/23/09

Investigators

Benjamin E. Greer, M.D., Principal Investigator, University of Washington, Department of OB/Gynecology, 1959 NE Pacific St. Seattle, Washington. (206) 543-3669. **EMERGENCY NUMBER: (206) 543-3669 If there is no answer or it is after 5:00 pm, call 206/598-6190 and ask the operator to page the Gynecology Oncology Resident on call.**

Charles Drescher, M.D., Co-Principal Investigator, Pacific Gynecology Specialists, 1101 Madison Medical Tower Suite #1500, Seattle, Washington. (206) 965-1700. **EMERGENCY NUMBER: (206) 965-1700**

**Study Doctor:** \_\_\_\_\_ **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 have been asked to take part in this study because you have malignant stromal tumor of the ovary that has come back after previous chemotherapy treatment.

**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 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. The GOG is funded by the Federal Government through the National Cancer Institute (NCI).

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

The purpose of this study is to determine the effectiveness of the chemotherapy drug paclitaxel in treating ovarian stromal tumors. The study will also compare the side effects (good and bad) that are caused by the treatment. The study will also evaluate the usefulness of the blood test inhibin to predict how patients respond to treatment. Inhibin is a protein hormone that can be measured in the blood.

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

Approximately 45 patients will be treated on 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. 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 that may include a pelvic exam
- Blood tests (approximately 1 tablespoon of blood) to evaluate your blood counts, calcium, liver and kidney function, and the protein inhibin
- Urine test
- Chest x-ray
- CT scan of the abdomen and pelvis or other sites to measure the cancer
- If you are able to become pregnant, a pregnancy test will be done to be sure that you are not pregnant.

**Summary of study 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 enrolled on the study and receive treatment paclitaxel in your vein (IV) over 3 hours every three weeks. Treatment will be given as an outpatient in your doctor's office, clinic or hospital. Treatment will continue until there is evidence of complete disappearance of the cancer at which time you will receive 2 additional cycles of therapy and then stop. However, if there is evidence that the tumor is growing or the side effects are not acceptable then treatment will be stopped. You may choose to stop therapy at any time.

**During treatment on this study**

All aspects of this treatment will be under the close supervision of your physician 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. The scans are done to see if your tumor is responding to the treatment. These tests are part of regular cancer care for ovarian stromal but may be done more frequently because you are on this study.

- Weekly blood counts
- Before each cycle of therapy (*every 3 weeks*), you will have a physical exam and updated medical history; routine blood tests to evaluate your blood counts, calcium, and liver and kidney function; inhibin blood test
- If you have measurable disease that can be evaluated by CT scan or chest x-ray, the test will be repeated every other cycle of treatment (every 6 weeks)

### When you are finished with your treatment

- You will have exams by doctor every 3 months for 2 years, then every 6 months for the next three years and then annually. CT scans will be done 3 months for 2 years, then every 6 months for the next three years until your cancer has progressed, then they will not be required. At the time you stop treatment, if your inhibin test is elevated, the test will be repeated every 3 months for two years.

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

Treatment will continue until there is evidence of complete disappearance of the cancer at which time you will receive 2 additional cycles of therapy and then stop. However, if there is evidence that the tumor is growing or the side effects are not acceptable then treatment will be stopped. You may choose to stop therapy at any time. When you stop treatment we would like to keep track of your medical condition for life. You will have a physical exam every 3 months for the first two years and then every six months for three more years. Keeping in touch with you and checking on your condition helps us to look at the long-term effects of the study treatment.

### **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 paclitaxel 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.

### **Can anyone else stop me from being in the study?**

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. Most of these are listed here, but there may be other side effects that we cannot predict. 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. 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.

Risks and side effects related to **paclitaxel** include:

**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 tiredness, shortness of breath or fatigue
- Allergic reaction (including chills, rash, hives, itching, flushing, swelling, low blood pressure, wheezing and shortness of breath). Rarely this may be life-threatening.
- Numbness, tingling, burning and/or 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, or performing other activities of daily living.
- Temporary loss of hair
- Muscle and joint aches
- Changes (high or low) in blood pressure
- Redness, tenderness, discoloration or swelling of the skin where the drug is given
- Time away from work

**Less likely, but potentially serious:**

- Slowing or irregular heart rate
- Nausea and/or vomiting
- Diarrhea
- Redness, irritation, or sores in the mouth or throat (that can lead to difficulty swallowing and dehydration)
- Fatigue
- Lightheadedness
- Blood tests that show changes in liver function
- Confusion; mood changes
- Skin damage (if there is leakage of drugs into tissue during treatment)
- Changes in taste
- Irritation and swelling of the skin in an area previously treated with radiation therapy
- Rash
- Inflammation of the colon
- 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
- Heart problems such as heart attack or heart block
- Severe lung problems (including shortness of breath, inflammation of the lungs, low levels of oxygen in the blood, and damage that could be permanent)
- Death

**Reproductive risks:** If you are able to become pregnant, a blood test will be performed before the study to be sure you are not pregnant. You should not become pregnant while on this study because the treatment in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while

on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. You should notify your health care team immediately if you think you have become pregnant while participating in this study,

**Diagnostic Radiation Risks:** There are some risks from the CT scans and chest x-ray used to monitor your health and tumor status. These tests will 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

These doses can vary from person to person and may vary by machine. If you receive 3000 mrem, your risk of harm might be as high as 1 in 500. If you have more procedures that expose you to radiation, your risk will go up. Risks 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 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 treatment may slow or stop the growth of the cancer or the cancer may worsen despite treatment. We hope that the information learned from this study will help future patients with ovarian stromal tumors.

### **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
- 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.

### **How will information about me 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)
- 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 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.

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. 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. 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 or his/her staff about health insurance problems or other financial concerns.

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.

**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.

If any important new information about the study develops that may affect your health, welfare, or willingness to stay on the study, your doctor will tell you. You may be asked to sign another consent form at that time.

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 I call if I have questions or problems?**

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

**Participant's Statement**

I have been given a copy of all 8 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

Copies to:      Participant  
                            Medical Records  
                            Research File