

Northwest Community Clinical Oncology Program (NWCCOP)
315 Martin Luther King Jr. Way
Tacoma, WA 98405
Phone: (253) 403-1461
Fax: (253) 403-1615

Sponsored and Funded by the National Cancer Institute

CONSENT FORM

CIRB G0219: A PHASE III, RANDOMIZED TRIAL OF WEEKLY CISPLATIN AND RADIATION VERSUS CISPLATIN AND TIRAPAZAMINE AND RADIATION IN STAGE IB2, IIA, IIB, IIIB AND IVA CERVICAL CARCINOMA LIMITED TO THE PELVIS

INVESTIGATORS:

Lauren K. Colman, MD, Chris Chen, MD, W. Welby Cox, MD, FACP, Xinda Wang, MD, Daniel Moore, MD, Troy Wadsworth, MD, 1003 South 5th Street-3rd Floor, Tacoma, WA 98405 (253) 403-1677.

Robert McCroskey, MD, Sibel Blau, MD, Andrea Rose, MD, 400-15th Avenue SE, Puyallup, WA 98372 (253) 841-4296.

Frank Senecal, MD, Thomas Baker, MD, Lorrin Yee, MD, Moacyr Oliveira, MD
1624 South I Street, Tacoma, WA 98405 (253) 383-3366.

Paul Robertson, MD, Steven Gorton, MD, James Lechner, MD, Harry Griffith, MD,
Xingwei Sui, MD, 4525 Third Ave. SE, Suite 200, Lacey, WA 98503 (360) 754-3934.

Dustan Osborn, MD, Ronald Goldberg, MD, Nicole Grous, MD, Min Kang, MD, 3920 Capital Mall
Drive SW, Suite 100, Olympia, WA 98502, 360-753-4700 and 222-2nd Street NE, Suite B, Auburn, WA
98002
(253) 887-9333.

John Rieke, MD, Suraj Singh, MD, Carolyn Rutter, MD, 1003 South 5th Street, 1st Floor, Tacoma, WA
98405 (253) 403-4994.

Michael Liao, MD, 400 -15th Ave SE, Puyallup, WA 98372 (253) 697-4829

CIRB G0219: A PHASE III, RANDOMIZED TRIAL OF WEEKLY CISPLATIN AND RADIATION VERSUS CISPLATIN AND TIRAPAZAMINE AND RADIATION IN STAGE IB2, IIA, IIB, IIIB AND IVA CERVICAL CARCINOMA LIMITED TO THE PELVIS

GENERAL

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.

You are being asked to take part in this study because you have cancer of the cervix.

WHY IS THIS STUDY BEING DONE?

To determine if combining Tirapazamine (TPZ) with Cisplatin during radiation therapy increases progression-free survival (PFS) compared with Cisplatin and radiation therapy. Tirapazamine is an investigational agent.

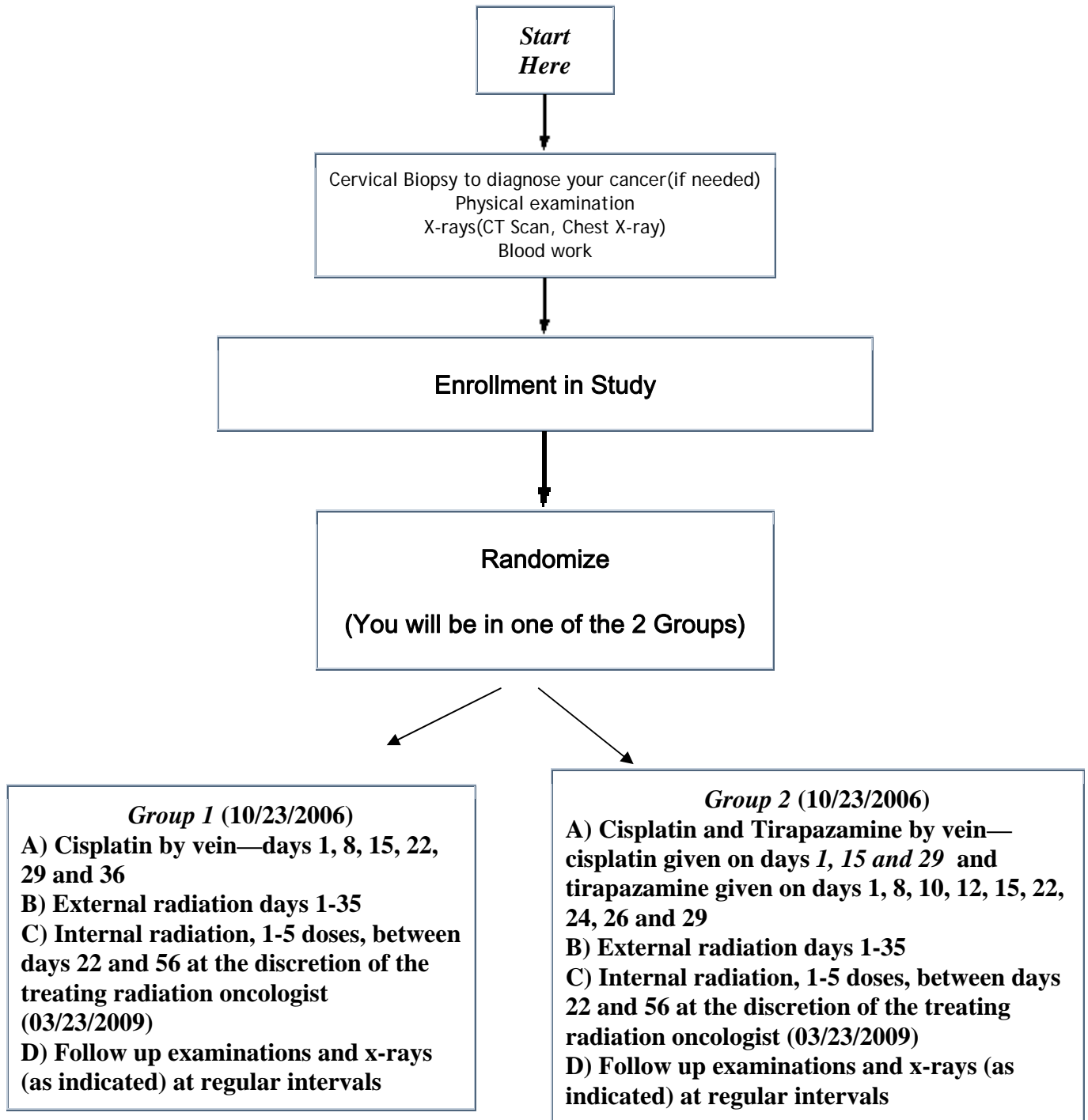
HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 750 people will take part in this study.

WHAT WILL HAPPEN IF YOU TAKE PART IN THIS RESEARCH STUDY?

Study Plan

One way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



Before you begin the study...

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- A cervical biopsy will have been performed. A second tumor biopsy may sometimes be needed to confirm eligibility for this study.
- About 1 tablespoon (7-10 ml) of blood will be drawn (taken) from a vein.
- A physical examination to include pelvic examination, blood counts, and check-up of liver and kidney status through blood studies.
- Detectable tumor will be measured.
- An audiogram (hearing test) if you have hearing loss
- A Chest X-ray
- A pregnancy test (if indicated)
- A consent form must be signed by you or your legally authorized representative prior to entry into study. Current FDA, NCI and institutional regulations concerning informed consent will be followed.

During the study...

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are being done more often because you are in this study and to see how the study is affecting your body.

- physical examination to include pelvic examination
- tumor measurements
- blood work to evaluate white blood cell counts, platelet counts and hemoglobin
- Blood tests to evaluate liver and kidney status and electrolyte levels.
- Blood counts will be repeated every week throughout your treatment. Other tests will be repeated as necessary. Additional x-ray procedures will be performed as determined necessary by your physician(s). Results from these check-ups will be submitted to the GOG for analysis as a part of the study.

You will be "randomized" into one of the study groups described below. 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 in either group.

If you are in Group 1 (often called "Arm A" or "Regimen I") you will receive standard external radiation therapy daily for five weeks. Following external radiation, intracavitary radiation (radiation delivered directly to the cervix through the vagina) will be administered. Depending on the type of intracavitary treatment administered, you may receive 1-5 intracavitary placements. The administration of cisplatin will take approximately 30-60 minutes each time. The radiation therapy will be given over eight weeks. The cisplatin chemotherapy will be given in six treatments, weekly during the course of the radiation therapy.

If you are in Group 2 (often called “Arm B” or “Regimen II”), radiation therapy will be administered as outlined for Group 1. Tirapazamine chemotherapy will be given in addition to cisplatin. The tirapazamine will be administered into your vein and will take approximately two hours each time. The tirapazamine will be given before the cisplatin. The administration of cisplatin will take approximately 30-60 minutes each time. The radiation therapy will be given over eight weeks. The cisplatin will be given in three treatments and the tirapazamine will be given in nine treatments during the course of the radiation therapy.

After you finish chemotherapy and radiation therapy...

- About 1 tablespoon (7-10 ml) of blood will be drawn from a vein in your body after you finish receiving your chemoradiation treatment to prepare serum for research to measure the level of proteins involved in angiogenesis.

HOW LONG WILL YOU BE IN THE STUDY?

After you are finished taking the chemotherapy and radiation (approximately 8 weeks after beginning treatment), the study doctor will ask you to visit the office for follow-up exams every 3 months for the first two years, every 6 months for the next three years and then annually for the rest of your life. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of the study.

CAN YOU 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 you are receiving 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.

The study doctor may stop you from taking part in this study at any time if he/she believes it is best for you; if you do not follow the study rules; or if the study is stopped.

WHAT SIDE EFFECTS OR RISKS CAN YOU EXPECT FROM BEING IN THE STUDY?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. 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 drugs and receiving the radiation. In some cases, *side effects may be serious, long lasting, may never go away, be life threatening or even fatal.*

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 **Cisplatin** include those which are:

Likely

- Fatigue
- Lowered white blood count which may increase the risk of infection
- Lowered red blood cells which may lead to anemia, tiredness, or shortness of breath
- Decrease in kidney function
- Loss of appetite and weight loss
- Diarrhea, constipation, nausea and vomiting, and abdominal pain
- Complete hair loss
- Numbness or tingling in fingers or toes
- Skin rash
- Changes in taste
- Ringing in the ears and hearing loss
- Changes in electrolytes in the blood such as magnesium and potassium

Less Likely

- Allergic reactions
- Chills and fever with aches and pains
- Lowered platelets may lead to an increase in bruising or bleeding
- Sores in mouth and throat (that can lead to difficulty swallowing and dehydration)
- Altered vision
- Skin irritation and swelling if the drug leaks from the vein into which it is being injected into the surrounding skin

Rare but serious

- Seizures
- Secondary cancers such as acute leukemia
- Kidney failure requiring dialysis
- Deafness
- Hemolytic uremic syndrome (low red blood cell count, low platelet count and kidney damage)
(02/11/2008)

Risks and side effects related to **Radiation** include those which are:

Likely

- tanning or reddening of the skin which is exposed to the beam
- burning or pain during urination or defecation
- diarrhea
- pubic hair loss

Less Likely

- damage to the small or large intestine or rectum or ureter or bladder

Rare but serious

- nerve damage which may cause numbness or weakness in the legs

Risks and side effects related to **Tirapazamine** include those which are: ()

Likely

- reversible hearing loss or ringing in the ears
- reversible blurred vision, decreased visual acuity or night blindness
- visual disturbances, slashing lights and/or floaters
- nausea
- vomiting
- diarrhea
- muscle pain
-

Less Likely

- decreased red blood cells which may lead to anemia, tiredness or shortness of breath
- decreased white blood cells which may increase the risk of infection
- loss of sensation in hands/feet
- Irritation or sores in the lining of the mouth
- swelling of the esophagus
- sleepiness
- skin rash or flaking of outer layer of skin
- allergic reaction that causes fever, aches and pains in the joints, skin rash and swollen lymph glands
- Belly pain
- Constipation
- Cough
- Fatigue or tiredness
- Fever that may or may not be associated with dangerously low levels of a type of white blood cell (neutrophils)
- High blood pressure
- Infection
- Injection site reaction/leaking of some blood into tissue
- Loss of appetite
- Pain
- Shortness of breath

Rare but serious

- heart attack
- decreased blood supply to heart muscle
- decreased white blood cells with fever and infection

Although previous studies using cisplatin and tirapazamine in combination with radiation have not shown any drug-to-drug interactions (effects that one drug may have on the other within your body) that have increased the risks above and beyond those already listed, there may be unknown risks that could occur.

Reproductive risks: You should not become pregnant while on this study because the drugs 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. Some methods might not be approved for use in this study.

Your health care team will discuss the risks and side effects associated with a tumor biopsy only if it is needed to confirm your diagnosis and eligibility for this study. In that case, they would ask you to sign a separate permission form for the biopsy.

The only side effects you may encounter from the two blood draws to prepare the serum for laboratory testing are those routinely associated with blood draws including slight discomfort, bleeding or bruising at the site of the blood draw.

For more information about risks and side effects, ask your study doctor.

Adverse events that are considered serious or that are unexpected are reported to the GOG Administrative Office. These reports, administered through the Adverse Event Expedited Review System (AdEERS) are then forwarded to the appropriate regulatory agencies and the study chair for evaluation regarding their relationship to study treatment.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Taking part in this study may or may not make your health better. While doctors hope chemotherapy with cisplatin and tirapazamine along with radiation will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about these chemotherapy drugs and radiation as a treatment for cancer. This information could help future cancer patients.

WHAT OTHER CHOICES DO YOU HAVE IF YOU DO NOT TAKE PART IN THIS STUDY?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment
- Getting comfort care, also called palliative care, for stage IVA disease. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

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

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential, and GOG procedures include removing your name and other identifying information from data collected during the Study, in order to protect your privacy. However, we cannot guarantee total confidentiality. Portions of your medical records will be sent to the GOG Administrative Office, the GOG Statistical and Data Center, the GOG Tissue Bank and to the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials, to be reviewed and analyzed by physicians and other Study personnel. Your records may be accessed by GOG representatives and by the NCI for research, quality assurance, and data analysis purposes.

Your records may also be reviewed by the National Cancer Institute of Canada (NCIC), the Nordic Society of Gynecological Oncology (NSGO) and the Australia New Zealand Gynecological Oncology Group (ANZGOG). Your records may also be reviewed by the drug manufacturing company (Sanofi).

In addition, your records may be reviewed by the Food and Drug Administration (FDA), or other agencies of the Department of Health and Human Services (DHHS) for research or regulatory purposes. Also, information from the Study may be given to government agencies in other countries where the study drug may be considered for approval.

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.

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.

The National Institutes of Health (NIH) has issued GOG a Certificate of Confidentiality, which protects GOG from being forced to disclose personal information about you in response to a subpoena or other request in a federal or state legal proceeding.

When the research results are published or discussed in conferences, no information will be included that reveals your identity.

[Note to Local Investigators: The Department of Health and Human Services (DHHS) has recommended that HIPAA Privacy Rule requirements be addressed by the local institution. This may be done either in a stand-alone authorization or as part of the informed consent document, depending on institutional policy.]

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

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. 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 you or your insurance company more than the cost of getting regular cancer treatment.

The Division of Cancer Treatment and Diagnosis, NCI, will provide you with the NCI sponsored/supplied agent, tirapazamine, free of charge for this study. Every effort will be made to ensure adequate supplies of the tirapazamine free of charge, for all participants for the duration of the study. However, you or your health plan may need to pay for costs of the supplies and personnel who give you the tirapazamine. If, during the study, tirapazamine becomes approved for use in your cancer, you and/or your health plan may have to pay for drug needed to complete this study.

You will not be paid for taking part in this study. The institution receives payment that covers some but not all of the costs of 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 YOU ARE INJURED BECAUSE YOU 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/her at the number listed on the cover page.

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. The study will not pay for medical treatment.

WHAT ARE YOUR RIGHTS IF YOU 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.

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.

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 YOUR QUESTIONS ABOUT THE STUDY?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor at the number listed on the cover page.

For questions about your rights while taking part in this study, call the MultiCare Health System Institutional Review Board (a group of people who review the research to protect your rights) at 253-403-3877.

*You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).

WHERE CAN YOU GET MORE INFORMATION?

You may call the National Cancer Institute'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 NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials/>
- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

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

Signature

You have been given a copy of all pages of this form. You have read it or it has been read to you. You understand the information and have had your questions answered. You agree to take part in this study.

Patient's name (printed or typed)

Patient's Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date

GENERAL INFORMATION ABOUT THE COLLECTION AND USE OF SPECIMENS FOR RESEARCH

You are being asked to give permission for some of your tissue and blood to 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, 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 regular 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 will utilize all possible methods 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 specimens 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 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 tumor and blood specimens can be collected 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 notify the GOG regarding your wishes about using your coded specimens and clinical information 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 (left over after your diagnosis) and blood to be submitted and used for this research study. **The choice to let us collect one or more of 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 allow your specimens to be collected and used for this research study. The results of the laboratory testing will be used for research only. This research study does not involve any genetic testing. Tumor and blood specimens will only be collected from patients who give permission to allow their specimens to be used for this research study.

Tumor and Blood Requirements for Research

We are asking you for permission to have some of your tumor tissue that was left over after your doctors determined your diagnosis to be submitted and used for this research study.

We are asking you for permission to draw 2 tablespoons of blood before starting treatment and 1 tablespoon of blood when you go off-treatment to prepared serum, obtain a platelet count and prepare blood for submission and use for this research study.

What Will Happen To Your Tumor and Blood If You Agree (10/23/2006)

If you give permission for some of your tumor that was left over after your doctors determined your diagnosis 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.

If you give permission for your blood to be drawn and used for this research study, your health care team will use your blood specimen to prepared serum, obtain a platelet count and prepare plasma. Serum is the liquid part of blood that remains after the blood is allowed to clot, and the blood cells and clot are removed. Platelets are a specific type of blood cell and the number of platelets (platelet count) in your blood is needed as a control because platelets may influence the results of this laboratory test. Plasma is the liquid part of blood that remains after the blood cells

are removed. Your health care team will freeze your serum and plasma and then send these frozen specimens to the GOG Tissue Bank in Columbus, Ohio. **(02/20/2007)**

Your health care team will submit a form with each specimen shipped to the GOG Tissue Bank. Information about the collection, processing, storage and shipment of the tumor, serum or plasma is recorded on this specimen form. The platelet count information will also be recorded on the specimen form.

The GOG Tissue Bank is approved by the National Cancer Institute (NCI) to store, process and distribute specimens including tumor and blood from patients who agree to participate in the studies conducted by the GOG. The GOG Tissue Bank will be responsible for sending tumor, serum and plasma from the patients who agree to participate in this part of the research study for testing.

Tumor, serum and plasma will be used for the following reasons.

- **To create tissue microarrays (abbreviated TMAs).** Very small pieces of tumor tissue (called cores) will be removed and arranged in large wax blocks called TMAs. Each TMA will contain tumor pieces from 50 to 200 patients who participate on this study.
- **To determine the level of proteins in fixed tumor, serum and plasma.** Different laboratory tests will be used to measure the amount of certain proteins in fixed tumor from one person at a time, in TMAs with tumor from 50 to 200 patients at a time, and in serum and plasma. Proteins are natural substances made up of amino acids. In this research study, the tests will measure proteins involved in the processes called hypoxia (low oxygen levels) and tumor angiogenesis (blood flow).

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 will be studied to determine if the amount of any of these proteins can be used to identify which patients in the future might be more or less likely to have a good prognosis (chance for long term survival) or respond to the study treatment drug, for example.

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 tissue, that was left over after your doctors determined your diagnosis, to be submitted and used for this research study?

Yes No

2. Do you give permission for your blood to be drawn at two times to prepare serum, obtain a platelet count and prepare plasma for submission and use for this research study? (10/23/2006)

Yes No

Please sign your name after you circle your answers.

Your signature: _____ Date: _____

Signature of Doctor/Nurse: _____ 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 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 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 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? (10/23/2006)

Yes No

Please sign your name after you circle your answers.

Your signature: _____ Date: _____

Signature of Doctor/Nurse: _____ Date: _____

Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information for Research

Participant's Name: _____

Birth Date: _____

1. What is the purpose of this form?

The Gynecology Oncology Group (GOG) is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter a GOG research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you receive, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that identify you, such as your social security number and medical record

You may request a blank copy of the GOG data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my personal health information?

The Northwest CCOP will collect your health information and share it with the GOG Statistical and Data Center and the GOG Administrative Office if you enter a cooperative group research study. The GOG centers will use your information in their cancer research study, GOG-0219: A PHASE III, RANDOMIZED TRIAL OF WEEKLY CISPLATIN AND RADIATION VERSUS CISPLATIN AND TIRAPAZAMINE AND RADIATION IN STAGE IB2, IIA, IIB, IIIB AND IVA CERVICAL CARCINOMA LIMITED TO THE PELVIS

4. *Who will be able to use my personal health information?*

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. The Northwest CCOP may also permit these groups to come in to review your original records that are kept by the Northwest CCOP so that they can monitor their research study.

- the GOG Administrative Office;
- the GOG Statistical and Data Center;
- the Clinical Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute that supports the research of the GOG;
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- Members of review groups established by the GOG in order to ensure the validity of its research program.
- Centralized laboratories and facilities which store and evaluate biologic specimens if you agree to provide biologic specimens.
- Other people or organizations assisting with the GOG research effort including those companies and agencies sponsoring the research.

5. *How will information about me be kept private?*

The GOG will keep all patient information private to the extent possible, even though the GOG is not required to follow the federal privacy laws. Only researchers working with the GOG will have access to your information. The GOG will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

6. *What happens if I do not sign this permission form?*

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. He/she will make sure your written request to withdraw your permission is processed correctly.

Karyn Hart, RHIT, CCRP
Program Coordinator
Northwest CCOP
315 Martin Luther King Jr., Way
Tacoma, WA 98405
(253) 403-1461

9. How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by the Northwest CCOP. You do not have the right to review and/or copy records kept by the GOG or other researchers associated with the research study.

Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Patient
or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Permission: _____ Date: _____

Printed Name of Person Obtaining Permission: _____