

SAMPLE CONSENT A

Informed Consent Template for Cancer Treatment Trials

PHASE III RANDOMIZED STUDY OF CONCURRENT CHEMOTHERAPY AND PELVIC RADIATION THERAPY WITH OR WITHOUT ADJUVANT CHEMOTHERAPY IN HIGH-RISK PATIENTS WITH EARLY-STAGE CERVICAL CARCINOMA FOLLOWING RADICAL HYSTERECTOMY

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 cervical cancer that was removed by surgery and has spread to the lymph nodes or to the connective tissue of the uterus.

Why is this study being done?

The purpose of this study is to compare the effects, good and/or bad, of giving additional chemotherapy to you after the usual treatment of chemotherapy and radiation for your cervical cancer. The standard treatment for your type of cervical cancer is cisplatin chemotherapy plus radiation. The study will determine whether adding chemotherapy with carboplatin and paclitaxel (experimental for your type of cervical cancer) to standard radiation and cisplatin chemotherapy improves survival without increasing side effects. Cisplatin, carboplatin, and paclitaxel are FDA (Food and Drug Administration) approved drugs used to treat a number of different types of cancers, however carboplatin and paclitaxel are experimental for the treatment of cervical cancer. In this study, you will receive either radiation plus cisplatin alone or radiation plus cisplatin followed by carboplatin and paclitaxel.

One of the standard treatment options for your stage and type of cervical cancer is external beam radiation therapy. Both three-dimensional radiation therapy and IMRT allow the radiation beam to treat an area that is shaped like your tumor and also to penetrate as deeply as your tumor is located. By treating this way, the dose of radiation to the healthy areas near your tumor is minimized, and the dose to your tumor is maximized.

This study also will study biologic factors that may help to predict and treat cervical cancer. In addition, this study will gather information about the effects of radiation therapy and chemotherapy on your overall quality of life.

How many people will take part in the study?

About 400 people will take part in this study.

What will happen if I take part in this research study?

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.

- History and physical examination
- Blood tests
- Contrast-enhanced CT (a computerized tomography scanner that sends x-rays through the body at many different angles) or MRI of the abdomen and pelvis (an image of your stomach and pelvis produced by magnetic rays) OR a whole-body PET-CT (a type of nuclear medicine imaging used to provide images that pinpoint the location of abnormal metabolic activity within the body.)
- Chest x-ray or CT scan of the chest (unless you had a whole-body PET-CT)
- PET-CT (for patients with positive lymph nodes who did not have a whole-body PET-CT)

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 part of regular cancer care.

During chemotherapy and radiation

- Weekly history and physical examination
- Weekly blood tests

In addition, if you experience hearing problems while on the study or have experienced hearing problems in the past, you will be receiving an audiogram (a test that measures your hearing ability).

You will need these tests and procedures that are part of regular cancer care. They are being done more often because you are in this study.

If you are assigned to the group that receives additional chemotherapy

- History and physical examination before the start of each chemotherapy cycle (to be done every 3 weeks for 4 cycles)
- Blood tests before the start of each chemotherapy cycle (to be done every 3 weeks for 4 cycles)

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 study doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

If you are in Group 1 (often called "Arm A") ...

You will receive radiation plus weekly cisplatin. The radiation therapy will be given every day, 5 days a week. The treatment takes about 5-15 minutes each day. The cisplatin chemotherapy that will be given with the radiation therapy will be given every week, every Monday or Tuesday, for 6 cycles. The days that you receive your chemotherapy, you will be at the hospital about 5-6 hours. The chemotherapy is given through the IV (a thin plastic tube inserted into a vein).

If you are in Group 2 (often called "Arm B" or the experimental arm)...

You will receive radiation plus weekly IV cisplatin chemotherapy as in Group 1 stated above. Take a break for 4 to 6 weeks. After a break of 4 to 6 weeks, you will then receive more chemotherapy with carboplatin and paclitaxel. Carboplatin will be given through an IV infusion over 30 minutes and paclitaxel will be given through an IV infusion over 3 hours. You will receive both drugs on the same day every 3 weeks for 4 cycles.

Your study doctor may decide in addition to the external beam treatment you may receive a different type of radiation treatment known as a "vaginal cuff boost". The vaginal cuff boost is where the physician places radiation inside the vagina to treat the top of the vagina. The physician places an applicator that has a hollow tube into the vagina, and then the radiation goes through the hollow tube and treats the vagina. The applicator is similar to placing a large tampon in the vagina. This internal treatment takes about 2-5 minutes for each treatment.

When you are finished receiving all treatment, you will have the following tests and procedures:

Every 3 months for 2 years, every 6 months for 3 years, and then yearly

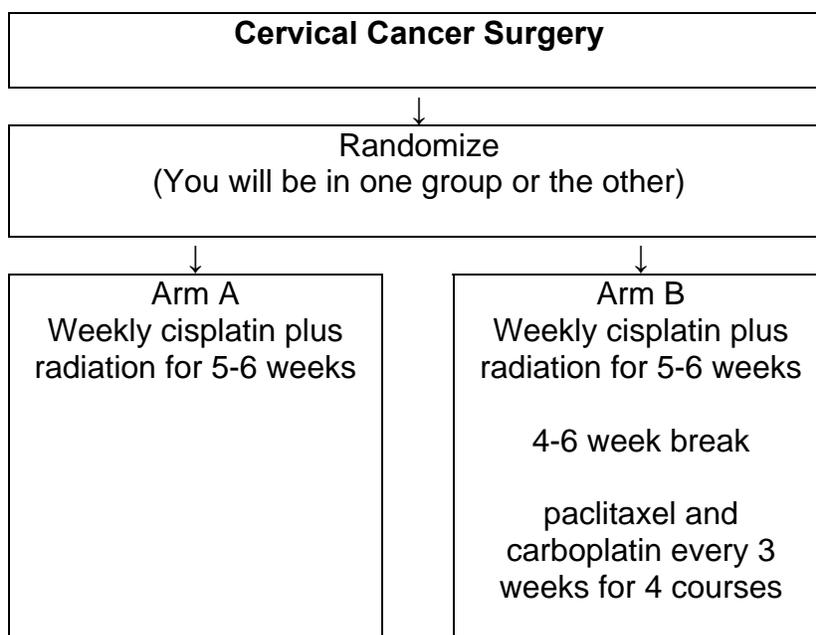
- History and physical examination
- Blood tests

Yearly

- Pap smear
- Contrast-enhanced CT or MRI of the abdomen and pelvis
- Chest x-ray or CT scan of the chest

Study Plan

Another 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.



How long will I be in the study?

You will be asked to take radiation plus cisplatin chemotherapy for 5 to 6 weeks. If you are assigned to the group that receives additional chemotherapy with paclitaxel and carboplatin, you will wait 4-6 weeks and then receive the chemotherapy for about another 4 months.

After you are finished with treatment, the study doctor will ask you to visit the office for follow-up exams every 3 months for the first 2 years, every 6 months for the next 3 years, and then every year.

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 that he/she can evaluate any risks from the treatment. Another reason to tell your study 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 in your best interest; 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. Everyone taking part in the study will be watched carefully for any side effects. However, researchers 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 treatment. 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 the radiation include those that are:

Likely

- Tiredness
- Diarrhea
- Nausea and vomiting
- Rectal irritation
- Urinary frequency or difficulty in urination
- Loss of pubic hair
- Reddening and irritation of the skin in the radiated area
- Decrease in blood counts that may cause infection, bleeding, and bruising

Less Likely

- Painful intercourse
- Vaginal narrowing and shortening

Rare but Serious

- Poor nutrition
- Rectal ulcer
- Bleeding or narrowing of the rectum
- Blood in the urine
- Bowel obstruction
- Damage to the vaginal wall, which could lead to a fistula (abnormal passageway between the bladder and the vagina or between the rectum)
- Long-term kidney damage leading to dialysis (separation of blood and toxins) if the lymph nodes are radiated
- Spinal cord damage leading to paralysis (if the lymph nodes are radiated)

Risks and side effects related to cisplatin include those that are:

Likely

- Decrease in blood counts that may cause infection, bleeding, and bruising
- Loss of appetite
- Nausea and vomiting
- Hearing loss or ringing in the ears
- Numbness or tingling in the hands or feet

Less Likely

- Muscle cramps or spasms
- Loss of coordination
- Involuntary movements or shaking
- Rash
- Vision problems
- Hair loss
- Low mineral levels in your blood
- Decrease in liver function causing temporary elevation in blood tests
- Metallic taste

Rare but Serious

- Loss of muscle or nerve function, which may cause weakness or numbness in your hands and feet
- Decreasing ability of the kidneys to handle the body's waste, which may be permanent
- Allergic reactions, which can cause difficulty in breathing, fast heartbeat, and sweating
- Acute myeloid leukemia

Risks and side effects related to carboplatin include those that are:

Likely

- Decrease in blood counts that may cause infection, bleeding, and bruising
- Nausea and vomiting
- Numbness or tingling in the hands or feet

Less Likely

- Low mineral levels in your blood
- Decrease in liver function causing temporary elevation in blood tests
- Hearing loss or ringing in the ears

Rare but Serious

- Loss of muscle or nerve function, which may cause weakness or numbness in your hands and feet
- Allergic reactions, which can cause difficulty in breathing, fast heartbeat, and sweating
- Temporary loss of vision to light and colors

Risks and side effects related to paclitaxel include those that are:

Likely

- Decrease in blood counts that may cause infection, bleeding, and bruising
- Nausea and vomiting
- Numbness or tingling in the hands or feet
- Fatigue

- Complete hair loss

Less Likely

- Muscle aches and joint pain
- Muscle cramps or spasms
- Loss of coordination
- Involuntary movements or shaking
- Rash, itchiness, redness, hives
- Diarrhea
- Sores in your mouth
- Sore throat
- swelling of your stomach and/or stomach lining
- swelling of your colon
- Low or high blood pressure
- Vision problems
- Decrease in liver function causing temporary elevation in blood tests
- Skin irritation
- Changes in taste
- Light-headedness

Rare but Serious

- Loss of muscle or nerve function, which may cause weakness or numbness in your hands and feet
- Allergic reactions, which can cause difficulty in breathing, fast heartbeat, and sweating
- Slowing of your heart or irregular heart rhythm
- Swelling and/or failure of your liver
- Inflammation of the lungs
- Swelling of the brain
- Seizures
- Mood changes

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

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While researchers hope the addition of paclitaxel and carboplatin 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 researchers learn more about radiation and cisplatin with or without carboplatin and paclitaxel as a treatment for 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 a study
- Taking part in another study
- Getting no treatment

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

Will my medical information be kept private?

Data are housed at Radiation Therapy Oncology Group (RTOG) Headquarters in a password-protected database. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Your local IRB
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- The Cancer Trials Support Unit (CTSU), a service sponsored by the NCI to provide greater access to cancer trial

[Note to Local Investigators: The NCI has recommended that HIPAA regulations be addressed by the local institution. The regulations may or may not be included in the informed consent form depending on local 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 your insurance company more than the cost of getting regular cancer treatment.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at

<http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

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

It is important that you tell your study doctor, _____ *[investigator's name(s)]*, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him/her at _____ *[telephone number]*.

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 my rights if I take part in this study?

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

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.

A Data Monitoring Committee (DMC) will be regularly meeting to monitor safety and other data related to this study. The Committee members may receive confidential patient information, but they will not receive your name or other information that would allow them to identify you by name.

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?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ [name(s)] at _____ [telephone number].

For questions about your rights while taking part in this study, call the _____ [name of center] Institutional Review Board (a group of people who review the research to protect your rights) at _____ (telephone number). *[Note to Local Investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]*

***You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).** *[*Only applies to sites using the CIRB.]*

Please note: This section of the informed consent form is about additional research that is being done with people who are taking part in the main study. You may take part in this additional research if you want to. You can still be a part of the main study even if you say ‘no’ to taking part in this additional research.

You can say “yes” or “no” to each of the following studies. Below, please mark your choice for each study.

Quality of Life Study: Consent Form

We want to know your view of how your life has been affected by cancer and its treatment. This “quality of life” study 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.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to complete 3 questionnaires at the following times:

- Before you begin treatment on this study,
- When you have completed radiation plus cisplatin chemotherapy,
- At 6 months after you have completed radiation plus cisplatin chemotherapy,
- At 12 months after you have completed radiation plus cisplatin chemotherapy, and
- At 24 months after you have completed radiation plus cisplatin chemotherapy.

It takes about 15 minutes to fill out each questionnaire.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this study, the only thing you will be asked to do is fill out the 3 questionnaires. You may change your mind about completing the questionnaires at any time.

Just like in the main study, we will do our best to make sure that your personal information will be kept private.

Please circle your answer.

I choose to take part in the quality of life study. I agree to fill out the 3 quality of life questionnaires.

Yes

No

Use of Tissue and Blood for Research: Consent Form

About Using Tissue and Blood for Research

You have had a biopsy (or surgery) to see if you have cancer. Your doctor will remove some body tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care.

We would like to keep some of the tissue that is left over for future research. If you agree, this tissue will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How is Tissue Used for Research" to learn more about tissue research. This information sheet is available to all at the following web site: http://www.rtog.org/tissue%20for%20research_patient.pdf

As a result of your participation in the trial, you also will have blood tests performed before you start treatment and at completion of your chemotherapy treatment (Arm A: completion of cisplatin; Arm B: completion of carboplatin/paclitaxel). We would like to keep for future research about 3 tablespoons of the blood taken at that time. If you agree, this blood will be kept and may be used in research to learn more about cancer and other diseases.

The research that may be done with your tissue and blood is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your tissue and blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the tissue and blood for future research is up to you. No matter what you decide to do, it will not affect your care or your participation in the main part of the study.

If you decide now that your tissue and blood can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue. Then any tissue and blood that remain will no longer be used for research. Remaining tissue will be returned to the institution that submitted it, and remaining blood will be destroyed.

In the future, people who do research may need to know more about your health. While the [doctor/institution] may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Benefits

The benefits of research using tissue and blood include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, check "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at _____ [IRB's phone number].

No matter what you decide to do, it will not affect your care.

1. My specimens may be kept for use in research to learn about, prevent, or treat cancer, as follows:
 - Tissue Yes No
 - Blood Yes No

2. My specimens may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease), as follows:
 - Tissue Yes No
 - Blood Yes No

3. Someone may contact me in the future to ask me to take part in more research.
Yes No

Where can I 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

I have been given a copy of all _____ [insert total of number of pages] pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant _____

Date _____