

Patient Informed Consent Form

for

NSABP B-46-I/USOR 07132

**A Phase III Clinical Trial Comparing the Combination of TC Plus
Bevacizumab to TC Alone and to TAC for Women with
Node-Positive or High-Risk Node-Negative,
HER2-Negative Breast Cancer**

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CONFIDENTIAL

MARQUETTE GENERAL HEALTH SYSTEM

Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

**TITLE: A Phase III Clinical Trial Comparing the Combination of TC Plus
Bevacizumab to
TC Alone and to TAC for Women with Node-Positive or High-Risk Node-Negative,
HER2-Negative Breast Cancer**

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This consent form gives you detailed information about the research study which the doctor will discuss with you. The purpose of this study includes evaluation of the safety as well as the effectiveness of the investigational therapy.

This is a clinical trial which is a type of research study. You are being asked to take part in this study because you have early stage breast cancer that has been removed by surgery. Your doctor has told you that chemotherapy and other therapy after surgery will decrease the chance of your cancer returning. Your breast tumor has already been tested and found to be a type of breast cancer called HER2-negative. This means that the tumor cells do not have too much HER2 protein on their surfaces. This study is only for women with HER2-negative breast cancer.

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 the study doctor for more information.

Who is conducting the study?

Two research groups will be conducting the B-46-I/07132 study: the National Surgical Adjuvant Breast and Bowel Project (NSABP) and US Oncology Research, Inc. (USOR). The trial is being conducted locally by Marquette General Health System Hematology/Oncology.

Why is this study being done?

This study is being done for the following reasons:

- The main purpose of this study is to learn if adding a drug called bevacizumab to treatment with two chemotherapy drugs for early stage HER2-negative breast cancer will prevent breast cancer from returning.
 - Bevacizumab is considered investigational because it is still being researched and has not received approval from the U.S. Food and Drug Administration (FDA) for use in treating early stage breast cancer. Bevacizumab is called a targeted therapy because it works by blocking a protein called vascular endothelial growth factor (VEGF) that helps new blood vessels form. Without new blood vessels, the growth of the tumor is slowed.
 - Two of the chemotherapy drugs used in this study are docetaxel and cyclophosphamide. These drugs are used in standard combinations of chemotherapy for breast cancer.
- A second purpose of this study is to learn if adding bevacizumab to treatment with docetaxel and cyclophosphamide will help women with HER2-negative breast cancer live longer.
- Another purpose of this study is to learn if adding bevacizumab to docetaxel and cyclophosphamide works better in treating breast cancer than a combination of three chemotherapy drugs (docetaxel, doxorubicin, and cyclophosphamide).
- This study will also compare the two chemotherapy combinations given without bevacizumab to see if one chemotherapy combination is better than the other in treating breast cancer.
- The researchers also want to learn about the side effects of the combination of drugs used in this study.
- In order to learn more about cancer tumors, this study includes special research tests that will be done on tumor tissue that was removed during your breast cancer surgery. Information about this study requirement will be explained to you in more detail later in this consent form.

How many people will take part in the study?

About 3900 women from different cancer treatment centers 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 tests and exams to find out if you can be in the study. These tests and exams 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.

- Medical history
- Physical exam
- Blood tests:

- To check your blood counts
- To check how well your kidneys and liver are working
- Chest x-ray or scan of the chest, for example a CT scan, PET scan, or combined PET/CT scan
- Mammogram (an MRI is permitted in place of a mammogram before joining the study)
- Echocardiogram or MUGA scan (to see how well your heart pumps blood)
- Bone scan, PET-CT scan, or PET scan (only if you have bone pain or your blood tests show an increase in a bone-related protein)
- CT scan, PET scan, or PET-CT scan of the liver (only if your blood tests show abnormal liver function)
- Blood test, if needed, to confirm if you are premenopausal or postmenopausal
- Pregnancy test (if you are a woman of childbearing potential)

You will also need to have a urine test to check for protein to make sure you are able to receive bevacizumab. This test is not part of regular cancer care and is being done for the purpose of the study.

During the study: If all required tests and exams show that you can be in the study and if you choose to take part, you will be “randomized” to one of the three study groups described on the following pages. 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 any of the three study groups.

After you have been assigned to one of the three study groups, you will begin your study therapy within 2 weeks after you join the study. You will receive your study drugs according to one of the schedules described in the next section. The schedules are repeated every 21 days. This 21-day period is called a *cycle*.

Study therapy - Group 1:

You will receive doxorubicin, cyclophosphamide, and docetaxel through a vein once every 21 days for 6 cycles. Each treatment will take about 1½ to 2 hours. To help prevent some of the side effects of docetaxel, you must take another drug called dexamethasone before each docetaxel treatment. Dexamethasone may be given to you by vein just before your treatment, or your doctor may give you tablets to take by mouth the day before and again in the morning on the day you receive docetaxel. If your doctor gives you tablets, you must follow the schedule and take each dose of dexamethasone at the times your doctor tells you to take them. If you forget to take a dose or do not take it as scheduled, you must tell the doctor or nurse before your docetaxel treatment.

Also, starting the day after you receive your treatment, you will need another drug, either pegfilgrastim (Neulasta®) or filgrastim (Neupogen®). These drugs help to prevent low white blood cell counts that may lead to infection. The drug you receive will be given as an injection under your skin. Your doctor or his/her staff may give you this injection or may teach you to give it to yourself, or they can teach a friend or relative to give the injection to you. The injection may be given on 1 or more days, depending on which drug your doctor decides is best for you. Some patients experience bone pain with these drugs.

Study therapy - Group 2:

You will receive docetaxel and cyclophosphamide through a vein once every 21 days for 6 cycles. Each treatment will take about 1½ hours. To help prevent some of the side effects of docetaxel, you will also need dexamethasone as described above for Group 1 study therapy.

Study therapy - Group 3:

On the first day of your treatment, you will receive docetaxel and cyclophosphamide through a vein. Also, beginning on your first day of study therapy, you will receive bevacizumab through a vein. This combination of chemotherapy and bevacizumab will be given to you once every 21 days for 6 cycles. For the first treatment, it will take about 3 hours for you to receive all of the drugs. If you have no problems receiving the drugs during the first cycle, it will take about 2½ hours to receive cycle 2 of your study therapy, and cycles 3 through 6 will each take about 2 hours. To help prevent some of the side effects of docetaxel, you will also need dexamethasone as described above for Group 1 study therapy.

After you complete the treatment cycles that include chemotherapy and bevacizumab, you will continue to receive bevacizumab once every 21 days until about 1 year after your first dose of bevacizumab. It will take about 30 minutes for you to receive each bevacizumab treatment.

A summary of the study therapy is outlined on the table below:

Group 1	Group 2	Group 3
<p style="text-align: center;">Doxorubicin + Cyclophosphamide + Docetaxel Given through a vein every 21 days for 6 cycles</p>	<p style="text-align: center;">Docetaxel + Cyclophosphamide Given through a vein every 21 days for 6 cycles</p>	<p style="text-align: center;">Docetaxel + Cyclophosphamide + Bevacizumab Given through a vein every 21 days for 6 cycles</p>
		<i>Followed by</i>
		<p style="text-align: center;">Bevacizumab Given through a vein every 21 days until 1 year after the first dose</p>

Other therapy

Hormonal therapy: If your breast cancer is affected by hormones (estrogen or progesterone), your doctor will also prescribe at least 5 years of hormonal therapy. You will begin the hormonal therapy after you complete your chemotherapy. Your doctor will discuss this further with you.

Radiation therapy: If you had a lumpectomy or your doctor has advised you to have radiation therapy for other reasons, your doctor will discuss the plans for your radiation therapy with you.

Tests and exams during study therapy:

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

- Physical exam, which will include checking your blood pressure, before every study treatment
- Blood tests before every study treatment:
 - To check your blood counts
 - To check how well your liver and kidneys are working

If you are in Group 3, you will also need a urine test to check for protein every 6 weeks during bevacizumab therapy. This test is not part of regular cancer care and is being done for the purpose of the study.

Tests and exams following completion of chemotherapy:

About 3-4 weeks after your last dose of chemotherapy, you will need to have the following tests and exams. They are part of regular cancer care.

- A brief physical exam which will include checking your blood pressure
- Blood tests:
 - To check your blood counts
 - To check how well your liver and kidneys are working

If you are in Group 3, you will also need a urine test to check for protein. This test is not part of regular cancer care and is being done for the purpose of the study.

Tests and exams during therapy with bevacizumab alone (Group 3 patients only):

During this time period, you may need to have your annual mammogram, which is required about 1 year after your last mammogram (or MRI) before you joined the study. Having a mammogram is part of regular cancer care.

You will also need to have the following tests and exams. They are not part of regular cancer care and are being done for the purpose of the study.

- Blood pressure check every 3 weeks
- Physical exam every 6 weeks
- Urine test to check for protein every 6 weeks
- Office visit 3 months after your last dose of bevacizumab (Your study doctor or study staff may contact you by phone to see how you are doing instead of having an office visit for this time point.)

After study therapy is completed until 10 years after joining the study:

You will need to have the following tests and exams. They are part of regular cancer care.

- Physical exam about every 6 months until 5 years after you joined the study, and then about every 12 months until 10 years after you joined the study
- Mammogram about every 12 months until 10 years after you joined the study

How long will I be in the study?

You will be in the study for 10 years. During that time, your study therapy will take about 4½ months if you are in Group 1 or Group 2 and about 12 months if you are in Group 3. After you complete your study therapy, your study doctor will ask you to visit the office for follow-up exams (as described above) for 10 years from the time you joined the study. We would like to keep track of your health during that time. Keeping in touch with you and checking on your condition helps us to look at the long-term effects of the study therapy.

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

You can choose to stop in one of two ways:

- You can stop your study treatment, but still allow your study doctor to report your health status to the NSABP and USOR; or
- You can stop your study treatment and request that no new information be reported to the NSABP and USOR.

Also, your study doctor may stop you from taking part in this study if he or she believes it is in the best interest of your health, if you do not follow the study rules, or if the study is stopped by the NSABP and USOR.

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, 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. During the study, we will do tests and exams to see if the dose of the drugs you are receiving during your therapy should be changed or delayed. The tests will also help monitor any side effects you may have. 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 cyclophosphamide, docetaxel, and doxorubicin:

Likely

These side effects occur in **10% or more** of patients receiving cyclophosphamide and docetaxel and (for Group 1) doxorubicin:

- Fever (with or without infection or low white blood cells)
- Infection (with or without low white blood cells)
- Low white blood cell count (may lead to infection)
- Low red blood cell count (may lead to tiredness or shortness of breath)
- Low platelet count (may lead to increased bruising or bleeding)
- Weakness or loss of strength
- Fatigue (feeling tired)
- Shortness of breath
- Fluid retention (swelling or bloating)
- Taste changes
- Sores or irritation in the lining of the mouth and throat
- Loss of appetite
- Nausea
- Vomiting
- Diarrhea
- Dehydration
- Constipation
- Numbness, tingling, prickling, and burning in the hands and feet
- Pain in muscles or joints
- Hot flashes (in premenopausal women)
- Hair loss (usually temporary)
- Nail changes, including discoloration or peeling; nail loss can happen
- Rash, inflammation, peeling, or darkening of the skin. This usually occurs on the palms of the hands and soles of the feet but may also appear on the arms, face, or body
- Red colored urine (not blood and temporary) – only for patients in Group 1

Less likely

These side effects occur in **3-9%** of patients receiving cyclophosphamide and docetaxel and (for Group 1) doxorubicin:

- Irregular heart beats
- Changes in blood pressure (high or low)
- Dizziness
- Changes in blood tests that show possible injury to the liver
- Ulcers in the stomach or bowels
- Eye problems, including redness, irritation, tearing, blockage of the tear ducts, and blurred vision
- Hardening of the walls of the veins used for chemotherapy

Rare but serious

These side effects occur in **less than 3%** of patients receiving cyclophosphamide and docetaxel and (for Group 1) doxorubicin:

- Allergic reaction that could be severe, including chills, rash, hives, itching, flushing, swelling, low blood pressure, wheezing, and shortness of breath
- Liver failure
- Heart problems, such as chest pain (unstable angina), irregular heart beats, fainting, heart attack, heart failure, and inflammation of the sac around the heart
- Lung damage, such as shortness of breath, inflammation or scarring of the lungs that can be permanent, and Acute Respiratory Distress Syndrome, a condition where there is severe damage to the lungs
- Gastrointestinal problems, such as irritation, inflammation, bleeding, blockage, or perforation (opening of a hole) in the stomach or bowel.
- Kidney damage, including kidney failure
- Anemia (low red blood cell count) that may be severe enough to require a red blood cell transfusion
- Severe infection
- Acute leukemia (cancer of the blood cells)
- Skin and tissue damage in the area surrounding the vein where the chemotherapy drugs are injected
- Irritation and redness of the skin in areas where radiation was given
- Stevens-Johnson Syndrome which is a group of symptoms that may include a blister-like rash that may be severe enough to require hospitalization and may cause tissue death; fever; inflamed eyes; redness, swelling and painful sores on lips and in the mouth
- Blood clots that may be life-threatening
- Bladder irritation that causes bleeding
- Inflammation of the pancreas causing abdominal pain

Risks and side effects related to bevacizumab (Group 3):

Likely

These side effects occur in **10% or more** of patients receiving bevacizumab:

- Nausea
- Vomiting
- Diarrhea
- Constipation
- Dehydration
- Loss of appetite
- Taste changes
- Protein in the urine
- Increased tears in the eyes
- Runny nose
- Nose bleed
- Inflammation of the lining of the mouth
- Lack of energy or feeling tired
- Shortness of breath

- Peripheral sensory neuropathy (for example, numbness or loss of feeling in the fingers or toes, or problems doing ordinary things with your fingers, like buttoning a shirt)
- Fainting
- Fever
- High blood pressure
- Hand-foot syndrome (pain or blistering on the hands or feet)
- Dry skin, flaking and inflammation of the skin, change in skin color
- Pain
- Infection in the blood or bladder
- Low number of white blood cells, sometimes associated with fever, that may result in infection
- Bleeding from the rectum

Less likely

These side effects occur in **3-9%** of patients receiving bevacizumab:

- Abdominal pain
- Blockage in the intestine
- Low red blood cell count (may lead to tiredness, shortness of breath)
- Bleeding from the lining of the mouth or vagina
- Blood clots in the veins of the legs
- Pulmonary embolism (blood clot in a vessel in the lung)
- Blocking of an artery by a blood clot, which can lead to a stroke or heart attack
- Problems with the heart or increase in heart rate (pulse)
- Heart failure, especially in patients who have taken certain chemotherapy treatments in the past
- Increased blood sugar
- Allergic reaction including reactions during the infusion (including chills, rash, hives, itching, flushing, swelling, low blood pressure, wheezing, and shortness of breath)
- Decreased blood potassium
- Decreased blood phosphorous
- Decreased sodium
- Increased blood alkaline phosphatase

Rare but serious

These side effects occur in **less than 3%** of patients receiving bevacizumab:

- Low platelet count (may lead to increased bruising or bleeding)
- Low levels of oxygen in the blood
- Perforation of the gastrointestinal tract (a tear or a hole in the gut) that may be associated with an abdominal abscess or infection
- Fistula (an abnormal tube-like connection between internal organs and skin or other tissues that are not normally connected) may occur, for example, between the gastrointestinal tract and the skin or between the gastrointestinal tract and the vagina. A rare type of fistula (tracheo-esophageal) is described below.

- Tracheo-esophageal fistula (an abnormal connection between the windpipe (trachea) and the esophagus (the tube that connects the mouth to the stomach))
- Delay in wound healing, failure of a wound to heal or spontaneous opening of a wound. You should inform the study doctor if you are considering surgery.
- Hole in the nasal passage (nasal septum perforation)
- Bleeding, including bleeding associated with the gastrointestinal tract or bleeding in the brain or coughing up blood
- Reversible posterior leukoencephalopathy syndrome (RPLS) or hypertensive encephalopathy. This may include symptoms of impaired brain function (headaches, vision changes, confusion, or seizures), and often, high blood pressure.
- Weight loss (not all patients had severe weight loss)

Some side effects are more common in elderly patients than in younger patients. These side effects include blood clots in the arteries which can lead to a stroke or a heart attack. In addition, elderly patients have a higher risk of a decrease in the number of white cells in the blood.

It is important that you contact your study doctor as soon as you experience any side effects whether you think the treatment has caused them or not. You must also tell your study doctor if you have any illnesses or if you have started any new medication. This includes medications available without a prescription (over the counter) and alternative medicines, for example, herbal medicines. If you have any questions or concerns about any of the information provided above, about the possible side effects of treatment, or the possible consequences of treatment for those side effects, please ask your study doctor or study staff for more information.

Reproductive risks: The drugs in this study can affect an unborn baby. Therefore, you should not become pregnant while on study therapy and for at least 6 months after your last dose of bevacizumab. You should ask about counseling and more information about non-hormonal methods of preventing pregnancy. If you feel you might be pregnant, even though you practiced birth control, notify your study doctor immediately. A pregnancy test will be performed.

You should also not breastfeed a baby while on study therapy and for at least 6 months after the last dose of bevacizumab.

Women may experience changes in their menstrual periods. Even after the study is complete, women may experience changes in their ability to get pregnant. Some of the drugs used in this study may make you unable to have children in the future.

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

What are my responsibilities?

- Keep your study appointments. If you cannot keep an appointment, contact your study doctor or study staff to reschedule as soon as you know that you will miss the appointment.
- Tell your study doctor or study staff about any medications you are taking.
- Tell your study doctor or study staff about any side effects, doctors' visits, or hospitalization that you may have whether or not you think they are related to the study therapy.

- Tell your study doctor if you have been in a research study in the last 30 days or are in another research study now. While participating in this research study, you should not take part in any other research project without approval from your study doctor. This is to protect you from possible injury arising from such things as extra drawing of blood samples, possible reaction between research drugs, or other hazards.

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 that adding bevacizumab to chemotherapy will be more useful in treating breast 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 bevacizumab given with chemotherapy as a treatment for breast cancer. This information could help future breast 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
- 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?

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:

- the National Surgical Adjuvant Breast and Bowel Project (NSABP);
- US Oncology Research, Inc. (USOR);
- Genentech, Inc. (one of two companies that are supplying bevacizumab for some institutions and other support for this study);
- F. Hoffmann-La Roche, Ltd. (a second company that is supplying bevacizumab for this study);
- sanofi-aventis (the company that makes docetaxel and is providing support for this study);
- a local Institutional Review Board (IRB), a group of people who review the research study to protect your rights [Marquette General Hospital IRB]; and
- government agencies, including the U.S. FDA and the Office for Human Research Protections (OHRP). These agencies may review the research to see that it is being done safely and correctly.

In addition, researchers from USOR who are conducting this study are also conducting a different study (USOR 06-090) with the same treatments for patients in Group 1 and Group 2. If you are randomized to either Group 1 or Group 2, some of your medical information will be shared with researchers from USOR and combined with data from the USOR study. Types of information that may be shared include personal information such as your date of birth, the type and stage of your cancer, the treatment you received, side effects that you had during treatment, and how well the treatment worked. Your name, address, phone number, and other information that could let the researchers know who you are will not be shared.

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.

Tests and drugs for which there is no charge in this study:

- Urine tests to check for protein for all patients before joining the study and, for patients in Group 3, at the scheduled time points described earlier in this consent form.
- For patients in Group 3, the physical exams and the checks of your blood pressure during bevacizumab therapy given after completion of chemotherapy.
- Collection, shipping, testing, and storage of your tumor sample for research purposes.
- If you are in Group 3, bevacizumab will be provided for this study at no cost to you by Genentech, Inc. or F. Hoffmann-La Roche, Ltd. However, you or your health plan will need to pay for the costs of supplies and personnel who give you this drug.

Docetaxel, cyclophosphamide, and doxorubicin are commercially available. You and/or your health plan/insurance company will be responsible for the costs of these drugs and for the supplies and the personnel required to give these drugs.

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://www.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.

INSTITUTIONAL FUNDING:

Funds are provided from the study sponsor to Marquette General Hospital on a per patient basis to help with the institution's costs of participating in this study.

Whom can I call if I have questions or problems?

In the event that physical injury occurs as a result of this research, facilities for treatment of injury will be available; however, you will not automatically be provided with reimbursement for medical care or other compensation. For more information concerning the research and research-related risks or injuries, you can notify Dr. _____, or his/her associates, who may be reached by phoning the office at (906) 225-3922. During the evenings, weekends, or holidays you may phone Marquette General Health System at (906) 228-9440, and request to speak with the medical oncologist on call. You can also call the Patient Advocate at Marquette General Health System at (906) 225-3183, if you have any questions, comments, or concerns about the study or your rights as a research subject.

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.

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.

Tumor Sample Submission for the NSABP B-46-I/USOR 07132 Study

How will a sample of my tumor be used for research?

Required submission of tumor: By signing this consent form, you are agreeing to have a small sample of tumor, which was removed during your breast cancer surgery, sent to the NSABP for use by the NSABP and USOR. This sample will be used for the research purposes of the B-46-I/07132 study and is required in order to take part in this study. The tumor sample will be stored at the NSABP. Some of the research will be done soon, but others will be done in the future when the best methods to test the samples are ready.

Researchers from USOR are conducting a different study (USOR 06-090) with the same treatments as those for patients in Group 1 and Group 2. If you are randomized to either Group 1 or Group 2 therapy, some of your tumor sample may be sent to USOR for the research purposes of the USOR 06-090 study. The remaining tumor sample will be stored at the NSABP.

Optional use of tumor after all tests related to the B-46-I/07132 study are completed: After all the tests required for the study are completed, there may still be some remaining tumor sample. The NSABP and USOR would like to be able to use the remaining tumor sample for future research not related to the B-46-I/07132 study. If you agree, the remaining tumor sample may be used in research to learn more about cancer and other diseases.

About using tumor for research: The research that will be done with your tumor sample is not designed to specifically help you. It might help people who have cancer in the future. Your

sample may be used for genetic research (about diseases that are passed on in families), but you would not be able to be identified. Reports about research done with your sample will not be given to you or your doctor. These reports will not be put in your health records. The research using your tumor sample will not affect your care.

People who do research with your tumor sample may need to know more about your health. While the NSABP may give them reports about your health, they will not give them your name, address, phone number, or any other information that will let the researchers know who you are. Your tumor sample will be used only for research and will not be sold. The research done with your sample may help to develop new products in the future, but you will not be paid.

If you change your mind after your tumor sample is sent to the NSABP, *contact your study doctor* and let him or her know that you no longer want the NSABP and USOR to use your tumor sample, and it will no longer be used. Otherwise, your tumor sample will be kept until used up or until the NSABP and USOR decide to destroy it.

Benefits and risks: The possible benefits of research using your tumor sample include learning more about what causes cancer and how to treat it. There is a risk of the release of information from your health records. The NSABP and USOR will protect your records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

Costs of the sample submission: There will be no cost to you or your insurance company for the collection, shipping, testing, and storage of the tumor sample for this study.

Required use of tumor sample for the NSABP B-46-I/USOR 07132 study:

I understand that by signing this consent form, my tumor sample will be used for specific research related to the B-46-I/07132 study. I understand that this is required for me to take part in the study. I also understand that if I am assigned to Group 1 or Group 2 therapy in this study, part of my tumor sample may be used with other samples in the USOR 06-090 study.

Optional use of tumor after all tests related to the B-46-I/07132 study are completed:

Please read the sentences below and think about your choice for sentence #1 and sentence #2. After reading each sentence, circle “yes” or “no.” If you have questions, please talk to your study doctor or health care team member. Remember, no matter what you decide about the use of your remaining tumor sample, you may still take part in the B-46-I/07132 study.

1. My tumor sample may be kept for use in future research to learn about, prevent, or treat cancer.

YES

NO

2. My tumor sample may be used for research about other health problems (for example: causes of diabetes, Alzheimer’s disease, or heart disease).

YES

NO

Contact in the Future for Other Research

Please read the sentence below and think about your choice for sentence #3. After reading the sentence, circle “yes” or “no.” If you have questions, please talk to your study doctor or health care team member. Remember, no matter what you decide, you may still take part in the B-46-I/07132 study.

3. My study doctor (or someone he or she chooses) 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 receive a copy of this form. If you want more information about this study, ask your study doctor.

Signatures

I have been given a copy of all pages of this 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.

Date

Patient's signature

Print patient’s name

Date

Signature of person conducting the
informed consent discussion

Print name of person conducting the
informed consent discussion