COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

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Study Title: *A Phase II Study with Orteronel as Monotherapy in Patients with Metastatic Breast Cancer (MBC) that Expresses the Androgen Receptor (AR)*

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Funding Source: *SCRI Development Innovations, LLC*

Invitation to Participate and Description of Project

You are invited to take part in a research study. The research study is called "*A Phase II Study with Orteronel as Monotherapy in Patients with Metastatic Breast Cancer (MBC) that Expresses the Androgen Receptor (AR)"*. The research study is designed to look at anti-androgen drugs and their effect on breast cancer. You have been invited to take part because you have estrogen-receptor (ER) or progesterone receptor (PR)-positive breast cancer or "triple negative" breast cancer (negative for ER, PR, and HER2).

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: the purpose and nature of the research study, the procedures that will be performed, the risks of the study drug(s) and procedures, possible benefits, possible alternative treatments, your rights as a participant and other information about the research study. You should take whatever time you need to discuss the research study with your physician and family. The decision to participate or not is yours. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign and date where indicated on this form.

If you choose to participate, you will be told of any significant new findings that develop during the course of your participation in this study that may affect your willingness to continue to participate.

The research study is being sponsored by SCRI Development Innovations, LLC (SCRI Innovations). SCRI Innovations is called the Sponsor and Yale University is being paid by SCRI Innovations to conduct this research study. Dr. Gina Chung is the principal investigator of this study at Yale Cancer Center.

Purpose

The purpose of this study is to test a new anti-androgen drug, Orteronel, as treatment for subjects with metastatic breast cancer. Subjects will be eligible only if androgen receptors are present on their tumor cells (tumor specimens from previous biopsies will be tested). In addition to having androgen receptors, subjects must fit into one of 2 groups to be eligible:

1) Subjects with estrogen-receptor (ER) or progesterone receptor (PR)-positive breast cancer. Subjects in this group may have received previous chemotherapy, but are required to have become resistant to standard anti-estrogen treatments. Subjects with HER2-positive breast cancer are eligible in this group as long as they are also ER-positive or PR-positive, and have previously had treatment with trastuzumab.
2) Subjects with "triple negative" breast cancer (negative for ER, PR, and HER2). Subjects in this group must have previously received standard chemotherapy (1, 2, or 3 regimens) and become resistant.

The study drug that will be used in this research study, Orteronel, is investigational drug. This means it has not been approved for use by the United States Food and Drug Administration (FDA) in any type of cancer. Orteronel has already been tested, however, in at least 1000 healthy volunteers and cancer patients. It is expected to suppress androgen levels in both the circulation and in relevant hormone-dependent cancers. Approximately 50% of breast cancers require the presence of estrogen (the major female hormone) to grow, and the anti-estrogen drugs block access of estrogen to the cancer cells. Breast cancers likely to respond to anti-estrogen therapy have estrogen "receptors" on the surface of the cancer cells – measurement of the estrogen receptors predicts whether anti-estrogen drugs should be used.

Some breast cancers also have androgen (male hormone) "receptors" on the cancer cell surface. Although the level of androgens in females is very low, there is evidence that even very low levels can stimulate cancer growth when androgen receptors are present. Recently, potent anti-androgen drugs have proven effective and well tolerated in the treatment of prostate cancer (another cancer that depends on the presence of hormones to grow), and some of these new anti-androgens are being tested in patients with breast cancer.

There are two parts to this clinical research study. At first, 6 subjects will be enrolled to assess the safety of the study regimen. After all 6 subjects complete at least 4 weeks of study drug, the data will be

evaluated to look for any significant safety concerns. This is called a lead-in phase. If no safety issues are present, then the study treatment phase will begin.

It is expected that approximately 86 men and women with advanced breast cancer will participate in this study (6 in the lead-in phase and 80 in the study treatment phase) at 15 sites around the United States. It is expected that approximately 30 subjects will be enrolled at Yale Cancer Center.

Study Procedures

Tests and procedures that would be performed for your regular cancer care whether you are on this study or not, are called "standard of care." All of the tests and procedures listed below that will be performed at your study visits, should you choose to participate in this study, are standard of care unless noted with an asterisk (*).

Screening Period

If you agree to participate and sign and date this form, approximately 7 days before you start study drug, you will need to undergo a series of tests and procedures to determine if you are eligible to participate in the research study. You will come to the study site for screening tests and it is possible that more than one screening visit may be needed. Some of these tests may have been done already as part of your standard-of-care treatment. No study-related procedures will be done before you decide to participate in this study and agree to do so by signing this form. The following tests or procedures will be performed during the visit(s):

- Your medical history will be discussed, including the history of your cancer, previous therapy, and pre-existing diseases.
- Physical examination, including measurements of your height, weight, and vital signs (includes resting heart rate, blood pressure, breathing rate, and oral temperature).
- Evaluation of how well you can perform normal daily activities, called an Eastern Cooperative Oncology Group (ECOG) performance status.
- Review of current medications you are taking.
- Blood sample (about 2 tablespoons) for routine blood counts and chemistry tests.
- *Blood sample (about 2 tablespoons) for serum hormone testing.
- *If you have had a history of diabetes, a blood sample that requires you to fast (no food or drink after midnight before coming for the test).
- A routine urine test will be done.
- An electrocardiogram (ECG), which is a test to check the electrical activity in your heart.
- If it is possible for you to become pregnant, a pregnancy test (serum or urine) will be done.

- An echocardiogram (ECHO)(a picture of the heart obtained by using ultrasound) or a multi-gated acquisition (MUGA) scan (a test to measure heart function, involving injection of a radioactive tracer/dye and images of the blood moving through the heart) will be done to find out how well your heart is pumping blood.
- You will have: a computerized tomography (CT) scan of the chest and a CT scan of the abdomen/pelvis. In addition, you may have a CT scan or MRI of the head and/or a bone scan, if your study doctor feels it is necessary. At this visit, you may have a PET/CT scan instead of CT scans. This will be up to your study doctor. These tests produce a picture of your body using a small amount of radiation. You will have these tests done within 4 weeks before you start taking the study drug.

After your study doctor reviews the results of these screening tests, you may not be able to take part in this research study. If this happens, your study doctor will talk to you about the reasons for this decision, and will talk to you about other treatment options.

Treatment Period

Orteronel is an oral study drug that you will take at home. You will take 300 mg of orteronel (consisting of three 100-mg tablets at each administration) twice a day with or without food while you are in the study. The doses of study drug should be taken at the same time each day, approximately 12 hours apart, but not less than 6 hours apart.

Missed doses of study drug may be taken later, if it is at least 6 hours before your next scheduled dose. If you are scheduled to take your next dose in less than 6 hours, resume dosing at the next scheduled time. If you experience severe nausea or vomiting, you should take the study medication with or following meals.

On Day 1 of each Cycle, you will be asked about any missed doses. If a dose is missed, please keep a record of it to share with the study staff.

Study Assessments
Study drug will be given in 4-week (28 day) cycles (±5 days) for all subjects.

Day 1 of Each 28-Day Cycle
The following assessments will be performed on Day 1 of each cycle. If you are one of the first six subjects to be enrolled in this study (Lead-in subjects), you will have some of these procedures and tests more frequently as noted below.

- Your medical history will be reviewed.
- A physical examination, including measurements of weight and vital signs, will be done (weekly during Cycle 1 for Lead-in subjects).

- ECOG performance status will be done.
- You will be asked if you have felt unwell since your last visit and to describe any symptoms you might be having (weekly during Cycle 1 for Lead-in subjects).
- You will be asked about any medicines (including over-the-counter and herbal medicines) you are taking at the moment (weekly during Cycle 1 for Lead-in subjects).
- Blood samples will be taken for routine tests (weekly during Cycle 1 for Lead-in subjects).
- *Blood sample (about 2 tablespoons) for serum hormone testing (**for Cycles 2 and 4 only**).
- You will have to return any unused study drug and tell the study staff if you missed any doses.

Day 1 of Cycle 3 and Every Other Cycle Following (Cycles 5, 7, 9, etc), except where noted

- *If you have had a history of diabetes, you will have a fasting blood test done.
- A 12-lead ECG will be done.
- CT scans of the chest /abdomen/pelvis will be done, if your scans during screening were abnormal.
- You may have a CT scan or MRI of the head and/or a bone scan, if your study doctor feels it is necessary.

End of Treatment

You will be permitted to continue taking orteronel until your cancer becomes worse, or you are discontinued due to unacceptable toxicity or because of a decision on your part or that of your study doctor to discontinue study drug. You will return to the study center as soon as possible after stopping the study drug, but no longer than 30 days after you stop taking study drug. The following assessments and tests will be done at this visit:

- Your medical history will be reviewed.
- A physical examination, including measurements of weight and vital signs, will be done.
- ECOG performance status will be done.
- You will be asked if you have felt unwell since your last visit and to describe any symptoms you might be having.
- You will be asked about any medicines (including over-the-counter and herbal medicines) you are taking at the moment.
- Blood samples will be taken for routine tests.
- *Blood sample (about 2 tablespoons) for serum hormone testing.
- *If you have had a history of diabetes, you will have a fasting blood test done.
- A routine urine test will be done.

- You will have to return any unused study medication and tell the study staff if you missed any doses.
- CT scans of the chest /abdomen/pelvis will be done if your cancer hasn't gotten worse, if your scans during screening were abnormal, and if you haven't had these tests done within the previous 8 weeks.

Follow-up Period

If you stop taking the study drug for a reason other than your cancer getting worse, the study doctor will ask to see you once every 6 months for 2 years and once a year after that for up to 5 years. You will be asked about any illnesses or symptoms that you are experiencing. Imaging scans may be done to check the status of your cancer.

If you stop taking the study drug because your cancer has gotten worse, the study doctor or someone from the study staff will contact you once every 6 months for 2 years and once a year after that for up to 5 years to ask you about your health status. This may happen during a clinic visit or by telephone.

HOW LONG WILL I BE IN THE STUDY?

Your treatment in this study will continue until one of the following occurs: (1) you withdraw your agreement to continue to take part in this research study; (2) your cancer becomes worse; (3) you have severe side effects; (4) the research study ends; or (5) you have completed study treatment.

You may be removed from this research study if you do not follow the instructions for the study. You may also be removed from the study for other reasons your doctor or the study sponsor feels are appropriate. If this happens, further treatment outside the study will be discussed with you.

ARE THERE ANY OTHER MEDICATIONS I CAN OR CANNOT TAKE DURING MY PARTICIPATION IN THE STUDY?

You will not be allowed to receive any other treatment for your cancer while you are in this study. You may be able to have other treatments for your cancer after your study treatment ends. You should tell your doctor at each visit about any over-the-counter and prescribed medications that you take. This way, your doctor will be able to make sure that you are not taking something that shouldn't be taken with the study drugs. If you require any of these medications and a replacement cannot be found, you will not be able to take part in this study.

Potential Risks, Side Effects, Discomforts and Inconveniences

During the study you may have discomforts and risks from orteronel and from the study procedures, as described below. Discomforts and risks may vary from person to person. Everyone in the study will be watched carefully for side effects; however, we do not know all the discomforts and risks that may happen. You may experience some, none, or all of these discomforts. There is also the risk of a rare or previously unknown side effect occurring. **If any side effects occur, you must tell your doctor** who may give you treatment to ease the undesirable effects you may experience. In addition, if a severe reaction to orteronel occurs, your doctor may stop the study treatment. You will be monitored closely for all side effects.

Risks associated with Orteronel:

Most Common (30% or more)

- Constipation
- Diarrhea
- Nausea
- Vomiting
- Feeling Tired

Very Common (10% or more to less than 30%)

- Pancreatic enzyme increases in blood
- Weight decreased
- Decreased appetite
- Changes in the electrolytes in the blood (such as sodium and potassium)
- Muscle spasms
- Headache
- Rash
- High blood pressure
- Swelling of feet or legs
- Dizziness
- Pain or discomfort in the muscles, bones, or joints

- Upset stomach and/or pain in the stomach or abdomen
- Changes in electrocardiogram (QTc length)
- Muscle weakness
- Urination at night

Common (5% or more to less than 10%)

- Increase in liver enzymes
- Depression
- Increase in a type of fat in blood
- Dry mouth
- Numbness, tingling, or pain, especially in the hands and feet
- Low blood pressure

Least Common (Less than 5%)
The following were observed in a few patients (less than 5%) treated with orteronel and can be severe.

- Sinus tachycardia (Rapid heartbeat)
- Adrenal insufficiency (decreased hormones made by the adrenal glands which can also lead to thinning of the bones, decreased sexual drive and decreased muscle mass)
- Androgen deficiency (This may result in hot flushing, decreased sexual drive, loss of energy, changes in electrocardiogram, and mood swings. Long-term effects of may also include decreased bone density, decreased muscle mass, and a change in how your body metabolizes glucose and lipids.)
- Pancreatitis (inflammation of the pancreas, which is a stomach organ that aids digestion and also makes insulin). Signs of pancreatitis can include an increased level of pancreatic enzymes in the blood. Symptoms of pancreatitis may include nausea, vomiting and abdominal pain. Abdominal pain may be severe and persistent, and may be felt from the abdomen to the back. Severe pancreatitis can lead to hospitalization, and if very severe, may be fatal. If you experience any severe nausea, vomiting, or stomach pains, you should immediately consult with the study doctor.
- Blood clots in the leg or lung
- Inflammation of the lungs that can cause difficulty in breathing and coughing

Orteronel decreases hormones made by the adrenal gland and can also lead to thinning of the bones, decreased sexual drive and decreased muscle mass.

With any drug, unusual, unexpected, or previously unreported side effects could occur, including side effects that are not listed or detailed above. You could also have an allergic reaction to the drug (your body has a reaction to the study medication). Therefore, it is important that you report all unusual symptoms and side effects that you experience as soon as they occur.

Other Risks

Blood Collection:
The risks of taking blood may include pain, redness, swelling and/or bruising where the needle enters your body, light-headedness and fainting. On rare occasions, local blood clot formation or infection with redness and irritation of the vein has occurred. The blood pressure cuff may cause discomfort or bruising to the upper arm.

Reproductive Risks:

A breakdown product of the study drug caused changes in genes or chromosomes in laboratory tests. Changes in genes or chromosomes could increase your risk of developing another cancer. In mice these changes were observed only at study drug levels many times greater than the study drug levels to which you will be exposed. However, the effects in humans of this breakdown product are not known. For more information ask your study doctor.

Male Subjects

If a genetic or chromosomal change happens in your sperm and you father a baby, the change could be passed on to your child and could have an adverse effect on the developing fetus. The effect of the study drug itself on human sperm has not been studied. The effects of the study drug on a developing fetus and the risks of birth defects are unknown and may be unforeseeable.

Therefore, men should not father a baby or donate sperm while on the study. If sexually active, an effective method of birth control should be used and, even if you are surgically sterilized (i.e., have had a vasectomy), you must agree to use an appropriate method of barrier contraception (latex condom with spermicidal agent) during the entire study treatment period, and for 4 months after the last dose of study treatment. Or, you should completely avoid having heterosexual intercourse during the entire drug treatment period, and for 4 months after the last dose of study drug has been taken.

If your partner becomes pregnant while you are participating in this study, it is important that you notify your study nurse/doctor immediately. The doctor will advise you of the possible risks to your unborn child and discuss options for managing the pregnancy with you.

Female subjects

We do not know if the study drug, orteronel, will affect mother's milk or an unborn child. Therefore, women who are breast feeding or pregnant are not allowed to take part in the study. Due to unknown risks and potential harm to the unborn child/infant, you should not become pregnant, nurse a baby, or participate in egg donation while on this study.

You must have a negative pregnancy test prior to enrolling in the study.

Unless you cannot have children because of surgery or other medical reasons (you had an effective tubal ligation, or had the ovaries or uterus removed; or you are post-menopausal) you must use 2 effective methods of birth control from the time of signing the informed consent form, throughout the entire study drug treatment period, and for 4 months following the last dose of study drug. It is highly recommended that at least of these 2 methods be "highly effective" (see examples below).

Highly effective methods	Other effective methods (barrier methods)
Intra-uterine devices (IUD)	Latex condom
Hormonal (birth control pills/oral contraceptives, injectable contraceptives, contraceptive patches, or contraceptive implants)	Diaphragm with spermicide; Cervical cap; Sponge
If one of the highly effective methods cannot be used, using two effective methods at the same time are recommended.	

You must use birth control methods as directed above, unless you completely avoid having heterosexual intercourse.

While participating in the study, if you become pregnant or suspect that you are pregnant you must inform your study doctor immediately. If pregnancy is confirmed, the study drug will be permanently discontinued.

There may also be side effects, other than listed above that we cannot predict. Other drugs will be given to make side effects that occur less serious and less uncomfortable. Many side effects go away shortly after the drug or procedure is stopped, but in some cases side effects can be serious, long lasting or permanent.

For more information about risks and side effects, ask the researcher or contact their office at 203-785-6197.

Benefits

If you agree to take part in this research study, you may or may not benefit from this research. We hope the information learned from this research study may benefit other patients with metastatic breast cancer in the future.

Economic Considerations

You will not be paid for taking part in this study. Tests and procedures that would be performed for your regular cancer care whether you are on this study or not are called "standard of care." All of the tests and procedures listed in this consent form that will be performed at your study visits are standard of care unless noted with an asterisk (*). There will be no charge to you or your insurance provider for the orteronel. There will be no charge to you or your insurance provider for tests or procedures noted with an asterisk as these are performed for study purposes only. All other tests and procedures will be charged to you or your insurance provider in the usual way as these are standard of care. This may include other tests and procedures not listed in this consent if your doctor feels it is necessary for your care, such as additional laboratory tests.

Taking part in this research study may lead to added costs for you or your insurance provider. You are encouraged to speak with your insurance provider prior to entering the research study to find out your individual coverage. If you have difficulty determining your individual insurance coverage, you may call Dr. Chung's office for assistance at 203-785-6197.

You or your insurance provider will be charged for continuing medical care and/or hospitalization that are not a part of the research study.

Treatment Alternatives

You do not have to participate 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.
- Receiving no treatment at this time.
- Getting comfort care, also called palliative care; this type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer.
  Comfort care does not treat the cancer directly but instead is meant 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.

Confidentiality and Authorization to collect, use and disclose Protected Health Information

For purposes of this study, Yale University, Yale-New Haven Hospital, and Dr. Gina Chung will use medical information collected or created as part of the study, such as medical records and test results, which identifies you by name or in another way. Your consent to participate in the study means you agree that Yale University, Yale-New Haven Hospital, and Dr. Gina Chung may obtain your medical information that they request for study purposes from your physicians and your other health care providers from the past or during your participation in the study.

The protected health information that will be collected in this study includes demographics, medical history, physical examinations, routine lab tests, review of adverse events and medications you take (past and present), vital signs, diagnostic tests such as MRI scans, response assessments such as CT scans, ECHOs or MUGAs, pregnancy tests, blood samples for research purposes only, survival follow-up information and records about any study drug(s) that you received.

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases such as HIV or hepatitis. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the study staff will get information that identifies you and your protected health information. This may include information that might directly identify you, such as your name, date of birth, and medical record number**.** This information will be de-identified prior to providing it to the sponsor, meaning we will replace your identifying information with a code that does not directly identify you. The study doctor will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the Principal Investigator or selected members of the study team. Any information that can identify you will remain confidential.

The records for this trial will be stored in locked cabinets and/or offices and password protected computers. The study team will only give this coded information to others to carry out this research study or to sponsor representatives to comply with federal laws and regulations. It is anticipated that records containing the information that links you to your coded information will be maintained indefinitely, as there are no plans at this time to destroy these records at the end of the study.

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others

who are appropriate to have access to your EMR (e.g., health insurance company, disability provider.)

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University and the Human Investigation Committee (the committee or Institutional Review Board that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Your providers who are participants in the Electronic Medical Record (EMR) system
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The study doctor, Dr. Gina Chung, and the Yale study team
- The U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about the new drug product involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- The study sponsor, SCRI Innovations, the manufacturer of study drug, Millennium Pharmaceuticals Inc., and/ or their representatives
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at Yale School of Medicine and Yale-New Haven Hospital is required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned

in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Authorized representatives of the Food and Drug Administration (FDA**)** and the manufacturer of the study drug being tested, Millennium Pharmaceuticals, Inc., may need to review records of individual subjects. As a result, they may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

The sponsor will see the research information we collect about you when they come to Yale to monitor the conduct of this research study. The "Sponsor" includes any persons that work for or are hired by the sponsor to conduct research activities related to this study. For this study the sponsor is SCRI Innovations. Yale researchers will also send the sponsor your health information during the study or at the end of the study. When Yale researchers send information about you to the sponsor, they will not send information that directly identifies you such as your name.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, you will not be allowed to look at or copy your study related information until after the research is completed.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In Case of Injury

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Medical care will be available to you for any injury or illness that happens that is directly caused by your participation in this study. You will be billed for the costs of the care that are not paid by your insurance company or other third party payer. Some insurance companies and third party payers may not pay for treatment of injuries that are from participation in a research study. This includes hospitalization costs. If your insurance company or third party payer does not pay for these costs, you will be billed for them. You should check with your health benefit plan to find out if the costs of care for treatment of injuries from being in this research study are covered.

You will not receive any other kind of payment. There are no plans to pay you for such things as lost wages, disability, or discomfort as part of this study. You do not give up any of your legal rights by signing this consent form.

Voluntary Participation and Withdrawal

Participation in this study is voluntary. You are free to choose not to take part in this research study. Refusing to take part in this research study will not lead to penalty or loss of benefits to which you are otherwise entitled. Your health care outside the study and the payment for your health care will not be affected if you do not agree to participate. However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing From the Study:
If you decide to participate in this research study, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. They will make sure that proper procedures are followed and a final visit is made for your safety. This will cancel any future research study appointments.

The researchers may withdraw you from participating in the research if necessary. This may occur if your cancer becomes worse, you have severe side effect, the research study ends, or you do not follow the instructions for the study. You may also be removed from the study for other reasons your doctor or the study sponsor feels are appropriate. If this happens, further treatment outside the study will be discussed with you.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale-New Haven Hospital.

If you fail to give your consent by not signing this document, or if you cancel your consent later, then you will not be eligible to participate in this study and will not receive any treatment provided as part of the study. Unless and until you do cancel the consent, it will remain valid and effective.

Withdrawing Your Authorization to Use and Disclose Your Health Information:
You may withdraw or take away your permission to use and disclose your health information at any time. You do this by telling the study staff or by sending written notice to the study doctor Dr. Gina Chung at the address listed on page one of this form. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project as described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use and give out information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to participate in this research.

Study Participant (print name)	Signature	Date
Person obtaining consent (print name)	Signature	Date
Person obtaining consent (print name) – only if applicable, otherwise blank	Signature	Date
Interpreter/ Witness (print name) – only if applicable, otherwise blank	Signature	Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Gina Chung at 203-785-6197. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.