NRG ONCOLOGY
Radiation Therapy Oncology Group

RTOG 1115

(ClinicalTrials.gov NCT #: 01546987)

Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer

Amendment 3: June 12, 2018

RTOG 1115
Informed Consent Template for Cancer Treatment Trials
(English Language)

Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer

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 prostate cancer.

Why is this study being done?

The purpose of this study is to compare the effects of hormone therapy (androgen deprivation) and TAK-700 plus radiation therapy with hormone therapy (androgen deprivation) and radiation therapy on you and your prostate cancer to find out which is better.

TAK-700 is a new drug that is experimental, which means that this drug is not approved by the United States Food and Drug Administration (FDA). TAK-700 is a pill intended to further reduce the levels of testosterone and other male hormones that may also cause continued growth of your prostate cancer.

There are 2 treatment groups in this study:
1) Patients who receive hormone therapy plus radiation therapy only
2) Patients who receive hormone therapy and TAK-700 plus radiation therapy

If you agree to participate in this study, you will receive one of these two treatments.

How many people will take part in the study?

About 900 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 have to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- A complete medical history will be collected including information on your general health, past surgeries and past treatments for prostate cancer and medications that you are taking (pain medications, over the counter medications, herbal remedies, vitamins, and supplements)
    - Tell the study doctor if you have any changes in your medication while on study. You should also talk to your study doctor before taking any other drugs, herbal supplements or therapy, including over the counter drugs and drugs prescribed by another doctor

- Blood tests to measure your blood chemistry, blood counts, the health of your arteries and heart (for example, cholesterol), and blood sugar level
- The following additional blood tests will be performed to evaluate your cancer:
    - Stress and male sex hormone levels such as testosterone
    - Prostate Specific Antigen (PSA), which is a tumor marker that may be used to track your prostate cancer
- A complete physical examination including vital signs (blood pressure, heart rate, and temperature), height and weight
- Certain imaging tests may be performed if you haven't had them done within the 90 days of starting the study. These are routinely performed to evaluate your disease. You could have a computed tomography (CT) scan (with contrast) or magnetic resonance imaging (MRI) of your abdomen (stomach area) and pelvis (hip area). In addition, bone scans will be completed to measure your disease.
- Electrocardiogram (ECG) to measure the health of your heart
- MUGA scan (Multi Gated Acquisition Scan) or Echocardiogram (ECHO) also to measure the health of your heart

Screening tests may require more than 1 visit to the clinic. Your study doctor will review the test results and tell you whether or not you are eligible for the study.

During the study … (12/17/13)

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will have the following tests and procedures. They are part of regular cancer care:

- Physical exam with vital signs, height and weight (every 3 months during treatment)
- Safety blood tests to monitor your blood chemistry and blood counts (monthly and then every 3 months during treatment, as determined by your doctor)
- Blood tests to monitor levels of Prostate Specific Antigen [PSA] (every 3 months during treatment)
- For patients who will receive brachytherapy only: Transrectal ultrasound assessment of the prostate and an assessment of urinary symptoms and function

You will have these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body:

- Blood tests to measure the following:
    - Stress and male sex hormone levels (testosterone at 12 and 24 months during treatment)
    - The health of your arteries and heart (for example, cholesterol)
    - Blood sugar levels
- You will be asked to record when you take your TAK-700 in a diary
- You will be asked about all medications you take (every 3 months during treatment)

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 1"): You will receive radiation treatments to the whole pelvis once daily, 5 days a week, Monday through Friday, for a total of 25 treatments. Each radiation treatment will take approximately 20 minutes but may be specific to the center in which you are being treated. If you choose to receive brachytherapy (permanent or temporary radiation seed implant), the total number of daily treatment sessions will be 25. If you are treated with external beam as a boost you will receive a total of 44 treatments. The logistics of the brachytherapy implant procedure (if you have chosen to undergo this type of treatment) should be thoroughly reviewed by your treating physician.

You also will receive hormone therapy for 24 months. Hormone therapy will begin 2 months before the start of the radiation treatments. There are two parts to the hormone therapy. You will take injections of a luteinizing hormone releasing hormone (LHRH) agonist, either under the skin or in the muscle (typically every 1 to 3 months), and you will take a pill, either flutamide three times per day or bicalutamide once per day. The pills will be taken from 2 months prior to radiation therapy until the end of radiation therapy while the injections will be given for a total cumulative dose of 24 months. The injected LHRH agonist will reduce the amount of circulating testosterone and the pill will interfere with the action of any remaining testosterone.

If you are in group 2 (often called "Arm 2"): You will receive radiation treatments to the whole pelvis once daily, 5 days a week, Monday through Friday, for a total of 25 treatments. Each radiation treatment will take approximately 20 minutes but may be specific to the center in which you are being treated. If you choose to receive brachytherapy (permanent or temporary radiation seed implant), the total number of daily treatment sessions will be 25. If you are treated with external beam as a boost you will receive a total of 44 treatments. The logistics of the brachytherapy implant procedure (if you have chosen to undergo this type of treatment) should be thoroughly reviewed by your treating physician.

You also will receive hormone therapy for 24 months. Hormone therapy will begin 2 months before the start of the radiation treatments. There are two parts to the hormone therapy. You will take injections of a luteinizing hormone releasing hormone (LHRH) agonist, either under the skin or in the muscle (typically every 1 to 3 months), and you will take a pill, either flutamide three times per day or bicalutamide once per day. Flutamide or bicalutamide will be taken from 2 months prior to radiation therapy until the end of radiation therapy while the injections will be given for a total cumulative dose of 24 months. In addition, you will take TAK-700 twice daily for 2 years. TAK-700 is a pill which interferes with the body's ability to make the male hormone testosterone. The injected LHRH agonist will reduce the amount of circulating testosterone and the pill will interfere with the action of any remaining testosterone. This study is testing if the combination of these 3 drugs further suppresses the action of testosterone and leads to an improved chance to cure the prostate cancer.

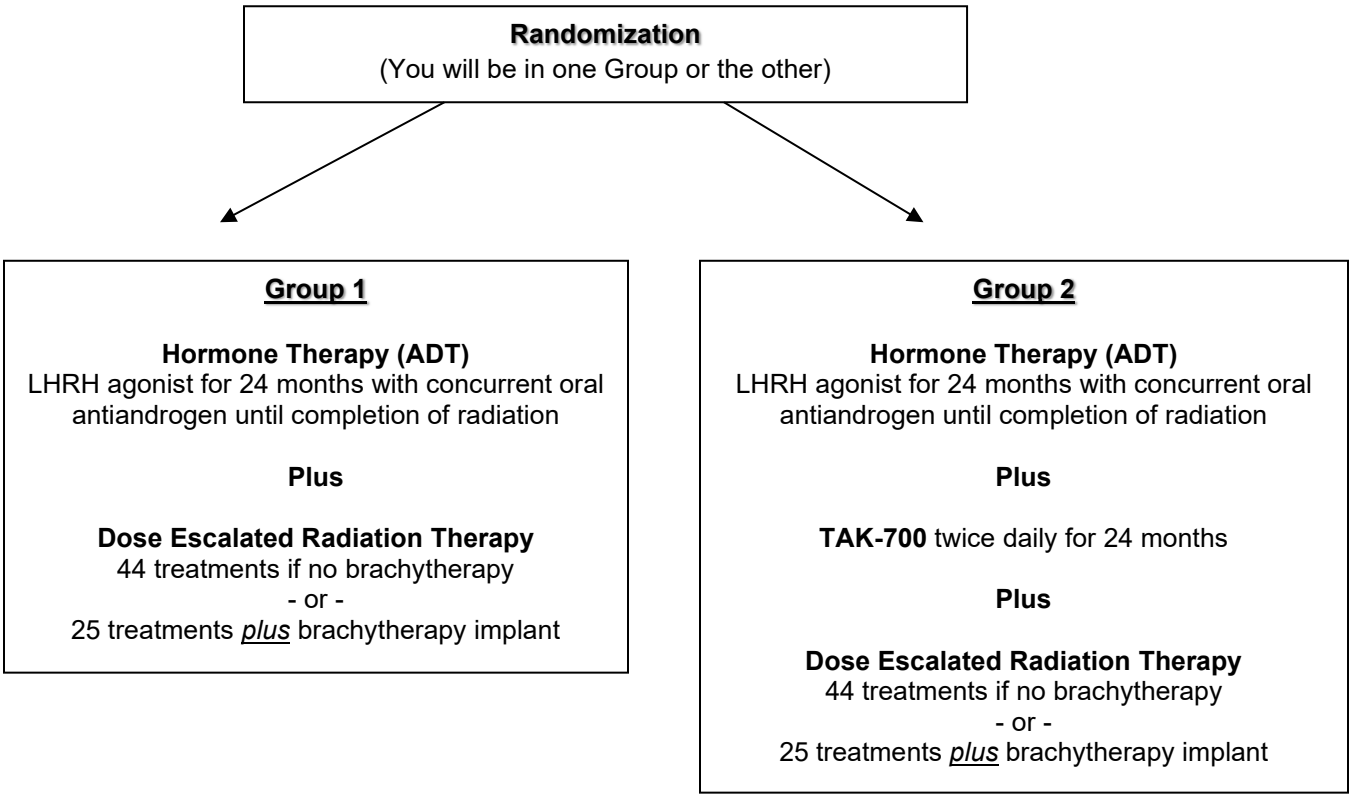
As noted above, TAK-700 is a new drug that is experimental, which means that it is not approved by the United States Food and Drug Administration (FDA). TAK-700 is a pill intended to further reduce the levels of testosterone and other male hormones that may also cause continued growth of your prostate cancer.

For all patients:
When you are finished hormone therapy plus radiation therapy *or* hormone therapy and TAK-700 plus radiation therapy, you will need these tests and procedures:

- At 30 months:
    - Blood for testosterone, PSA
- Every 6 months for 3 years, then at least annually:
    - A complete physical examination including vital signs (blood pressure, heart rate, and temperature), height and weight
    - Blood tests to measure prostate specific antigen (PSA)
    - Evaluation of any side effects that you may be having
- Every 12 months for 3 years:
    - Blood tests to measure the health of your arteries and heart (for example, cholesterol), blood sugar level, and testosterone
- As clinically indicated; every 6 months after PSA relapse
    - A bone scan

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 receive hormone therapy for 24 months. Radiation therapy will be given in 44 treatments over approximately 2 months. Or, if you choose to receive the brachytherapy implant, you will receive 25 daily treatments plus the implant procedure over a timeframe of approximately 6 weeks. If you are in Group 2 ("Arm 2"), you also will take TAK-700 for 24 months.

After you are finished receiving therapy, the study doctor will ask you to visit the office for follow-up exams every 6 months for 3 years and then once a year. The study doctors would like to keep track of your medical condition by seeing you every year for your lifetime.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the hormone therapy and radiation can be evaluated by him/her. 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? (12/17/13)

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 treatment. In some cases, side effects can be serious, long lasting, or may never go away.

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 therapy* include those which are:

Likely

- Increased urinary frequency or urgency
- Burning or discomfort/straining with urination
- Increased frequency of bowel movements or change in stool consistency
- Increased straining/discomfort with bowel movements
- Mild fatigue

Less Likely

- Rectal bleeding (usually mild)
- Chronic bowel/bladder symptoms as described above
- Temporary blockage of urination requiring use of a catheter
- Erectile dysfunction

For patients undergoing brachytherapy, risks associated with aspects of an invasive procedure such as those associated with anesthesia, infection, and bleeding must be considered and discussed with your treating physician. If permanent seed brachytherapy is used, there is a possibility of loss or migration of seeds leading to areas of under- or overdosage in certain parts of the prostate or elsewhere. Rectal or bladder complications may occur if these organs are affected because of seed misplacement.

Rare but serious

- Permanent rectal or bladder injury requiring surgery for treatment

Possible risk and side effects related to the *hormone therapy*:

Most Common (30% or more)	Very Common (10% or more to less than 30%)	Common (5% or more to less than 10%)
• Hot flashes • Erectile Dysfunction • Feeling tired • Nausea	• Constipation • Increase in a type of fat in blood	• Back pain • Vomiting • Depression • Anxiety or worry • Trouble sleeping • Muscle weakness • Sore throat or head cold

Possible risk and side effects related to the *hormone therapy and TAK-700* (4/16/14)**:**

Most Common (30% or more)	**Very Common (10% or more to less than 30%)**	**Common (5% or more to less than 10%)**
• Hot flashes • Erectile Dysfunction • Feeling tired • Nausea	• Constipation • Headache • Loss of appetite • Diarrhea • Dizziness • Skin rash, covering part or most of body • Joint pain • Increase in a type of fat in blood • Difficulty breathing during physical activity • Changes in electrocardiogram (QTc, length) • Hot flush • Liver enzyme increased in blood • High blood sugar (glucose) • Dizziness • Protein in urine • Change in sense of taste • High blood pressure • Low white blood cells (lymphocytes) • Decrease in number of blood platelets	• Back pain • Cough • Low blood cell count (red blood cells) • Vomiting • Depression • Upset stomach • Muscle spasms or cramps • Pain in the arms or legs • Trouble or difficulty breathing • Increased gas in the intestines • Low potassium in blood • Swelling of feet or legs • Infection of bladder or kidneys • Weight loss • Swelling of the stomach or abdomen • Anxiety or worry • Increase in creatinine in blood (decreased kidney function) • Blood in the urine • High potassium in blood • Low sodium in blood • Trouble sleeping • Muscle weakness • Sore throat or head cold • Inflammation of the pancreas

Less Common Risks (<5%)

Some other risks were observed in less than 5% of patients treated with TAK-700. The measurement of heart function (ejection fraction) was decreased in some patients. A few patients developed blood clots in the leg or lung. With limited experience we do not know if TAK-700 will cause such clots. In addition, several patients who had previous problems with urination, such as blockage in the tubes leading to and from the bladder, developed worsening symptoms during the study that led to a brief decrease in kidney function.

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.

A single case of an abnormal change in brain function called reversible posterior leukoencephalopathy syndrome (RPLS) was reported in a patient receiving TAK-700. RPLS is a collection of symptoms including headache, confusion, seizures, and vision loss associated with specific MRI imaging findings. Because TAK-700 could not be ruled out as a cause of the event, RPLS is a potential risk of the drug.

RISK TO THE UNBORN CHILD

The effect of TAK-700 on human sperm has not been studied. The effects on a developing fetus and the risks of birth defects are also unknown or may be unforeseeable. Therefore, men should not father a baby or donate sperm while on this study and for 4 months after the last dose of study drug treatment. If sexually active, an effective method of birth control should be used. 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 a spermicidal agent) during the entire study drug treatment period, and for 4 months after the last dose of study drug treatment. Or, you should completely avoid having heterosexual intercourse.

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

All possible adverse effects from the combination therapy of testosterone reducing drugs and the study drug, TAK-700, are unknown at this time. Your study doctor will discuss with you the possible risks involved with the other medicines that you are required to take in this study.

Risks associated with LHRH (GnRH) agonists:
Patients receiving treatment with LHRH agonists should undergo periodic monitoring of blood glucose and/or glycosylated hemoglobin (HbA1c) for signs of developing diabetes or worsening of blood glucose control in patients with diabetes, and also for the signs and symptoms suggestive of the development of cardiovascular disease.

Possible risks or side effects of other study procedures:
There are also risks associated with some of the study procedures. The risks are described below; however, any unknown risks that cannot be predicted are possible.

CT scans may use a contrast which in rare occurrences can cause an allergic reaction. There are also low levels of radiation used to produce an image and risk from radiation is minimal.

You may experience some pain, bruising, dizziness or (rarely) infection from the blood draws. Some patients may feel faint, may have nausea and/or feel cold and clammy as a result of a blood draw.

Your doctor will answer any questions you may have about these tests or procedures.

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. The information from this study will help researchers learn more about hormone therapy and radiation therapy as a treatment for prostate 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; this could include the following options, either alone or in combination with each other:
  - Radiation therapy
  - Hormone therapy
  - Surgery to the prostate
- 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? (4/16/14)

Data are housed at NRG Oncology Statistics and Data Management Center 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:

- NRG Oncology
- The National Cancer Institute (NCI) and other government agencies involved in keeping research safe for people, like the Central Institutional Review Board (CIRB) and the Food and Drug Administration (FDA)
- The Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- Millennium: The Takeda Oncology Company, the company that makes TAK-700.

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 study results. You can search this Web site at any time.

[Note to Informed Consent Authors: The above paragraph complies with the new FDA regulation found at 21 CFR 50.25(c) and must be included verbatim in all informed consent documents. The text in this paragraph cannot be revised.]

[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? (12/17/13)

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.

Millennium Pharmaceuticals, Inc will supply theTAK-700 at no charge while you take part in this study. Millennium Pharmaceuticals, Inc does not cover the cost of getting the TAK-700 ready and giving it to you, so you or your insurance company may have to pay for this.

Even though it probably won't happen, it is possible that the manufacturer may not continue to provide the TAK-700 for some reason. If this would occur, other possible options are:

- You might be able to get the TAK-700 from the manufacturer or your pharmacy but you or your insurance company may have to pay for it.
- If there is no TAK-700 available at all, no one will be able to get more, and the study would close.

If a problem with getting TAK-700 occurs, your study doctor will talk to you about these options.

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.

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 participating in this additional research.

You can say "yes" or "no" to each of the following studies. Please mark your choice below for each study.

Quality of Life Study (12/17/13)

Please note: If you have started androgen deprivation therapy (ADT) prior to registration, you will not be eligible to participate in the quality of life component of this study.

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 three questionnaires with questions that ask about how your cancer and your treatment affects your energy level, your quality of life, and your overall health status at the following times: *prior to study treatment, the week prior to radiation therapy, the last week of radiation therapy, one year and two and a half years after therapy starts*. It will take about 25 minutes to fill out the questionnaires. If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

In addition, if you agree to participate in the quality of life study, you will be required to have blood drawn to evaluate particular biomarkers and how they relate to fatigue that you may be experiencing. Biomarkers are either proteins or genes that may be related to or predict how someone reacts to a treatment. This procedure would require an additional 10mL, or approximately 2 teaspoons, of blood to be drawn at three visits in addition to the other tests *(prior to study treatment, 1 year after therapy starts, and two and a half years after therapy starts)*.

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 quality of life questionnaires and have blood drawn.

YES **NO**

About Using Tissue for Research (4/16/14)

You are going to have 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 to learn more about cancer and other diseases. If you agree, this tissue will be sent to a laboratory to evaluate biomarkers. Biomarkers are either proteins or genes (also called DNA) that may be related to or predict how someone responds to a treatment. Please read the information sheet called "Providing your Tissue for Research" to learn more about tissue research. This information sheet is available to all at http://cdp.cancer.gov/humanSpecimens/ethical_collection/patient.htm.

In addition, you will have blood tests before you start treatment and at 1 year and 2.5 years after treatment starts. We would like to keep about four teaspoons of blood for future research as well. If you agree, this blood will be kept and may be used in research to learn more about cancer and other diseases.

Your tissue and blood specimens may be helpful for research whether you do or do not have cancer. The research that may be done with your specimens 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 specimens 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 left over 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 specimens 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 or blood specimens. Then any tissue or blood that remains will no longer be used for research and will be returned to the institution that submitted it.

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

Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if your specimens are not used for this kind of research, the results will not be put in your health records. Your specimens will be used only for research and will not be sold. The research done with your specimens may help to develop new treatments for cancer in the future.

Benefits

The benefits of research using tissue and blood specimens 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. My specimens may be kept for use in research to evaluate biomarkers.
   - Tissue ☐Yes ☐ No

- Blood ☐Yes ☐ No

4. 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)

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 _____