FOX CHASE CANCER CENTER
TEMPLE HEALTH

FOX CHASE CANCER CENTER
AT TEMPLE UNIVERSITY HOSPITAL
All hospital services provided by Temple University Hospital

INFORMED CONSENT DOCUMENT

Bicalutamide with or without Metformin for Biochemical Recurrence in Prostate Cancer Patients (BIMET-1)

Principal Investigator: Daniel Geynisman, MD
Temple University Hospital Site Investigator: Alvaro Pereira-Rico, MD

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 should discuss your decision with your friends and family. You will 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 research study because you have been previously treated for prostate cancer and because you have a rising PSA (Prostate Specific Antigen).

The sponsor of this study is Dr. Daniel Geynisman at Fox Chase Cancer Center.

Why is this research study being done?

The purpose of this research study is to compare the effects of metformin and bicalutamide (a type of hormonal therapy that is already approved by the FDA) versus bicalutamide alone on lowering your PSA. PSA is a protein produced by cells of the prostate gland. The blood level of PSA often rises in men with prostate cancer. The study will also evaluate safety of the metformin and bicalutamide when given together.

It is thought that the combination of drugs used in this study may stop or slow the rising of your PSA and prevent your cancer from coming back or keep it in remission for a longer period of time. Metformin is a medication used to treat diabetes that is widely used as first line therapy for type II diabetes. Metformin is FDA approved, but not for cancer treatment and is being used as an investigational agent in this study.

In this study you will receive either metformin combined with bicalutamide or bicalutamide alone. If you are selected to receive bicalutamide, you will not be eligible to receive metformin as part of this study.

In addition to the treatment part of this study, the researchers plan to test samples of your tumor and some of your blood. The purpose of this research is to determine whether the presence of certain proteins and genes predict if this drug will be an effective treatment for prostate cancer. Also, in addition to the treatment part of this study, the researchers want to know your view of how your life has been affected by cancer and its treatment. As part of this study you will be asked to complete questionnaires about your quality of life.

We do not know if you will benefit from this research study. It is possible that your condition will get better, but it is also possible that there will be no effect on your condition or that your condition will get worse. We can use what we learn from this research study to help other people with the same disease.

How many people will take part in this research study?

About 66 people will take part in this research study.

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

Before you begin the research study

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

- Physical examination (This exam will include checking your heart rate, blood pressure, and temperature and measuring your height and weight)
- Review of your current medications, medical history, and performance status (evaluation of how active you are)
- Blood test to measure your blood counts, kidney function, liver function, fasting lipids, blood sugar, blood insulin levels, blood mineral levels, Vitamin B12, PSA and testosterone (about 2 table spoons)
- Scans of your body (bone scan, CT chest/abdomen/pelvis, and/or Chest x-ray)
    - A CT scan is a computerized x-ray that gives your study doctor pictures of the inside of your body
    - A bone scan requires an injection of a radioactive material into a vein. A special camera will then take a picture of all your bones while you lay very still on a table

You will undergo the following procedures that are not part of regular cancer care and are being done only because you are in this study.

- Blood test for glycosylated hemoglobin (HgbA1C) to see if you have diabetes and
    - If you do, how well it is controlled
- Fasting blood test to measure glucose levels (about 1.4 teaspoon)
- Fasting blood tests to measure insulin levels (about 2.7 teaspoon)
- Blood for research (about 5 table spoons)
- A Quality of Life Questionnaire

During the research study

For the purposes of this study, each 4-week period is considered a “cycle”. Each cycle is numbered in order. Please see study chart below for more information about what will happen to you during Cycle 1 and future treatment cycles.

Tests and procedures

If you choose to be and tests show you can be a part of this research study you will have the following tests, exams and procedures during the research study. If the exams, tests and procedures show that you can be in the research study, and you choose to take part, then you

will need the following tests and procedures. They are part of regular cancer care. They are being done more often because you are in this research study.

- Physical examination and performance status
- Review of your current medications and side effects
- Routine blood test to measure your blood counts, kidney function, liver function, fasting lipids, PSA and testosterone (about 2 tablespoons)
- Blood draws for additional testing related to the clinical trial (about 2.5 tablespoons)
- Blood draw for research purpose (about 5 table spoons, taken once)

You will be asked to provide samples of your tumor tissue (if available from a previous surgery or biopsy) and some of your blood for testing. You can still participate in this study even if you do not give permission for your tumor tissue and your blood to be submitted and used for this optional research. For more information on this research, please see the last three sections of this document. One section provides general information about the collection and use of specimens for research. Another section describes specific information about the use of specimens for this research study. The last section focuses on issues regarding future research.

You will be "randomized" into one of the research study groups (called “Arms”) described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the research 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 group. Whether you are randomized to Arm A or to Arm B, you will be given a Patient Pill Diary for each cycle to keep a record of the pills you take each day, any side effect you developed, any other medications you are taking or anything else you would like e to tell your doctor about.

Arm A

If you are in group 1 (often called "Arm A") you will be observed for 2 cycles (8 weeks). During this period of observation, you will be seen by your doctor every cycle (every 4 weeks) for physical exam and blood test. Beginning Cycle 3 (Week 9) you will begin taking one 50 mg tablet of bicalutamide by mouth each day. You will continue to be seen by your doctor every cycle for physical exams and blood tests. You will be asked to keep a medication calendar, also called a pill diary during this study. In the medication calendar, you will record every dose of bicalutamide that you take and the time that you took the dose. If your cancer has not become worse and your doctor has decided you should continue receiving treatment, you will take this medication continuously through the end of Cycle 8 (Week 33). You may be able to continue taking bicalutamide after Week 33 (after completion of the study treatment), if your doctor thinks it is necessary and has decided that cancer is not getting worse.

Arm B

If you are in group 2 (often called "Arm B") you will begin metformin treatment. You will start with 500 mg of metformin ((1 tablet) by mouth twice daily with food (Week 1). It is important to take this medication the same time every day, each dose should be taken 10-12 hours apart. If you tolerate this dose, you will increase dose of metformin during Week 2. You will take 500 mg metformin (1 tablet) by mouth for breakfast and 1000 mg metformin (2 tablets) by mouth for dinner. If you tolerate this dose, you will further increase dose of metformin during Week 3. You will take 1000 mg metformin (2 tablets) by mouth for breakfast and 1000 mg metformin (2 tablets) by mouth for dinner. The target dose of

metformin is 1000 mg (2 tablets) by mouth twice daily. If you cannot tolerate the higher dose, Metformin will be continued at the highest dose you can tolerate. During this period of metformin initiation, you will be seen by your doctor every cycle (every 4 weeks) for physical exam and blood test.

If your disease gets worse, your doctor may decide to have you start taking Bicalutamide earlier than planned. Otherwise, beginning Cycle 3 (Week 9) you will begin taking one 50 mg tablet of bicalutamide by mouth each day in addition to your metformin treatment. You will be asked to keep a medication calendar, also called a pill diary during this study. In the medication calendar, you will record every dose of metformin that you take and the time that you took the dose You will continue to be seen by your doctor every cycle for physical exams and blood tests. If your cancer has not become worse and your doctor has decided you should continue receiving treatment, you will take this medication continuously through the end of Cycle 8 (Week 33). You may be able to continue taking bicalutamide after Week 33 (after completion of the study treatment), if your doctor thinks it is necessary and has decided that cancer is not getting worse.

Study Chart

The chart below shows what will happen to you during the study as explained previously. The left had column shows the treatment week and the right hand column tells you what to do on that day. For the purpose of this study one cycle = 4 weeks.

ARM A

Day	**What you do…**
PRIOR TO ENROLLMENT	• Vital signs • Height, weight • Physical exam • Review your current medications • Routine blood tests – blood counts, kidney/liver function, PSA, testosterone, fasting lipid panel, vitamin B12 level, HbA1c (about 2 tablespoons of blood) • ECOG Performance Status – Assessment of your activity level • CT scan (chest, abdomen, pelvis) • Chest x-ray (if you do not have a CT scan of your chest) • Bone scan • Quality of Life questionnaire • Research blood – (about 5 table spoons)
Cycle 1 – 2 (Week 1 – 8)	• You will be under observation and will not be taking any study medication
Cycle 1 Day 1	• Weight • Routine blood tests – PSA, testosterone (1 table spoon of blood)
Day 1 of Cycles 2 - 8	• Physical exam, vital signs, and weight • Review your current medications • Routine blood tests – blood counts, kidney/liver function, PSA, testosterone (about 2 tablespoons of blood) • ECOG Performance Status – Assessment of your activity level

	• Assessment of any side effects
Day 1 of Cycle 3	• **Begin taking Bicalutamide 50 mg daily and continue taking the medication through the end of Cycle 8 (Week 33) – unless your doctor has instructed you to stop** • Physical exam, vital signs, and weight • Review your current medications • Routine blood tests – blood counts, kidney/liver function, PSA, testosterone, fasting lipid panel, HbA1c (about 2 tablespoons of blood) • Research blood – (about 5 table spoons) • ECOG Performance Status – Assessment of your activity level • Assessment of any side effects
Day after completing Cycle 8 (Week 33)	• **Stop taking Bicalutamide** • Physical exam, vital signs and weight • Review your current medications • Routine blood tests – blood counts, kidney/liver function, PSA, testosterone, fasting lipid panel, vitamin B12 level, HbA1c (about 2 tablespoons of blood) • Research blood – (about 5 table spoons) • Quality of life questionnaire • ECOG Performance Status – Assessment of your activity level • Assessment of any side effects • If your doctor has determined that your cancer is responding well and that you have been tolerating the medication well, he/she may ask you to continue taking Bicalutamide.

ARM B

Day	**What you do…**
PRIOR TO ENROLLMENT	• Vital signs • Height, weight • Physical exam • Review your current medications • Routine blood tests – blood counts, kidney/liver function, PSA, testosterone, fasting lipid panel, vitamin B12 level, HbA1c (about 2 tablespoons of blood) • ECOG Performance Status – Assessment of your activity level • CT scan (chest, abdomen, pelvis) • Chest x-ray (if you do not have a CT scan of your chest) • Bone scan • Quality of life questionnaire • Research blood – (about 5 table spoons)
Cycle 1 Day 1 Week 1	• You will start with 500 mg of metformin (1 tablet) by mouth twice daily with food (during Week 1) • Weight • Routine blood tests – PSA, testosterone (1 table spoon of blood)

Cycle 1 Week 2	• If you have no side effects, you will increase dose of metformin. You will take 500 mg metformin (1 tablet) by mouth for breakfast and 1000 mg metformin (2 tablets) by mouth for dinner (take tablets with food).
Cycle 1 Week 3	• If you have no side effects, you will increase dose of metformin again. • You will take 1000 mg metformin (2 tablets) by mouth for breakfast and 1000 mg metformin (2 tablets) by mouth for dinner (take tablets with food).
Day 1 of Cycles 2 - 8	• Physical exam, vital signs, and weight • Review your current medications • Routine blood tests – blood counts, kidney/liver function, PSA, testosterone (about 2 tablespoons of blood) • ECOG Performance Status – Assessment of your activity level • Assessment of any side effects
Day 1 of Cycle 3	• **Begin taking Bicalutamide 50 mg daily and continue taking the medication through the end of Cycle 8 (Week 33) – unless your doctor has instructed you to stop** • **Continue metformin 1000 mg twice daily (or maximum tolerated dose) through the end of Cycle 8 (Week 33) – unless your doctor has instructed you to stop** • Physical exam, vital signs, and weight • Review your current medications • Routine blood tests – blood counts, kidney/liver function, PSA, testosterone, fasting lipid panel, HbA1c (about 2 tablespoons of blood) • Research blood – (about 5 table spoons) • ECOG Performance Status – Assessment of your activity level • Assessment of any side effects
Day after completing Cycle 8 (Week 33)	• **Stop taking Bicalutamide and Metformin** • Physical exam, vital signs, and weight • Review your current medications • Routine blood tests – blood counts, kidney/liver function, PSA, testosterone, fasting lipid panel, vitamin B12 level, HbA1c (about 2 tablespoons of blood) • Research blood – (about 5 table spoons) • Quality of life questionnaire • ECOG Performance Status – Assessment of your activity level • Assessment of any side effects • If your doctor has determined that your cancer is responding well and that you have been tolerating the medication well, he/she may ask you to continue taking Bicalutamide.

After you are finished study treatment.

Your doctor will follow you regularly after completion of your treatment to access your disease status and health. During the time that you are on study, you will be followed every cycle (4 weeks) for medical monitoring and testing. After going off-treatment, you will be followed every 12 months until you are on study for 5 years.

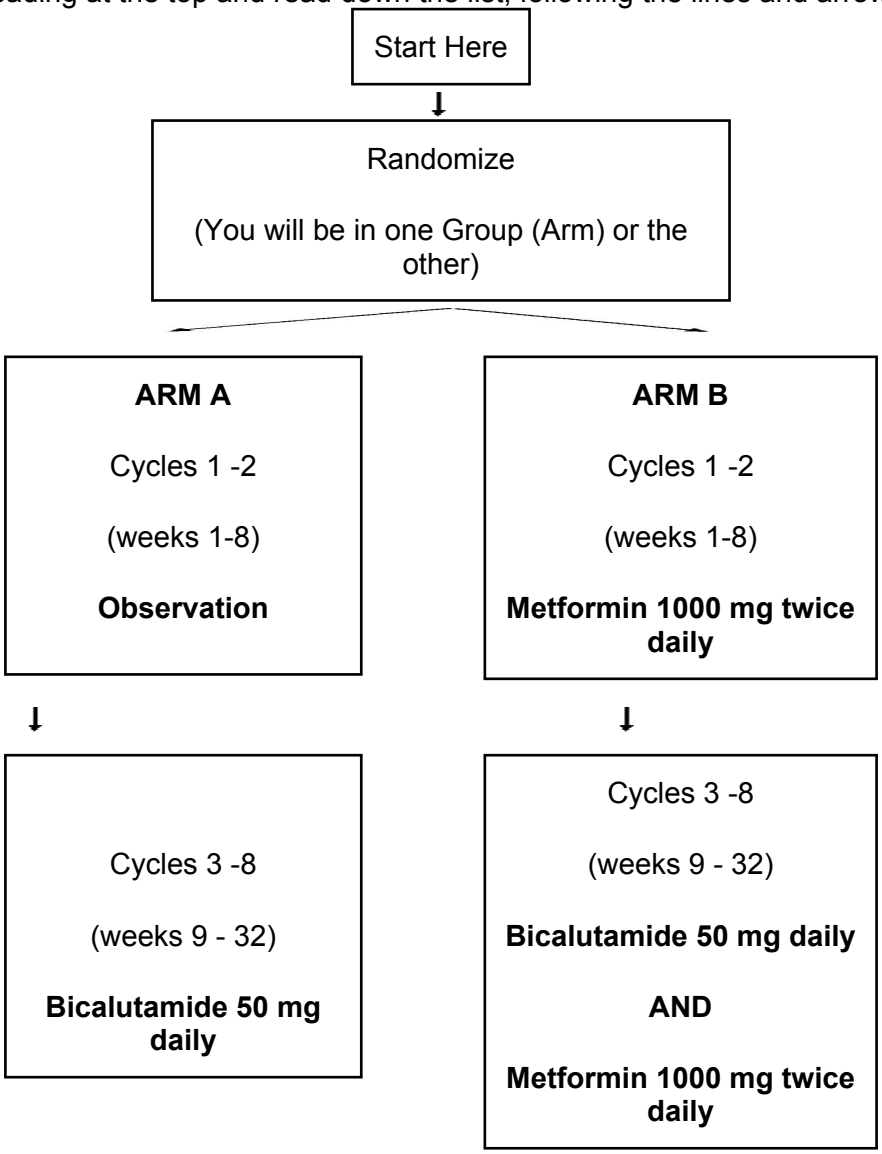
Questionnaires

We are asking you to fill out questionnaires for this research study. These questionnaires will tell us about your quality of life. You will spend 15 minutes to fill out the questionnaires. We will ask you to fill them out 2 times during this research study.

You do not have to answer any questions that make you uneasy. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the questionnaires in a locked file to protect your privacy.

Study Plan

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



The Metformin starting dose is 500 mg twice a day and will be gradually increased to the target dose of 1000 mg twice a day.

How long will you be in the research study?

Your drug treatment on this research study ends at the finish of Cycle 8 (week 33), unless your doctor decides that you are candidate for additional treatment. After you are finished taking study medication the study doctor will ask you to visit the office for follow-up exams for at least every 12 months for 5 years. We will keep track of your overall condition annually for up to 5 years. If we do not see you in office, we would like to keep track of your medical condition for the rest of your life. We would like to do this by calling you on the telephone once a year to see how you are

doing. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of the study.

Can you stop being in the research 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 drugs can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

Can you be removed from this research study?

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

What side effects or risks can you expect from being in the research study?

You may have side effects while on the research study. Everyone taking part in the research study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the drugs. In some cases, side effects can be serious, long lasting, or may never go away. There is also a risk of death.

You should talk to your study doctor about any side effects that you have while taking part in the research study.

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

Likely (>20%)

- Diarrhea (increased frequency of bowel movements with loose, watery stools)
- Nausea (feeling sick to your stomach)
- Vomiting (throwing up)

Less Likely (5-19%)

- Abdominal Pain
- Abdominal Distention (enlarged/swollen)
- Indigestion
- Passing gas
- Headache
- Tiredness

Rare but serious

- Lactic acid build up which may cause muscle aches, shortness of breath, or severe belly pain

Risks and side effects related to **bicalutamide** as listed below are risks observed when used in combination with other drugs for prostate cancer and may not affect your experience in this study.

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

Likely (≥ 20%)

- Hot flashes
- Back pain
- Constipation – difficulty having a bowel movement
- Generalized pain
- Tiredness
- Pelvic Pain

Less Likely (5% to 19%)

- Loss of sexual desire
- Not able to have or to keep erection during sexual intercourse
- Nausea – feeling sick to your stomach
- Diarrhea – increased frequency of bowel movements with loose, watery stools
- Belly pain
- Constipation – difficulty having a bowel movement
- Elevated liver enzymes: Liver enzymes are proteins made by the liver that are measured in the blood, with a blood draw. Liver enzymes indicate how well your liver is functioning. Elevated liver enzymes may cause no symptoms, however higher liver enzyme levels may cause you to feel overly tired or weak, you may bruise or bleed more easily, and you may experience abdominal pain or have a yellowing of the skin or eyes.
- Chest pain
- Hypertension (high blood pressure) Symptoms may include headache, dizziness, palpitations, blurred vision, ringing in the ears and nose bleeds
- Swelling of your arms or legs
- Anemia (low hemoglobin, low hematocrit or low red blood cell count) Red blood cells carry oxygen and nutrients throughout the body. Symptoms that may be experienced as a result of low red blood cell counts may include feeling tired and weak, shortness of breath, increased heart rate, dizziness or lightheadedness, headache, chest pain and pale skin
- Hyperglycemia (high blood sugar) Symptoms of high blood sugar may include increased hunger, increased thirst, dry mouth and increased urination
- Bone pain
- Muscle pain and weakness
- Rash
- Shortness of breath
- Dizziness
- Headache
- Difficulty sleeping
- Change in appetite, weight loss or weight gain
- Presence of blood in the urine
- Excessive urination at night

- Frequent urination during the day
- Difficulty urinating
- Infection
- Flu symptoms
- Indigestion: discomfort in abdomen including bloating, discomfort, nausea and burping
- Passing gas
- Vomiting
- Sweating
- Joint tenderness, pain, and stiffness
- Anxiety
- Cough
- Sore throat (pharyngitis)
- Bronchitis: inflammation of the airways that carry air into your lungs resulting in a cough often with mucus, shortness of breath, wheezing, low fever and feelings of tightness in the chest
- Abnormal tingling, pricking, chilling, burning or numb sensation on the skin with no apparent physical cause
- Urinary Tract Infection (UTI)

Rare but serious (< 5%)

- Heart failure – a lowered ability of the heart to pump blood
- Severe liver damage
- Bone fractures

Radiation Risk for Diagnostic Imaging

- It is unlikely that there will be any harmful effects from the radiation exposure you will receive from participating in this study.
- At high levels of exposure, scientists agree that radiation can cause cancer.
- At low exposure levels most scientists agree that the risk, if any, is very low. You will have low levels of radiation exposure with diagnostic imaging procedures.

Blood Draw Risks

- Fainting
- Bleeding
- Bruising at the place on your arm where the blood was drawn or needle inserted
- Pain
- Swelling
- Infection (rare)

Biopsy Risks

- Bleeding
- Pain
- Infection, which can be life-threatening or fatal in rare cases

Reproductive Risks

- Study treatments may make you sterile (unable to have children)
- The drugs in this study may affect a baby, before or after the baby is born

- You should not father a baby while on this research study because the drugs you take could possibly hurt an unborn baby
- If you become pregnant while you are on the research study, you may not continue to take part in the research study

For men:

- You should not make a woman pregnant while you are in this study
- Check with the study doctor about birth control methods and how long to use them. Some methods might not be approved for use in this study

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 use of metformin combined with bicalutamide will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about combination of metformin and bicalutamide as a treatment for cancer. This information could help future cancer patients.

What other choices do you have if you do not take part in this research study?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

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

Will your 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:

- Fox Chase Cancer Center and affiliated Joint Centers, The Institutional Review Boards of The Fox Chase Cancer Center and Temple University, Temple University, Temple University Health system, Inc., and its affiliates or subsidiaries and other authorized representatives of these organizations.
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

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.

You will be given a separate form to review regarding the steps we will take to guard your privacy as part of your participation in the research study. By signing that additional

authorization, you will be providing your consent to use and disclose information described in that form connected with your participation in this research study.

What are the costs?

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.

Bicalutamide and Metformin are commercially available and will be billed to you in the same way you are usually billed for medicines.

If your insurance will not pay for medicines you may need to help with side effects, you may have to pay for them.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage . You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

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

Will you be compensated?

You will not get paid for taking part in this research study.

What if you are injured while taking part in this research study?

If you are injured as a result of your participation in this research study, seek immediate medical care. Temple University Health System or its subsidiaries will treat the injury, though there is no commitment to provide monetary compensation or free medical care. Other financial compensation (such as lost wages or pain and suffering) for such injuries is not available. 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.

What are your rights if you take part in this research study?

Taking part in this research study is your choice. You may choose either to take part or not to take part in the research 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.

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.

New findings

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.

Who can answer your questions about the research study?

Important Contact Numbers	
If you are enrolled at the Fox Chase location (333 Cottman Ave)	
If you have questions about:	Please Call:
This study, including if you get sick or hurt	Dr. Daniel Geynisman at 215-728-4300
If you have a concern or complaint	Risk Management Department at 215-728-2591
Your rights as a research participant on this study	FCCC Institutional Review Board at 215-214-3754
Your bills or health insurance coverage	Clinical Trial Financial Counselor at 215-214-3768
If you are enrolled at the Temple University location (3401 N Broad St)	
If you have questions about:	Please Call:
This study, including if you get sick or hurt	The Dr. Pereira-Rico at 215-707-2777
If you have a concern or complaint	Risk Management Department at 215-728-2591
Your rights as a research participant on this study	FCCC Institutional Review Board at 215-214-3754
Your bills or health insurance coverage	Social Work Department at 215-707-7569

Where can you get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI website at http://cancer.gov

- For NCI's clinical trials information, go to: http://cancer.govclinicaltrials/
- For NCI's general information about cancer, go to: http://cancer.gov/cancerinfo/

By signing below, you tell us that you have gotten all of the information you need; that you have received clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

Signature of Participant	**Print Name of Participant**	**Date**

By signing this form the Physician obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

Signature of Physician Obtaining Consent	**Print Name of Physician Obtaining Consent**	**Date**

By signing this form the person obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

Signature of Person Obtaining Consent	**Print Name of Person Obtaining Consent**	**Date**

Informed Consent Document for Use of Tissue and/ or blood for Research

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

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

About Using Tissue and blood for Research

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. If you agree, this tissue will be kept and may be used in research to learn more about cancer and other diseases. If you would like to read more about how tissue is used for research, you can visit the National Cancer Institutes website at http://www.cancer.gov/clinicaltrials/learningabout/providingtissue

You will also be requested to donate some blood for research purpose (about 2.5 table spoons), which may be helpful in the future.

Your tissue and/ or blood may be helpful for research whether you do or do not have cancer. The research that may be done with your tissue is not designed specifically to help you. It might help people who have cancer and other diseases in the future.
Reports about research done with your tissue and/ or blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the left over tissue and/ or blood for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your tissue can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue. Then any tissue that remains will no longer be used for research.

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

Sometimes tissue is used for genetic research (about diseases that are passed on in families). Even if your tissue is used for this kind of research, the results will not be put in your health records.

Your tissue will be used only for research and will not be sold. The research done with your tissue may help to develop new products in the future.

Benefits

The benefits of research using tissue include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.
You will not receive any benefit from these possible results.

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, circle "Yes" or "No." If you have any questions, please talk to your doctor or nurse, or call our research review board at 215-214-3754.

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

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

YES NO

2. I agree that extra blood (2.5 table spoons) can be taken and kept for use in research to learn more about, prevent, or treat cancer

YES NO

3. My tissue 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).

YES NO

3. Someone may contact me in the future to ask me to take part in more research.

YES NO

By signing below, you tell us that you have gotten all of the information you need; that you have received clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

_____	_____	_____
Signature of Participant	**Print Name of Participant**	**Date**

Informed Consent Document for Quality of Life 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 2 questionnaires: one on your first visit, and one at the end of study. It takes about 15 minutes to fill out each questionnaire.

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

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

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

Please circle your answer.

I choose to take part in the Quality of Life Study. I agree to fill out the two Quality of Life Questionnaires.

YES NO

By signing below, you tell us that you have gotten all of the information you need; that you have received clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

_____	_____	_____
Signature of Participant	**Print Name of Participant**	**Date**