Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE: A Phase II Study of the Addition of Opaganib to Androgen Antagonists in Patients with Prostate Cancer Progression on Enzalutamide or Abiraterone

PROTOCOL NO.: 103193
WIRB® Protocol #20200552
Pro95537

SPONSOR: Medical University of South Carolina

INVESTIGATOR: Michael Lilly, MD
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Charleston, South Carolina 29425
United States

STUDY-RELATED PHONE NUMBER(S): 843-792-9007 (24 hours)

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. You are being asked to take part in this study because you have prostate cancer.

The overall goal of this study is to look at the safety and effectiveness of the investigational drug opaganib in participants with metastatic castration-resistant prostate cancer (mCRPC). It is an investigational drug because it has not been approved by the Food and Drug Administration (FDA) for treatment of cancer. This combination of drugs has not previously been studied in humans. Participation in this study will require you to complete seven study visits over the first 3 months and if you show disease control at that time you will continue to be seen every 4 weeks for as long as you are on study. During these visits, you will be asked to provide blood and urine samples, undergo radiographic scans or imaging procedures and complete surveys about your quality of life or any pain you may be experiencing. After you come off of the study you will enter a follow-up period for up to 3 years where study team members will follow your care by clinic visit, phone contact and/or medical record review every three months to collect information on the status of your cancer.

If opaganib is proven effective, you may benefit from participating in this study, but that cannot be guaranteed. The greatest risks of this study include symptoms of gastrointestinal discomfort, complications from blood draws and loss of confidentiality. Participating in this study might make it so you cannot receive other treatments with demonstrated survival advantage and side effects from the investigational drug could prevent

you from getting these treatments in the future. You do not have to participate in this study to have your condition treated.

If you choose not to participate in this study, you will continue to see your regular doctor and receive treatment for your prostate cancer.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. You may discuss your decision with your friends and family. You can also discuss it with your health care team. Ask the study doctor or study staff to explain any words or information that you do not clearly understand.

The purpose of this study is to look at the safety and effectiveness of the investigational drug opaganib in participants with metastatic prostate cancer. The study drug, opaganib has been studied in a clinical trial to find the most tolerated dose level. The results of this clinical trial and other lab studies have indicated that opaganib may be effective at slowing tumor growth. You are being asked to participate in this study because you have prostate cancer that has progressed (gotten worse) on your current therapy.

This study is sponsored by MUSC with funding from a grant from the National Institutes of Health (NIH) to conduct this study. The investigator in charge of this study is Dr. Michael Lilly. Dr. Lilly will receive payment to support activities required to conduct and manage this study. No one on the research team will receive a direct payment or an increase in salary for conducting the study

This study will be conducted at MUSC and up to two other cancer centers. About 60 participants will participate in this clinical study, with up to 20 participants being enrolled at MUSC.

B. PROCEDURES

Before you begin the study:

If you agree to be in the study, you will need to have the following exams, tests and procedures to find out if you are eligible. These exams, tests and procedures are part of regular cancer care and may be done even if you do not join this study. If you have had some of them recently, they may not need to be repeated. This will be up to the study doctor. It may take about 2 hours to complete all of the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking
- Vitals and weight
- About 2 teaspoons of blood will be taken to look at your blood counts, the health of your tissue, kidneys and liver, to look at your prostate health and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- A urine sample will be collected
- Radiographic scans or imaging using Computed Tomography (CT) scan (a series of images taken with x-rays), positron emission tomography (PET) scan or magnetic resonance imaging (MRI) of the chest,

pelvis and abdomen and a bone scan. These scans will give a detailed picture of the areas of the body taken from different angles. The procedures for these are described below.

The CT scanner is a doughnut-shaped machine. During the procedure, a technologist will take you into the CT scan room where you will lie down on the participant table (usually on your back) inside of the CT machine. You should get comfortable because it is very important not to move during certain parts of the test. During this scan, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. You may also receive signals from the technologist or from the machine about your breathing. If you have any discomfort during the test or after the injection, be sure to tell the technologist.

During an MRI you will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will hear a loud machine-like noise.

Before or during the CT or MRI, you may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs.

A PET Scan is a diagnostic tool used to detect cancer and find out the cancer's stage (a way of describing where the cancer is located, if or where it has spread, and whether it is affecting the functions of other organs in the body). Before the scan, you'll get tracers through a vein in your arm, through a solution you drink, or in a gas you inhale. Your body needs time to absorb the tracers, so you'll wait about an hour before the scan begins. Next, you'll undergo the scan, which can last anywhere from 30 to 45 minutes. This involves lying on a narrow table attached to a PET machine, which looks like a giant letter "O." The table glides slowly into the machine so that the scan can be conducted. You'll need to lie still during the scan. The technician will let you know when you need to remain still. You may be asked to hold your breath for several seconds. You'll hear buzzing and clicking noises during the test.

During a bone scan the doctor will inject (through an IV in your vein) radioactive substance. A short time later, a machine measures how much radiation has been taken into the bones. The test does not hurt but you may have to stay in a certain position to get a good picture.

You will also have the following research procedures during the screening part of the study. These will only be done if you agree to be on the study and you sign this informed consent document:

- About 4 teaspoons of blood will be taken to look at how well you blood is clotting, phosphorous levels and other tumor markers produced by cancer cells in the body and for research purposes.
- Questionnaires looking at your quality of life and how you are feeling.
- Questionnaire to look at any pain you might be experiencing.

If the exams, tests and procedures show that you can be in the study, you will be registered to the study and will begin study participation.

During the study:
The study is divided into intervals called "cycles." These cycles are made up of 28 days. During these cycles, you will be given opaganib. There will be no changes to your scheduled abiraterone or enzalutamide treatment as a result of this study. You will continue to see your regular doctor and will continue your other therapy as they have prescribed. If the treating investigator determines that you need to discontinue Abiraterone or Enzalutamide due to toxicity, you may continue on Opaganib alone.

Dose Assignment of Opaganib:
There are two dose levels of opaganib that are described below. If you are in one of the first groups of subjects to get the study drug, you will be assigned to dose level 1, which is the starting dose level. If the starting dose level does not cause significant side effects, the study sponsor may increase the dose to dose level 2. All participants receive the active drug. If the investigator decides that the dose level is not well tolerated by the participants, the dose level could decrease for the whole study or the study could stop completely.

Dose Level	Opaganib
1	250mg twice a day
2	500mg twice a day

The opaganib should be taken twice a day about 12 hours apart after a light meal. You will be asked to write on a study drug diary or form to help keep track of when you take the tablets as well as any symptoms or side effects that you may have. You will fill out this diary form each day.

If you forget and miss a dose, you should take the dose as soon as possible. If the next dose is due in less than 8 hours, you should skip the missed dose and take the next dose as scheduled. You should write any missed or skipped doses in your drug diary.

If you vomit after taking the medication, you should not take another dose at that time. At your next scheduled dose, take your normal dose. Write your symptom of vomiting on the study drug diary and discuss this information with the study doctor.

Day 1:
After you are registered to the study you will come into clinic for your Day 1 study visit and to receive your study medication. You will have the following standard of care exams, tests and procedures. If you have had some of them recently, they may not need to be repeated. This will be up to the study doctor. It may take about 2 hours to complete all of the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking
- Vitals and weight
- About 2 teaspoons of blood will be taken to look at your blood counts, the health of your kidneys and liver and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- A urine sample will be collected

You will also have the following research procedures:

- About 2 teaspoons of blood will be taken to look at how well you blood is clotting, the health of your tissues and prostate, phosphorous levels and other tumor markers produced by cancer cells in the body.
- Questionnaires looking at your quality of life and how you are feeling.
- Questionnaire to look at any pain you might be experiencing.

Day 29:
You will have the following standard of care exams, tests and procedures. You will need to bring your pill bottle(s) and drug diary to this visit. It may take about 2 hours to complete all of the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking
- Vitals and weight
- About 1 teaspoon of blood will be taken to look at your blood counts, the health of your kidneys and liver and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- A urine sample will be collected

You will also have the following research procedures:

- About 1 teaspoon of blood will be taken to look at the health of your tissue and prostate.
- The study doctor will ask about any side effects you may be experiencing as well as review your study drug diary and any remaining pills.

Day 57:
You will have the following standard of care exams, tests and procedures. You will need to bring your pill bottle(s) and drug diary to this visit. It may take about 2 hours to complete all of the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking
- Vitals and weight
- About 1 teaspoon of blood will be taken to look at your blood counts, the health of your kidneys and liver and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- A urine sample will be collected

You will also have the following research procedures:

- The study doctor will ask about any side effects you may be experiencing as well as review your study drug diary and any remaining pills.

- About 3 teaspoons of blood will be taken to look at the health of your tissue, prostate and for research purposes.
- Questionnaire to look at your mental status.

Day 85:
You will have the following standard of care exams, tests and procedures. You will need to bring your pill bottle(s) and drug diary to this visit. It may take about 2 hours to complete all of the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking
- Vitals and weight
- About 2 teaspoons of blood will be taken to look at your blood counts, the health of your kidneys and liver, to look at your prostate health and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- A urine sample will be collected

You will also have the following research procedures:

- About 1 teaspoon of blood will be taken to look at the health of your tissues and other tumor markers produced by cancer cells in the body.
- The study doctor will ask about any side effects you may be experiencing as well as review your study drug diary and any remaining pills.

Day 113:
You will have the following standard of care exams, tests and procedures. You will need to bring your pill bottle(s) and drug diary to this visit. It may take about 2 hours to complete all of the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking
- Vitals and weight
- About 1 teaspoons of blood will be taken to look at your blood counts, the health of your kidneys and liver and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- A urine sample will be collected
- The investigator will obtain the results of your radiographic scans or imaging using CT scan, PET scan or MRI of the chest, pelvis and abdomen and bone scan.

You will also have the following research procedures:

- The study doctor will ask about any side effects you may be experiencing as well as review your study drug diary and any remaining pills.

- About 4 teaspoons of blood will be taken to look at how well you blood is clotting, phosphorous levels, the health of your tissue and prostate and other tumor markers produced by cancer cells in the body and for research purposes.
- Tumor response assessment.
- Questionnaires looking at your quality of life and how you are feeling.
- Questionnaire to look at any pain you might be experiencing.
- Questionnaire to look at your mental status.

Every 28 days:
After Day 113 you will come in every 28 days for the following standard of care exams, tests and procedures. You will need to bring your pill bottle(s) and drug diary to this visit. It may take about 2 hours to complete all of the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking
- Vitals and weight
- About 2 teaspoons of blood will be taken to look at your blood counts, the health of your kidneys and liver and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- A urine sample will be collected

You will also have the following research procedures:

- About 2 teaspoons of blood will be taken to look at the health of your tissue and prostate.
- The study doctor will ask about any side effects you may be experiencing as well as review your study drug diary and any remaining pills.

Every 56 days:
After day 113 every 56 days you will have some additional tests and procedures. You will need to bring your pill bottle(s) and drug diary to this visit. It may take about 2 hours to complete all of the tests below:

- About 1 additional teaspoon of blood will be taken to look at your prostate health.
- The investigator will obtain the results of your radiographic scans or imaging using CT scan, PET scan or MRI of the chest, pelvis and abdomen and bone scan.

You will also have the following additional research procedure:

- Tumor response assessment.

End of Treatment:
You will have the following standard of care exams, tests and procedures completed as a part of your end of treatment visit. You will need to bring your pill bottle(s) and drug diary to this visit. It may take about 2 hours to complete all of the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking
- Vitals and weight
- About 2 teaspoons of blood will be taken to look at your blood counts, the health of your tissue, kidneys and liver, to look at your prostate health and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- The investigator will obtain the results of your radiographic scans or imaging using CT scan, PET scan or MRI of the chest, pelvis and abdomen and bone scan.
- A urine sample will be collected

You will also have the following research procedures:

- The study doctor will ask about any side effects you may be experiencing as well as review your study drug diary and any remaining pills.
- About 4 teaspoons of blood will be taken to look at how well you blood is clotting, phosphorous levels, the health of your tissue and other tumor markers produced by cancer cells in the body and for research purposes.
- Tumor response assessment.
- Questionnaires looking at your quality of life and how you are feeling.
- Questionnaire to look at any pain you might be experiencing.
- Questionnaire to look at your mental status.

30 days post treatment:
About 30 days after you stop taking the study drug you will meet with the study doctor to discuss any side effects you may be experiencing.

After the Study:
After you complete the end of study visit, you will enter a follow up period. The study team will follow your care by clinic visit, review of medical record and/or telephone call every 3 months for up to 3 years after the last participant is enrolled to the study.

Optional Blood Sample Collections for Additional Research:
Up to 12 patients on the study will have blood samples collected for the researchers to learn more about the level of study drug in your body over a given period of time, and how the study drug interacts with other medications you are taking. These collections are optional and will not affect your participation in the study should you choose to not have these samples collected.

If you do agree to the sample collections, the following amounts of blood will be collected:

Up to 3 teaspoons of blood will be collected within 7 days of starting treatment, about 1 teaspoon per hour over 4 hours.
Up to 5 teaspoons of blood will be collected on study Day 29, about 1 ¼ teaspoons per hour over 4 hours.
Please discuss with your study doctor any questions you may have about the optional sample collections. After you have made a decision on whether to participate, please **initial** one of the lines below:

_____ **YES,** I agree to the optional blood sample collections for additional research.

_____ **NO,** I do NOT agree to the optional blood sample collections for additional research.

Withdrawal
You are free to withdraw from this study at any time. If you decide to withdraw from this study you should notify the research team by speaking with them in clinic, by phone and/or in writing immediately. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, your safety and welfare are at risk, or the study sponsor decides to stop the study.

If you experience any of the side effects listed in the Risks and Discomforts section or if you become ill during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make the decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return to the clinic for a final close-out visit or evaluation.

C. DURATION

Participation in the study will take about 7 visits over a period of about 3 months then you will continue to be seen every 4 weeks until your disease progresses or you discontinue treatment. Once you come off study you will be in follow up for up to 3 years. During this time the study team will follow your care by clinic visit, phone contact and/or medical record review every three months to collect information on the status of your cancer.

D. RISKS AND DISCOMFORTS

While on this study, you are at risk for the side effects listed below. Not everyone will get these side effects. You may have none or several. Most people do not experience all of the side effects listed. A side effect may get worse while on study drug, or more side effects may develop as the longer you stay on study. This depends on your general health and the amount of the study drug you receive (the dose).

Many side effects are inconvenient but not damaging to your health.

They are almost always reversible and usually go away shortly after study drug is complete. However, some side effects are serious medical conditions that may cause your death or cause your condition to deteriorate. The study doctor will closely monitor and treat/prevent the side effects you might have through the study period. Other drugs and procedures may be given to make side effects less serious and less uncomfortable. There may be side effects which are unknown at this time.

Opaganib

Common adverse events occurring in greater than or equal to 10% of subjects:

- Nausea
- Fatigue
- Vomiting
- Diarrhea
- Muscle spasms
- Hot flashes
- Acute kidney injury

Less common adverse events occurring in less than 10% of subjects:

- Urinary retention or inability to completely empty the bladder
- Ringing in the ears
- A fungal infection in the mouth and throat called thrush
- Rapid heart rate
- Sweating
- A feeling of unusual tightness, stiffness or pull in the muscles
- Acid reflux or gastroesophageal reflux disease (GERD)
- Rash
- Pain, including pain the pelvic area
- Numbness
- Lower extremity weakness
- High blood pressure
- Increase in lipid levels or fat particles in the blood
- Increase in blood glucose levels
- Hearing impaired
- Generalized muscle weakness
- Excess gas
- Fingernail changes

- Shortness of breath
- Dry mouth
- Choking sensation
- Chest discomfort
- Changes in liver function tests (AST, ALT and bilirubin)
- Loss of appetite
- Anemia or reduction in hemoglobin in the blood that may cause shortness of breath and tiredness
- Abnormal reflexes
- Abdominal discomfort

Neuropsychiatric Effects
These are side effects that affect your nervous system or have psychiatric effects.

Common adverse events occurring in greater than or equal to 10% of subjects:
- General change in mood and mood swings
- Vision changes including visual disturbances and blurred vision
- Dizziness
- Changes in taste
- Feeling of sleepiness or drowsiness

Less common adverse events occurring in less than 10% of subjects:
- Anxiety
- Agitation
- Damage to the nerves that causes weakness, numbness and pain in the hands and feet
- Abnormal reflexes
- Difficulty speaking
- Hallucinations
- Memory loss
- Feeling of pins and needles in the legs and arms
- Pain, burning or tingling of the skin when touching part of the body
- Headache

Reproductive Risks
You should not father a child while on this study as the treatment may indirectly affect an unborn child. If you are sexually active and are at risk of causing a pregnancy, you and your female partner(s) must use a method to avoid pregnancy that works well or you must not have sex. Examples of acceptable methods of birth control includes: birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant.

Unless you cannot have children because of surgery or other medical reasons, you must be using an effective form of birth control before you start the study, during the study and up to 12 weeks after discontinuing the study. There may be risk to a fetus or nursing child which are unknown at this time.

Procedure Risks

CT scan **-** There is always a slight risk from being exposed to any radiation, including the low levels of x-rays used for a CT scan.

However, the risk from the x-rays is usually very low compared with the potential usefulness of the test to manage your treatment. In rare cases, you may have an allergic reaction to the contrast material given. If you are taking metformin (or similar drugs by mouth to treat high blood sugar), such treatment will be stopped for 2-3 days around the time a scan is planned in order to avoid kidney side effects. The radiologist doing these tests will explain the risks and ask you to sign a separate consent form.

PET scan - There is a chance that you may experience discomfort, pain, or swelling at the site where the radiotracer FDG is injected. You could have an allergic reaction but this has been rarely observed. The amount of radiation put into your body is small and the radiation from the radiotracer will be gone from your body in a few hours.

MRI scan **–** Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which in the process could possibly harm you. Precautions will be taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI. Having an MRI can cause some discomfort for you. You may feel claustrophobic (fear of being enclosed in a small space) in the scanner. The scan can be loud and temporary hearing loss has been reported from this loud noise. You will be asked to wear ear plugs to make you more comfortable. At times during the test, you may be asked not to swallow for a while, which can be uncomfortable.

Bone Scan - In this study, you will be exposed to some radiation from the bone scans. The amount of radiation you will get is like the amount from other x-ray exams routinely used in medicine. Public policy is to keep exposure levels as low as possible.

Contrast dye may be used with some procedures, which has a small possibility of a severe allergic reaction and may also cause kidney problems, especially if you are dehydrated or have poor kidney function.

ECG Risk

Electrocardiogram (ECG) - You may experience a minor discomfort, similar to removing a bandage, when the electrodes are removed from your skin. You may have slight redness or inflammation due to the adhesive used to attach the electrodes to the skin that will go away on its own.

Blood Draw Risks
The risks of drawing blood include temporary discomfort from the needle stick, bruising and infection. Fainting could occur.

Loss of confidentiality
There is a risk of loss of confidentiality since medical records will be reviewed during this study. MUSC and its study team members will take every effort to ensure that your information is kept confidential during this study.

Unknown risks
The experimental study drug may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

E. MEDICAL RECORDS AND CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you are an MUSC participant you have an MUSC medical record. If you have never been an MUSC participant, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law; however, there is the possibility that your research information will be disclosed.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self or others

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

If you agree to take part in this study, there may or may not be direct medical benefit to you. Your participation in this study may provide important information regarding the study drug and that may lead to future clinical studies. Other participants with cancer may benefit in the future.

G. COSTS

You and/or your insurance company will be billed for all routine clinic visits and all standard laboratory tests (e.g. routine blood counts and blood chemistry tests). Some health plans will not pay these costs for people taking part in studies. Check with your insurance company to find out what they will pay for, as if they refuse to pay you will be held financially responsible.

The study drug opaganib will be provided by the study and will not be charged to you. The following procedures are not considered standard of care and will be paid for by the sponsor:

- Blood tests to look at how well your blood is clotting, phosphorous levels, the health of your prostate and tissue and to look at other tumor markers produced by cancer cells in the body
- Blood collected for research purposes
- Research questionnaires about quality of life and pain

Please ask Dr. Michael Lilly if you would like to know more about which tests and studies are being done solely for research purposes.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, once you are enrolled on the study you will be paid $75 cash for each study visit you complete; not to exceed a total of $750.00 during your time on study.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

You may receive payment by other options besides the ClinCard. Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may also include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

If you choose not to participate in this study, you will continue to see your regular doctor and receive treatment for your prostate cancer. Standard therapy for prostate cancer include other forms of androgen deprivation, radiation therapy or chemotherapy standard of care.

If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home.

If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

J. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

K. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you.

L. DISCLOSURE OF RESULTS

Research results, including individual research results, will not be disclosed to you.

M. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;

- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

In addition to the main study, you have the option of participating in the optional portions of this study. Your protected health information may be used or shared with others outside of MUSC for this research as well. Please initial below if we may use/disclose your protected health information for the optional research portion/s of this study.

____Yes, you may use my protected health information for the optional research portions of this study.
____No, you may not use my protected health information for the optional research portions of this study.

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

O. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

P. CLINICAL TRIALS.GOV

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.

Q. COLLECTION OF SPECIMENS

As part of this study, we would like to store the specimens collected from you for future research on prostate cancer. This future research may be conducted by Dr. Lilly or by other researchers who obtain IRB approval for their research. This research may involve genetic studies. This research will not include whole genome sequencing. The specimens will be coded/anonymized. This will protect your confidentiality and anonymity; it will also have other consequences:

1. Results of any future research will not be given to you or your doctor.
2. Even though your name and other personal identifiers will not be connected to the sample, other information about you might still be connected. For instance, information about your race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your specimen. Such information might be important for research or public health. It is possible that this information (including genetic information) might come to be associated with your racial or ethnic group.
3. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur.

You may request at any time that your research samples be removed from storage and not be used for future research.

If you decide you want your samples removed, you may contact Dr. Michael Lilly via written communication at the following address:

Hollings Cancer Center
Medical University of South Carolina
86 Jonathan Lucas Street
Charleston, SC 29425

Once the request is received, and if your samples have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until completely used.

R. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please **initial** by your choice below:

____Yes, I agree to be contacted
____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part or to stop taking part in the study will have no penalty and will not affect your current or future medical care or any benefits to which you are otherwise entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Michael Lilly at (843) 792-0592 or (843) 792-9007 (24 hours). I may contact the Medical University of SC Participant and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." W**e collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about participants who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.
15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our participant directory for use by clergy and visitors who ask for you by name.
2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Psychotherapy notes.
3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice

at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of participants. As a member of these exchanges, MUSC shares certain participant health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.

Revised September 2013.