Cover Page for Consent Form

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
A Phase II open-label, parallel group study of Abiraterone Acetate plus Prednisone in African American and Caucasian Men with metastatic castrate-resistant prostate cancer

Investigator: Daniel George, MD

You are being asked to take part in this research study because you have metastatic prostate cancer (prostate cancer that has spread to other parts of your body). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Daniel George will conduct the study and it is funded by Janssen Scientific Affairs. Janssen Scientific Affairs will pay Duke University to perform this research, and these funds may reimburse part of Dr. George's salary. Dr. George and members of Dr. George's study team, Dr. William Berry and Dr. Andrew Armstrong, have received personal compensation from Janssen in the past for consulting and may receive such compensation in the future. Some of the research on blood and tissue samples will be funded by the National Cancer Institute.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. George or one of his colleagues will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to evaluate the response to abiraterone acetate and prednisone in African American and Caucasian men with metastatic castrate resistant prostate cancer.

Abiraterone acetate is used in the treatment of metastatic prostate cancer. On April 28, 2011, the United States Food and Drug Administration approved abiraterone acetate in combination with prednisone to treat patients with late-stage (metastatic) castration-resistant prostate cancer who have received prior docetaxel (chemotherapy). Abiraterone acetate is a drug that blocks the remaining or residual male hormones in the body that may be helping your prostate cancer to grow. On December 10, 2012, the United States Food and Drug Administration approved abiraterone acetate in combination with prednisone to treat patients with late-stage (metastatic) castration-resistant prostate cancer who have not received prior chemotherapy. Abiraterone acetate is being used in this study in individuals who have not received prior docetaxel therapy for castration-resistant prostate cancer.

Prednisone is a man-made hormone commonly referred to as a "steroid". Prednisone has been approved in the US, Canada, and Europe for various disorders and diseases, such as asthma, Lupus, and chronic

obstructive lung disease. Although prednisone is commonly prescribed to patients with castrate-resistant prostate cancer (CRPC), it has not been approved to treat this disease by the FDA.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Up to 130 people will take part in this study across the 8 study sites (Duke University Medical Center, the Duke Cancer Network, and 6 different hospitals and medical facilities) with up to 85 people participating at all Duke-affiliated sites.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

- You will be asked questions about yourself and your health problems, including past surgeries and past treatments for CRPC.
- You will be asked about medications that you are currently taking, including over-the-counter medications, herbal remedies, vitamins, and supplements.
- You will have a physical examination, which will include measuring your temperature, blood pressure, height, weight, heart rate, breathing rate, and health status.
- You will be asked about any disease-related symptoms you are experiencing.
- You will be asked to fill out a questionnaire about your race and ethnicity.
- You will have an electrocardiogram (ECG) performed to measure the electrical activity of your heart.
- You will have a computed tomography (CT) scan or a magnetic resonance imaging (MRI) of your chest, abdomen, and pelvis, and if needed, other areas to evaluate your disease. A CT scan uses special x-ray equipment to take pictures of the body. The MRI scan uses magnetic and radio waves, meaning that there is no exposure to ionizing radiation. For the CT and MRI scan, you will be asked to lie down and keep still in the scanner for approximately 20 minutes. An x-ray of your chest may also be performed if necessary.
- You will have a bone scan to identify abnormal processes involving the bone such as tumor, infection, or fracture. A bone scan uses bone-seeking radioactive material that is injected into a vein so it travels through the bloodstream. The radiation is detected by a camera that slowly scans your body and takes pictures of how much the radioactive material collects in the bones.
- A small sample of your blood (about 3 to 4 tablespoons) will be collected. Do not have anything to eat or drink, except water, for 12 hours before your blood is drawn. This blood will be collected for routine safety blood tests, Prostate Specific Antigen (PSA) and testosterone levels,

and for other specialized research laboratory tests. These specialized research laboratory tests are used for biomarker and DNA research.

- If available, archival tumor tissue will be collected from your previous biopsy or surgical specimen for DNA research.

If you are eligible to take part in the study, you will be asked to return to the clinic to receive your study drug. If you are not eligible, the study staff will discuss other treatment options with you.

Eligible subjects will receive abiraterone acetate with instructions to take 4 tablets once daily in the morning, one hour before a light breakfast at approximately the same time each day. Abiraterone acetate should be taken on an empty stomach, with no food for 2 hours before and at least 1 hour after the dose is taken. Subjects will also be instructed to take 1 tablet of prednisone by mouth twice daily.

For the purposes of this document, "study drug" will refer to abiraterone acetate in combination with prednisone.

The study can be divided into periods of time called "cycles". A cycle in this study will last 28 days. At the start of each cycle, you will be asked to visit the clinic to have regular pre-scheduled check-ups and lab assessments. During Cycle 1 of this study you will be asked to come to the clinic twice for assessments: on Day 1 and Day 15.

Visits During Study Drug
If you qualify for the study, you will receive a one-cycle supply of study drugs at the Cycle 1, Day 1 visit. You will then return to the clinic at the start of each cycle (about once a month), for Cycles 2, 3, and 4. After the Cycle 4 clinic visit, you will only return to clinic every 3 cycles (about once every 3 months). During Cycle 1, you will be asked to make an additional visit on Day 15.

On Study Day 1 and Day 15 of Cycle 1:

- You will be asked about medications you are currently taking, including over-the-counter medications, herbal remedies, vitamins, and supplements.
- You will be asked about any new or continuing side effects or illnesses you have had since your last visit.
- You will have a physical examination, which will include having your weight, temperature, blood pressure, heart rate, and breathing rate measured.
- A sample of your blood (about 2 to 3 tablespoons) will be collected. This blood will be tested for routine safety blood tests and PSA level (day 1 only).

On Study Day 1 of Cycles 2 and 3:

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- You will be asked about medications you are currently taking, including over-the-counter medications, herbal remedies, vitamins, and supplements.
- You will be asked about any new or continuing side effects or illnesses you have had since your last visit.
- You will have a physical examination, which will include having your weight, temperature, blood pressure, heart rate, and breathing rate measured.
- A sample of your blood (about 2 to 3 tablespoons) will be collected. This blood will be tested for routine safety blood tests, PSA level, and biomarker tests (Cycle 2 only).

On Study Day 1 of Cycle 4 and Every 3rd Subsequent Cycle:

- You will be asked about medications you are currently taking, including over-the-counter medications, herbal remedies, vitamins, and supplements.
- You will be asked about any new or continuing side effects or illnesses you have had since your last visit.
- You will have a physical examination, which will include having your weight, temperature, blood pressure, heart rate, and breathing rate measured.
- You will have a CT scan or MRI of your chest, abdomen, and pelvis, including other areas if needed, and a bone scan prior to seeing your study doctor. An assessment of your disease progression will be conducted at these visits.
- Your study doctor will determine your response to the study drug. If your cancer appears to be progressing (getting worse) on the bone scan, you will be asked to return for another bone scan in approximately 6 to 8 weeks later. The second scan is needed to confirm whether or not the cancer is truly progressing.
- A sample of your blood (about 3 to 4 tablespoons) will be collected. This blood will be tested for routine safety blood tests (Day 1 of every Cycle), PSA level (Day 1 of every Cycle), circulating tumor cell count (Day 1 of every 3 Cycles), and serum lipid and hormone levels (Cycle 4 Day 1). Do not have anything to eat or drink, except water, for 12 hours before your blood is drawn on Cycle 4 Day 1 only.

End of Study Visit:
An End of Study visit will be scheduled within 7 days of your last dose of study drug. At this visit, the following procedures will be performed:

- You will be asked about medications you are currently taking, including over-the-counter medications, herbal remedies, vitamins, and supplements.

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- You will be asked about any new or continuing side effects or illnesses since your last visit.
- You will have a physical examination, which will include having your weight, temperature, blood pressure, heart rate, and breathing rate measured.
- A sample of your blood (about 3 to 4 tablespoons) will be collected. This blood will be tested for routine safety blood tests, PSA level, circulating tumor cell count, and serum hormone levels.

Follow-up Safety Visit:
A follow-up safety visit will be scheduled 25-31 days after your last dose of study drug. At this visit, the following procedures will be performed:

- You will be asked about medications you are currently taking, including over-the-counter medications, herbal remedies, vitamins, and supplements.
- You will be asked about any new or continuing side effects or illnesses since your last visit.
- You will have a physical examination, which will include having your weight, temperature, blood pressure, heart rate, and breathing rate measured.
- You will have a CT scan or MRI of your chest, abdomen, and pelvis, including other areas if needed, and a bone scan prior to seeing your study doctor.
- A sample of your blood (about 2 to 3 tablespoons) will be collected. This blood will be tested for routine safety blood tests.

Additional blood:
If your blood collected at baseline for DNA research is not evaluable, a additional sample of your blood (about 1 teaspoon) may be collected in order to complete the DNA research. This sample can be collected anytime during the study. Your study doctor or nurse will explain if this applies to you.

Subject Responsibilities

If you are eligible and decide to take part in the study, you will need to do the following things:

- Report to the study clinic for all scheduled visits and other visits as requested by the study staff
- Follow instructions on taking study drugs. Abiraterone acetate must be taken on an empty stomach. No food should be consumed for at least two hours before the dose of abiraterone acetate is taken and for at least one hour after the dose of abiraterone acetate is taken.
- Report any reactions or unwanted side effects (adverse events) to your study doctor

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- Report taking any additional medications to your study doctor. This includes vitamins, dietary supplements, herbal or alternative remedies, medications that are prescribed by a doctor, and over-the-counter medications. If you feel that you need to take a new medication or herbal remedy, you must call the study doctor and get approval before taking the medication.

The study staff will record the above information in your study records and follow any adverse event (side effect) that may occur. It is important that you immediately report any new symptoms or worsening of symptoms that you have to the study staff.
Receiving any other prostate cancer therapy or other investigational drugs is not allowed while you are taking the study drugs. Taking steroids other than prednisone should be discussed first with your study doctor. The study staff will discuss these restrictions with you in more detail.

Participation in this research study is completely voluntary. If you choose not to sign this consent form you will continue to receive care, but not as part of this study.

INFORMATION ABOUT DNA TESTING

Please read the following basic principles which relate to your participation in genetic studies.

Some of the blood samples collected will be used for genetic studies. Your genes are made of DNA, which is short for deoxyribonucleic acid. A gene, or DNA, contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child. For this study, we will be examining how differences in your genes may affect how you respond to the study drug.

(a) Participation in the study and obtaining results. Individuals participating in this study have prostate cancer. The studies described are for research purposes only and you will receive no results from these genetic studies.

(b) Incidental Findings: It is possible that this genetic study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician unless the information indicates that you may be at risk for a disease known at the time of testing to potentially cause premature death if untreated. In that case, we will attempt to notify you using the contact information you have provided, so that you can speak with Dr. George at Duke University Health System (DUHS). DUHS staff will not provide this information in a voice mail, email, or otherwise prior to contacting you. Please notify us of any change in your contact information.

If you do not want to be notified of any incidental findings, please place your initials below.

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_____ Please do not notify me of any incidental findings obtained from this research.
Initials

If you prefer, we can ask you at the time of notification whether or not you want to receive incidental findings information. In this case, please place your initials below.

_____ Please ask me at the time of notification whether or not I want to receive incidental findings
Initials information.

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact us at 919-668-8108 during business hours.

After providing the information to you, Dr. George may arrange for you to meet with him and/or a genetic counselor or refer you to another appropriate health care provider to review the incidental findings information with you or your physician.

(c) Use and ownership of samples: By agreeing to participate in this research, you authorize DUHS and members of its staff to use your tissue, blood or other samples for the purposes described in this consent form. DUHS will maintain these samples indefinitely or until they are exhausted. These samples are unavailable for clinical (diagnostic) purposes. Therefore, if you need any future diagnostic testing, a new sample will be obtained from you. Tissue, blood, or other samples collected as part of this study may be valuable for scientific, research, or teaching purposes or for the development of a new medical product. DUHS and/or the developers will assert all rights of ownership in the samples and all rights arising from use of the samples. There is no plan to compensate you for any use of the samples.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

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OPTIONAL FUTURE RESEARCH

As part of this study, archival samples of your tumor tissue and research blood samples will be collected and used for DNA research. If there are any samples left over, we would like to use the tissue or blood samples for future prostate cancer research. The samples might be used for additional genetic tests based on race, or tests to predict clinical benefit. The samples will be stored at the Duke Biospecimen Repository and Processing Core (BRPC) facility.

Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information; this risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family. You should discuss your participation in this study with your family and ask the study doctor about any questions or concerns you may have. Your samples and genetic information may be used for research for many years in the future.

Please read each sentence below and think about your choice. After reading each sentence, initial either "Yes" or "No". Regardless of what you decide, it will NOT affect your care. You can participate in the main part of the study without participating in this optional future research.

Tissue Samples

_____ "Yes, I agree to allow my leftover tissue samples to be used for future research."
Initials

_____ "No, I do not agree to allow my leftover tissue samples to be used for future research."
Initials

Blood Samples

_____"Yes, I agree to allow my leftover blood samples to be used for future research."
Initials

_____"No, I do not agree to allow my leftover blood samples to be used for future research."
Initials

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HOW LONG WILL I BE IN THIS STUDY?
If you decide to participate, you will be on this study for the rest of your life. You will be asked to remain active on study drug until your cancer worsens (according to the CT, MRI, or bone scan results), you are unable to tolerate the study drug, your doctors determines that you should begin another cancer treatment, or you decide to withdraw consent. During your first 3 months in the study, you will make about 5 visits to the clinic. Afterwards, you will visit the clinic about once every 3 months for up to 24 months. If you remain on study for the full 24 months, you will visit the clinic a total of about 13 times (including the end of study and follow-up safety visits).

After your follow-up safety visit, you will visit the clinic about once every 3 months for up to 24 months after starting the study. If you discontinued study drug for reasons other than disease progression, clinic study staff will collect information related to the progression of your disease (for example standard of care scans, standard of care labs, new therapies) to follow you until your disease gets worse. After all of your study visits are completed, we will continue to contact you by phone every 6 months to find out the status of your health.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
More than 1900 male subjects with prostate cancer have received abiraterone acetate, either alone or combined with other drugs. Since the way the abiraterone is being used in this study is investigational, not all of the potential adverse (bad) effects in humans are known. Also the risks or discomforts described below may occur more often or be more severe than been previously seen. In addition to the possible adverse effects listed below, there is always the possibility of uncommon or unexpected adverse effects that you may experience.

You may have side effects from taking the study drug (abiraterone acetate, prednisone). Everyone taking part in the 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 could give you medicines to treat the side effects. Many side effects caused by study medication may go away soon after you stop taking the study regimen. In some cases side effects can be serious, long lasting, or may never go away. It is not possible to tell which side effect will affect you or how mild or severe the side effect might become. We can only tell you what other people have experienced. Please talk with your doctor about these side effects.

You should tell your doctor about any side effects, problems or unusual experiences that you have while taking part in this study. This will decrease the chance that the side effects continue or become worse.

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Sometimes there are other medications that your study doctor can give you to make the side effects better or make you more comfortable. If severe side effects do develop, you and your study doctor may decide it is in your best interest to stop taking part in the study.

At present, known side effects that could be related to the abiraterone acetate include:

Frequent (20% or more) [May occur in 20 or more patients in 100]

- edema peripheral (swelling of the legs as a result of the body keeping too much fluid)
- hypokalaemia (low blood potassium, a mineral that helps regulate heart rate/function, fluid balance in the body and is needed for adequate body function)
- hypertension (high blood pressure)

Very Common (10% to 19%) [May occur between 10 and 19 patients in 100]

- Alanine aminotransferase increased and/or aspartate aminotransferase increased (enzymes in the blood that measure thte function of the liver)
- urinary tract infection

Common (5% to 9%) [May occur between 5 to 9 patients in 100]

- dyspepsia (uncomfortable feeling in upper belly, indigestion)
- hematuria (presence of blood in the urine)
- fractures (a break in the bone)

Less Common (less than 5% [May occur in fewer than 5 patients in 100]

- hypertriglyceridaemia (high levels of fats (triglycerides) in the blood)
- cardiac failure (heart failure, the heart is unable to supply enough blood flow to meet the body's needs.)
- angina pectoris (chest pain)
- arrhythmia (changes in the rhythm of the heart)
- atrial fibrillation (a fast and irregular heartbeat)
- tachycardia (rapid heartbeats)

Uncommon (less than 1%) [May occur between 1 and 9 patients in 1000]

- adrenal insufficiency (decreased function of adrenal glands that normally help maintain blood pressure, balance minerals and fluid in your body)
- Rhabdomyolysis (breakdown of muscle tissue) and myopathy (muscle weakness and/or muscle pain).

Rare (less than 0.1%) [May occur between 1 and 10 patients in 10000]

- allergic alveolitis (swelling and irritation of the lung)
- failure of the liver to function (called acute liver failure).

There is a small chance of severe allergic reaction to the drug which may be life-threatening.

Abiraterone Acetate should be used with caution in subjects with a history of cardiovascular disease. Before taking abiraterone acetate, high blood pressure must be controlled and low potassium must be corrected. One subject died while taking abiraterone acetate without prednisone in an early trial. His doctor felt that he died as a result of a heart attack associated with severely low blood potassium, and that this was probably related to abiraterone acetate. Potassium is needed for proper function of your heart and other essential body systems. It is especially important that you contact your study doctor right away if you cannot come to your regularly scheduled visit or get your blood tests, since some subjects have no symptoms when their blood potassium is low. Contact your study doctor immediately if you feel weak, if you have constipation, or if you have muscle pain or cramps. These symptoms may be caused by low blood potassium. Also, if your appetite decreases, or if you develop diarrhea, you should contact the study doctor, since potassium may become low if you are not eating well, or your potassium may be lost through diarrhea.

Prednisone together with abiraterone acetate, will be given to you in this study in order to reduce or eliminate some side effects, such as high blood pressure, low blood potassium, and swelling of the legs as a result of the body keeping too much fluid.

No specific laboratory experiments in animals were performed to investigate the effect of abiraterone acetate on the fertility of male and female animals or the effect of abiraterone acetate on the fetus in pregnant animals. However, in general toxicity studies in laboratory animals abiraterone acetate affected the reproductive organs in male and female animals. Therefore abiraterone acetate must not be taken by women who may become pregnant.

One of the potential side effects of this study drug is that it may reduce the production of cortisol, a hormone, by the adrenal glands. The adrenal glands are responsible for the production of several hormones that regulate salt and water retention, blood pressure, sugar levels and the body's ability to respond to stress (such as illness or severe injury). In this study, you will be taking prednisone, a medication that works like cortisol, which may improve the study regimen side effects. However, prednisone may reduce your body's ability to respond to stress. Therefore, if you experience any illness or severe injury you should notify your study doctor or any other healthcare provider immediately, as an increased dose of prednisone or corticosteroid may be required. We will still be monitoring all side effects listed above. Other side effects will also be carefully watched. If they do happen, appropriate medication will be prescribed.

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If you experience any illness or discomfort during the study, you should notify your study doctor immediately. Your doctor will then examine you to determine if you should continue in the study.

Other Information about abiraterone acetate

Based on animal studies abiraterone acetate may harm the unborn child. Male patients who are receiving abiraterone acetate and have partners of childbearing potential are advised to use a method of birth control with adequate barrier protection (condoms) as determined to be acceptable by the study doctor during the study regimen period and for 1 week after the last dose of abiraterone acetate.

In laboratory experiments, abiraterone acetate inactivated some enzymes that are involved in breaking down other drugs. Since certain drugs that you take may interact with the study drug, you should inform your study doctor of all the medications you are taking, or if you suspect you are experiencing any side effects.

Also, in laboratory experiments in mice, rats, and monkeys, Abiraterone acetate caused abnormal results in blood tests that measure the function of the liver and a change in the appearance of the liver under the microscope. The liver changes in the animals went back to normal after Abiraterone acetate was discontinued.

Fewer than 10% of patients taking Abiraterone acetate have had abnormal liver function laboratory test results. Rarely, failure of the liver to function may occur, which can lead to death. Interruption or discontinuation of the study regimen with abiraterone acetate was sufficient to normalize the liver enzymes in majority of these cases. However, your liver function will be monitored closely by blood tests for the first 3 months of the study. If elevations in your liver function enzymes are observed, the dose of your study medication may be adjusted or discontinued.

There is a small chance of severe allergic reaction to the drug which may be life-threatening. Some things that happen during an allergic reaction are:

- a rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

You should get immediate emergency medical help and also contact the study doctor or study staff if you have any of these side effects during the study. There is always a risk involved in taking a new drug, but every precaution will be taken to minimize the risk.

Sometimes during a study the Sponsor or Janssen Scientific Affairs may learn new facts about the study medications. It is possible that this information might make you change your mind about being in the study. If new information is discovered, your study doctor will tell you about it in a timely manner.

The study drugs must be taken by the person for whom it has been prescribed. It also must be kept out of the reach of children or persons of limited capacity to understand.

Possible Adverse Effects due to Prednisone:
Prednisone is a type of drug called a corticosteroid. Corticosteroids can weaken your body's ability to fight off infection, and can make infections hard to diagnose or treat. If you develop fever, or suspect you have an infection, you should alert your study doctor immediately.

Other side effects caused by corticosteroids are:

- fluid retention,
- eye problems such as cataracts (clouding of the lens of the eye or its surrounding transparent membrane that obstructs the passage of light),
- eye problems such as glaucoma (a disease of the eye marked by increased pressure within the eyeball that can result in damage to the optic disk and gradual loss of vision),
- stomach bleeding,
- indigestion,
- seizures and swelling of the brain,
- insomnia (wakefulness),
- emotional changes,
- mood swings,
- severe depression.

Taking corticosteroids over a long period of time can cause a condition called Cushing's syndrome. Symptoms of Cushing's syndrome include:

- weight gain,

- a "moon-faced" appearance,
- thin fragile skin,
- muscle weakness,
- brittle bones,
- purplish stripe marks on the skin.

Also, if you are diabetic, corticosteroids can make your glucose level more difficult to control. If you are not diabetic, incidents of increased blood sugar levels have occurred, as well as increases in calcium levels.

You should also tell the study doctor if you have ever had a reaction to prednisone.

Rarely, adrenal insufficiency (loss of function of adrenal glands that normally help maintain blood pressure, balance minerals and fluid in your body) may occur due to long term use of steroid medicines. Symptoms of adrenal insufficiency include:

- weakness and fatigue,
- low blood pressure,
- nausea,
- vomiting,
- diarrhea,
- irritability and/or restlessness.

It is recommended that prednisone never be stopped suddenly. If you need to stop the prednisone, your doctor will advise you on how to gradually cut down the dose and stop the drug safely (called a "taper"). If you were to stop taking prednisone suddenly, you could become very weak and tired, develop very low blood pressure, very low blood sugar, and abnormalities of the minerals in your bloodstream. While usually not severe, if not treated, these reactions are potentially fatal. Additionally, these symptoms can occur at times of major illness and extreme physical stress where it may actually be necessary to temporarily increase your dose of prednisone to decrease your chance of developing this condition. Anytime you see a doctor for any reason, you should tell him/her that you are on prednisone.

You may ask your doctor for printed information about prednisone and the potential side effects (this is called a package insert).

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Handling Abiraterone Acetate Tablets:
This medicine may cause harm to the unborn child if taken by women who are pregnant. It should not be taken by women who are breast-feeding. Women who are pregnant or who may be pregnant should wear gloves if they need to touch abiraterone acetate tablets. You should notify any caregivers and study personnel of this information, to ensure the appropriate precautions are taken.

Reproductive Risks:
Your participation in this research may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a condom used with a spermicide in order to be in this study and for 1 week afterward. Even if you have had a surgical sterilization (such as a vasectomy) you should use a condom with a spermicide because of known risks to a developing fetus. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should promptly notify her doctor.

Based on its mechanism of action, Abiraterone acetate may harm a developing fetus. Therefore, women who are pregnant or women who may be pregnant should not handle abiraterone acetate without protection, e.g. gloves.

Risks of Radiation:
All tests and procedures involving radiation for this study are considered standard of care, meaning they are routinely done for your disease type. You will not receive any extra radiation by participating in this study.

Risks of Drawing Blood:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Drug Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before taking any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
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Investigator: Daniel George, MD

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There is no promise that the study drug you receive will help you. Participation in this research study is based on the expectation that the benefit associated with participation, even considering the risk of harmful reactions to the study drugs, may be better than the alternative treatments. Please discuss with your study doctor which alternative treatments are available for you. It is hoped that potential benefits may include improving disease related symptoms and decreasing the size of your tumor. You should be aware that this study regimen you receive may be harmful. Information obtained from your participation may help other people with your condition in the future.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
If you decide not to take part in this study, other approved treatments are available to you, which the study doctor will explain to you. You may receive treatment to control the symptoms you may be having as a result of your disease. Other options may include chemotherapy and radiation therapy. You may also choose to have no treatment for your cancer; receiving only palliative care to manage your symptoms and make you feel more comfortable. Study staff will discuss these alternative treatments and the risks and benefits associated with these treatments with you before you take part in this study.

Please talk to your doctor about these and perhaps other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to Janssen Scientific Affairs and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of Janssen Scientific Affairs, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code

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will be kept in a locked file in Dr. George's office or in the office of a designated study team staff member. Neither the local sites nor the patients will receive information regarding individual subjects' results. The blood and tissue samples collected for this study will be stored at DUHS and labeled with your unique code number, and access to your samples will be limited to designated study team staff members. DUHS cannot assure the de-identification of images sent outside of Duke.

As part of this study, Dr. George and his study team will ask you to have certain tests. Some of these blood and x-ray studies would have been done as part of your regular care. He will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

You also provide consent for the release of copies of your CT scans, laboratory test results, and medical reports for review as part of this research study. Information about your disease status may be requested and reviewed on a regular basis after you have completed all visits in this study. This is necessary to ensure that the study is performed according to the approved protocol, and that the data collected is correctly recorded. By signing this consent form, you are authorizing access to your medical records data collected from your participation in this study. Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives of Janssen Scientific Affairs and its designees), National Institutes of Health, National Cancer Institute, Duke Cancer Institute, and the Duke University Health System Institutional Review Board. If any of these groups review your research record, they may also need to review your entire medical record. This information may be further disclosed by the sponsor of this study, Duke University. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

Some information collected about you only for this research study may be kept in a research study record separate from your medical record, and some research information may also be part of your medical record. You will not have access to this research information until the end of the study. However, it will be available to your physicians if needed for your care.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

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WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. George**.** At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

The study sponsor, Janssen Scientific Affairs, has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the Dr. George or other study personnel about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible. . Research blood samples required by the study will be paid for by Janssen Scientific Affairs. In order to make sure that tests and studies done solely for research purposes are charged correctly, we will carefully monitor your Duke Hospital and Clinic charges as long as you are participating in this study. These tests and studies are not a part of routine care, and people who are not part of the study do not usually have them performed.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

Janssen Scientific Affairs will provide Abiraterone acetate free of charge to you while you take part in this study. At the end of the study, or if you decide to withdraw from the study before it ends, you may be asked to return all unused Abiraterone acetate. Your study doctor may request that you return for a checkup before you stop your study drug if he/she thinks that stopping it suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a person completes the study.

Prednisone (medications to treat side effects of the study drug) will be prescribed by your study doctor as part of standard of care. You and/or your insurance company will be responsible for the payment of doctor's visits, physical exams, CT and bone scans and routine blood tests that would be part of your routine cancer care. You may wish to contact your insurance company to discuss this further.

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WHAT ABOUT COMPENSATION?
You will not be compensated for your participation in this study. However, you will receive compensation for parking in the form of a parking pass.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., your Duke physicians or Janssen Scientific Affairs to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. George at [redacted] during regular business hours and at [redacted] and ask for Dr. George to be paged after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, your participation is voluntary. If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to Janssen Scientific Affairs.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. George in writing and let him know that you are withdrawing from the study. His mailing address is [redacted]

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, if your study doctor determines that it is no longer in your best interest to continue, you do not follow the procedures of the study, or you start another CRPC therapy. Janssen Scientific Affairs, Duke University, or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified, and, your study doctor will discuss other options for treatment.

You may withdraw your consent at any time. The information collected prior to your withdrawal of consent will still be part of the study data. However, no new information will be collected.

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At the conclusion of the study, or if you decide to withdraw from the study, you must return all unused study drug to Dr. George. Dr. George may request that you return for a checkup before you stop your study drug if he thinks that stopping the drug suddenly may harm you. He may also ask you to complete the tests that would ordinarily occur when a person completes the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. George at [redacted] during regular business hours and at [redacted] and ask for Dr. George to be paged after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at [redacted]

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.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	
Signature of Subject	Date	Time
_____	_____	
Signature of Person Obtaining Consent	Date	Time
_____	_____	_____
Signature of Legal Representative	Date	Time
_____		
Relationship to Subject		