ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called "**Abiraterone with Discontinuation of Gonadotropin-Releasing Hormone Analogues in Metastatic Prostate Cancer**". Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Dr. Benjamin Gartrell, MD. You can reach Dr. Gartrell at:
Office Address: 1695 Eastchester Road
City, State Zip Bronx, NY 10461
Telephone #: 718-405-8505
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

This research is not funded

Why is this study being done?

The goal of this study is to find out if patients with prostate cancer being treated with the medications abiraterone and prednisone can discontinue hormone injections (examples include leuprolide, goserelin, triptorelin and degarelix). Abiraterone and prednisone are pills used to treat patients with prostate cancer. When abiraterone and prednisone are used, hormone injections are usually continued to maintain a low testosterone level in the blood. This study is being done to find out if testosterone in the blood will stay low while abiraterone and prednisone are used without continued hormone injections.

Abiraterone with prednisone is approved by the U.S. Food and Drug Administration (FDA) to treat prostate cancer. However, the FDA approval provides guidance that hormone injections should be continued with abiraterone and prednisone.

Why am I being asked to participate?

You are being asked to participate in this study because you have prostate cancer and you are being treated with hormone injections (examples include leuprolide, goserelin, triptorelin and degarelix) to keep the testosterone level in your blood low and you are being treated with, or are about to start taking the medications, abiraterone and prednisone. In routine clinical care, your

doctor would continue your hormone injections. In this clinical trial, patients starting abiraterone and prednisone will stop their hormone injections.

How many people will take part in the research study?

You will be one of about **36** people who will be participating in this study.

How long will I take part in this research?

It will take you about 3-24 months to complete this research study. Your participation could last longer. During this time, we will ask you to make study visits every 3 months to Montefiore Medical Center. You will stay on abiraterone and prednisone for as long as your doctor believes it is helping you. You may stay on abiraterone and prednisone after you are finished participating in this research study if your doctor believes it is still helping you.

What will happen if I participate in the study?

The Screening Visit will take about 1 hour. During this visit, we will do tests and procedures to see if you eligible to take part in this research study. The study doctor will review the results of these tests and procedures. If you aren't eligible, the study doctor will tell you why. At this visit we will:

- Ask you about your medical history
- Perform a physical exam
- We will measure your "vital signs" (blood pressure, temperature, heart and breathing rates) and your height and weight
- Draw a blood sample

If you are eligible for the study, we will ask you to stop taking your hormone injection (examples include leuprolide, goserelin, triptorelin and degarelix) during the duration of the study which is expected to be 3-24 months, but could be longer. Without your hormone injection, your testosterone could rise and your prostate cancer may get worse. This could result in symptoms such as pain or difficulty with urination. If this happens, please call the study doctor at the number provided in this consent form.

If you are eligible for the study, you will be treated with abiraterone plus prednisone and you will stop your hormone injection.

Study visits will occur every 3 months and will take about 1 hour. At this visit we will:

- Ask you about your medical history
- Perform a physical exam
- We will measure your "vital signs" (blood pressure, temperature, heart and breathing rates) and your height and weight
- Draw a blood sample
- Review your study drug diary

To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein. 3 tubes of blood will be drawn, about 3 teaspoons.

A description of this clinical trial will be available on 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.

Genetic Testing

This study will not involve genetic research or genetic testing.

Information Banking (Future Use and Storage)

We will store information about you in a "bank", which is a library of information from many studies. This information can be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose or treat disease, including genetic research. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy the information in the bank but if the information was already shared with other researchers, we cannot get it back.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility**.**

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

INITIAL YOUR CHOICE BELOW
_____ I consent to be contacted in the future to learn about:
_____ New research protocols that I may wish to join.
_____ General information about research findings

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

If you take part in this study, you or your insurance will pay for abiraterone and prednisone and all blood work and other tests that are conducted during this research study.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr Gartrell by calling 718-405-8505.

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- ***Drugs may cause a reaction that, if not treated promptly, could be life-threatening. It is important that you report all symptoms, reactions and other complaints to the research study doctor.***
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.
- You may carry out all your normal daily activities.

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information and specimens will be kept as long as they are useful for this research.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

The only people who can see your research records are:

- the research team and staff who work with them
- groups that review research (the Einstein IRB, and the Office for Human Research Protections, and the US Food and Drug Administration

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any side effects or risks to me?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. Side effects may be mild or very serious. There is also a life threatening risk of Adrenal Insufficiency when taking abiraterone plus prednisone, caused from an interruption of your daily usage of prednisone and or with concurrent infection or stress.

You will be given a medical alert card for this life threatening risk of Adrenal Insufficiency, to be kept with you at all times.

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

Blood Draw
Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless "black and blue" may develop. Very rarely, fainting may occur.

Side effects and risks of Taking Abiraterone plus prednisone
The most common laboratory abnormalities (>20%) are anemia, low white blood cells, abnormal liver blood tests, elevated cholesterol, elevated blood sugar, low potassium and low phosphorous.

Common side effects (≥10%) are fatigue, joint swelling or discomfort, muscle discomfort, swelling of the legs, hot flush, diarrhea, constipation, vomiting, cough, high blood pressure, shortness of breath, urinary tract infection, upper respiratory tract infections, insomnia, and bruising.

Less common side effects 1-10%) include upset stomach, increased urinary frequency, fractures of bone, abnormal heart rhythms, heart failure, chest pain, falls, rash, blood in the urine and fever.

Rare (less than 1%) but serious side effects include liver failure which can be severe and fatal and adrenal insufficiency (this is low level of cortisol (stress hormone)) which could be life threatening in situations of severe stress

There may be other risks of abiraterone and prednisone that are currently unknown.

Taking Study Drug with Other Medications

For your safety during this study, call your study doctor BEFORE you take any:

- New medications prescribed by your doctor
- Other medications sold over-the-counter without a prescription
- Dietary or herbal supplements

Stopping Hormone Injections
When you stop taking your hormone injection (examples include leuprolide, goserelin, triptorelin and degarelix) your testosterone could rise and your prostate cancer may get worse. This could result in symptoms such as pain or difficulty with urination. If this happens, please call the study doctor at the number provided in this consent form.

Allergic Reaction to Study Drug
Any drug can cause an allergic reaction which could be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you are having trouble breathing, call 911 immediately.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include avoiding hormone injections while taking abiraterone and prednisone. Your cancer may improve during treatment with abiraterone and prednisone. However, abiraterone and prednisone is an FDA approved therapy and is available to you outside of this research study.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you. Abiraterone and prednisone is an FDA approved therapy and is available to you outside of this research study. There may be additional treatment options that are available to your outside of this this research study.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. You will need to return your study drug diary at this visit. The final study visit will take about 1 hour. At this visit, we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Draw a blood sample
- Ask you to return your study drug diary

Can the study end my participation early?

We will not let you participate in the study any more if the investigator believes that are no longer benefitting from therapy or your testosterone rises and you need to resume hormone injections. In addition, your participation will end if the investigator stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time

Printed name of the person conducting the consent process	Signature	Date	Time