Informed Consent Model for S1014

*NOTES FOR LOCAL INSTITUTION INFORMED CONSENT AUTHORS:

This model informed consent form has been reviewed by the DCTD/NCI and is the official consent document for this study. Local IRB changes to this document are allowed. (Institutions should attempt to use sections of this document that are in bold type in their entirety.) Editorial changes to these sections may be made as long as they do not change information or intent. If the institutional IRB insists on making deletions or more substantive modifications to the risks or alternatives sections, they may be justified in writing by the investigator and approved by the IRB. Under these circumstances, the revised language, justification and a copy of the IRB minutes must be forwarded to the SWOG Operations Office for approval before a patient may be registered to this study.

Readability Statistics:	
Flesch Reading Ease	60 (targeted above 55)
Flesch-Kincaid Grade Level	8.5 (targeted below 8.5)

- Instructions and examples for informed consent authors are in *[italics]*.
- A blank line, _____, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
- The term "study doctor" has been used throughout the model because the local investigator for a cancer treatment trial is a physician. If this model is used for a trial in which the local investigator is not a physician, another appropriate term should be used instead of "study doctor".
- The dates of protocol updates in the header and in the text of the consent is for reference to this model only and should not be included in the informed consent form given to the prospective research participant.
- The local informed consent must state which parties may inspect the research records. This includes the NCI, the drug manufacturer for investigational studies, any companies or grantors that are providing study support (these will be listed in the protocol's model informed consent form) and SWOG.

  SWOG must be listed as one of the parties that may inspect the research records in all protocol consent forms for which patient registration is being credited to SWOG. This includes consent forms for studies where all patients are registered directly through SWOG, all intergroup studies for which the registration is being credited to the (whether the registration is through the SWOG Data Operations Office or directly through the other group), as well as consent forms for studies where patients are registered via CTSU and the registration is credited to SWOG.
- When changes to the protocol require revision of the informed consent document, the IRB should have a system that identifies the revised consent document, in order to preclude continued use of the older version and to identify file copies. An appropriate method to identify the current version of the consent is for the IRB to stamp the final

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copy of the consent document with the approval date. The stamped consent document is then photocopied for use. Other systems of identifying the current version of the consent such as adding a version or approval date are allowed as long as it is possible to determine during an audit that the patient signed the most current version of the consent form.

*NOTES FOR LOCAL INVESTIGATORS:

- The goal of the informed consent process is to provide people with sufficient information for making informed choices. The informed consent form provides a summary of the clinical study and the individual's rights as a research participant. It serves as a starting point for the necessary exchange of information between the investigator and potential research participant. This model for the informed consent form is only one part of the larger process of informed consent. For more information about informed consent, review the "Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials" prepared by the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials for the National Cancer Institute. The Web site address for this document is http://cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/
- A blank line, _____, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
- Suggestion for Local Investigators: An NCI pamphlet explaining clinical trials is available for your patients. The pamphlet is titled: "If You Have Cancer…What You Should Know about Clinical Trials". This pamphlet may be ordered on the NCI Web site at *https://cissecure.nci.nih.gov/ncipubs* or call 1-800-4- CANCER (1-800-422-6237) to request a free copy.
- Optional feature for Local Investigators: Reference and attach drug sheets, pharmaceutical information for the public, or other material on risks. Check with your local IRB regarding review of additional materials.

*These notes for authors and investigators are instructional and should not be included in the informed consent form given to the prospective research participant.

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S1014, "Abiraterone Acetate Treatment for Prostate Cancer Patients with a PSA of More Than Four Following Initial Androgen Deprivation Therapy, Phase II"

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have prostate cancer that is only partially responding to hormone therapy. Abiraterone acetate is a hormonal tablet that has been approved by the Food and Drug Administration (FDA) for more advanced prostate cancer patients who have received chemotherapy. It is considered investigational for your type of prostate cancer. We will be looking to see if abiraterone acetate improves the effectiveness of standard hormonal shots or injections. The prostate specific antigen (PSA) is a blood test used in prostate cancer screening and also to follow prostate cancer. In this study, we will follow your PSA level to help determine if abiraterone acetate is beneficial. The main goal of this study is to see if abiraterone acetate with prednisone reduces PSA.

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Who is doing this study?

SWOG is sponsoring this trial. SWOG is an adult cancer clinical trials organization. SWOG is funded through the National Cancer Institute, and its network consists of about four thousand physicians at almost three hundred institutions throughout the United States. Your study doctor has met all requirements to be a member of SWOG and to perform National Cancer Institute-funded research through this Group.

Why is this study being done?

The purpose of this study is to find out what effects, good and/or bad, abiraterone acetate has on you and your prostate cancer. The effect of the prostate cancer will be measured by a blood test (prostatic specific antigen or PSA).

How many people will take part in the study?

About 38 people will take part in this study.

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

Before you begin the study …

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

- History and physical exam including measuring your blood pressure
- CT scan of your abdomen and pelvis
- Bone scan
- Blood prostate specific antigen (PSA) test
- Other blood tests including those to assess your blood counts, kidney and liver function, and testosterone level.
- CT or MRI scan of the brain if your doctor feels it's necessary

During the study …

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

Every 2 weeks for the first 3 months:

- Blood tests to monitor your liver

Every 4 weeks:

- History and physical exam including measuring your blood pressure
- Blood prostate specific antigen (PSA) test
- Other blood tests including those to assess your blood counts, kidney and liver function.

Every 12 weeks:

- CT scan of your abdomen and pelvis
- Bone scan

Treatment will consist of taking 4 abiraterone acetate tablets a day. Abiraterone acetate must be taken on an empty stomach. You should not eat for at least two hours before the dose of abiraterone acetate and for at least one hour after abiraterone acetate is taken. You will also take one prednisone tablet twice a day. Prednisone is a type of drug called a corticosteroid. It is a standard treatment for prostate cancer and may improve your symptoms. Prednisone also reduces some of the potential side effects associated with abiraterone acetate. Abiraterone acetate and prednisone can be taken together. Every 28 days is called a cycle. You will continue taking abiraterone acetate and prednisone as long as your disease does not get worse and side effects do not become too severe. To help keep track of the number of tablets you take and any side effects, you will need to keep a pill diary. The pill diary is called an Intake Calendar and you will need to bring it with you for your follow-up visits. Although it reflects a month's time, you should complete it daily. You need only complete one Intake Calendar for both drugs.

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When I am finished taking abiraterone acetate…

After you are done taking the study drug, there will be an end of study visit. A history and physical exam with routine blood tests will be done at that time. The study personnel will continue to follow your progress approximately every 3 months for the first year after you join the study and then every 6 months thereafter for up to 3 years.

How long will I be in the study?

You will be asked to take abiraterone acetate for as long as you tolerate the treatment and it is working. After you are finished taking abiraterone acetate, the study doctor will ask you to visit the office for follow-up exams for at least up to 3 years from the time you started the study.

Can I stop being in the study?

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

It is important to tell the study doctor if you are thinking about stopping so any risks from the abiraterone acetate can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

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

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

You may have side effects while on the study. 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 may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the abiraterone acetate. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

There is a small chance of severe allergic reaction to the study drug which may be life-threatening. Abiraterone acetate may cause harm to the liver. Fewer than 10% of patients who took the study drug have had abnormal blood levels of liver enzymes. Rarely, liver failure may occur, which can lead to death. Pausing or ending the treatment helped to make liver function normal again in most of these cases. Your liver function will be checked closely with blood tests every two weeks for the first 3 months of the study and then monthly after. If your liver tests are abnormal, the dose of your study drug will be reduced or stopped. Abiraterone acetate should be used carefully in patients with a history of heart disease. Before treatment with the study drug, high blood pressure must be

PROPOSED EFFECTIVE 08/01/2013

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controlled and low potassium must be corrected. Potassium is needed for proper function of your heart, and other important body systems.

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

Risks and side effects related to the abiraterone acetate include those which are:

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

- hypokalemia (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 <20%) [May occur between 10 and 19 patients in 100]

- edema peripheral (swelling of the legs as a result of the body keeping too much fluid)

Common (≥ 5% to <10%) [May occur between 5 to 9 patients in 100]

- dyspepsia (uncomfortable feeling in upper belly, indigestion)
- hematuria (presence of blood in the urine)
- Alanine aminotransferase increased and/or aspartate aminotransferase increased (enzymes in the blood that measure the function of the liver)
- urinary tract infection
- fractures (a break in the bone)

Less Common (≥1% to < 5% [May occur in fewer than 5 patients in 100]

- hypertriglyceridemia (high levels of fats (triglycerides) in the blood)
- angina pectoris (chest pain from the heart)
- atrial fibrillation (a fast and irregular heartbeat)
- tachycardia (rapid heartbeats)

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

- adrenal insufficiency (decreased function of adrenal glands that normally help maintain blood pressure, balance minerals and fluid in your body)
- cardiac failure (heart failure, the heart is unable to supply enough blood flow to meet the body's needs.)
- arrhythmia (changes in the rhythm of the heart)
- abnormal ECG with QT prolongation (an abnormal finding on the ECG)
- bone density decreased (loss of strength of bones)
- myopathy (muscle weakness and/or muscle pain)

Unknown (frequency isn't determined since data was derived from post-marketing experience and there was no report from clinical studies)

- allergic alveolitis (swelling and irritation of the lung)

CLOSED EFFECTIVE 08/01/2013

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- failure of the liver to function (called acute liver failure).
- Rhabdomyolysis (breakdown of muscle tissue)
- Torsades de Pointes (rapid or irregular heart rate associated with feeling faint or lightheaded)

Possible adverse effects associated with the use of prednisone are: fluid and electrolyte disturbances, congestive heart failure in susceptible persons, hypertension, euphoria, personality changes, insomnia, mood swings, depression, exacerbation of infection (e.g., tuberculosis), exacerbation or symptoms of diabetes, psychosis, muscle weakness, osteoporosis, vertebral compression fractures, pancreatitis, esophagitis, peptic ulcer disease, dermatologic disturbances, convulsions, vertigo and headache, endocrine abnormalities, ophthalmic changes, and metabolic changes. Some patients have experienced itching and other allergic, anaphylactic or other hypersensitivity reactions. Withdrawal from prolonged therapy may result in symptoms of adrenal insufficiency including fever, myalgia and arthralgia.

Reproductive risks: You should not father a baby while on this study and for at least 1 week after you stop taking abiraterone acetate. Based on animal studies, abiraterone acetate may harm the unborn child. Male patients who are receiving abiraterone acetate and who have a partner of childbearing potential are advised to use a method of birth control with adequate barrier protection (e.g. condoms) as determined to be acceptable by your study doctor. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

<u>Handling abiraterone acetate tablets</u>:

This medicine may cause harm to the unborn child if given to 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 of this information to ensure that appropriate precautions are taken.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope abiraterone acetate will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about abiraterone acetate as a treatment for prostate cancer. This information could help future cancer patients.

CLOSED EFFECTIVE 06/6/2013

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

Your other choices may include:

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

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

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- SWOG
- A qualified representative of the manufacturer of abiraterone acetate, Janssen Scientific Affairs, LLC.

A description of this study will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the web site will include a summary of the results of the study. You can search this website at any time.

[Note to Local Investigators: The NCI has recommended that HIPAA regulations be addressed by the local institution. The regulations may or may not be included in the informed consent form depending on local institutional policy.]

CLOSED EFFECTIVE 08/01/2013

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Janssen Scientific Affairs, LLC will supply the abiraterone acetate at no charge while you take part in this study. Janssen Scientific Affairs, LLC will also provide funding for distribution of drug to the participating treatment sites. Janssen Scientific Affairs, LLC does not cover the cost

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of getting the abiraterone acetate ready and giving it to you, so you or your insurance company may have to pay for this.

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

- Abiraterone acetate is not currently approved by the FDA for sale in the United States for your type of prostate cancer. If the FDA approves the sale of this drug for your type of prostate cancer and if the manufacturer chooses to discontinue supplying the drug free of charge for this study, you might be able to get the abiraterone acetate directly from the manufacturer or your pharmacy but you or your insurance company may have to pay for it.
- If there is no abiraterone acetate available at all, no one will be able to get more and the study would close.

If a problem with getting abiraterone acetate occurs, your study doctor will talk to you about these options.

Prednisone, goserelin acetate, leuprolide acetate, and Degarelix are commercially available and will not be provided free of charge.

You will not be paid for taking part in this study.

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

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

CLOSED EFFECTIVE 08/01/2013

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

It is important that you tell your study doctor, _____ *[investigator's name(s)],* if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ *[telephone number].*

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your

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regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ *[name(s)]* at _____ *[telephone number]*.

For questions about your rights while taking part in this study, call the _____ *[name of center]* Institutional Review Board (a group of people who review the research to protect your rights) at _____ *(telephone number).*
[Note to Local Investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]

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

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

1. **Future Contact**
   I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.
   Yes No

Where can I get more information?

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

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

CLOSED EFFECTIVE 08/01/2013

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

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

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Signature

I have been given a copy of all _____ *[insert total of number of pages]* pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant _____

Date _____

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