UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE IN RESEARCH

CC#:125519: Radiologically Guided Biopsies Of Metastatic Castration Resistant Prostate Cancer to Identify Adaptive Mechanisms Of Resistance

This is a medical research study, and you do not have to take part. The study doctors, Eric J. Small, M.D. and Primo Lara, M.D., and their associates from the University of California, San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center and the University of California, Davis (UCD) Comprehensive Cancer Center will explain this study to you. If you have any questions, you may ask the study doctor.

You are being asked to take part in this study because you have castrate-resistant prostate cancer (CRPC) that either recurred or did not respond to treatment.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this study is to better understand how cancer treatment may affect cancer cells. The research will involve genetic, molecular, cellular, and immunologic experiments using blood and tumor specimens. It is hoped that the information gained from these studies will lead to a greater understanding of castrate-resistant prostate cancer and potentially, improvements in cancer treatment.

Stand-Up 2 Cancer is paying for this research. About 300 people will give blood and tumor tissue samples for this research at cancer centers in the United States. About 115 people will be enrolled at UCSF and UCD.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

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 your regular 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. The screening visit will take approximately 1 hour.

- History and physical examination
- Assessment of your ability to perform everyday tasks.
- Review of your laboratory work - while you are participating in this study, the study doctor will routinely review your laboratory results from blood tests that you receive as part of your routine cancer care.
- Blood (about 3-4 tablespoons) will be drawn for the following
    - PSA – if you have had PSA testing recently, you may not need to repeat this test
    - Coagulation – how well your blood clots
    - research tests

- Tumor Biopsy - A doctor will remove a piece of tumor tissue from bone or lymph nodes if it can be obtained. This is called a biopsy. This biopsy involves the use of a small needle which is directed into your tumor site with the guidance of an imaging machine such as a CT or MRI scan. This procedure takes about 30 minutes. You will sign a separate consent form for this procedure. This will be performed in the Department of Radiology.
- Review of imaging scans - while you are participating in this study, the study doctor will routinely review your imaging scans that you receive as part of your routine cancer care.

During the study
If the exams, tests, and procedures show that you can participate in the study, and you choose to take part, then you will need the following tests and procedures during the study.

- Every 3 months, you will return to the clinic for a blood draw. Your clinic visits will take less than 15 minutes. Blood (about 1-2 teaspoons) will be collected to monitor your PSA levels.
    - At month 3, additional blood (about 3 tablespoons) will be collected for research tests.
- At the time that your cancer progresses, you withdraw from the study, or the study is closed, you will be asked to return to the clinic for the following procedures. The visit will take approximately 1 hour.
    - Blood (about 3-4 tablespoons) will be drawn for the following
        - PSA
        - Coagulation – only if you agree to have the optional tumor biopsy
        - research tests
    - Tumor Biopsy (you will sign a separate consent form for the Dept. of Radiology on the day of your procedure):
        - *Optional*: If you enrolled in the study after starting androgen receptor (AR) targeted therapy (such as abiraterone acetate or enzalutamide), and if you agree, the researchers would like to remove another piece of tumor tissue from bone or lymph nodes, if it can be obtained. Please see description of procedure above. This is discussed in the *About Using Tissue for Research* section of this consent form.

          Required: If you enrolled in the study prior to starting androgen receptor (AR) targeted therapy (such as abiraterone acetate or enzalutamide), a biopsy of tumor tissue is required, if it can be obtained. The reason for this is to understand changes in your cancer's characteristics that occur while you are receiving treatment. Although this biopsy is required by the study, you can always opt to not undergo a second biopsy.

After your final visit, the study team will continue to follow you through review of your medical records every 3 months for the rest of your life, or until the study closes. Checking on your condition helps us look at the long-term effects of cancer treatments.

Study location: UCSF Helen Diller Family Comprehensive Cancer Center or UCD Comprehensive Cancer Center

HOW LONG WILL I BE IN THE STUDY?

You can take part in this study for as long as your disease does not progress or you receive your cancer care outside of UCSF or UCD, you decide to withdraw your consent to participate in this study or the study is closed. Withdrawing your consent to participate in this study will not affect your medical care/treatment whatsoever, and your doctor will continue to follow you as a patient.

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 your participation safely.

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 ARE THE RISKS OF THE STUDY?

Blood Draws: The risks of drawing blood include temporary discomfort from the needle stick, bruising, and rarely, infection.

Tumor Biopsy risks: The general risks associated with this procedure are pain, discomfort, infection, bleeding and injury to organs nearby.

Radiation (x-ray) risks: The amount of radiation you will be exposed to is relatively small. Such doses of radiation may be potentially harmful, but the risks are so small that they are difficult to measure. If you have had many x-rays, or if you might be pregnant, you should discuss this with the researchers before agreeing to be in this study.

Genetic research risks: Genetic information taken from the blood and tumor tissue specimens (also known as genotype data) for gene expression analysis may be shared broadly in coded form. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Your name will not be used in any published reports from research performed using your specimen.

Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts

about you such as your diagnosis, treatment history, and age. These facts are important because they will help us learn if the factors that cause castration resistant prostate cancer to get worse are the same or different based on these facts. Thus it is possible that study finding could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

Your samples will be given the same code number as your other study information. This code makes sure that no-one handling your samples will be able to identify you. For example, when your sample is sent to laboratories for DNA analysis, the sample may be identified by a randomly-generated bar code number. The link between your coded identification number and the bar code number on your sample is kept in a secure database and is not shared with the laboratories that analyze your sample. Reports about any research will not be given to you or your doctor. The research will not change the care you receive. Your specimen and any information about you will be kept until it is used up or destroyed. It will be used to better understand how the study treatment influences prostate cancer. In some instances these may have potential commercial value. Your personal health information cannot be used for additional research without additional approval from either you or a review committee.

Confidentiality: Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

For more information about risks, ask your study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There is no benefit to you. The blood and tissue specimens will be used only for research. The information learned from this study could help future cancer patients.

DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, you do not have to participate in this study. If you decide not to be in this study you will not lose any of your regular benefits, and you can still receive medical care from UCSF.

WILL MY MEDICAL INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information in your medical record is 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:

- UCSF Helen Diller Family Comprehensive Cancer Center
- UCSF research staff, UCSF's Committee on Human Research
- The National Cancer Institute (NCI) and other government agencies, e.g., the Food and Drug Administration (FDA), involved in keeping research safe for people.
- The University of California

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not be charged for donating your blood and tissue specimens. You will not be paid for donating your specimens. If any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

For UCSF patients, tell the study doctor, Eric J. Small, M.D., if you feel that you have been injured because of being in this research. You can tell the doctor in person or call him/her at 415-353-7171.

For UCD patients, tell the study doctor, Primo Lara, M.D. if you feel that you have been injured because of being in this research. You can tell the doctor in person or call him/her at 916-734-2011.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

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 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 the study doctor about any questions, concerns, or complaints you have about this study. Contact the study doctors, Eric J. Small, M.D., at 415-353-7171 or Primo Lara, M.D., at 916-734-3771.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

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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.

About Using Tissue for Research

If your cancer progresses while you are participating in this research study, your study doctor would like to obtain another sample of your tumor tissue. The biopsy will be similar to the biopsy you have when you first enroll into this study. The biopsy will involve the use of a small needle which is directed into your tumor site with the guidance of an imaging machine such as a CT or MRI scan. This procedure takes about 30 minutes. You will sign a separate consent form for this procedure. This will be performed in the Department of Radiology. The tissue will be used in experiments to better understand how cancer treatment may affect cancer cells.

Additionally, after tests are completed on your blood and tumor tissue specimens, we would like your permission to keep any remaining specimens for possible use in future research studies. Reports from future research done with your blood and tissue specimens will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

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

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

For UCSF patients -	For UCD patients -
Dr. Eric Small	Dr. Primo Lara
1600 Divisadero Street, 3rd Floor, Box 1711	4501 X St., Suite 3016
San Francisco, CA 94115	Sacramento, CA 95817

In the future, other investigators may need to ask to use your samples. While the study doctor may give them reports about your health, he will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

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

Benefits
The benefits of research using tissue include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks
The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Making Your Choice
Please read the sentence below and think about your choice. After reading the sentence, put your initials in the "Yes" or "No" box. If you have any questions, please talk to your doctor or nurse, or call our research review board at 415-476-1814.

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

1. *I agree to the additional tumor biopsy.*

YES	*NO*

2. My left-over samples may be kept for use in for future research.

YES	*NO*

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent
Date	Witness (only required if the participant is a non-English speaker)