IRB NUMBER: 14-15544
IRB APPROVAL DATE: 09/13/2022
IRB EXPIRATION DATE: 09/12/2023

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

CC#145512 Gallium-68 Citrate PET to Detect MYC Amplification in Metastatic Castrate Resistant Prostate Cancer

This is a medical research study. Your study doctors, Rahul Aggarwal, MD and Spencer Behr, MD, and their associates from the Departments of Medicine and Radiology and Biomedical Imaging at the University of California, San Francisco will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study investigator.

You are being asked to take part in this study because you are a patient with metastatic prostate cancer whose tumor has grown despite hormonal therapy. Metastatic means the cancer has spread to areas of your body outside of your prostate.

Why is this study being done?

The purpose of this study is to develop new techniques to image prostate cancer metastases and to detect whether a certain protein called MYC is promoting tumor growth. Ultimately we hope to apply these imaging techniques to help guide treatment decisions and monitor disease status for patients with prostate cancer.

Gallium citrate PET has been used in prior studies to image patients with suspected sites of infection. It is not approved as a standard imaging test for patients with prostate cancer.

This study is being funded by the Department of Defense, the Prostate Cancer Foundation, and UCSF research funds.

How many people will take part in this study?

Approximately 50 patients with prostate cancer will participate in the current study.

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

If you agree to participate on this study, you will be asked to participate in a PET scan using gallium citrate injection. You also have the option of undergoing optional tumor biopsy under the study CC#155518 “Precision Oncology and Molecular Targeting in Advanced Prostate Cancer: Identifying Predictive Markers of Response (The ‘PROMOTE’ Study)”, in which you will undergo a tumor biopsy following your gallium citrate PET scan. Prior to the PET scan, you will be asked a number of questions concerning your health and you will be asked to undergo standard of care staging scans including CT or MRI scan and bone scan. Your study doctor will go over the procedures required in the study CC#155518 described above.

You will also have the option of undergoing a second gallium citrate PET scan within 12 weeks following the first scan, to evaluate for response to treatment for your prostate cancer.

If you give your consent to be in this study by signing this form, you will have tests and procedures (called "screening") done. These are done to reduce the risks of taking part in this study and to make sure it is okay for you to be in the study.

It is possible that after these tests are reviewed, you will not be able to be in the study. There may be other reasons why you cannot be in this study. These reasons will be discussed with you by your study doctor or the clinic staff.

Screening (before you begin the main part of the study)

After you have signed this consent, the screening tests listed below will be done within 42 days before you receive the imaging scan. You will need to have the following exams, tests or procedures to find out if you can be in the main part of the study. Most of these exams, tests or procedures are and are part of your regular cancer care (unless notes otherwise as Research Purposes). If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

The total time to complete the screening tests and procedures is about 8 hours. The screening procedures do not have to be completed in one day and you are allowed to take breaks if you have multiple procedures in one day.

- A complete medical history and your current medical condition will be collected including information about your current health status and medications that you are taking (including over-the-counter medications and supplements)
- Physical Examination
- Questions about how your disease is affecting your daily life.
- Vital signs (blood pressure, heart rate, temperature), height and weight

To measure your disease, you will have one or more of the following tests done (these scans must be completed within 12 weeks of Day 1 of the study):

- **CT and/or MRI scan of the abdomen and pelvis (chest only if medically necessary)**:

  A **CT scan** is a radiological test that uses special x-ray equipment to make detailed pictures of body tissues and organs. For the CT scan, you may be given a "contrast material" (a special dye that makes it easier for doctors to see different tissues in your body). The contrast material may be given orally or intravenously. Oral contrast material is given to you to drink and is used to help outline the stomach and intestines. Intravenous (IV) contrast material is given to you by injecting the contrast material into a line which is attached to a needle in your arm, and is used to get clearer pictures of your body cavity. After you have been given the contrast material (either by mouth, by vein), you will lie flat on a table that will move you into the CT scan machine. You will be asked to lie still and may be asked to hold your breath for a few seconds. Each CT scan will take about 15 minutes to a half hour.

  If a CT scan cannot be performed, an **MRI scan** will be performed. An MRI scan takes an image of your body to observe the location and size of your tumor. For the MRI scan, you may be given a "contrast material" (a special dye that makes it easier for doctors to see different tissues in your body). Gadolinium is contrast material that causes some tumors to appear much brighter than normal tissue on MRI scans (these tumors may not be visible without gadolinium). The contrast material may be given to you in your arm through an intravenous catheter (a tiny tube inserted

into a vein). You will then lie down on a narrow bed which will be placed in a tunnel that is 6 feet long by 22 inches wide and open at each end. You will lie there quietly for about one hour, during which time you will hear a loud machine-like noise. The MRI scan is done in the Radiology Department and takes approximately an hour and a half to complete.

- **Bone scan if medically necessary**

  A bone scan is a test that makes detailed images of your bones and any tumors on them. Before the bone scan a small amount of radioactive substance is injected into your vein. About 3 hours later you will lie on a table under a machine which will make an image of your bones. The test itself will take about 1 hour, but the whole process takes up to 4 hours.

During the main part of the study:

You will need the following tests and procedures.

Day 1 – Imaging:

This visit will take up to 6 hours

The following procedures will be done for research purposes:

Gallium citrate PET scan (research test): It is a special type of test to show activity of the cells in your tumor. Your PET scan will begin with an injection of a radioactive substance into a vein in your arm. After a period between 1 to 6 hours, during which time you are free to move about, you will be positioned within the CT or MR scanner. Once positioned properly, the bed will move you into the scanner. As pictures are being taken, you will be asked to remain very still so clear images will be taken. The imaging time takes about 45 minutes. It is possible that the radiologist may ask you to complete a second whole body scan at the same visit. This second scan would also take approximately 45 minutes. You do not need to fast prior to the scan or the gallium citrate injection.

Blood sample (OPTIONAL): If you agree to it, a blood sample will be drawn by inserting a needle into a vein in your arm (~4 tablespoons). This test will be done toto detect the MYC gene in your circulating tumor DNA. You can decide whether or not to participate in this optional research study at the end of the consent form.

Within 42 days of the baseline gallium citrate PET:

You will have the option of having a tumor biopsy

The following procedures will be done for research purposes:

Tumor Biopsy: A fresh tumor biopsy is performed to obtain a small piece of tumor tissue using a special needle. This procedure will be done at the site where we can most easily get a piece of the tumor and the biopsy can involve the lungs, liver, bone, lymph node, skin or other. The biopsy needle will be inserted into tumor tissue and a small piece of the tumor will be removed. 1-3 passes with this needle will be made. This procedure takes about 30 minutes. You will sign a separate consent form for this procedure.

Within 12 weeks of the baseline gallium citrate PET:

You will have the option of undergoing a second gallium citrate PET scan to assess response to treatment for your prostate cancer. The timing and procedures for the scan will be identical to those listed above for the first gallium citrate PET scan.

How long will I be in the study?
The PET scan will take a total of about one to two hours. If you elect to undergo subsequent tumor biopsy, this will be completed within 2 weeks following the PET scan.

Can I stop being in the study?
Yes. You can decide to stop at any time. A 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 serious. Many side effects go away soon after the scan has been performed. In some cases, side effects can be serious, long lasting, or may never go away. You should talk to your study investigator about any side effects you experience while taking part in the study.

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

- **Blood drawing (venipuncture) risks:** The risks of drawing blood include temporary discomfort from the needle stick, bruising, and rarely, infection.

- **Radiation risks:** This study involves exposure to radiation from routine CT x-ray and bone scan. In addition, you will have PET scans and an optional CT guided biopsy, which are not necessary for your medical care and are for research purposes. This amount of radiation may involve a low risk of cancer. However, we believe that this risk, given your overall medical condition is not clinically relevant. If you have any questions regarding the use of radiation or the risks involved, please consult your study doctor.

- **CT scan risks:** CT scans involve the risks of radiation. In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction. The allergic reaction can be mild (itching, rash) to severe (difficulty breathing, shock, or rarely, death). The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The study doctors will ask you about any allergies or related conditions you may have before the procedure is done. If you have any of these allergies or conditions, you may not be allowed to have a CT scan in the study.

  Having a CT scan may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia when placed inside the CT scanner, or by lying in a still position for a long time. If contrast material is used, you may feel discomfort when it is injected into your body. You may feel warm and flushed and/or get a metallic taste in your mouth. Rarely, the contrast material may cause nausea, vomiting or a headache.

- **MRI risks:** Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which in the process could possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI.

  Having an MRI may mean some added discomfort for you. In particular, you may be bothered by

feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear ear plugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.

Contrast agent (gadolinium) risks: A few side effects of gadolinium injection such as mild headache, nausea, and local pain may occur. Rarely (less than 1% of the time) low blood pressure and lightheadedness occurs. This can be treated immediately with intravenous fluids. Very rarely (less than one in one thousand), patients are allergic to gadolinium. These effects are most commonly hives and itchy eyes, but more severe reactions have been seen which result in shortness of breath.

Patients with severe kidney disease sometimes have a bad reaction to gadolinium contrast. The condition is called nephrogenic systemic fibrosis (NSF). It can cause skin to tighten or scar and can damage internal organs. Sometimes it can be life-threatening. There are no reports of NSF in patients with normal kidney function. Before you have a MRI scan requiring an injection of gadolinium contrast, you will have a blood test in order to check the function of your kidneys. Based on your medical history and the results of the test, a doctor will decide whether it is safe for you to undergo the MRI scans.

- **Bone scan risk**: A bone scan involves exposure to radiation. (See Radiation Risks above). Some people may have a closed-in feeling while under the camera. As in any injection, you may have swelling or bruising at the injection site.

- **Gallium citrate PET scan risk**: The PET scan involves the risks of radiation (see Radiation Risks above). The contrast material (radioactive form of citrate) is used. This substance can be easily eliminated from the body either through radioactive decomposition or excreted through urine.

- **Tumor biopsy risks**: The biopsy has small but serious risks. While we make every effort to minimize the pain related to the procedure, the procedure is usually uncomfortable and sometimes painful. Wherever the biopsy is done in your body, it can lead to bleeding in that area, damage of organs near where the biopsy is done, or infection. While it is uncommon, sometimes bleeding or pain from the biopsy will require you to stay overnight in the hospital or require you to go to the operating room to control any bleeding. We check your laboratory values before the biopsy to make sure that the procedure is as safe as possible and to minimize your chance of having a complication. Additionally, if the biopsy involves the lungs, it can cause the lungs to deflate and if this occurs, you might require treatment to correct this. We try to take as little tissue as possible when we do the biopsy, and this means that sometimes the biopsy procedure can be unsuccessful and require a repeat biopsy to get enough tissue. Other potential risks will be described to you and discussed with you by doctors who conduct these biopsies. If a CT guided tumor localization is necessary, there will be additional radiation exposure. (See Radiation Risks above).

- **Intravenous line:** The temporary placement of an intravenous line may cause discomfort when inserting the needle, as well as bruising; bleeding; and rarely, infection.

- **Unknown Risks:** The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help

doctors learn more about new PET imaging techniques in prostate cancer and it is hoped that this information will ultimately help in the treatment of future patients.

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

Participation in the study is completely optional. You have the option of not taking part in the study or removing yourself from the study at any time. 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
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

How will information about me be kept confidential?

We will do our best to make sure that information about you is kept confidential. If information from this study is published or presented at scientific meetings, your personal information will not be used.

Your signed consent form will be added to your UCSF medical record. If you do not have a UCSF medical record, one may be created for you. The study radiologist will view the PET images confidentially.

There is a possibility that while reviewing your images we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. A qualified person from the research team will talk to you if there is an incidental finding. Unless you otherwise request us not to do so, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

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

- University of California
- 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 Department of Defense may review research records as part of their responsibility to protect human volunteers in research.

What are the costs of taking part in this study?

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

Will I be paid for taking part in this study?

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

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

It is important that you tell your study investigator Dr. Aggarwal 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 [redacted].

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 University of California funding, 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 Institutional Review Board 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 your study doctors about any questions, concerns, or complaints you have about this study. Contact your study doctor(s), [redacted].

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 Institutional Review Board at 415-476-1814.

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OPTIONAL RESEARCH

Please note: This section of the informed consent form is about optional research studies. You can still be a part of the main study, even if you say "no" to taking part in any of these additional studies.

Optional Blood Sample for ctDNA testing

If you agree to it, the study team would like to collect about 4 additional tablespoons of blood on the Day 1 Imaging visit for circulating tumor DNA (a research test). This blood will be used for research purposes to detect the MYC gene in your blood.

Benefits
This test is solely a research test and will not directly benefit you. The data that is collected from doing these tests will not be reported to you.

Risks
Drawing blood may cause temporary discomfort from the needle stick, bruising, and infection.

Sharing Genetic Information
Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. We may give certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to a [insert: public or controlled access] government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you [describe any rare instances that this may occur].

Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. 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. 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. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research 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.

There will be no direct benefit to you from allowing your data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease. If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing at

and any remaining data will be destroyed. However, we cannot retract any data has been shared with other researchers.

Future Research Studies
Your study doctor would like your permission to keep any remaining specimens, after tests are completed on your blood and tumor tissue 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.

Optional Follow up Gallium citrate PET scan

Your study doctor would like to complete a second gallium citrate PET scan to obtain information about how prostate cancer treatments affect the appearance of the PET scan. This second gallium citrate PET scan would be performed within 12 weeks of the first one.

Things to Think About
The choice to have a follow up gallium citrate PET scan 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 remain will no longer be used for research.

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 sentences 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

1. I agree to an optional blood draw on the Day 1 Imaging visit for ctDNA research testing.

YES	*NO*

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

YES	*NO*

3. *I agree to the optional follow up gallium citrate PET scan.*

YES	*NO*

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CONSENT

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

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.

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

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

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