NCT # 02919111

Patient Name: _____
DOB: ____/____/_____
UCSF MRN: _____

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

Evaluation of Gallium-68 HBED-CC Prostate Specific Membrane Antigen (PSMA) imaging in prostate cancer patients

WHAT IS THIS STUDY ABOUT?

This is a medical research study. Your study doctor, [redacted] and his associates from the UCSF Department of Radiology will explain this study to you. Medical research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your friends, family, and health care team. If you have any questions, you may ask your study doctor.

You are being asked to participate in this study because you have been diagnosed with prostate cancer and there is clinical concern that you may have disease out side of the prostate. In this study we will be testing Gallium-68 PSMA PET (Positron Emission Tomography) imaging. PSMA (or prostate specific membrane antigen) is a protein found on most prostate cancers. Ga-68 PSMA is an imaging agent that binds to prostate cancer cells and can be imaged using PET. A PET scan uses a special camera to detect energy given off from radioactive material to make detailed pictures of areas where the Ga-68 accumulates in the body. The PET scan if often combined with an MRI or CT scan, which helps to more accurately map the location of where in the body the radioactive material has collected.

Ga-68 PSMA is an experimental imaging agent that is not yet approved by the US Food and Drug Administration (FDA).

WHY IS THIS STUDY BEING DONE?

The purpose of this study is:

- To determine the ability of Ga-68 PSMA to detect the presence of prostate cancer metastasis.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

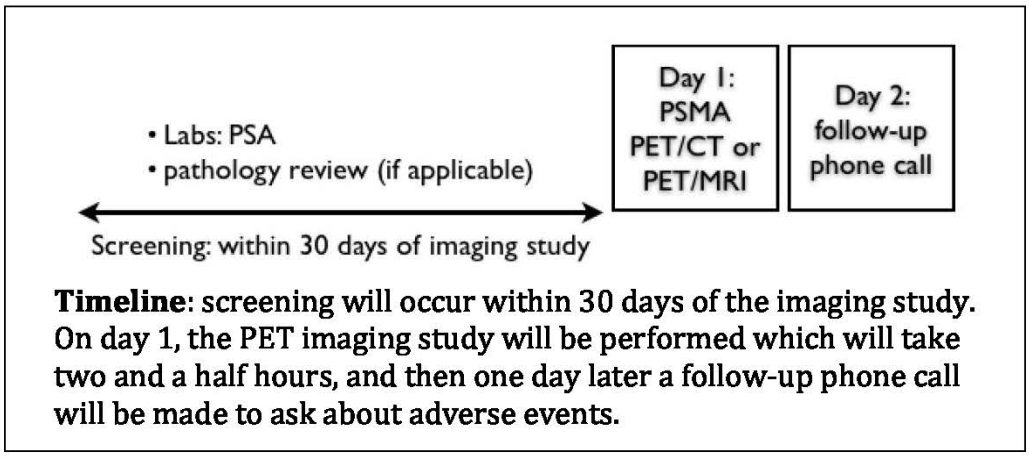
Approximately 1,350 people will be enrolled in this study.

WHAT WILL HAPPEN TO ME IF I TAKE PART IN THIS RESEARCH STUDY?

Before you begin the study...

To find out if you can be in the study, the following procedures with occur:

- **Medical chart review:** Your medical chart will be reviewed by the study doctors.



Timeline: screening will occur within 30 days of the imaging study. On day 1, the PET imaging study will be performed which will take two and a half hours, and then one day later a follow-up phone call will be made to ask about adverse events.

During the main part of this study...

If the screening procedures show that you can continue to be in the study, and you choose to take part, then you will have the following tests and procedures done. All study procedures will be done at UCSF China Basin Imaging Center in San Francisco, California, during a single study visit.

- **Gallium-68 HBED-CC PMSA administration**: A venous catheter will be placed in your arm, and the Ga-68 PSMA will be given by intravenous (IV) injection.
  - Your infusion will take about 1-2 minutes.

- **PET Imaging**: A PET scan will be done around 60 minutes after the injection of the Gallium-68 HBED-CC PSMA imaging agent. The pictures taken will allow researchers to look for tumors cells that accumulate the imaging agent. If you need it, you can get some medication from your referring provider, such as lorazepam (Ativan), to keep from feeling anxious or nervous during the scan. During imaging you will be asked to lie still and may be asked to hold your breath for a few seconds.
  - At the time of receiving the imaging agent, you may be given Lasix through your IV. If you have known allergies to sulfa containing medications, please tell your study doctor as you may have an allergic reaction to Lasix. Lasix is administered in order to clear you urinary system and will make you urinate.

You will feel the urge to urinate soon after administration. Patients who cannot tolerate Lasix will not receive Lasix, and will be asked to drink water.

- *Imaging will be performed by either PET/CT or PET/MRI*:
  - ☐ **PET/MRI imaging**:
    - Imaging will be performed using a PET/MRI, which will take 50 to 60 minutes to complete. Prior to the PET/MRI scan you will be asked to remove all metal from your clothing, pockets, shoes, and person. You will be asked to wear clothing compatible with the PET/MRI environment. You will be provided with earplugs or headphones that you must wear during the entire scan. Protective padding will be placed between your body and the inner walls of the scanner. During the scan you will hear loud sounds that are a normal part of the scan.
    - For PET/MRI you may receive a gadolinium based contrast agent (dye). Intravenous (IV) contrast material is given to you by injecting the contrast material into a line that is attached to a needle in your arm, and is used to get clearer pictures of your body cavity.
  - ☐ **PET/CT imaging**:
    - Imaging will be performed using a PET/CT, which will take 30 to 40 minutes to complete. Imaging of your whole body will be obtained. During imaging you will lay flat on a table inside the PET/CT machine.
    - For PET/CT you may receive an iodinated contrast agent (dye). Intravenous (IV) contrast material is given to you by injecting the contrast material into a line that is attached to a needle in your arm, and is used to get clearer pictures of your body cavity. It is standard of care at UCSF to receive iodinated contrast with a PET/CT.

You will be contacted by phone one to three days after the study to determine if you experienced any adverse events. If a node near the prostate was noted on imaging with PSMA PET and the node was not removed at surgery, you will be reimaged using CT in order to determine if the abnormal node was removed. We will reimage you because it is important to determine if the abnormal node was removed or not in terms of additional treatment planning as well as helping determine the accuracy of the PSMA imaging study. Additionally, you may be imaged using CT or MRI 6-12 months after PSMA imaging to see if your tumors change in size on therapy. For some participants, your referring clinician will be contact before and after the PSMA imaging study to complete surveys to help us understand the impact of PSMA PET on your care. Finally we will review your medical records and follow-up imaging after the PSMA PET to determine the accuracy of the imaging study.

HOW LONG WILL I BE IN THE STUDY?

Screening will take place within 30 days of the study. The imaging and follow-up phone call will take two days or until you decide to withdraw your consent for participation in this

study. The imaging day will take roughly three hours to complete. 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. You can stop taking part in this study at any time. If you decide to stop taking part in the study, we encourage you to talk to your medical team first.

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 SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

You may have side effects while on the study. Every one 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. Your health care team may give you medicines to help lessen side effects. You should talk to your study doctor about any side effects you experience while taking part in the study. There also is a risk of death.

Risks and side effects related to Gallium-68 HBED-CC PSMA administration include:

- **Transient nausea and diarrhea**: patients have reported developing nausea and diarrhea after injection of Gallium labeled compounds. In all cases this has resolved without intervention within 45 minutes.
- **Radiation risks**: This research study involves exposure to radiation Gallium-68 HBED-CC PSMA administration. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately 6.1 mSv, which is slightly more than 2 times the yearly natural background of radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation may involve a low risk of cancer. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.
- **Placement of venous catheter**: The placement of a venous catheter is associated with the development of bruising and infection. It may also be associated with a risk of bleeding.

Risks and side effects related to the imaging procedures:

- **PET/MR scan risks (*MRI imaging only*)**: MR imaging is safe; but accidents, injuries, and deaths have occurred during MRI procedures. These events are rare, especially if appropriate safety precautions are followed. More specifically:

- **Metallic objects**: Study staff will determine if it is safe for you to enter the PET/MRI environment. It is extremely important that you answer their questions completely.
- **Heating and burns**: In order to minimize the chances of warming or burns, padding will be placed between you and the bore wall of the magnet.
- **Tingling sensation**: Discomforts associated with certain PET/MRI scanning techniques may include a temporary tingling sensation in certain parts of the body including, but not limited to, the arms, legs, fingertips, and nose. This sensation is not expected to last long and is typically not painful.
- **Noises**: Discomforts associated with certain PET/MRI scanning techniques may include listening to loud noises made by the scanner during the scanning procedure. You will be provided with earplugs to minimize the noise. If the noise is uncomfortable for you, please ask the PET/MRI Scan Operator to discontinue the scan.
- **No know effects adverse effects of magnetic fields**: There is no evidence in scientific literature that individual or even frequent repeated exposures to high static magnetic fields poses a health concern.

- **MRI contrast administration (*MRI imaging only*)**: Intravenous contrast will be administered through the venous catheter during the PET scan. The most common adverse reactions are nausea, feeling "hot", headaches and abnormal tastes. These agents also have known rare risks that severe allergic reactions and a disease called nephrogenic systemic fibrosis (NSF). NSF can be prevented by not administering gadolinium based contrast agents to patients with renal disease. Your renal function will be checked, and the agent will not be administered if you have renal disease.
- **CT contrast administration (*CT imaging only*)**: Contrast material (iodine dye) is associated with a slight risk of developing an allergic reaction, from 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 before the procedure. If you have any of these problems or severe kidney disease, you may not receive contrast material as part of the study.
- **CT radiation risks (*CT imaging only*)**: Imaging using a PET/CT adds additional radiation dose to the imaging study. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately 4.5 mSv, which is less than 2 times the yearly natural background of radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation may involve a low risk of cancer. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.
- **Detection of new lesions and incidental findings**: The Ga-68 HBED-CC PSMA imaging may detect previously unknown lesions. A report will be created describing the imaging findings and will be added to your medical record. New unexpected

findings may affect your care, and your referring clinician will discuss the results of this imaging study with you. These findings may lead to additional and unnecessary biopsies.

- **Unknown Risks**: The experimental imaging 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.

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

ARE THERE BENEFITS TO BEING IN THE STUDY?

There may be a medical benefit to you. The information obtained from the Gallium-68 PSMA imaging may provide additional information about sites of your disease compared to conventional imaging agents. Your images will be reviewed by a radiologist and nuclear medicine physician and a report will be sent to your referring clinician. These images will be available to your treating physician, and will be used in addition to conventional imaging studies to make clinical decisions. Additionally, the information learned from this study may benefit other patients with prostate cancer in the future by improving the quality and availability of imaging agents.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

You can chose to not enroll in this study. In this case you may be staged using standard of care imaging including CT, MRI, PET/CT and/or bone scans.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

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 privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. 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 UCSF Committee on Human Research
- The UCSF Helen Diller Family Comprehensive Cancer Center

- The University of California
- The National Cancer Institute (NCI) and other governmental agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people.
- The Society of Nuclear Medicine and Molecular Imaging

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. The cost of the imaging study will be charged to you or your health plan/insurance company, with an estimated cost of $6,000 for PET/MRI and $4,000 for PET/CT. Prior to the study being performed, your health plan/insurance company will be contacted to attempt to obtain preauthorization. If insurance authorization is not obtained, you will have the option to pay out of pocket for the imaging component of the study or undergo the standard of care imaging, which is likely to be covered by insurance. You will be notified of the insurance company pre-authorization decision prior to the imaging study taking place. If you have any questions in regards to billing and authorizations, please contact the radiology billing office[redacted]

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.

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 doctor, Dr. Thomas Hope, if you feel that you have been injured because of taking part in this study. You can contact your study doctor in person or by phone at [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 the University of California, depending on a number of factors. The University and the study sponsor do 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 your study doctor about any questions or concerns you have about this study. Contact your study doctor, [redacted] or his research associates, at [redacted]

For questions about your rights while taking part in this study, call the UCSF Committee on Human Research (a group of people who review the research to protect your rights) at (415) 476-1814.

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