NCT# 03007719

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

Study Title: **CC# 16709 Functional imaging of T-cell activation with [^{18}F]F-AraG in urothelial carcinoma patients receiving neoadjuvant therapy or patients with cancer receiving standard of care anti-PD-1/L1**

This is a medical imaging research study. Your study doctor Lawrence Fong, MD or one of his associates from the Helen Diller Family Comprehensive Cancer Center, UCSF Department of Interventional Radiology, or Genitourinary Medical Oncology will explain this study to you.

Medical research studies only include people who choose to take part. Please 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 doctor.

You are being asked to take part in this imaging study because you are either you are participating in a separate UCSF phase 2 clinical trial of neoadjuvant atezolizumab before definitive surgery (IRB# 14-15423, NCT02451423) for your localized bladder cancer or you are planning to start treatment with an anti-PD-1 or anti-PD-L1 medication for your locally advanced or metastatic cancer as part of standard medical care for your cancer.

Why is this study being done?

The purpose of this study is to investigate changes in your cancer's anti-tumor immune response (or activation of T-cell) levels before and after receiving an imaging tracer called [^{18}Fluorine]F-AraG during whole-body Positron Emission Tomography/Magnetic Resonance (PET/MR) imaging. The investigators are studying the ability of the imaging tracer to serve as a biomarker (or a predictor) of clinical response for how well patients can benefit from receiving immunotherapy, such as anti-PD-1 or anti-PD-L1.

In this study, your body will be scanned at two defined time points in a PET/MR machine to produce 3-D images of both the physiology (functioning) and anatomy of the body. These images are produced using [^{18}F]F-AraG, a radioactive substance (or tracer), injected through the vein in the arm. The images will capture how the tracer moves through the body and where it accumulates at different time points before it clears from your system.

[^{18}F]F-AraG is an imaging agent that has not been approved for routine clinical use by the United States Food and Drug Administration (FDA) and is therefore, an "investigational" use in this study.

Cellsight Technologies, Inc., the manufacturer of the imaging tracer, [^{18}F]F-AraG, is providing the tracer at no cost to you. The study is also funded by Genentech Inc. and an internal departmental fund to support the investigators.

How many people will take part in this study?

A total of 31 patients will be enrolled in this study; 12 patients will be enrolled into the neoadjuvant atezolizumab cohort or "Cohort 1" and 19 patients will be enrolled in the standard of care (SOC) anti-PD-1 or anti-PD-L1 cohort or "Cohort 2."

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

You will be placed in Cohort 1 if you are receiving or plan to receive neoadjuvant atezolizumab in the UCSF phase 2 clinical trial #14-1523 or Cohort 2 if you plan are receiving or plan to receive an anti-PD-1 or anti-PD-L1 medication as part of standard medical care. Only anti-PD-1 or anti-PD-L1 medications that are FDA approved for a given cancer will be used for participants in Cohort 2.

Cohort 1 patients treated with neoadjuvant atezolizumab as part of the companion Phase 2 trial of non-metastatic bladder transitional cell carcinoma (NCT02451423) will undergo whole body PET/MR imaging with [^{18}F]F-AraG at two time points: 1) within 7 days of initiating atezolizumab and 2) within 7 days before scheduled surgery. After each imaging time point, the study doctor will follow-up by telephone one day after the imaging and again, one week after the imaging to check on any side effects you may have.

Cohort 2 patients treated with standard of care anti-PD-1 or anti-PD-L1 will undergo whole body PET/MR imaging with [^{18}F]F-AraG at two time points: 1) within 7 days of initiating Cycle 1 of anti-PD-1 or anti-PD-L1 and 2) between Day 15 of Cycle 1 and Day 7 of Cycle 2 anti-PD-1 or anti-PD-L1. After each imaging time point, the study doctor will follow-up by telephone one day after the imaging and again, one week after the imaging to check on any side effects you may have.

At each imaging time point detailed above, an injection of [^{18}F]F-AraG will be given followed by up to 2 whole-body PET/MR scans.

Before you begin the main part of the study...
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. 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.

All procedures must be done within 28 days prior to the start of the first imaging appointment, unless otherwise noted. Patients in Cohort 1 do not need to repeat some of these screening tests if they have already been completed for eligibility on the companion Phase 2 trial.

Screening
This visit will take about 5 hours (or up to 8 hours if baseline tumor imaging is done).

- **Consent** to participate in this study

- **Health and medical history**
- **Physical exam**
- **Vital Signs:** Measure your blood pressure, temperature, pulse, breathing rate, and oxygen saturation; including height and weight.
- **Performance status:** Ask you how well you can do the regular activities of daily life
- **MRI screening:** You will be asked to fill out a MRI screening form.
- **Baseline tumor imaging: CT** chest, abdomen, pelvis, head, and/or neck with contrast (or **MRI** scan of the abdomen/pelvis with or without a **bone scan**) to assess your disease activity. These baseline tumor imaging exams can be completed within 42 days prior to the start of the first imaging study or on the day of, if the study doctor determines this is safe.
    - **A CT scan** 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 (via your mouth), intravenously (via a needle in your vein), or rectally (via your anus, which is less likely). 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. If necessary, rectal contrast fills up the loops of your lower bowel so the doctors can see your tumor better. After you have been given the contrast material (either by mouth, by vein, or rectum), 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. The CT scan is done in the radiology department and takes about half an hour.
    - 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.
    - 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, technetium 99m, 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.
- **Collect urine** sample to check for safety factors
- **Collect blood** samples (about 2 tablespoons) for:
    1. Routine safety tests
        a. Measuring the chemical parts of your blood (called biochemistry)

b. Counting the number of white and red blood cells and platelets (called hematology)

2. Pregnancy test for women of childbearing potential

- **Tissue collection**
  - Collection of leftover, "archival" tissue from a previous tumor biopsy or resection (including transurethral resections for patients with bladder cancer), if available.
  - If archival tissue is not available, extra tumor tissue obtained during a biopsy procedure done as part of your regular care (if indicated) can be used for this study. This means that the needle inserted during the biopsy procedure may be re-inserted to collect additional tissue for this study. 1-3 passes with this needle will be made. This procedure will be done at the site where we can most easily get a piece of the tumor. The tissue biopsy is used to examine the immune response and genetic changes in the tumor. This procedure takes about 30 minutes. If a biopsy procedure is not needed for your regular care, then we will not collect additional tumor sample for this study.

During the main part of the study...

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

The following assessments will be performed at each imaging time point 1) within 7 days of initiating atezolizumab/anti-PD-1 or anti-PD-L1 (for both Cohort 1 and Cohort 2) and 2) within 7 days before scheduled surgery (if Cohort 1) or between Day 15 of Cycle 1 and Day 7 of Cycle 2 anti-PD-1 or anti-PD-L1 (if Cohort 2). Each imaging appointment will take approximately 6 hours.

- **Vital signs** recorded before and after imaging
- **Electrocardiogram (ECG)** before and after imaging: records the electrical activity of your heart. Wires or "leads" will be attached to your chest with an adhesive and you will be asked to lie still while the machine prints out an electrical "record" of your heart activity. The procedure is done in the Cardiology Department and takes about 15-30 minutes.
- **Furosemide (Lasix) intravenous administration**:
  - The imaging tracer, [^{18}F]F-AraG is processed through your kidneys and taken up in the urine which decreases the resolution or sharpness of the images. In order to prevent this, you will intravenously receive 20 mg of furosemide (Lasix), a diuretic, within 10-30 minutes before receiving the tracer injection, and encouraged to drink 16oz of water approximately 30 minutes before Lasix administration.
  - You will then be asked to void 30 to 45 minutes after Lasix administration. A urinary catheter may be placed if there is difficulty with voiding.
- **[^{18}F]F-AraG PET/MR imaging:**
  - You will lie down on a narrow bed, which will then be placed in a tunnel that is about 6 feet long and open at each end. You will receive an injection of [^{18}F]F-AraG through an intravenous catheter (IV) and will be asked to remain still during the PET/MRI scans. You may have up to 2 whole-body PET MRI scans and after

the first whole-body scan, a repeat 3 minute tumor image will be done. You will have the opportunity to get up after each scan for a short break.
- The total scan time will take approximately 1hr and 30 minutes, but can last up to 3 hours.

When you are finished with the imaging portion of the study...

There will be a telephone follow-up the day after (day 2) and a week after (day 8) each imaging appointment to record any side effects you may experience. These telephone follow-ups will take approximately 10-15 minutes each.

Study location: All study procedures will be done at both the UCSF China Basin Imaging Center and at Helen Diller Comprehensive Cancer Center at Mission Bay, Mt. Zion, and Parnassus.

The study calendar on page 15 outlines the study tests and procedures and when (marked with an 'X') they are expected during the course of the study.

How long will I be in the study?

Participation in this study will take a total of 16 days.

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.

It is important to tell the study doctor if you are thinking about stopping so that your study doctor can evaluate any risks from the study procedures.

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 study procedures. In some cases, side effects can be serious, long lasting, or may never go away.

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

Side effects from [^{18}F]F-AraG PET/MR imaging

[^{18}F]F-AraG PET/MR imaging had been performed on six healthy volunteers, and none had serious side effects. The only side effect that was seen in more than one volunteer was positive white blood cell (WBC) esterase in the urine without urinary symptoms, and was therefore not clinically significant.

Risks related to study procedures:

Blood drawing (venipuncture) risks: Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

Collection of archival (left-over) tumor tissue: There are no risks associated with collecting the left-over samples from a scheduled tumor resection or biopsy. The samples will only be collected after the tumor tissue has already been removed from your body from a procedure you are already scheduled to have. This will not change or impact the risk of the procedure or surgery you are going to have or have already had.

Electrocardiogram (EKG/ECG): The ECG involves placing electrodes on the skin. You may experience an allergic reaction to the adhesive used to attach the electrodes to the skin. These symptoms are generally mild and clear up on their own. Please let your doctor know if you are aware of any allergies.

Urinary catheter risk: A urinary catheter is a tube that is placed through your urethra to empty your bladder. You may experience temporary discomfort. Although unlikely, insertion of this catheter can lead to trauma, bleeding and an increased risk of infection.

Intravenous catheter: A needle will be used to inject the imaging tracer, [^{18}F]F-AraG, into your vein. Although unlikely, insertion of the needle may cause pain or a stinging, bruising, bleeding, a blood clot, and leakage of study tracer or infection.

Radiation risks: This research study involves exposure to radiation from [^{18}F]F-AraG PET/MRI. This radiation exposure is not necessary for your medical care and is for research purpose only. The additional amount of radiation that you will receive as a result of participation in this study will be less than the yearly natural background radiation in the US (3mSv). The use of radiation involves minimal risk and is required to obtain the desired research information. IF you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the study doctor conducting the study.

CT scan risks: CT scans involve the risks of radiation (see above). In addition, if contrast material (iodine dye) is used, there is 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, you may not be allowed to have a CT scan with contrast.

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 one position for a long time. If contrast material is used, you may feel discomfort when it is injected *by vein*. You may feel warm and flushed and get a metallic taste in your mouth. Rarely, the contrast material may cause nausea, vomiting or a headache.

PET risks: The PET-CT involves exposure to radiation. The radiation exposure comes from a tracer which is a radioactive chemical injected into a vein in your arm. The tracer lets the doctor see how your cells are functioning. As with all injections, it may feel like a small sting and there may be possible bruising at the injection site. For some patients, having to lie still on the scanning table for the length of the procedure may cause some discomfort or pain. The radioactive solution does not remain in your system for a long period of time. See Radiation Risk.

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.

Because the risks to a fetus from MRI are unknown, pregnant women must not participate in this study.

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 on 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: The bone scan involves exposure to radiation. The bone scan involves an injection, in a vein in your arm, of a radiotracer (radioactive compound that localizes in the bone). As with all injections, it may feel like a small sting and there may be possible bruising at the injection site. You may become uncomfortable lying still for the duration of the examination. See Radiation Risks

Incidental findings: Although the imaging scans and procedures you will have in this study are being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. In the event that your scans reveal any potential health concerns, your images may be referred to a qualified UCSF clinician. If it is discovered that you have any incidental findings that require follow-up, the study doctor or a member of the UCSF clinical staff may contact you.

Reproductive risks: You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important to understand that you need to use birth control while on this study. 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.

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.

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

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 [^{18}F]F-AraG PET imaging. [^{18}F]F-AraG PET imaging performed in animals indicated that it is very specific in localizing activated T cells, a type of immune system cell in the body. It is hoped that the information from this study will help with expanding imaging of antitumor immune responses, which would be very useful in developing treatments for a wide variety of cancers and other diseases.

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

Your other choice is to not participate in this study.

How will information about me be kept confidential?

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:

- Cellsight Technologies, Inc.
- Genentech, Inc.
- The 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.

What are the costs of taking part in this study?

Some of the services you will receive are being done only because you are participating in this research study. Examples of these 'research only' services include: review of side effects, Lasix administration, [^{18}F]F-AraG imaging, and EKGs. Those services will be paid for by the study and will not be billed to you or your health insurance company. If you believe you have received a bill for a research related procedure contact the study team and the UCSF Medical Center office that sent the bill.

In addition, some of the services you will receive during this research study are considered to be "routine clinical services" that you would have received even if you were not participating in the research study. Examples are physical exams, baseline tumor imaging, and screening lab tests. These services will be billed to your health insurance company, and you will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs. Before you agree to be in this study, you may want to contact your healthcare payer/insurer to see if your plan will cover the costs required as part of your participation. You may request more information about the costs of participating in this study and discuss this with the study team.c

If you have any questions, your doctor and the study team will be able to provide you with answers.
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?

In return for your time, effort and travel expenses, you will be paid up to $400 for taking part in this study. We will give you a prepaid debit card worth $200 after each imaging time point.

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

It is important that you tell your study doctor, Lawrence Fong, MD, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him/her [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 or the study sponsor, 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, concerns, or complaints you have about this study. Contact your study doctor Lawrence Fong, MD [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 Office of the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on http://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.

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Optional Research

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 each of the following studies. Please mark your choice for each study.

About Using Blood and Tissue for Research

In the past, you may have had a biopsy or surgical procedure performed as part of your regular cancer care. If available, your study doctor would like your permission to collect that tissue sample to help better understand your body's immune response to target an attack on your cancer, in addition to helping develop new ways to monitor and treat diseases. During your participation in this study you may also undergo a tumor biopsy as part of your standard of care (if your doctor thinks it is safe) and your study doctor would also like your permission to collect leftover tumor tissue from these procedures. We would like to use the tissue to look for immune cells and changes in the genes of the cancer. All information forwarded for analysis will be made anonymous. No one will know that the samples belong to you.

We would also like to save ("bank") any leftover blood collected as part of research studies for future immune monitoring analyses.

If you decide to participate, your leftover tissue taken during biopsy procedures done as part of your regular care will be collected and any remaining blood sample from your research blood draws will be banked indefinitely.
The research that may be done with your blood and tissue is not designed specifically to help you. It might help people who have cancer and other diseases in the future. Results from the analysis will be published but your data will not be reported individually. Reports about research done with your blood and tumor tissue 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 let us keep your blood and tissue samples for research is optional and up to you. No matter what you decide to do, it will not affect your care. Sometimes blood and tissue samples are used for genetic research (about diseases that are passed on in families). Even if your samples are used for this kind of research, the results will not be put in your health records.

You will not be paid for allowing your blood and tumor samples to be used in research even though the research done with your samples may help to develop new products in the future. You

will not receive any payment or financial benefit from any products, tests, or discoveries derived from these samples.

Your sample and information may be kept indefinitely. However, if you decide that you do not want your samples and information to be stored, you can notify the study doctor, Lawrence Fong, MD at the address below, and let us know that you want your blood and tissue biopsy samples destroyed. We will destroy any identifiable samples however, if any research has already been done using the portion of your samples, the data will be kept and analyzed as part of those research studies.

Lawrence Fong, MD
University of California San Francisco
[redacted]

In the future, people who do research may need to know more about your health. While the study doctor may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Your tissue will be used only for research and will not be sold. The research done with your tissue 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 the UCSF Institutional Review Board at 415-476-1814.

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

1. My blood and tissue may be banked for use in future research and testing.

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
	Printed Name of Participant
Date	Signature of Person Obtaining Consent
	Printed Name of Person Obtaining Consent
Date	Witness Signature (Only required if the participant is a non-English speaker)

Study Calendar

		First (baseline) imaging			Second imaging		
	Screening (Day -28 to 1)	Day 1 (Image)	Safety Follow Up		Day 1 (Image)	Safety Follow-Up	
			Day 2 (Tele)	Day 8 (Tele)		Day 2 (Tele)	Day 8 (Tele)
Informed consent	X						
Medical history	X						
Physical exam	X						
Performance status	X						
Baseline staging scans	X						
Height	X						
Weight	X						
Vitals	X	X			X		
Pregnancy test	X						
Screening lab tests	X						
MRI screening form	X						
Tissue collection	X						
Furosemide (Lasix)	X	X			X		
[^{18}F]F-AraG PET/MR imaging		X			X		
Electrocardiogram		X			X		
Record side effects		X	X	X	X	X	X