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

Study Title: ^{68}Ga-citrate PET/MR Imaging for the evaluation of glioma in adults

This is a medical research study. Your study doctor, Dr. Susan Chang MD or one of her colleagues from the University of California San Francisco, Division of Neuro-Oncology and study investigator, Michael Evans PhD, or a member of the research team from the Department of Radiology & Biomedical Imaging 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 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 study because you have been diagnosed with a form of brain cancer. This study involves taking pictures of the brain with imaging technology. Two types of images will be taken. Contrast-enhanced magnetic resonance imaging (MRI) is used routinely to create pictures of the brain. This study will also be using positron emission tomography (PET) scans with Gallium-68 Citrate, a radiotracer used for imaging other types of tumors.

Why is this study being done?

The purpose of this study is to evaluate 68Ga-citrate uptake in patients with glioma. 68Ga-citrate is a radiotracer that can be a tool of tumor detection when the tumor exhibits specific biological abnormalities. You will undergo PET/MR acquisition of the head simultaneously.

An MRI uses powerful magnets and radio waves linked to a computer to create images of the body, in this case of the brain, that are remarkably clear and detailed. It is a standard imaging scan used to assess your brain tumor. The MRI scans taken in this study will help doctors view your brain tumor.

A PET scan is a nuclear medicine imaging technique that produces a 3-D image of cells and how they work in the body. In this case, 68Ga-citrate is being evaluated in its ability to detect tumor cells. Tumor cells are known to have abnormalities that can be detected with 68Ga-citrate, so the purpose of this study is to assess if this imaging technique can be used to improve visualization of tumor in the brain. Gallium citrate PET has been used in prior studies to image patients with suspected sites of infection, prostate cancer, or glioma. It is not approved as a standard imaging test for patients with glioma.

Who pays for this study?

This study is funded by the University of California San Francisco, Department of Radiology and Biomedical Imaging and the American Brain Tumor Association.

How many people will take part in this study?

About 40 people diagnosed with glioma will take part in this study.

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

If you agree to take part in this study and are determined to be eligible by your study doctor, you will be asked to read and sign this consent form before you are enrolled to participate in this trial and before any study procedures are performed.

To find out if you can take part in the study, the study doctor or a member of the research team will ask you questions about your health, current medications, medical and surgical history, and standard-of-care treatment plan. 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. 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 have the following tests and procedures per scan visit:

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 30 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.

- A complete medical history and your current medical condition will be collected including information about your demographics, current health status and medications that you are taking (including over-the-counter medications and supplements)
- Physical Examination
- Vital signs (blood pressure, heart rate, temperature), height and weight
- MRI Screening
- Pregnancy test: If you are a woman who is capable of becoming pregnant, a urine or blood pregnancy test, must be conducted on the day of each PET/MRI scan and the test result must be negative prior to the injection.

During the main part of the study...

68Ga-citrate injection: You will be injected with the Ga68-citrate radiotracer through an intravenous line by a Certified Nuclear Medicine Technologist, radiologist, or other certified professional.

PET/MR: You will be imaged in a PET/MR scanner between 120-360 minutes after the injection of 68Ga-citrate. Imaging will take 50 to 60 minutes to complete. Prior to the PET/MRI scan, you will be asked to wear clothing compatible with the PET/MRI environment. You will lie down on a narrow bed, which will then be placed in a tunnel that is 6 feet long by 22 inches wide and open at each end. You will need to lie there quietly, during which time there will be a loud banging noise. Gadolinium, an MRI contrast material that makes tissue and tumors more visible in the MRI, will be administered through an intravenous line when you are on the PET/MR scanner. You may feel warm during this procedure.

Vital signs and adverse events: Your vital signs, such as heart rate, breathing rate, blood pressure, and blood oxygen levels, will be collected. You will be monitored for adverse events during the visit. This information is collected to see how the study is affecting your body.

Access to your genetic information: Your medical records, specifically surgical pathology reports, will be accessed to gather information on PTEN status, if the information is available.

(Optional) Follow up 68Ga-citrate PET scan: You will have the option of undergoing a second and/or third 68Ga-citrate PET scan to see if there are any changes in comparison to your first scan. The procedures for the optional scans would be identical to those listed above. You will be able to indicate your choice in a section below.

Study location: All study procedures will be done at UCSF Mission Bay, Byers Hall, or UCSF China Basin Imaging Center.

How long will I be in the study?

The length of time that you will be in the study will be about 3-6 hours. If you agree to participate in the optional portion of this study described below, you will repeat the main part of the study for an additional 3-6 hours per scan.

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. 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 the PET/MRI scans. 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.

- **68Ga-citrate PET:** This is a standard radiotracer used for imaging other tumors in the body. Any serious risk of 68Ga-citrate PET scans is considered very unlikely. All of the known risks are described below.

- **Radiation risks:** This research study involves exposure to radiation from the PET/MRI scan. This radiation exposure is not necessary for your medical care and is for research purposes only. The use 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 your study doctor.

- **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.

- **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. Because the risks to a fetus from the radioactive injection, pregnant women must not participate in this study.

Risks and side effects related to having an MR exam, having an IV placed or receiving IV fluids include those that are:

Likely

- 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. You will be allowed to have a family member or a friend accompany you into the MR room.

- Placing an IV catheter may cause temporary discomfort from the needle stick, bruising, and infection. For your PET/MRI scan, you will have an IV catheter placed, one in a vein in your left or right arm. The IV catheter will be used to inject the radiotracer 68Ga-citrate for the PET scan and your subsequent gadolinium contrast for the MRI scan.

Less Likely

- Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear earplugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.

- Less frequent complications of injection of fluids or contrast through an IV catheter would be infiltration, or leakage of IV fluids out of the vein into the surrounding tissue causing swelling, redness, and pain. A much less frequent complication would be phlebitis, or inflammation of the vein.

Rare but serious

- Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which could in the process possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocketknives 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.

- **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 are no direct benefits for participating in this study but it is hoped that the information gained from this study will help researchers learn more about practical ways of evaluating and standardizing treatment in patients with brain tumor.

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

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will receive the same treatment if you choose to participate in the study or not.

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.

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:

- The University of California
- Government agencies, e.g., the Food and Drug Administration (FDA), involved in keeping research safe for people.

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 and your insurance will not be charged for any of the study activities.

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. Chang or Dr. Evans, if you feel that you have been injured because of taking part in this study. Dr. Chang can be reached by telephone at [redacted] or you may call Dr. Evans [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 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 doctor about any questions, concerns, or complaints you have about this study. Dr. Chang can be reached by telephone [redacted] or you may call Dr. Evans [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.

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OPTIONAL RESEARCH

Please note: This section of the informed consent form is about optional research studies that are being done with people who are taking part in the main study. You may take part in these optional 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 optional studies.

You can say "yes" or "no" to the study below.

Optional Follow up 68Ga-citrate PET scans

Your study doctor would like to complete a second and/or third 68Ga-citrate PET scan to see if there are any changes in comparison to your first scan. The second and/or third scans would be performed within one year of your first one.

Things to Think About

The choice to have follow up 68Ga-citrate PET scans is up to you. No matter what you decide to do, it will not affect your care. Each scan will involve repeating the main part of the study for a second and/or third time. The risks to you would be identical for each scan. The greatest risk to you is the additional radiation from the PET scan(s). If you have any questions regarding the use of radiation or the risks involved, please consult your study doctor.

Please read each sentence below and think about your choice. After reading each sentence, put your initials in the "Yes" or "No" box. If you have any questions, please talk to your doctor, or call our research review board at IRB's phone number.

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

1. I agree to an optional second 68Ga-citrate PET scan.

YES	*NO*

2. I agree to an optional third 68Ga-citrate PET scan.

YES	*NO*

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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 (if applicable)

Interpreter License Number (if applicable)