NCT04927663

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

Study Title: A First-in-Human, Phase 1 PET imaging Study of ^{11}C-YJH08, a Selective Glucocorticoid Receptor-Targeting Agent, in Patients with Advanced Solid Tumor Malignancies

Principal Investigator:	Rahul Aggarwal, MD Associate Professor of Medicine University of California San Francisco [redacted]

This is a clinical research study. Your study doctors, Spencer Behr, MD, from the UCSF Department of Radiology and Biomedical Imaging, and Rahul Aggarwal, MD, from the UCSF Department of Genitourinary Medical Oncology or one of their associates, will explain the study to you.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends, and health care team.

You are being asked to take part in this study because you have advanced hormone-resistant prostate cancer**.**

STUDY SUMMARY

Introduction: The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: This is called a "first in human" study because it is the first time ^{11}C-YJH08 will be given to humans. This means that the safety and risk information we have is based on how animals have reacted to ^{11}C-YJH08.

^{11}C-YJH08 is a small-molecule radiotracer that binds to glucocorticoid receptors (GR) so that they show up better on Positron Emission Tomography (PET) scan.

The researchers want to see if PET imaging using ^{11}C-YJH08 can be useful for detecting GR expression in cancer cells.

Study Procedures: If you choose to be in this study, you will undergo a Positron Emission Tomography (PET) imaging with an ^{11}C-YJH08 injection. For this imaging, you

will receive an injection of ^{11}C-YJH08, and a PET (PET/CT or PET/MR) scan will be performed 10-60 minutes afterward. The scan will last for about 90 minutes. You may have either PET/CT or PET/MR with ^{11}C-YJH08 injection, but whichever combination of the scan you have at baseline must remain consistent throughout your participation in this study (in other words, if you underwent PET/CT at baseline, you should have the same type of scan throughout the study).

There are 3 study groups – Group A, B and C. The study will begin enrolling participants in Group A to receive an ^{11}C-YJH08 PET (PET/CT or PET/MR) scan at a single time point. After Group A has finished enrolling, participants will enroll in Group B and C to receive an ^{11}C-YJH08 PET (PET/CT or PET/MR) scan at 2 time points. Participants in Groups A, B and C may choose to have an optional tumor biopsy within 14 days after baseline PET imaging. The study doctor will let you know which group you will be in. More information about the 3 different study groups is detailed below.

Your study participation will either end after completing the ^{11}C-YJH08 PET (PET/CT or PET/MR) imaging or after the optional tumor biopsy for your study group.

Possible Risks: There are risks to taking part in a research study. The rare but serious risk of participation includes:

- All body allergic reaction known as anaphylaxis may occur. Anaphylaxis causes your immune system to release a flood of chemicals that can cause you to go into shock — your blood pressure drops suddenly and your airways narrow, blocking breathing. Signs and symptoms include a rapid, weak pulse; a **skin** rash; and nausea and vomiting.

Possible Benefits: There will be no direct benefit to you from participating in this study. However, this study will help doctors learn more about ^{11}C-YJH08 PET imaging, and it is hoped that this information will help in the treatment of future patients with solid tumor that has spread to the liver.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Having a regular PET (PET/CT or PET/MR) scan that does not use ^{11}C-YJH08
- Not having ^{11}C-YJH08 PET (PET/CT or PET/MR) scan
- Taking part in another study

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

You are being asked to take part in this study because you have advanced hormone-resistant prostate cancer.

Why is this study being done?

The purpose of this study is to determine if Positron Emission Tomography (PET) imaging using ^{11}C-YJH08 can be useful for detecting glucocorticoid receptor (GR) expression in cancer cells, Anti-androgen therapy (including enzalutamide) can cause more GR to be produced in cancer cells, which can make the cancer cells resist hormone therapies. If we can find a better way to detect whether GR is increasing during therapy, it may lead to more successful therapies using GR antagonists.

^{11}C-YJH08 is not approved by the Food and Drug Administration (FDA) as a radiotracer for PET imaging. The use of ^{11}C-YJH08 in this study is investigational.

The National Institutes of Mental Health (NIMH) and the Department of Defense (DoD) are providing funding to support the conduct of the study.

How many people will take part in this study?

About 26 people will take part in this study in 1 of 3 groups. Group A will enroll about 6 patients; Groups B and C will enroll about 10 patients in each Group.

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

This study has 3 groups. If you participate in this study, you will be in either Group A. Group B, or Group C. The study will begin enrolling participants in Group A to receive an ^{11}C-YJH08 PET (PET/CT or PET/MR) scan at a single time point. After Group A has finished enrolling, participants will enroll in Group B or C to receive an ^{11}C-YJH08 PET (PET/CT or PET/MR) scan at 2 time points. You may have either PET/CT or PET/MR with ^{11}C-YJH08 injection, but whichever combination of the scan you have at baseline must remain consistent throughout your participation in this study (in other words, if you underwent PET/CT at baseline, you should have the same type of scan throughout the study). The study doctor will let you know which group you will be in.

Group A: The study will begin enrolling in Group A. Participants in Group A have any solid tumor that has gotten worse (progressed) after receiving treatment with systemic therapies like enzalutamide, apalutamide or darolutamide outside of this study. After enrollment, Group A participants will have an ^{11}C-YJH08 PET (PET/CT or PET/MR) scan at a single time point.

After Group A completes enrollment, the study will enroll participants in Groups B and C.

Group B: Participants in Group B have advanced hormone-resistant prostate cancer and have started treatment with systemic therapies outside of this study. Participants in Group B will undergo two ^{11}C-YJH08 PET (PET/CT or PET/MR) scans: One will be done at the beginning of the study, and the second ^{11}C-YJH08 PET (PET/CT or PET/MR) scan will be done if your disease gets worse (progresses). Each ^{11}C-YJH08 PET (PET/CT or PET/MR) scan will be done while receiving systemic therapies. You are to continue systemic therapies until all the ^{11}C-YJH08 PET (PET/CT or PET/MR) scans are completed.

Group C: Participants in Group C have any solid tumor other than prostate adenocarcinoma. Participants in Group C will undergo two ^{11}C-YJH08 PET (PET/CT or PET/MR) scans. One will be done at the beginning of the study, and the second ^{11}C-YJH08 PET (PET/CT or PET/MR) scan will be done if your disease gets worse (progresses).

Before you begin the main part of the study:

After you have signed this consent, the screening tests listed below will be done within 28 days except for staging scans, which need to be completed within 12 weeks of baseline PET (PET/CT or PET/MR) scan, and may be completed on the same day as your baseline PET ((PET/CT or PET/MR) scan. You will need to complete the following tests and procedures before you can be in the main part of the study. Some of these tests and 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.

- You will be asked about your current medical condition and past illnesses.
- Your vital signs (heart rate and blood pressure) will be measured.
- You will be asked about any medications you are taking (including over-the-counter medications and supplements).
- You will be asked about any side effects, you are having.
- Your demographic information (age, race, height, weight, and body mass index) will be collected.
- You will have staging scans. A CT or MRI (with contrast if medically permitted) scan of the chest, abdomen, and pelvis.
    - **CT scan:** 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, intravenously, or rectally (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 that is attached to a needle in your arm and is used to get clearer pictures of your body cavity. A 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.

- **MRI scan:** An MRI scan takes an image of your head or 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 1 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.

- You will be asked about your ability to perform daily tasks such as dressing yourself and getting out of bed.
- About 2-3 tablespoons of blood will be collected to test for:
  - Complete blood count (CBC) with differential and platelet count
  - Serum Creatinine
  - Total Bilirubin
  - Aspartate Aminotransferase (AST)
  - Alanine Aminotransferase (ALT)
  - Prostate-specific antigen (PSA)
  - Serum Testosterone

During the main part of the study:

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

Visit 1, Baseline ^{11}C-YJH08 PET (PET/CT or PET/MR) scan

- **^{11}C-YJH08 Administration:** A nuclear medicine technologist who specializes in PET scanning will administer a single dose of **^{11}C-YJH08 intravenously (IV)** in your arm using a small needle or plastic tube. The infusion will take 1-2 minutes.
- **Vitals:** Before and after you have your ^{11}C-YJH08 injection, your vital signs (heart rate and blood pressure) will be measured. About 60 minutes after your

^{11}C-YJH08 injection, your vital signs (heart rate and blood pressure) will be measured. Then at 2 hours after your ^{11}C-YJH08 injection, your vital signs (heart rate and blood pressure) will be measured.

- **AE Assessment:** About 60 minutes after your ^{11}C-YJH08 injection, you will be asked about any side effects, you are having. Then about 2 hours and again at 24 hours after your ^{11}C-YJH08 injection, you will be asked about any side effects, you are having.
- **EKG/ECG:** Before you have your ^{11}C-YJH08 injection and 2 hours after your ^{11}C-YJH08 injection, you will have an electrocardiogram (EKG/ECG) performed. EKG/ECG 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. This takes about 15-30 minutes.
- **Follow-up visit:** Following 1 day after your ^{11}C-YJH08 injection, you will ask to return to your doctor's office. During this office visit, you will be asked about any side effects, you are having. You will also have about 2-3 tablespoons of blood collected to test for:

    - Complete blood count (CBC) with differential and platelet count
    - Serum Creatinine
    - Total Bilirubin
    - Aspartate Aminotransferase (AST)
    - Alanine Aminotransferase (ALT)

Group B and C only – at time of disease progression:

You will have a second ^{11}C-YJH08 PET scan, as described above.

Study location:

All study procedures will be done at the UCSF Mission Bay campus. PET imaging and ^{11}C-YJH08 injection will be done at the UCSF Department of Radiology and Biomedical Imaging at China Basin.

How long will I be in the study?

If you are in Group A, your participation will end after ^{11}C-YJH08 baseline imaging is completed and any optional tumor biopsy you agreed to have is performed.

If you are in Group B or C, you will be followed on the study until your cancer gets worse (progresses), and your study participation will end after your second ^{11}C-YJH08 imaging is completed, and any optional tumor biopsy you agreed to have is performed.

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 will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the ^{11}C-YJH08 injection can be evaluated by your doctor and you can discuss what follow-up care and testing could be most helpful.

The study doctor may stop you from taking part in this study at any time if he 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 getting ^{11}C-YJH08 injection. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

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

Risk and side effects related to ^{11}C-YJH08 injection

Rare but serious

All-body allergic reaction known as anaphylaxis may occur. Anaphylaxis causes your immune system to release a flood of chemicals that can cause you to go into shock — your blood pressure drops suddenly and your airways narrow, blocking breathing. Signs and symptoms include a rapid, weak pulse; a **skin** rash; and nausea and vomiting.

Risks related to Study Procedures

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

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, 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.

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 into your 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.

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 occur. This can be treated immediately with intravenous fluids. Very rarely (less than 1 in 1,000), 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 an MRI scan requiring an injection of gadolinium contrast, you will have a blood test to check the function of your kidneys. Based on your medical history and the results of the test, your doctor will decide whether it is safe for you to undergo the MRI scans.

Radiation risks: This research study exposes you to radiation. Some or all of this radiation is only for research purposes. Typically (in the U.S.) we receive about 3 mSv (millisieverts) of radiation from the environment each year. The additional radiation you will receive by participating in this study (in any 12 months) is approximately 35.76 mSv, or 12 times the normal yearly exposure. We don't know for certain whether this much additional radiation increases the risk you will develop a cancer in the future. If you have had a lot of x-rays, or other procedures involving radiation, you should discuss the risk with the physician conducting the study, or your regular doctor. You should consider whether the additional risk of study radiation is acceptable to you. Due to risk to the fetus, if you are pregnant or breast feeding, you should not participate in this study. If you have any questions about the radiation used in this study, or the risks involved, please consult the physician conducting the study.

PET/CT scan risks: The PET/CT scan exposes your body to radiation, see radiation risk above. The radiation levels come 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. For some patients, having to lie still on the scanning table for the length of the procedure may cause some discomfort or pain. After the scan, your arm may be a little bit sore or have some redness where the IV was placed in your arm. The radioactive solution does not remain in your system for a long period of time.

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 earplugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.

Conscious sedation risks: If sedation medication is given for an MRI scan, it will be given through an IV or by mouth. You may feel pain from the initial needle stick. Possible bruising from where the needle went into the skin may occur, as well as rarely, an allergic reaction to the medication. Vomiting or inhaling food contents from the stomach are also risks of sedation. These risks are minimized if you do not eat for a minimum of 6-8 hours before any procedure.

Electrocardiogram (ECG) risks: 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 the study doctor know if you are aware of any allergies you have.

Unknown Risks: The experimental imaging agent 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. Additionally, if the study doctors observe any abnormal findings during the research images, they will inform your primary physician.

- 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 ^{11}C-YJH08 PET imaging, and it is hoped that this information will help in the treatment of future patients with cancer like yours.

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

Your other choices may include:

- Having a regular PET scan that does not use ^{11}C-YJH08
- Not having a PET scan
- Taking part in another study
- Not participating in any study

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other cancer studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share the de-identified information and specimens.

Your specimens will be stored in a repository, also called a 'tissue bank', at UCSF. The manager of the tissue bank and select tissue bank staff members will have access to your specimens and information about you, but they will not release any identifying information about you to researchers using your specimens. We may give your specimens and 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 an unrestricted or controlled-access government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Your specimens and information will be kept indefinitely until they are used up or destroyed.

Research results from these studies will not be returned to you and will not be put in your medical record. The research will not change the care you receive.

Researchers may use your specimens to look at all of your DNA (this is called 'whole genome sequencing"). DNA contains information that determines things like eye color, height, or disease risk that are passed on from parent to child. 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.

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,

Rahul Aggarwal, MD
University of California San Francisco
[redacted]

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

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 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 and may 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.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Mental Health (NIMH)
- Representatives of the Department of Defense (DoD)
- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

Are there any costs to me for 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.

If you have questions about what costs you will be responsible for, please talk with the study investigator before deciding to enroll in the study. Depending on the type of study, some of your costs could be substantial.

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, Rahul Aggarwal, MD, 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 the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the 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. Contact your study doctor, Rahul Aggarwal, MD, at [redacted]-[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 PARTICIPATION

This section of the informed consent is about optional future contact of participants in the main study. You can still be in the main study even if you say "no" to allowing optional future contact.

1. Tumor Biopsy

We want to know if you are willing to have an optional tumor biopsy within 14 days after baseline imaging. If you agree, your tumor tissue will be sent to a UCSF laboratory to test for certain proteins. The purpose of the biopsy is to see if there are associations between protein levels in your tumor tissue and ^{11}C-YJH08 PET imaging findings.

A biopsy involves removing a small piece of the tumor tissue, usually with a needle. A CT scan or ultrasound may be used to help guide the needle. This procedure will be done at the site where we can most easily get a piece of the tumor and can involve the lungs, liver, bone, lymph node, skin, or other area. The biopsy needle will be inserted into tumor tissue and a small piece of the tumor will be removed. This will be 1-3 times. This procedure takes about 30 minutes. You will sign a separate consent form for this procedure.

Benefits

There will be no direct benefit to you from having optional tumor biopsies for the study. Information from tumor tissue will be used to better evaluate the use of the ^{11}C-YJH08 PET (PET/CT or PET/MR) imaging method for future patients.

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 to 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 the doctors who conduct this biopsy. If a CT-guided tumor localization is necessary, there will be additional radiation exposure. (See Radiation Risks in the main part of the consent form).

2. Future Contact

We want to know if we may contact you in the future to see if you are interested in participating in other research studies.

If you agree and we contact you to tell you about a study, you have no obligation to actually participate in any study. You can decide when you are told about the study if you want to receive more information about the study. There would be a new consent process for that study.

If at any time you decide you no longer want to be contacted about future studies, please let us know [redacted].

Making Your Choice

Please read the sentence below and mark your choice by putting your initials in the "Yes" or "No" box. If you have any questions, please talk to your doctor or nurse, or call our research review board at 415-476-1814.

No matter what you decide to do, it will not affect your care or your participation in the main study.

1. **I agree to have a tumor biopsy within 14 days after baseline imaging is completed for this study.**

YES	***NO***

2. **Someone may contact me in the future about taking part in more research.**

YES	***NO***

CONSENT

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

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

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

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

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