Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

You are invited to voluntarily participate in a research study of an imaging agent, or "radiotracer," called ^{18}F-FSPG, also known as ^{18}F-fluoropropyl-glutamic acid, being conducted by Carina Mari Aparici, MD, and Brian Shaller, MD, at the Stanford Cancer Center. You were selected as a possible participant in this study because you have lung nodules of unknown cause.

This document is to be used as a guide for a discussion between you and your Study Doctor and the study team. This form, called an informed consent document, was designed to help you understand why this study is being done; what part of the study is "research" or "experimental;" what will be asked of you if you choose to participate; possible risks; any inconveniences or discomforts you may experience; and other important information. This document is intended to provide the information that a potential participant might want to have in order to make an informed decision about whether to participate in the research study. If you have any questions or would like additional information, please ask the person obtaining consent or any other member of the study team.

If you choose to participate, this form may also be helpful as a reference or reminder about your role in the study, and whom to contact if you have any questions at any time during your participation. If you wish, you can also discuss this study and your role with your family doctor or medical provider.

PURPOSE OF RESEARCH

The study team hopes to learn if the experimental agent ^{18}F-FSPG is a better imaging agent for determining if lung nodules are cancerous than the current standard of care, ^{18}F-FDG.

Your normal medical care for such an evaluation would be a single imaging scan with ^{18}F-FDG. The study team would like to compare the results of that scan with a scan using ^{18}F-FSPG as the imaging agent.

The use of ^{18}F-FSPG in this research study is investigational ("experimental"). The word "investigational" means that ^{18}F-FSPG is not approved by the US Food and Drug Administration (FDA) for use in the United States as an imaging agent. This study is being conducted under an application submitted to FDA, called an "Investigational New Drug Application" or "IND." The extra scan and the associated visits are the only parts of this study that are not part of your regular medical care.

If you decide to terminate your participation in this study, you should notify Dr Shaller at 650-725-5071, or Dr Carina M Aparici at 650-723-6855.

This research study is looking for about 120 people with lung nodules of unknown cause to participate. The study is being done only at Stanford University.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

It is planned that each participant will take part in this study for about 1 month, consisting of the day of the scan and follow-up in about 30 days.

PROCEDURES

Research studies are usually dividing into at least 3 parts, typically consisting of:

1. Testing to see if you are eligible to participate in the study ("Screening")
2. Testing during the study to monitor your health and the effects of the study treatment ("Study Evaluation Procedures"), and
3. Evaluation after the diagnostic study procedures are complete ("Follow-up").

Testing/procedures for each of these parts are described separately below. Most of these examinations, tests, or procedures will be part of your regular medical care, and/or and may be done even if you do not join the study.

Before you join this study, the Study Doctors and/or the research study team will review this document with you, and ask you to sign this informed consent document. After you have signed this document, and received a signed copy, the study will begin with a Screening Visit.

Screening Visit

If you choose to participate, the first activity will be screening and consent at Visit 1. During this visit, the study will be discussed and you will be asked to sign this consent form.

Location: The location of the Screening Visit will be at:

Pulmonary Clinic, Boswell Building, 1st floor
Stanford Hospital
300 Pasteur Dr
Stanford, CA 94305
Phone 650-725-7061

Women of Childbearing Potential

If you are pregnant or currently breast-feeding, you may not participate in this study. It is not known whether the imaging agent is safe for the fetus (unborn child) or a breast-fed baby.

Administration of Study Agents and Scans

All participants will receive the same imaging agents and have the same tests. For this part of the study, you will undergo 2 medical imaging scans, one conducted with ^{18}F-FSPG as the imaging agent, and the other with ^{18}F-FDG. These scans may be conducted in any order, but they should be conducted at least 24 hours (1 day) apart, and within 30 days of each other. At one of these visits, you will provide a small blood sample and a nasal brushing. Your samples will be sent outside of Stanford for analysis.

Blood collection: Blood collection will typically be from a vein in your arm, using a blood collection needle. This is called venipuncture. If you have an implanted venous access port, this may be used for blood collection. Standard aseptic (clean) techniques will be used. About 2 tablespoons (30 mLs) of blood will be collected.

Nasal brushing: A nasal brushing will be conducted with a small brush about the size cotton swab. This will be done twice in a row.

Medical imaging scans: The imaging for this study is a combination scan, based on positron emission tomography (PET) and computed tomography (CT). As a combination scan, this is called a PET/CT scan. You will have 2 PET/CT scans, one that uses ^{18}F-FDG, and one that uses ^{18}F-FSPG as the imaging agent.

A **PET scan** is a computerized image that looks at blood flow and the extent of metabolic activity in your entire body. PET scans use a radioactive material called a "radio-isotope;" "radio-tracer;" or "radiolabel." The radio-isotope is attached to glucose (sugar), and combined this is the radiolabel. A tourniquet will be applied to your arm or leg to help find a vein, and a small amount of the radioactive ^{18}F-FDG or ^{18}F-FSPG will be injected into a vein about 1 hour before the scan. The radiolabel accumulates in areas of the body that are metabolically active, and this accumulation is detected by the scanner. Tumors are usually very metabolically active, more so than normal tissues. You will be asked to lie on a long narrow bench for a few minutes while the machine performs the scan. You may experience some discomfort or anxiety from being in the confined space. If this bothers you too much, the study team may provide you with a medication to help you stay calm. The camera will record the tracer's signal as it travels through your body.

A **computed tomography (CT) scan (an "X-ray")** will be performed without contrast (except for the PET agent) according to standard practice, and is a computerized imaging procedure that makes many cross-sectional images (often called slices), both

horizontally and vertically, of the body. For this study, the CT scan will be used to look at the anatomy of your entire body. You will need to remove all jewelry, piercings, and other metal items. **IT IS VERY IMPORTANT THAT YOU IMMEDIATELY TELL THE STUDY DOCTORS AND/OR THE CT TECHNICIAN** if any of the following apply to you:

- You are or could be pregnant
- You have, or previously had, kidney problems.
- You are taking Glucophage (metformin)
- You have recently taken or received barium ("barium study") or bismuth, or have recently taken Pepto-Bismol; Kaopectate; Maalox; Bismatrol; or other digestive aids
- You have a cardiac pacemaker or any other biomedical device, such as surgical clips, pins; screws; or metal plates in or on your body.
- You have any body piercings
- In some cases, these could mean you should not have a CT scan performed

The imaging for the CT signal is obtained in conjunction with the scan described for the PET scan and will provide the doctors with information about your body. You will be asked to lie still on a long narrow bench, or scanner bed, for a few minutes. A strap and/or pillows may be placed across your body to prevent movement so that the X-ray picture will be clear. The scanner bed you are on will then slide into a large, tunnel-shaped machine. You will be able to see the CT technician during the entire procedure, and there are microphones and speakers so you can communicate with the CT technician. You will have a call button. You will be asked not to move during the scan and to relax and breathe normally. You may experience some discomfort or anxiety from being in the confined space. If this bothers you too much, the study team may provide you with a medication to help you stay calm. During the CT scan procedure, the scanner will rotate around you, and make clicking sounds, which is normal. Tell the CT technician if you start to feel unusual, especially if you have a flushing sensation; a salty or metallic taste; a headache; and/or nausea / vomiting. These effects usually last for a few moments. Tell the CT technician immediately if you have any breathing difficulties; sweating; numbness; or heart palpitations. When the CT scan procedure and follow-up is finished, you may immediately resume your usual activities and diet.

PET/CT scan: PET scans are commonly combined with CT scans to get a better image of the inside of your body. These procedures were described above. This study uses both PET scans and CT scans in a combined procedure called a PET/CT scan. The entire procedure of the combined PET/CT scan will take about 30 to 60 minutes.

Location: The location of the Study Visits will be at the Nuclear Medicine and Molecular Imaging Clinic.

Nuclear Medicine and Molecular Imaging Clinic
Stanford Hospital, 2nd floor
300 Pasteur Dr
Stanford, CA 94305
Phone 650-723-6855

Study Follow-Up Procedures

You will be contacted within 24 to 72 hours after the ^{18}F-FSPG PET/CT scan for follow-up. This contact will probably occur by phone.

Your Tissue / Data Samples for Research and Genetic Testing

Research using tissue, such as your blood sample and the nasal swaps, is an important way to try to understand human disease. Sometimes, research may include the testing and study of genes, also known as DNA, and related materials called RNA, proteins, and/or metabolites. This type of testing is also called “genetic analysis” or called “pharmacogenomic research.” You are being given this information because the Study Doctors want to include your blood sample and the nasal swaps in a research project and because they want to save the samples for future research.

There are several things you should know before participating in this study and allowing your blood and nasal swaps to be studied. This subject is complicated, and there are many considerations. Ask for more information if you do not understand any part of this information.

Genes are in every cell of your body. Your genes were inherited from your biological parents and carry instructions for the body to grow, develop, and survive. Genes are made of a substance called DNA. Most genes and DNA are identical among human beings, but there are small variations between different people. These small genetic differences are why people have their own unique characteristics, such hair color, eye color, height, and other characteristics. Some traits affected by genetics are not visible, such as why different people have different responses, including side effects, to the same agent, or are more likely to get certain diseases or conditions. The proteins in your body were determined by your genes, and control how your body works. Differences in genes and therefore proteins can affect the way a disease develops, the way drugs act against the disease, or the way your body uses the drugs/imaging agents.

The purpose of this type of research is to understand the cause and detection of disease, such as cancer. In this study, the genetic research is being done to help improve the identification of cancer in individuals who have lung nodules of unknown cause.

You are not required to agree to provide the sample for this genetic testing, but agreeing to provide theses sample is required to participate in this study.

The samples collected in this study may be used for future research projects, including projects that are undetermined and may include "full genome sequencing" (ie, all your genes).

The data from your sample for this genetic research project will be used for research purposes only. This genetic research sample may be used for additional future undetermined research analyses including other cancer studies or with a group of other patients' samples to determine the natural difference in genes and proteins in groups of people with cancer; or to develop new gene research techniques; or in projects that may include "full genome sequencing" (ie, all your genes). The sample and data generated from them will be held by sponsor or their partners for many years or specify the indicated term, eg, for up to 50 years. These samples, and the data generated from them, may be shared with other researchers or entered into databases, provided confidentiality is upheld (you are not otherwise directly identified), and they are used only for research on the topics described in this document. The information in these databases may be kept forever, however, information that could directly identify you will not be included in these databases.

Although you will be told the results of study tests that are part of your regular medical care, the genetic testing described here will not be used for decisions about your medical care, and there may be no results from this genetic research for many years, therefore the results of the genetic testing may not be given to you, your doctor, or any other staff at the study center.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The Study Doctors might retain the identified samples, eg, as part of your routine clinical care, but not for additional research.

Your samples will be stored and identified by your unique study number, but not your name.

Providing genetic information to others

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

Be aware that that GINA 2008 does not specifically protect you against genetic discrimination by companies that sell life insurance; disability insurance; or long-term care insurance.

Adverse event monitoring will be performed as part of the procedures described above. During the study period, the Study Doctors will monitor you for any potential side effects. If the side effects are severe, the Study Doctors may temporarily stop study medication; change the dosage of your study medication; or withdraw your medication completely.

If, at any time, you have any symptom; side effect; or injury affecting you physically or mentally during the study, **you should tell the Study Doctors or nurses right away**, even if you do not think it was caused by the study medication.

If you have to go to the hospital for any reason, please tell the hospital staff that you are participating on a research study, and give them the contact information for the study team. You may be provided with a card with the study team contact information.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study team.
- Ask questions as you think of them.
- Tell the Study Doctor or study team if you change your mind about staying in the study.
- Tell the Study Doctor or study team about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Study Doctor or study team if you believe you might be pregnant or gotten your partner pregnant.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Study Doctor or research study team to reschedule as soon as you know you will miss the appointment.

About Pregnancy

During the study, if you become pregnant, or you think you may be, you must tell your Study Doctor. If you become pregnant during the study, the imaging agent may involve unforeseeable risks to the unborn baby, and your pregnancy will be followed to determine the outcome.

WITHDRAWAL FROM THE STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr Shaller at 650-725-5071 or Dr Aparici at 650-723-6855.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. This section describes the reasonably foreseeable risks, discomforts and inconveniences that you may experience. In addition, because this is a research study, there may be risks that are not yet known ("unforeseeable"). These deserve careful thought. You should talk with the Study Doctor if you have any questions.

You must tell the Study Doctor or study team about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study. Your Study Doctor may give you medications to try to help lessen some of the side effects. All patients in the study will be monitored for side effects.

If you experience serious problems, you may be asked to return to the study center for more tests. If you experience the following symptoms of an allergic reaction, contact the Study Doctor or the Study Team immediately.

- Allergic reaction, including rash, hives, or blisters; increased heart rate (a fast pulse or tachycardia); or abnormal or increased sweating
- Swelling of the face, mouth, lips, gums, tongue or neck
- Wheezing or difficulty breathing
- Dizziness and fainting

Possible Side Effects Associated with the PET/CT Scans:

- **Radiologic imaging (PET/CT scans)**: A PET/CT scan exposes you to radiation (discussed below). When you are in the scanner, you may experience discomfort or anxiety due to be in the small space inside the machine, or from the loud noises the scanner makes. If you become anxious or concerned in tight spaces, or from loud noises, tell the study team or technician **before the scan**. You may receive a medication to calm you if you need help with this.
- **Injection of radiotracers (PET/CT scans)**: Radiotracers (^{18}F-FSPG and ^{18}F-FDG) will be injected for the PET/CT scans. Following are the risks associated with injection of radiotracers.
    - Allergic reaction, which can include may include rash, hives, or blisters, and be severe and/or life-threatening. If you have **ever** had a history of severe allergies / allergic reactions, including anaphylaxis (eg, any bee-sting, food, shellfish, or nut reactions), or any previous reactions to medications; iodine; tape; or latex, **tell the study team or technician before the scan**. After the injection and

during the scan, if you experience any breathing difficulties; sweating; numbness; or heart palpitations, **tell the study team or technician immediately**.

- After the injection, there is a risk of pain, discomfort, or a burning sensation at the injection site; a flushing sensation; a salty or metallic taste in the mouth; a brief headache; or nausea/vomiting. These effects usually last for a few moments. Pain, discomfort, or a burning sensation at the injection site can usually be relieved by applying moist, warm compresses to the injection site.

- **Radiation from PET/CT scans**: You will be exposed to radiation during this research from 1 F18-FDG PET/CT and 1 F18-FSPG PET/CT scans. Your radiation exposure will be about 21.5 mSv. The additional amount of radiation exposure is approximately equal to 43% of the limit that radiation workers (for example, a hospital x-ray technician) are allowed to receive in one year. This additional amount of radiation involves minimal risk and is necessary to obtain the research information desired.

  Due to the risk of injury to the developing baby (fetus) from radionuclide angiography, you should notify your physician if you are pregnant, or suspect that you may be pregnant. Radiation exposure during pregnancy may lead to birth defects. If you are lactating, or breastfeeding, you should notify your physician due to the risk of contaminating breast milk with the radionuclide.
- **Allergic reactions**: All drugs and imaging agents have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. You should get medical help and contact the Study Doctors right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives, or blisters.

Other procedural risks:

- **Nasal brushing**: Nasal brushing may be accompanied by minor discomfort and a slight chance of temporary nose bleed.
- **Blood draws**: A blood draw may cause fainting; inflammation of the vein; stinging, discomfort, or pain; bruising; discomfort; redness; burning; or bleeding at the site where the needle is placed to draw the blood. There is a slight chance of infection. You may feel dizzy or you may faint. If you feel faint, you should immediately lie down to avoid falling.
- **IV catheters**: IV catheters may be accompanied by mild bruising and, in some cases, by swelling, redness, injection site pain and infection.
- **Genetic research risks:** This research involves genetic studies and information. Procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you. However, even without your name or other identifiers, your genetic information is unique to you, and there is a remote possibility that someone could trace the information in a central database back, and identify you. If a genetic disorder is discovered in your genes, there is a

remote possibility this information could become public and affect you or your family in an unfavorable way, including a possible risk of discrimination by employers or insurance providers.

- **Personal anxiety**: Following are some common concerns that research subjects may have.
  - You may be asked sensitive or private questions which you normally do not discuss. It may be necessary to answer some of these questions related to your health and medical status.
  - You may feel embarrassed during the physical exam. You may request that the physical exam be done by a clinician of the same gender.
  - You may be concerned about your personal information being revealed. Although the Study Team, FDA; and the funding sources (The Canary Foundation, the American Association for Cancer Research, and Department of Defense) do their best to protect your personal information, this can not be absolutely guaranteed.
- **Test results**:
  - May indicate that you have another disease or condition that you were not aware of. This may be concerning to you, and cause anxiety or other feelings.
  - Rarely, may not be correct.
    - A false negative is a test result that indicate a person does not have a condition, but they really do.
    - A false positive is a test result that indicates a person has a condition, but they really don't.
    - Incorrect results can cause as much concern and anxiety as a correct diagnosis.
  - May become known to others, which may affect their judgment of you.
- **Pregnancy / Reproductive Risk**: There is a risk that pregnancy could still result despite the responsible use of reliable method of birth control.
- **Other risks**: Since ^{18}F-FSPGis investigational ("experimental"), there may be other risks that are unknown ("unforeseeable") at this time.

It is important that you report <u>all symptoms and side effects</u> that you experience <u>as soon as</u> they occur, whether or not you think they are caused by the imaging agent ^{18}F-FSPG or study procedures. Contact Dr Shaller at 650-725-5071; Dr Aparici at 650-723-6855; or the Nurse Coordinators at 650-498-6000 (24 hours). If you are unable to reach anyone at the number(s) listed above, and you feel you may need medical attention, **call 911** or go to the nearest emergency room.

POTENTIAL BENEFITS

- The diagnostic testing with ^{18}F-FSPG may result in a better understanding of your medical condition, which may lead to better treatment choices. However, there is no guarantee that you will benefit in this or any other way.
- Although you may not directly benefit from participation in this study, information learned from this study may help other people in the future, including other people with cancer.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

You do not have to be in this study to receive a medical scan to evaluate your lung nodules of unknown cause. You may choose to not participate, and receive a PET/CT scan with ^{18}F-FDG only, or receive a different medical scan altogether.

The Study Doctors will discuss with you the risks and benefits of the alternatives, including which other choices might be suitable for you.

If you decide that you do not wish to take part in this study and wish to pursue any of these, or other alternatives, this will not change your regular medical care or the other treatment choices in any way.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You can also tell any other member of the study team.

You will be told of any significant new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study. After you hear about this information, you have the right to withdraw from the program.

If medically-relevant information about you or your test results that might affect your future treatment or your willingness to continue participation in this study is obtained, this information will be discussed with you.

You will be told the results of tests that are part of your medical care, but you may not be told the results of the research tests, including any future research tests.

ClinicalTrials.gov

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by US 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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Your research records may be disclosed outside of Stanford, including in computer databases and by other electronic methods, but you will only be identified by your unique study identifier, and not your name. Information linking your study identifier to your name will be kept in a secure location at Stanford and access will be limited to the Study Doctor and authorized members of the Study Team.

Patient information may be provided to Federal and other regulatory agencies as required. The US FDA, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Representatives of the Department of Defense may have access to the research records.

The purpose of this research study is to obtain data or information on the safety and effectiveness of ^{18}F-FSPG; the results will be provided to the Food and Drug Administration (FDA); other federal and regulatory agencies as required; and the funding sources (The Canary Foundation, the Department of Defense and the American Association for Cancer Research).

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
This study may help the study team; the funding sources (The Canary Foundation and the American Association for Cancer Research); and FDA evaluate the utility of ^{18}F-FSPG as an PET/CT imaging agent. Information from this study will be submitted to the funding source and international regulatory agencies including the FDA. The results from this research study are expected to be presented at scientific or medical meetings or published in scientific journals. **You will not be personally identified in the publications, although representatives of the sponsor and FDA and other international regulatory agencies may need to know who you are**.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (eg, necessary to maintain integrity of research). If you wish to revoke your authorization for the

research use or disclosure of your health information in this study, you must write to:

Carina Mari Aparici, MD
300 Pasteur Dr, H2200
Stanford Univ Med Center; MC 5281
Stanford, CA 94305-5427

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to identifiers such as your name and initials; address including ZIP code; phone numbers; dates including date of birth; age; biological gender (your sex); race; ethnicity; Social Security Number; medical record number (MRN); and other numbers or codes such as your unique study identifier that might identify you. During the study, researchers will also obtain information about your health status, life-style choices, medical history, and medical diagnoses, including family medical history and allergies; your current and past medications or therapies; your laboratory test results including blood and pregnancy tests; results of procedures, such as medical measurements or assessments, medical scans including PET/CT scans, results of genetic testing; and medical reports, such as radiology reports. **The researchers will also get information from your medical record (including hospital records from the Stanford Healthcare and your referring physician's records).**

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Carina Mari Aparici, MD
- Research Staff
- The Stanford University Administrative Panel on Human Subjects in Medical Research

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Stanford Data and Safety Monitoring Committee (DSMC); and/or any other unit of Stanford University as necessary
- The funding sources (The Canary Foundation and the American Association for Cancer Research, Department of Defense); or their representatives
- The Food and Drug Administration (FDA) and/or other state or international regulatory authorities
- The Office for Human Research Protections (OHRP) in the US Department of Health and Human Services (DHHS)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on **31 December 2068** or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (eg, if included in your official medical record).

_____
Printed Name of Adult Participant

_____ _____
Signature of Adult Participant Date

NOTE: *If using the Short Form Consent process for informed consent in another language pursuant to an "Alteration of HIPAA Authorization," neither the participant nor their LAR should sign the HIPAA "Authorization To Use Your Health Information For Research Purposes" above.*

FINANCIAL CONSIDERATIONS

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the Study Visits.

You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance**. Participation in this study is not a substitute for health insurance.

Some insurance companies or other 3rd-party payers may not pay for standard-of-care procedures or laboratory tests, including hospitalization, when they are done as part of a research study. You should consult with your health benefit plan to determine whether your medical costs associated with your care during this study are covered.

Payments

Compensation for study participation may be available in the amount of up to $500. Participants who complete the second PET scan are eligible for this compensation. The study team will provide more information on compensation.

Payments or reimbursement may only be made to US citizens, legal resident aliens, and those who have a work-eligible visa. You may need to provide your Social Security Number (SSN) or equivalent (ie, federal Taxpayer Identification Number, TIN) to receive payment. If your SSN/ TIN is required to receive payment, and you do not wish to provide your SSN/ TIN, you have the option of declining the payment.

This study includes the collection of research samples. Any of your samples which are used in research, including those used in genetic research, may result in new products; tests; or discoveries. In some instances, these products may have commercial value, and may be developed and owned by the study team; Stanford University; the funding sources (The Canary Foundation and the American Association for Cancer Research, Department of Defense) and/or others. However, donors of samples do not retain any property rights to the samples or data derived from them. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Any of your samples which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the study team; Stanford University; and/or others. However, donors of samples do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Funding Source
The Canary Foundation, a non-profit entity involved in early cancer detection and the Department of Defense are paying for (sponsoring) this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study team will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director and/or the research study staff will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, Complaints, or to Report an Injury or Side Effect: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should contact the Study Doctor, Brian Shaller, MD, at 650-725-5071, or Dr Aparici at 650-723-6855. You should also contact them at any time if you feel you have been hurt by being a part of this study.

If you are unable to reach anyone at the number(s) listed above, and you feel you may need medical attention, call or go to the nearest emergency room.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll-free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Study Doctor, please contact Dr Aparici at 650-723-6855.

Appointment Contact: If you need to change your appointment, please contact Dr Shaller at 650-725-5071 or Dr Aparici at 650-723-6855.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- Be given a description of any attendant discomforts and risks reasonably expected;
- Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- Be given an opportunity to ask questions concerning the experiment or the procedures involved;
- Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- Be given a copy of the signed and dated consent form; and
- Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? ___**Yes** ___**No**

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____
Printed Name of Adult Participant

_____ _____
Signature of Adult Participant Date

_____
Printed Name of Person Obtaining Consent (POC)

_____ _____
Signature of POC Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short-form foreign language informed consent document.

_____ _____
Signature of Witness Date
(eg, staff, translator/interpreter or family member)

_____
Print Name of Witness

The translated short form must be signed and dated by **BOTH** the participant **AND** the witness.

The English consent form (“referred to as the "Summary Form" in the regulations”):

Must be signed by **BOTH** the witness **AND** the Person Obtaining Consent (POC).

The non-English speaking participant does **NOT** sign the English consent.

The non-English speaking participant should **NOT** sign the HIPAA participant line.

If the participant is non-English speaking, the POC must ensure that:

Any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.