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

INTRODUCTION TO RESEARCH STUDIES

You are invited to participate in a research study of investigational imaging agents ^{68}Ga-RM2 and ^{68}Ga-PMSA11 being conducted by Andrei H Iagaru, MD, at the Stanford Cancer Center. You were selected as a possible participant in this study because you are suspected to have prostate cancer and are scheduled to have prostate biopsy.

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.

- This consent is sought for research and your participation is voluntary.
- The goal of this research project is to evaluate a new way to assess response to treatment. Your participation is expected to take approximately 2-3 weeks of active participation before treatment and another 2-3 weeks approximately 6 months after treatment.
- There are risks associated with the administration of radioactive materials. This amount of radiation involves minimal risk and is necessary to obtain the research information desired.
- We cannot and do not guarantee or promise that you will receive any benefits from this study.
- Your participation can help researchers develop new tools to better monitor or diagnose disease in the future.
- You will not feel any different while participating in this study.
- 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.

PURPOSE OF RESEARCH

This clinical research study hopes to find out whether the combination of imaging agents ^{68}Ga-RM2 and ^{68}Ga-PMSA11 is better at assessing response to therapy than standard imaging or biopsy. You were selected as a possible participant in this study because you are known to have prostate cancer and are scheduled to receive local treatment.

The scans in this research study and the use of ^{68}Ga-RM2 and ^{68}Ga-PMSA11 for those scans is investigational ("experimental"). The word "investigational" means that neither ^{68}Ga-RM2 or ^{68}Ga-PMSA11 are approved by the US Food and Drug Administration (FDA) for use in the United States. This study is being conducted under an application submitted to FDA, called an "Investigational New Drug Application" or "IND."

The parts of this study that are research (not part of your regular care) are the use of ^{68}Ga-RM2 and ^{68}Ga-PMSA11, and the associated PET/MRI scans.

If you decide to terminate your participation in this study, you should notify Dr. Iagaru at 650-725-4711.

This research study is looking for 100 people with suspected prostate cancer to participate. Stanford University is the only location enrolling research study participants.

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

Your participation in this research study is expected to take approximately 2-3 weeks of active participation before treatment and another 2-3 weeks approximately 6 months after treatment. The ^{68}Ga-RM2 and ^{68}Ga-PMSA11 scans will be done within 2 weeks of each other. You will be contacted by research staff 1-3 days after each scan to see how you are feeling. Study investigators will monitor your medical record for 12 months after your last scan, but you are not required to come to clinic for any study visits during follow-up.

PROCEDURES

If you are eligible and choose to participate, the Study Doctor and his research study staff will perform the following procedures:

Pre-Study

- Review this informed consent form with you and ask you to sign.
- Collect demographic information (age, gender, race, etc.)
- Review your medical history
- You will be assigned randomly to receive either (equal chance of either option)
    - ^{68}Ga-RM2 PET/MRI followed within 2 weeks by ^{68}Ga-PMSA11 PET/MRI OR
    - ^{68}Ga-PMSA11 PET/MRI followed within 2 weeks by ^{68}Ga-RM2 PET/MRI before and after treatment

Imaging Days

You will come to the clinic twice to receive an investigational imaging agent (^{68}Ga-RM2 or ^{68}Ga-PMSA11) and undergo PET/MRI imaging. The procedures are very similar for each imaging agent, and include:

- You will be asked to drink 1-2 glasses of water before you arrive at clinic.
- Record your vital signs (which includes your heart rate and blood pressure,)
- The radiolabeled investigational imaging agent will be administered through a needle in your vein
- You will be asked to pee immediately before image collection
- Approximately 45 minutes after administration of ^{68}Ga-RM2 or 45 minutes after administration of ^{68}Ga-PMSA11, PET/MRI image collection will begin.
    - During image collection, study personnel will collect both PET images, which detect the small amount of radiolabeled imaging agent, and MR images, which use strong magnetic fields, to look at your tissues and organs.
- Record vital signs after image collection is complete

Your study doctor or research staff will contact you by phone 24-72 hours post-scan to ask how you are feeling.

The above will be repeated approximately 6 months after treatment.

Information about the medical scans

Magnetic Resonance Imaging (MRI): An MRI does not require a radiation exposure. The scan will take about 30 to 60 minutes. The MRI scan evaluates blood flow and the extent of the cancer. An MRI scanner is large, tunnel shaped machine, and uses a strong magnet and radiofrequency magnetic fields to make images of the body interior. This magnet is very strong, and will attract or pull on some metals and affect some electronic devices, including magnetic access cards, and the magnetic strip on credit / debit /ID cards. Do not bring any metal objects into the magnet room. Any metal objects that you are carrying or have in your body could be a hazard to you or others. Watches;

hearing aids or other removable medical devices; jewelry / rings; credit / debit /ID cards; access cards; should be removed. You will be provided a way to secure these items. Because the magnetic field is so strong, tell the study team now, and also tell the MRI operator before entering the MRI room, if any of the following apply to you.

The scanning procedure is very much like an X-ray, but uses a strong magnetic field instead of X-rays. You will not be able to feel the magnetic field. You will be asked to lie on a long narrow bench for up to 60 minutes while the machine performs the scan. You will be asked not to move during the scan and to relax and breathe normally. During this time, you will not be exposed to X-rays, but rather the magnetic field. During the scan, the bench you are lying on will move into a narrow space in the scanner. Many steps have been taken to make the procedure comfortable, but you may still experience some discomfort or anxiety ("claustrophobia") from being in this confined space. The scanner will make repetitive tapping noises, which can seem very loud inside the scanner. You may be provided with earplugs or headphones to wear.

Dizziness or upset stomach (nausea) may occur if you move your head rapidly within the magnet.

Some parts of the MRI machine (radio frequency imaging coils and imaging software) that will be used have not been approved by FDA, but are similar to parts that have been approved by the FDA.

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

A **positron emission tomography (PET) scan** will be performed according to standard practice as part of the medical scan. A PET scan is a computerized image that looks at blood flow and the extent and activity of the cancer in your entire body. PET scans use

a radioactive material called a "radio isotope;" "radio tracer;" or "radiolabel." A tourniquet will be applied to your arm or leg to help find a vein, and a small amount of a radioactive tracer (^{68}Ga-RM2 and ^{68}Ga-PMSA11) 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 up to 60 minutes while the machine performs the scan. You will be asked to not eat or drink anything but water (i.e., "fast") for about 4 to 6 hours before the scan. The entire procedure will take about 30 to 60 minutes. You may experience some discomfort or anxiety from being in the confined space. If you become anxious or concerned in tight spaces, or from loud noises, tell the study team or technician **before the scan**. The camera will record the tracer's signal as it travels through your body.

Routine Clinical Follow-Up
Once study staff contact you after your second scan after treatment, your active participation in this clinical research study is complete. However, the Study Doctor and research study staff will continue to monitor your medical record to record the results of any biopsies or imaging scans performed as part of your standard medical care. This information is needed for investigators to study whether lesions detected by ^{68}Ga-RM2 or ^{68}Ga-PMSA11 are later confirmed to be malignant and if the treatment worked. Investigators will monitor your medical record for 12 months after the last image is collected.

If you transfer your regular medical care to outside Stanford during this 12 months chart review, study staff will contact you to get your permission to access medical records from your new treating physician.

Any of your samples (images) 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 Investigators, 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.

Future Use of Private Information and/or Specimens
Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for

future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Adverse event monitoring will be performed as part of the procedures described above. During the treatment period, the Study Doctors will monitor you for any potential side effects.

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 treatment.

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.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Study Doctor and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Study Doctor or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Study Doctor or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Study Doctor or research staff if you believe you might have gotten your partner pregnant.
- Ask questions as you think of them.
- Tell the Study Doctor or research staff if you change your mind about staying in the study.
- This study has magnetic resonance imaging (MRI) scans that are required. Tell the Study Team or the MRI operator if you have any tattoos on your body, including eyeliner and other permanent makeup.

WITHDRAWAL FROM 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. Iagaru at 650-725-4711.

If you withdraw from the study, or the investigational imaging agent administration is stopped for any reason, study staff will request permission to contact you 24-72 hours after investigational imaging agent administration to check on how you are feeling. You will not be required to return to clinic.

If you choose to withdraw from the study after undergoing one image collection, study staff will request your permission to continue monitoring your medical record for results from clinical biopsies and image collection, as outlined above. Please tell Dr. Iagaru if you also wish to withdraw from the medical chart review.

The Study Doctor may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The study doctor decides that continuing your participation could be harmful to you, or otherwise not in your best interest.
- Pregnancy
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

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 Risks from ^{68}Ga-RM2 or ^{68}Ga-PMSA11
The amount of targeting agent (RM2 or PMSA11) is so small that it does not affect body processes. We previously used ^{68}Ga-RM2 and ^{68}Ga-PMSA11 in patients with prostate cancer and no adverse events were recorded.

Possible Risks from Procedures
There are other risks and possible discomforts you might experience from the study procedures. The following discusses procedure risks related only to the research, and does not include risks of procedures that should be discussed as part of your regular medical care.

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.

Intravenous Injection: You may experience some temporary discomfort, bleeding, bruising, or rarely, infection, at the site of a needle stick.

Radiation Risk: You will be exposed to radiation during this research from 68Ga PSMA 11 and 68Ga RM2. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation exposure is about 23 mSv, which is approximately equal to 46% of the limit that radiation workers (for example, a hospital x-ray technician) are allowed to receive in one year. This amount of radiation involves minimal risk and is necessary to obtain the research information desired.

MRI (Magnetic Resonance Imaging – Part of the PET/MRI Scans) Risks:
Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. Exposure of the following to MRI magnetic fields may cause harm to you or others.

- If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately, these devices could malfunction when exposed to the very strong magnetic field.

- As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (metal plate; pin; screws; surgical clips; metallic fragments), devices (including hearing aids), or implants that are in or on your body before entering the magnet room. These pieces of metal could move while in your body, causing possible serious injury or death
- If you have any tattoos on your body, including eyeliner and other permanent makeup they could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.

All metal objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, if you have, or previously had kidney problems, or if you could be pregnant, this may mean you should not have an MRI scan performed. You should notify the operator/investigator of any of these events.

When you are in the MRI scanner, you may experience discomfort or anxiety due to be in the small space inside the machine, or from the loud noises the MRI scanner makes. Dizziness or upset stomach (nausea) may occur if you move your head rapidly within the magnet.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs.

Some of the radio frequency imaging coils, imaging software and devices being used in your scan are not approved by the FDA but are similar to counterparts that have been approved by the FDA. There is a small risk of heating from the cables associated with these devices. Please report any heating sensation immediately.

The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The

investigators, the consulting physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

PET scans (part of the PET/MRI scans) Risk: A PET scan exposes you to a small dose of radiation (discussed above). When you are in the PET 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**.

Injection of radiotracers: A radiotracer will be injected for the medical scans, such as PET/MRI scans. Following are the risks associated with injection of contrast agents.

- Allergic reaction, which can be severe and/or life threatening.
- Kidney problems or kidney failure, especially if you are taking Glucophage (metformin, a common medicine for diabetes).
- 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.
- If you are a smoker or exposed to cigarettes or nicotine, you may experience spasms in the arteries of your heart.

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 be concerned about your personal information being revealed. Although the Study Team, Stanford, and FDA does their best to protect your personal information, this can not be absolutely guaranteed.

Other risks: Since ^{68}Ga RM2 and ^{68}Ga PMSA11 is investigational (“experimental”), there may be other risks that are unknown (“unforeseeable”) at this time.

It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by ^{68}Ga-RM2, ^{68}Ga-PSMA11 or study procedures. You can contact the Study Team at 650 725 4711. 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

No treatment for prostate cancer is offered as part of this study. Your participation can help researchers develop new tools to better monitor or diagnose disease in the future.

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

ALTERNATIVES

Your participation in the study is voluntary. The alternative is not to participate.
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 Study Doctor.

You will be told of any important 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.

ClinicalTrials.gov

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.

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 Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of ^{68}Ga-RM2 and ^{68}Ga-PMSA11; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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 is a clinical research study to evaluate the safety and efficacy of ^{68}Ga-RM2 and ^{68}Ga-PMSA11, investigational imaging agents. This study may help the sponsor and FDA determine if ^{68}Ga-PSMA-11 and ^{68}Ga-RM2 are useful as PET/MRI imaging agents for prostate cancer. Your health information will be used to verify the study conduct and data entry, assess the imaging agent accuracy, and prepare regulatory documents for submission to the FDA for marketing approval. Your coded information may also be used in research related to the imaging agents, your cancer and related diseases, and/or diagnostics to inform treatment. 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 study. 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 (e.g., 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:

Dr. Andrei Iagaru
300 Pasteur Dr., Room H-2200
Stanford, CA 94305-5281

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, your personal identifiers (such as name and initials, address including ZIP code, phone numbers, dates including date of birth, age, Social Security Number, medical record number (MRN); and other numbers or codes such as your unique study identifier that might identify you) and demographics such as gender, race, ethnicity. During the study researchers will also obtain information about your health status, lifestyle choices, personal and family medical history (past, present and future) and allergies; information from clinical care (including medical reports, laboratory tests, biopsies and imaging). 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, Andrei Iagaru, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

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:

- NIH
- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration

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 December 31, 2068, or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

FINANCIAL CONSIDERATIONS

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the 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.

Payment/Reimbursement

You may be provided with reimbursement of up to $250 for your participation in this study for reasonable travel expenses associated with the study visits. Please ask the study team for more information.

Payments or reimbursements may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your Social Security Number (SSN) or equivalent (i.e., 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.

Sponsor / Funding Source

NIH is providing financial support and/or material for 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 Study Doctor and the research study staff 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 Study Doctor 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 ask the Protocol Director, Dr. Andrei Iagaru. You should also contact him at any time if you feel you have been hurt by being a part of this study. You may contact him now or later at 650-725-4711.

If you are unable to reach anyone at the number 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.

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 to be 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.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
If needed: Signature of Legally Authorized Representative (LAR) (e.g., parent, guardian or conservator) Date

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

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 consent.

_____ _____
Signature of Witness Date

_____

Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) 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.*