

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Andrei Iagaru, MD.

IRB Use Only

Approval Date: January 15, 2019

Expiration Date: January 15, 2020

Protocol Title: High quality imaging and dosimetry of Yttrium-90 (90Y) SIRT using a digital PET/CT

Are you participating in any other research studies? _____ Yes _____ No

PURPOSE OF RESEARCH

You are invited to participate in a research study of evaluating the image quality and feasibility of digital PET/CT imaging after selective internal radiation therapy (SIRT). We hope to learn if the images produced by the digital PET/CT scanner can provide superior information about the distribution of the particles delivered for SIRT compared to the ^{99m}Tc-MAA SPECT/CT images. You were selected as a possible participant in this study because your doctors referred you to the Nuclear Medicine and Interventional Radiology Clinics for evaluation of extent of disease and you are scheduled to undergo SIRT. After you undergo SIRT, we would like you to have a digital PET/CT scan; the digital PET/CT scan is the research portion of the study.

If you decide to terminate your participation in this study, you should notify Dr. Andrei Iagaru, the Protocol Director,

Stanford University expects to enroll up to 75 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

This is a 3-year research study. Your active participation in this study is expected to be between 1-2 hours post- SIRT for only one visit.

PROCEDURES

- After you have had the SIRT procedure, the research portion of the study will begin. You arrive to Nuclear Medicine for your research scan.
- You will be asked to lie still on the padded table during the scan because movement can interfere with the results.
- You will be asked to breathe normally during both the CT and the PET portion of the scan.

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- Nuclear Medicine technologists will administer contrast during the CT scan to help show tumor morphology on the scan.
- The table will move slowly through the tube-shaped digital PET/CT scanner for 30 minutes while images are acquired.
- Our technologist will monitor you throughout the duration of the scan.
- The scan should take approximately 30-minutes.
- You will only undergo one (1) digital PET/CT scan. After this scan, the research part of the study is over.

Depending on the timing of your SIRT procedure, your schedule, as well as the Nuclear Medicine staff, you may receive your post-SIRT procedure research scan the same day, or the day after your SIRT therapy.

If your imaging is happening on the same day, the IR nurses will leave your IV in to be used by Nuclear Medicine to give the CT contrast. After imaging is over, the IV will be removed. If your imaging is happening the next day, then IR will remove the IV before sending you home. A new IV will be placed for the CT contrast material the next day. After imaging is over, the IV will be removed. If you have an iodinated contrast allergy, the contrast injection will be omitted.

Women of Childbearing Potential

If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unnecessary risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study (*we are able to use the results if you received a pregnancy test prior to undergoing ⁹⁰Y SIRT*). You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Undergo the digital PET/CT scan as instructed

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- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

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. Andrei Iagaru, the Protocol Director, at

If you withdraw from the study your images will not be analyzed or used in the research study.

The Protocol Director 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 Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- 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. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

- Patients who are claustrophobic may feel some anxiety while positioned in the scanner;

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- Some patients find it uncomfortable to hold one position for more than a few minutes;
- As a participant, you will receive exposure to radiation from the CT portion of the PET/CT scan, that is not necessary for your medical care and is for research purposes only. The additional amount of radiation exposure is up to approximately 5.0 mSv, which is approximately equal to 10% 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.
- If you are pregnant or breast-feeding, you may not participate in this study.
- here is a small volume (50 ml) of iodinated contrast to be given during the CT scan. This will require the introduction of an intravenous (IV) catheter. As with any IV catheter, there is some discomfort associated with introduction of the catheter. There can also be some redness and swelling associated with the catheter placement, but these will usually subside quickly. With the contrast injection, there is a risk of contrast extravasation (leakage) into the skin which can cause swelling and mild pain. You will be offered a hot or cold compress to help mobilize any extravasated contrast, and if very severe, you would be offered the appropriate supportive care, which in rare instances includes transfer to the emergency room and surgical consultation.
- If you have had a previous reaction to iodinated contrast agents or a history of severe allergies, (e.g., to medications, iodine, contrast agents, tap, latex, bee-sting, food, shellfish, nuts), please notify study team and scan operator.
- If there is any reason for you not to have the iodinated contrast, it will be omitted at physician discretion.

POTENTIAL BENEFITS

We cannot and do not guarantee or promise that you will receive any benefits from this study. The information obtained from your ⁹⁰Y digital PET/CT scan will be reported and shared with the referring physicians involved in your care, which could potentially impact clinical-decision making moving forward.

ALTERNATIVES

The alternative is not to participate.

PARTICIPANT'S RIGHTS

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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, Dr. Andrei Iagaru.

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.

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.

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.

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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?

The purpose of this research is to assess the image quality of the digital PET/CT scanner. The Protocol Director, research team, and the sponsor, and other regulatory agencies as required will have access to the results.

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.

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

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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, Protocol Director
Stanford Radiology,
Division of Nuclear Medicine and Molecular Imaging

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 your name, MRN, age, gender, medical condition; and your ^{99m}Tc-MAA SPECT/CT and ⁹⁰Y digital PET/CT images.

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, Dr. Andrei Iagaru
- 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:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- GE Healthcare
- The Food and Drug Administration
- Your Referring Physician

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.

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When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2030, 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) _____
(e.g., parent, guardian or conservator) Date

Print Name of LAR

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

Participant ID:



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FINANCIAL CONSIDERATIONS

Payment

You will be paid \$150 for participation in this study.

Payments 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 to receive payment.

Costs

There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to the study visit.

Sponsor

GE Healthcare is providing some financial support 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 Protocol Director 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 Protocol Director 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.

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CONTACT INFORMATION

Questions, Concerns, or Complaints: 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 may contact him now or later at You should also contact him at any time if you feel you have been hurt by being a part of this study.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Andrei Iagaru. You may contact him now or later at.

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 (or toll free at. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, 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

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- 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

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

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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.*

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