CONSENT FORM

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

PURPOSE OF RESEARCH

You are invited to participate in a research study of lung perfusion (how blood flows through lung over time). We hope to learn whether perfusion characteristics of lung tumors may be predictive of response to treatment and whether lung perfusion characteristics can be used to follow response to treatment. We are also studying whether these perfusion characteristics correlate with levels of circulating-tumor-DNA in your blood. You were selected as a possible participant in this study because you are identified as having a lung tumor.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time without prejudice to your or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. Max Diehn at 650-725-4783.

This research study is looking for 20 people with lung tumors which can be imaged with perfusion CT. Stanford University expects to enroll 20 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

The perfusion CT will take approximately 15 minutes extra of your time. A total of three perfusion CTs will be performed as part of this research study: one at the time of your radiation treatment-planning scan, one within 48 hours of your first radiation treatment, and one at the time of your first follow-up diagnostic CT (typically performed 3 months after you complete radiation therapy). This totals to an extra 45 minutes of your time.

The investigational procedures of this study requiring your direct participation will be complete at the time of your first follow-up imaging study (3 months after your radiation therapy). You will also be followed-up 1-year after your radiation therapy. After this point, you will be followed by your physician according to standard of care, but you will still be considered a participant in

this study for the purpose of analyzing outcomes. Therefore, your involvement will be for the duration that you are receiving cancer therapy and follow-up at Stanford.

PROCEDURES

If you choose to participate, Dr. Diehn and his research study staff will ask you to participate in this study by undergoing an extra CT sequence called a perfusion CT in which a specific section of the lung is scanned over time with low dose CT after the injection of intravenous contrast and imaged serially. You will then undergo your regular standard of care CT scans as part of your clinical care. You will receive a minimal increase in radiation dose compared to your normal CT examination. The extra sequence will require approximately 30-60 seconds of extra CT scanning and approximately 15-30 minutes of total extra time. At your 1-year follow-up, you will have physical assessment, concurrent medication review and adverse events evaluation. A diagnostic CT scan will also be done for this follow-up time point as per standard of care.

Examples of images (case studies) and some study results may be used to provide feedback to the CT manufacturers (GE Healthcare, Siemens Medical Solutions), who indirectly support this research by providing or upgrading scanner equipment and software. Any images or results shared with GE Healthcare or Siemens will be de-identified, and your personal information will not be shared with them.

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. 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 breastfeeding during this study, you or your child may be exposed to extra radiation.

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. 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 a 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.

If you choose to participate in this study, you will have the option to have your blood drawn at the time of each perfusion CT scan to assess the level of circulating-tumor DNA in your blood. This is an optional correlative study and is not required for participation in this study. The levels of circulating-tumor DNA in your blood will be correlated with the perfusion characteristics of your tumor. These levels will not be used to guide therapy in any way. Obtaining these levels

IRB Use Only
Approval Date: November 10, 2020
Expiration Date: November 10, 2021

will help the investigators of this study learn how to interpret the perfusion characteristics seen in your lung tumor demonstrated by the perfusion CT scans.

____ I consent to participate in the correlative blood research

____ I do not consent to participate in the correlative blood research

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- 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.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study. This is to protect you from possible injury arising from such things as extra x-rays and possible interactions with the contrast material used in the CT scans.

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.

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
- 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. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

This research study involves exposure to radiation from CT scans that is not necessary for your medical care and is for research purposes only. The additional amount of radiation exposure is up to about 22 mSv, which is approximately equal to 44% of the limit that radiation workers (for example, a hospital x-ray technician) are allowed to receive in one year.

POTENTIAL BENEFITS

Although there will be no direct benefit at the time of the study, the knowledge we gain may provide future benefit to subjects who undergo routine clinical CT studies.

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

ALTERNATIVES

The alternative is not to participate. Your treatment and care will not be affected by your decision to participate or not participate. Participation/non-participation will not affect the routine radiologic evaluation of studies and clinical care of the patients.

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 will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

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.

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 study is, through image analysis and assessment, to establish the optimal selection of image acquisition parameters and contrast medium injection parameters for routine clinical CT studies of various organ systems imaged with the latest technology in CT scanners. You were selected as a possible participant in this study because you are identified as having a lung tumor. Your lung perfusion data will be de-identified and then analyzed. Images without any identification may be used in clinical presentations or publications.

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 or undergoing your scheduled CT 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. Max Diehn
Department of Radiation Oncology, Stanford Cancer Institute
875 Blake Wilbur Drive, MC 5847
Stanford, California 94305-5105

What Personal Information Will Be Used or Disclosed?
Your health information related to this study may be used or disclosed in connection with this research study which may include your de-identified CT images, CT report and laboratory information. Other health information that may be used in relation to this study includes patient name, medical record number, age at onset of disease, extent of disease, current age, weight, height, therapies to date, diagnosis, and medical treatment plan, imaging information and any other information related to the malignancy.

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. Max Diehn)
- 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 and Siemens Medical Solutions
- 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 expire on January 1, 2059.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

You will receive no payment for your participation.

Costs

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

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.

The protocol director will obtain insurance authorization for treatments associated with this study prior to your participation. Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any co-payments and/or deductibles as required by your insurance.**

Sponsor

Financial support for this study is provided by the American Society of Radiation Oncology.

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.

CONTACT INFORMATION

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.

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. Max Diehn at 650-725-4783. You should also contact him at any time if you feel you have been hurt by being a part of this study.

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.

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.

IRB Use Only
Approval Date: November 10, 2020
Expiration Date: November 10, 2021

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
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.*