Title of Study: Intra-procedural Spectral CT for embolization and ablation in interventional oncology			
Title of Consent (if different from Study Title):			
Principal Investigator: **Sirish Kishore, MD**	VAMC:	VA Palo Alto HCS	IRB# 76216

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

CONCISE SUMMARY

You are being asked to participate in a study to better determine if a new imaging technique can be used to improve your minimally invasive tumor treatment. You are either undergoing an embolization or an ablation procedure in interventional radiology where the goal is to provide treatment directly into your liver or kidney tumor.

For embolization, these treatments are delivered into the blood vessels feeding the tumors in your liver. Improving these treatments relies on better understanding the blood flow into the tumor, identifying the tumor target, and improving the amount of treatment that can be delivered into your tumor while lowering the amount delivered to your normal liver or lungs.

For ablation, we direct a needle into your liver or kidney tumor using imaging guidance to deliver energy in the form of heat, cold, or electricity to destroy tumor cells, and preserve your normal structures in your liver or kidney. Improving this treatment relies upon improved identification of the tumor, improved ability to guide the needle to the target, and improved ability to monitor the delivery of energy during and immediately after treatment. We are attempting to use a special type of CT scan during the procedure to accomplish these improvements. We typically perform CT scans whether or not you decide to participate, but if you participate, the scan will add 0.5 sec to the standard acquisition time, and will not significantly increase your radiation dose.

Your participation is completely voluntary. If you decide not to participate, you will still receive treatment of your liver or kidney cancer, and you will still undergo a CT as part of that treatment.

This research study is looking for 30 people with primary liver or kidney cancer. The VA Palo Alto expects to enroll all 30 research study subjects.

PURPOSE OF RESEARCH

If you choose to participate, the investigators will schedule you for all visits and procedures. You are being enrolled because, as part of your standard of care treatment, you will undergo an embolization or ablation treatment of your liver or kidney tumors. This procedure will be performed whether or not you participate in the study.

For an embolization procedure, you will have a catheter (a long, narrow tube), placed into the large blood vessel of your leg or wrist (called an artery), which will then be used to find the arteries of the liver feeding the tumors. Once these arteries are identified using contrast (or "dye") injection and x-rays, the arteries will be injected with a radiotracer or small radiation-emitting particles. During this procedure, a CT scan is typically performed to map the blood vessels feeding the tumor. Currently, the CT scan only tells us which blood vessels are feeding the tumor but do not provide additional information. Once the procedure is completed, the catheter is removed and a small plug is placed on the artery to close it. Only a small band-aid is left on the skin. No large incisions or sutures are used. The following is the only aspect of the procedure that is not part of your routine care:

- Obtaining a spectral CT scan that lasts for 1.0 sec instead of 0.5 sec to determine if tumor targeting can be improved

All other aspects of the procedure are part of your routine care.

For an ablation procedure, you will undergo several CT scans to allow a needle to be placed under image guidance into the tumor in your liver or kidney. During this procedure, a CT scan is typically performed to identify the tumor to allow for a needle to be placed into it, as well as monitor the ablation in real time as energy is delivered through the needle to treat the tumor. Once the procedure is completed, the needle is removed and a sterile dressing is applied. A final CT is obtained to rule out any complication of the procedure, as well as confirm that the target tumor has been treated satisfactorily. The following is the only aspect of the procedure that is not part of your routine care:

- Obtaining a spectral CT scan that lasts for 1.0 sec instead of 0.5 sec to determine if tumor targeting and ablation monitoring can be improved

All other aspects of the procedure are part of your routine care.

As a participant, your responsibilities include:

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

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 you are entitled to.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take about one year to complete. Your involvement would be for only for the day of your treatment. Follow up is done as a part of your clinical care, but no research will be done during this time.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

This study involves the following risks, discomforts, and possible inconveniences: Transcatheter arterial radioembolization and mapping arteriography procedure: This is standard-of-care and will be part of your treatment whether you participate in this study or not. The full risks of the procedure will be discussed with you prior to the procedure by your treatment team. There are risks involved with the mesenteric angiography and the embolization during this procedure. A mesenteric angiogram is a procedure in which a catheter (long narrow tube) is guided from a blood vessel in the leg (common femoral artery) into the blood vessel of the liver (hepatic artery) and is an essential part of procedure. Potential side effects and complications include groin soreness and bruise formation (less than 4%), damage to the blood vessels as a result of wire and catheter manipulation that results in failure to treat the liver (less than 1%), formation of a blood clot resulting in blockage of a blood vessel (less than 1%), infection (less than 1%). Risks from the embolization procedure include side effects resulting from particles lodging into areas outside the liver (called non targeted embolization). Although this is rare (less than 2%), blockage of the blood vessels relating to the lungs, stomach, pancreas, gall bladder, and digestive tract may result in ulceration or inflammation. Reports of particles lodging into the lung resulting in death are extremely rare. In addition, embolization has the possible risk of placing the liver into failure. Liver failure will usually not resolve and can lead to death. This potential complication is rare (less than 1%). You will likely have pain after the procedure in the abdomen near the liver. This usually resolves within 1 week and is well controlled with pain medication, which will be provided if needed. However, pain can last up to one month, or in rare instances, longer.

Percutaneous ablation procedure: This standard of care procedure for treating liver or kidney tumors will be discussed with you prior to the procedure by your treatment team.

There are risks associated with percutaneous ablation including injury to the adjacent organs such as the lung or colon, injury to the native organ (e.g. kidney or liver), bleeding, and infection. You may have pain near the ablation for 1 week, which is often well controlled with pain medication.

Intra-procedure Computed Tomography (CT) Scan: This study involves undergoing a CT scan during the procedure. This is an FDA approved use of this device. Whether or not you participate, an intra-procedure CT will be performed. If you participate, the CT scan will only add 0.5 seconds to the standard CT scan which is performed during these procedures to obtain the required images. There is no increase in radiation, as most of the scan modifications for the technique are then performed after the images have been obtained.

POTENTIAL BENEFITS

There is unlikely to be any direct personal benefit for participating in this study. However, there is a possibility that the information obtained in this study may help in the future development or improvement of treatment for patients who suffer from your condition.

ALTERNATIVES

As this is not a treatment study there are no alternatives to the study. You may choose to not participate.

Your study doctor will discuss the risks and benefits of other treatments for your disease with you before you decide whether or not you want to participate in this study. You do not have to participate in this study to receive treatment for your cancer. If you decide not to participate in this study, your decision will not affect your medical care in any way. Your condition may already have been discussed and decided at a multidisciplinary tumor board involving several experts in the fields of surgery, radiology, hepatology, medical oncology and interventional radiology. Therefore, it is important that you discuss the benefits and risks of all treatment options with your doctor before signing this consent. If you choose to participate in the study, your study doctor will let you know if any new treatment for your condition becomes available which may affect your willingness to continue participation in this study.

FINANCIAL CONSIDERATIONS

Will I get paid?
There is no payment for participation in this study.

Will I have to pay anything?

There will be no costs to you for any of the treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

COMPENSATION for Research Related Injury

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence.

Sponsor

Canon, Inc is providing financial support and/or material for this study.

Consultative or Financial Relationships

The investigators do not have any financial relationships with Canon, Inc.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

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.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled and your decision will not affect your ability to receive medical care for your condition. If you want to stop being in the study you should tell the investigators or study staff. You can do this by phone by calling Dr. Sirish Kishore at 650-493-5000 ext 61706.

If you withdraw from the study,

- You will not undergo the spectral CT scan
- You will continue to undergo standard-of-care treatments for your liver or kidney tumors

The investigators 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 investigators and/or study staff.
- The investigators decide that continuing your participation could be harmful to you.
- Pregnancy (if applicable).
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONFIDENTIALITY

A confidential participant identification number will be used to ensure that information cannot be linked or traced to any person or family. 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.

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 information on the safety and effectiveness of insert name of the liquid biopsy assays; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

The purpose of the data collected for this project is for scientific research only and there will be no attempt to identify directly or indirectly any subjects in the research data. We will keep your name and all the information you tell us in this study confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

Information about you participating in this research study may be added to your VA Medical Records.

We will keep your name and all the information you tell us in this study confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

Your information will not be used or distributed for future research studies even if all identifying information is removed.

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.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

How will my health information be used in the study?

Your health information will be used to determine whether a perfusion CT scan will help to determine the amount of blood flow to a cancer tumor in the liver.

What Personal Health Information Will Be Used or Shared?

The following health information, linked to you by your name and SSN will be used for this research:

- Medical history and physical examination information
- Progress notes
- Laboratory Test Results on blood, tissue, urine, saliva
- Operative reports
- X-ray, MRI and CT scans
- Discharge summary
- Telephone number

Who May Use or Share Your Health Information?

By signing this document, you allow the following individuals and entities to obtain, use and share your health information for this research study:

- The Principal Investigator, Sirish Kishore, and members of the VA research team.
- Departments within the VA Health Care System responsible for the oversight, administration, or conduct of research.

- The Stanford University Administrative Panel on Human Subjects in Medical Research and other Stanford University Officials responsible for the oversight, administration, or conduct of research.

Who May Receive and Use Your Health Information

The investigators may share your health information with the following individuals as part of this research study.

- Canon, Inc (Sponsor)
- The Palo Alto Veterans Institute for Research (PAVIR), who administers the funding for this project, and any agents or outside entities hired by PAVIR to assist them in carrying out their responsibilities
- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Other outside individuals or entities hired by the VA Palo Alto Health Care System to do certain work in support of the VA Health Care System
- The Food and Drug Administration

We will protect your health information as required by all laws, however health information shared with others may no longer be protected by Federal laws or regulations and might be shared by the parties above.

Do I have to sign this form?

No. Signing this form is voluntary. The VA may not condition treatment, payment, enrollment or eligibility for benefits based on signing this form. If you decide not to sign the form, you will not be able to take part in this study.

If I sign now, can I decide later not to continue in the study?

Yes. You are free to take back your permission and stop being in the study. The investigators will not collect any more information about you after you take back your permission, but they can continue to use your information that was collected before you took back your permission.

Your request to take back your permission must be done in writing. Either give your written request to the investigator or send it by mail to: Dr. Sirish Kishore, 3801 Miranda Ave MC114, Palo Alto, CA 94304

Does My Permission for the use my Personal Health Information Expire?

Yes. Your information cannot be used forever. Your permission related to the use and sharing of your health information expires when this research study is completed or on 6/1/2050.

HIPAA regulations require you to give separate written permission (signature) for the use of your protected health information.

_____ _____

Signature of Participant Date

What happens if I think I've been hurt by being in this study?

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence. You should contact the Principal Investigator if you feel you have been hurt by being a part of this study.

Who can I talk to about a Research Related Injury?

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence.

Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?

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 principal investigator, Sirish Kishore, MD 650-493-5000 ext 61706. 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 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 and would like to speak someone independent of the research team please contact the Stanford Institutional Review Board (IRB) 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.

What are my rights if I take part in this study?

You have the 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.

_____ _____
Signature of Participant Date

_____
Print Name of Participant

Person Obtaining Consent:

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

HIPAA regulations require the participant to give separate written permission (signature) for the use of their protected health information.

Person Obtaining Consent HIPAA Authorization confirmation:

☐ Confirm the participant signed the VA HIPAA Authorization section of this consent form