Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: A prospective study of the augmented whole-body scanning via magnifying PET/CT (AWSM-PET/CT) technique's abilities to improve upon the diagnostic accuracy of the standard-of-care (SOC) PET/CT for malignant lesion detection

Principal Investigator: Yuan-Chuan Tai

Research Team Contact: Jennifer Frye and Alyssa Massman 314-747-1604

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study sponsored by the National Institutes of Health and conducted by the Principal Investigator: Yuan-Chuan Tai. This study seeks to learn more about a magnifying device that can be used in conjunction with standard PET/CT imaging (positron emission tomography combined with computed tomography). The primary goal of the study is to see if the device provides additional information which may be helpful to doctors in staging/restaging or confirming if cancer is present based on the standard PET/CT scan. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The purpose of this study is to learn more about a magnifying device that is added to the PET/CT scanner and to see if a scan taken with this device can provide additional information that would be helpful to doctors in the future.
- As a voluntary participant, you will be asked to have your currently scheduled standard PET/CT scan done with the magnifying device in place. This will add approximately 15 minutes of additional time to the standard scan.
- You were selected because you are currently scheduled to receive a standard PET/CT scan.

- Your active participation will require approximately 3 hours of your time. The study will follow your medical record for up to 9 months after the scan is completed.
- You will need to come to Barnes-Jewish Hospital (downtown main campus location)
- The risks to you are similar to having the standard PET/CT scan. You might experience some discomfort from lying on the scanning table for up to an additional 15 minutes needed to complete the part of the scan with the magnifying device in place. More detail about risks is provided under the "What are the risks of the study?" section of this document
- You will not benefit from this study, but we hope that other people may benefit in the future from a more specific imaging test to help doctors find the best treatment.
- You or your insurance company will be responsible for the cost of the standard PET/CT scan. You will receive payment for your additional time spent with the research imaging. More information can be under the "Will I be paid for participating?" section of this document
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because your doctor has scheduled you to have a standard of care (SOC) PET/CT scan. When injected with a specific imaging medication which is allowed to circulate in the body a PET/CT scan can provide more information about cancer cells based on how they are working or functioning in the body. Your doctor has scheduled you for this test because you either are suspected of having cancer, have a diagnosis of cancer or have been or are currently being treated for cancer and additional imaging is needed.

The purpose of this research is to study an investigational imaging device that is added to the PET/CT scanner. The device is called augmented whole-body scanning via magnifying PET or AWSM-PET. The goal of the study is to see if additional images from AWSM-PET provide more detail than the standard PET/CT scan and whether or not the AWSM-PET images provide additional information to doctors that might help determine the best treatment for patients in the future. If you are scheduled to undergo biopsy or surgery, the accuracy of the device will also be evaluated by comparing the scan results to your surgery or biopsy results.

The AWSM-PET device is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

For this study, your currently scheduled PET/CT scan will be scheduled or rescheduled to occur on a scanner that can hold the AWSM-PET device. The following information explains how the SOC PET/CT scan is performed. Information noted as *RESEARCH SPECIFIC* will be done if you choose to participate in the study.

Depending on the type of PET/CT scan you are scheduled to receive, you may be requested to not eat anything for at least four hours prior to the scan. If you are a female of childbearing potential, you will be asked to provide a urine sample for a pregnancy test prior to any scan procedures. An intravenous (IV) catheter will be placed in your arm for administration of the imaging medication. At the time the IV is placed in your arm, it may also be necessary to draw a small sample of blood to check your glucose or blood sugar level.

The PET imaging mediation will be allowed to circulate (uptake) in your body while you rest comfortably. You may also be given saline or water through your IV line while it circulates. The amount of time the imaging medication circulates will be approximately 50-70 minutes. For the scan, you will be asked to empty your bladder in the restroom before being placed on your backside on the scanning table. Your arms will either be positioned to rest above your head or secured to your sides. The scanner is actually a combination PET and CT (computed tomography) scanner, and the scans are often referred to as PET/CT scanning. The PET/CT scanner allows us to take pictures of the function (PET) and structure (CT) of the body at the same time. A SOCPET/CT normally scans from the base of the brain to your upper thighs and takes approximately 20 minutes to complete.

RESEARCH SPECIFIC: The AWSM-PET device will be placed at the end of the scanning table which means more of your body will be scanned so that we are able to confirm that the standard length of your body passes through both the standard PET and the AWSM-PET portions of the scanner. The AWSM-PET will add no more than 15 minutes to the total scan time.

You will need to be at the hospital for approximately 2 ½ -3 hours to complete the SOC-PET/CT with AWSM-PET scan. Participation in this study will not result in a delay of any treatment your doctor(s) may have planned.

Your SOC PET/CT scan will be reviewed by the radiologist. The images and scan results will be placed in your medical record.

RESEARCH SPECIFIC: Two additional radiologists who are specific to this study will also review your scan. One doctor will be assigned to review the PET/CT with AWSM-PET (research study scan) followed by your SOC-PET/CT scan. The second doctor will review the scans in the opposite order (SOC-PET/CT followed by PET/CT with AWSM-PET). The results of the AWSM PET will not be placed in your medical record and will not be used to determine your care unless a life threatening or treatment altering finding is discovered.

Your active participation on the research study ends after the scan is completed. The study team will continue to follow your medical records for up to 9 months. If you undergo a biopsy or surgery for any reason the results of the biopsy or surgery will be recorded in your study records. The AWSM-PET scan results will be compared to the results of your biopsy/surgery (if available) or imaging and medical records to see how accurate the new scanning method is.

Will you save my research information to use in future research studies?

We would like to use the scan data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in diagnosing and staging different types of cancer, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your scan data you give up any property rights you may have in the scan data.

Your scan data will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study conducted by investigators at Washington University.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The risks described below include risks associated with the SOC PET/CT scan. Any study specific risks are noted by *RESEARCH SPECIFIC*

Risks associated with IV insertion and blood drawing:
Likely: Discomfort, swelling, bruising, or bleeding at the site of needle insertion
Less Likely: Dizziness or feeling faint
Rare: There is a rare risk of infection at the site of IV placement.

Risks Associated with PET/CT & AWSM PET/CT Imaging
Likely: Mild discomfort from lying on the imaging table.

- *RESEARCH SPECIFIC:* adding up to an extra 15 minutes of scan time may make discomfort from lying on the scanning table more likely.

Less Likely: Mild back or shoulder discomfort during the scan.

- *RESEARCH SPECIFIC:* some people might feel claustrophobic or closed in with the AWSM PET device added to the end of the scanning table.

Rare: There is a rare risk of an allergic-type or other adverse (bad) reaction to radioactively labeled drugs. While none have been encountered to date with the radioactive materials used for standard imaging, such a reaction could be serious and may result in death. It was recently reported by the FDA that the CT scan may cause a malfunction of electronic medical devices. There is a rare risk of malfunction of worn or implanted electronic medical devices with CT scanning. If you wear or have electronic medical devices implanted such as a pacemaker or a drug pump, please make sure to tell your

study doctors and research staff.

Women Capable of Becoming Pregnant
If you are a woman capable of becoming pregnant, we will ask you to have a urine pregnancy test on the day of the scheduled scan. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses (including the SOC PET/CT scan) but there will be no additional charges to you or your insurance company for the added AWSM-PET/CT research specific portion of the scan.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. It can take 4 to 6 weeks for the check request to be processed and have your check mailed to the address you provide. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

We recognize and appreciate the time and effort to participate in a research study. You will receive parking validation on the day of your scan and compensation to cover additional costs you may encounter, such as meals, extra time at the hospital away from work or family, and/or other unforeseen expenses related to your participation and completion of the imaging study visit. The amount you will be compensated is $150 if you complete the AWSM PET. If you agree to participate but the AWSM-PET scan was aborted due to your inability to tolerate the scan or if it was not performed due to technical factors you will receive $25 for your time and trouble.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study through the National Cancer Institute (NCI). This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact Yuan-Chuan Tai, the principal investigator at 314-362-8429 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Representatives from the National Institute of Health or the National Cancer Institute
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements.
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Siteman Cancer Center
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly

identify you.

To help protect your confidentiality, we will store all paper documents behind two locks. All electronic data will be password protected and stored on a password protected computer. Your standard of care imaging data will become part of your medical record. The study specific AWSM-PET scan data will be stored by your assigned study specific ID and backed up on an encrypted hard drive which is password protected and stored behind two locked doors when not in use.

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.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not

discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

Can we contact you by email and/ or text message?

We would like to contact you by email and / or text message for the purposes listed below. Some of these messages may contain health information that identifies you.

- Scheduling or confirming appointments or providing additional instructions about the day of your scan including where to park.

Only the research team will have access to your email and / or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email or text message.

- Text messaging is not a secure communication method.

- There is always a risk that the message could be intercepted or sent to the wrong email address or phone number. To avoid this, we will send a test message to ensure we have the correct address or telephone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Leaving the study early may mean your SOC-PET/CT scan will need to be rescheduled. This could cause anxiety or possibly a delay in your treatment.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because there is a problem with the scanner or the AWSM-PET imaging device.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Yuan-Chuan Tai, the investigator at 314-362-8429**.** If you experience a research-related injury, please contact: Yuan-Chuan Tai, the investigator at 314-362-8429 or the study coordinators at 314-747-1604.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 04/28/27.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)