Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Imaging CCR2 Receptors with 64Cu-DOTA-ECL1i in Head and Neck Cancer

Principal Investigator: Farrokh Dehdashti

Research Team Contact: Jennifer Frye (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. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION:

This is a research study conducted by Dr. Farrokh Dehdashti having to do with newly diagnosed head and neck cancer. 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 the consent document below. 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 see if a specialized scan can be used in the future to give doctors more information and help determine the best possible treatment for a person with a new diagnosis of head and neck cancer.
- As a voluntary participant, you will be asked to spend approximately 3 hours at the hospital for the scan.
- You were selected because you are scheduled to receive surgery or other treatment for your newly diagnosed head and neck cancer.
- Your active time in this study will be for about 3 hours on a day before your scheduled surgery or start of treatment.
    - You will be in the study until your surgery has been completed or you have started non-surgical treatment.

- You will need to come to Barnes-Jewish Hospital Main Campus located in central St. Louis near Kingshighway Blvd. and Highway 40/64.
- The main risks to you are a small amount of radiation exposure from the injection of the study medication and discomfort from lying on the scanning table. More detail about risks is provided on pages 5 and 6 of this document.
- You will be paid up to $250 for participating in this study. You will not have costs for participating.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have been diagnosed with head and neck cancer and will be scheduled for surgery or other treatment.

The purpose of this research study is to see if a Positron Emission Tomography (PET) imaging agent called ^{64}Cu-DOTA-ECL1i can provide more information about your cancer. The primary goal is to see if ^{64}Cu-DOTA-ECL1i PET imaging can predict how well you will respond to surgery or other treatment.

^{64}Cu-DOTA-ECL1i 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?

To participate in this study, you will be asked to read and sign this consent form before any study procedures are performed. Your study doctor and staff will determine if you are eligible to continue to participate by reviewing your medical history, medical records, current medications, and imaging scans. Standard medical procedures that are part of your regular cancer care and probably would be done even if you do not join the study will be reviewed along with those procedures that are done for research purposes only**.**

Imaging Day: After obtaining informed consent study procedures will begin. If you are woman capable of becoming pregnant, a blood or urine pregnancy test will be performed to confirm you are not currently pregnant and can continue on study. Two IVs will be placed in a vein of your arm or hand. If possible we will try to place one IV in each arm. One IV will be used to give you the ^{64}Cu-DOTA-ECL1i PET imaging agent. The second IV, whenever possible,will be used to draw blood samples at several different time points during the imaging day.

- Your current height and weight will be recorded.
- A sample of blood (approximately 3 teaspoons) of blood will be taken from your IV line for standard laboratory testing (complete blood count and organ function). Additional blood samples described below will be taken and used to measure how quickly ^{64}Cu-DOTA-ECL1i is taken up by your organs from the blood stream (serum stability) and how quickly it is processed and leaves your body (metabolites).
- Your blood pressure, heart rate, breathing rate, and temperature (Vital signs) will be recorded.

- An electrocardiogram (ECG or tracing of your heart) will be recorded. For this test, stickers will be placed on your chest, shoulders, arms and legs. A series of wires will be hooked up to the stickers allowing a machine to recording a tracing of your heart.

You will be asked to empty your bladder in the restroom before the start of the scan. Throughout the scanning day you will be asked to drink water or other fluids and use the restroom as frequently as possible. You might also receive saline or water through your IV line to help you use the restroom more often.

Scan #1 All Patients: At all scanning time points you will be made as comfortable as possible while laying on your back on the imaging table. Warm blankets will be provided along with cushions to place under your knees. You will be asked to lie with your arms resting either down to your sides or above your head depending on the type of scan being done and what is most comfortable for you. The scanner will be a combination PET/CT scanner and is used to take pictures of your body. PET scanners allow us to image the function of different cells and organs in the body. The CT scan (computed tomography) is a type of x-ray scan that images the anatomy (size or structure) of the body in two dimensions. The combined PET/CT scanner is a special type of scanner that allows us to image both structure (CT) and function (PET) following the injection of ^{64}Cu-DOTA-ECL1i.

For the first scan you will be asked to lie on the imaging table. Following a low dose CT scan of your head and neck you will be positioned in the scanner so that your known site of disease is at the center of the scan. The ^{64}Cu-DOTA-ECL1i imaging tracer will be given to you through one of your IV lines. The PET scan will start at the same time you are given the imaging tracer.

- You will rest comfortably inside the scanner for approximately 65-70 minutes while the scan is acquired.
- Approximately 5 minutes after the start of the scan a small sample of blood (approximately ½ a teaspoon) will be drawn from your IV line for serum stability and metabolite measurements. At the end of the scan a second (approximately ½ teaspoon) sample of blood will be drawn for the same purpose. (whenever possible)
- At the end of the scan you will be removed from the scanner and given a short break. During this time, your vital signs will be recorded.
- You will be asked to empty your bladder in the restroom.

Scan #2 All Patients: After a short break you will be asked to lie on the scanning table again. A low dose CT scan of your upper body (from head to upper / mid chest) will be obtained. The total amount of time needed for this scan will be about 15 minutes.

Discharge Imaging Day before you leave the PET facility at the end of the imaging day the following tests / procedures will be performed:

- Your vital signs and ECG will be recorded.
- A small sample of blood (approximately 3 teaspoons) will be collected for standard laboratory testing (complete blood count and organ function).

Scanning Follow up: at least 24 hours after your scanning day you will be contacted by telephone. You will be asked how you have been feeling since your scanning day in an attempt to see if you have had any complications or problems that might be associated with the injection of ^{64}Cu-DOTA-ECL1i or the PET/CT scans. If you are going to surgery soon after the scan has finished this follow up might not occur until after your surgery day.

Study Discharge: You will be considered off study after you have had surgery as planned. If, for some reason you do not receive surgery the study will follow your medical record until you have started on a recommended treatment.

Tissue Testing: different types of cancers are known to express different types of proteins. The role of these proteins in cancer is still being studied. One protein that is being studied in a number of different types of cancer is CCR2 (C-C motif chemokine receptor 2). Overexpression of CCR2 may be associated with more aggressive forms of cancer. If tissue is available (from your original biopsy, or at the time of surgery) we will request a small sample of tissue for CCR2 testing. The results of the CCR2 testing of your tissue will be compared to your ^{64}Cu-DOTA-ECL1i scans to see if the scans give additional information about CCR2 levels.

Study Results: the results of your standard laboratory testing will be reported and included in your medical record. The results of your ^{64}Cu-DOTA-ECL1i scans, CCR2 tissue testing, your ECG tracings and vital sign measurements are done only for study purposes and will not be made available to you or your doctors through your medical chart. If any of these tests provide additional information which is significant enough to change or influence your medical care (for example a scan that shows different or additional treatment might be needed or surgery may not be the best possible treatment for you at this time) this information will be communicated to your treatment team by phone call or secure email. If this would happen the doctor / team who is treating you will discuss the findings with you. The imaging team is always available to answer your questions as well.

Will you save my research information and/or biospecimens to use in future research studies?

We would like to use the data and tissue 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 understanding CCR2's role in 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 data and tissue you give up any property rights you may have in the data and tissue.

Your data and tissue 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 for use in future research studies indefinitely and cannot be removed.

Identifiers may be removed from your private information including data and tissue and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your active participation will last for approximately 3 hours on a day before you are scheduled to undergo surgery or start treatment. You will be contacted by phone at least 24 hours after your scan do for a quick (5 min) follow up assessment.

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.

Some risks described in this consent document, if severe, may cause death.

IV Placement and Blood Drawing:

- **Mild / Likely:** discomfort from placement of the IV in your arm or hand or from the needle used to draw blood
- **Serious /Less Likely:** There is a slight risk of bruising, some people feel dizzy or faint when an IV is placed or blood is drawn from them
- **Life Threatening / Rare:** There is a rare risk of infection at the site of IV placement or blood drawing.

ECG: You may feel discomfort from the placement and removal of the electrode patches from the skin. Remaining still while the ECG is taken (less than 1 minute) may cause anxiety.

Vital Signs: You may feel discomfort from the squeezing of the blood pressure cuff around your arm.

64Cu-DOTA-ECL1i Injection:

Mild / Likely: pain or discomfort at the injection site. Temporary altered taste sensation. You may notice a metallic or other unusual taste at the back of your throat following injection. If this occurs it usually is gone within a short period of time after the injection.

Life Threatening / Rare: While none have been reported to date, there is a possibility of an allergic reaction to 64Cu-DOTA-ECL1i. Signs or symptoms of allergic reaction include a rash, fast pulse rate, sweating, a feeling of dread, swelling of the face, mouth, throat or extremities, wheezing or difficulty breathing, or a sudden drop in blood pressure making you feel dizzy or lightheaded.

PET/CT Scan:

Mild / Likely: discomfort from lying on the imaging table including but not limited to backache, shoulder and arm discomfort and general feeling of stiffness following the scan.

Life Threatening / Rare: Malfunction of worn or implanted electronic medical devices If you have electronic medical devices implanted such as a pacemaker or a drug pump, please make sure you tell your study doctors and research staff. The CT scan may cause a malfunction of electronic medical devices.

Radiation Exposure: This study will expose you to radiation from the injection of the radioactive drug ^{64}Cu-DOTA-ECL1i and from CT scanning used as part of the PET/CT scan. The amount of radiation from this, when averaged over your entire body, is approximately 18% of the amount a person who works with radiation is allowed to have in one year.

The risk from the radiation exposure in this study is too small to be measured. It is not a big risk when compared with other risks you take every day. If you want to know more about radiation exposure, please see the "Radiation Fact Sheet" at http://hrpo.wustl.edu or ask the study staff for a copy.

Failed Tracer Production or Scanner Problems

There is a possibility that the ^{64}Cu-DOTA-ECL1i imaging tracer which is made especially for you will not be available on the planned day of scanning due to failed production or the scanner needed to perform your scan may not be working properly. These failures are possible and may not be known until you have arrived for your study procedure. This situation may be an inconvenience to your time. Depending on where you are with your treatment plan, another date for ^{64}Cu-DOTA-ECL1i production and PET/CT scan may be scheduled if you are agreeable.

Women Capable of Becoming Pregnant

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. 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.

Radiation Exposure in Women Capable of Becoming Pregnant

You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before exposing you to research-related radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

Sexually Active Male
If you are a sexually active male it is important that your partner not become pregnant during your participation in this study. There may be unknown risks to the unborn child or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you believe or know that your partner has become pregnant during your participation in this study, please contact the research team member identified at the top of this document as soon as possible.

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.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because scans such as ^{64}Cu-DOTA-ECL1i PET/CT imaging may help personalize treatments based on the function of an individual's particular cancer.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

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

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

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 will also need to provide your address so a check can be mailed to you. It can take 4-6 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. In addition to parking fees, you will receive compensation to cover additional costs you may encounter, such as meals, extra time at hospital away from work or family, and/or other unforeseen expenses related to your participation and completion of the imaging visits of study. The amount you will be paid is broken down into $100 for each imaging time point and $50 for the blood draws for a total of up to $250. Overnight hotel stay(s) may be available if needed. If you arrive for your scheduled scan and the tracer production fails, you will receive $25 for you time and trouble. If you do not complete all parts of the study, you will be paid for those parts you do complete.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health is funding this research study. This means that Washington University is receiving payments from the National Institutes of Health 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 the National Institutes of Health 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 the investigator at 314-362-1474 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 indicated 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. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institutes of Health
- Your primary care or treatment physician if a medical condition that needs urgent attention is discovered
- 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.
- 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. The tissue that is being tested will be de-identified to a study specific ID. It will only be available to study team members and will be stored behind two locked doors at all times. The results from tissue testing will be recorded on either a paper document or electronically and will be protected as indicated above.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your protected health information relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your health care records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

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.

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.

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.

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?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Confirming appointment dates and times and to provide maps or parking instructions to our imaging facility.

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions 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.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- 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 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 email communications sent or received on any electronic devices used for work or through a work server.

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

_____ 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.

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 staying in the study may be harmful, you need treatment that is not allowed while on the study, you fail to follow instructions, you develop a major side effect, the scanner or imaging tracer is not available and rescheduling would delay your treatment or the study is cancelled.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact Dr. Farrokh Dehdashti at 314-362-1474. If you experience a research-related injury, please contact: Dr. Farrokh Dehdashti at 314-362-1474.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 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: 09/17/24.

_____ _____
(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)