Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Novel CCR2 PET for Pancreatic Cancer Imaging and Prediction of Response to Standard and CCR2-Targeted Therapy

Principal Investigator: Farrokh Dehdashti

Research Team Contact: Jennifer Frye 314-747-1604 or Alyssa Massman 314-362-7026

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.

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 pancreatic cancer that will be treated with either surgery or chemotherapy or a combination of chemotherapy and surgery.

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 pancreatic cancer. The primary goal is to see if ^{64}Cu-DOTA-ECL1i PET imaging can predict how well you will respond to treatment (surgery or chemotherapy).

^{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 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.
Study participants are divided into 2 groups or cohorts. The cohort that you are asked to join depends on what type of treatment your doctor has recommended for you or you have already received. Participating in either cohort involves many of the same procedures. .

All Patients: 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. An IV will be placed in a vein of your arm or hand. The IV will be used to give you the ^{64}Cu-DOTA-ECL1i PET imaging agent and 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).
- 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 64Cu-DOTA-ECL1i.

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

- You will rest comfortably inside the scanner for approximately 75 minutes while the scan is acquired.
- . At the end of the scan you will be removed from the scanner and given a short break. Your vital signs will be recorded after the scan has been completed.
- 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. Following a low dose CT scan a scan of your body (from head to upper thighs) will be obtained. The total amount of time needed for this scan will be about 20 - 30 minutes.

Discharge Imaging Day before you are allowed to 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 you 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. You may have started standard treatment by this time so we will also talk about how treatment is going. The study will also follow your medical record to see how your treatment is going as well.

Treatment – Following the scanning day you will receive treatment for your pancreatic cancer. This may be a surgical procedure (Cohort 1a), or chemotherapy (Cohort 1b). plus standard of care testing CT or MRI scans (called restaging scans) to see how well you are responding to treatment.

If your initial scan shows CCR2 uptake in your known site(s) of disease, you will be invited to return to the PET facility for repeat scanning at the time of restaging which may be after months of therapy or prior to surgery depending on the type of therapy you are receiving. If your initial scan does not show CCR2 uptake in your known site(s) of disease you may be invited to return to the PET facility for repeat scanning if you are diagnosed with recurrent or progressive disease. . This will be done the same way as the imaging day described above and will include scans #1 and #2.

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, at the time of surgery if you will be receiving surgery, or if you have a biopsy done as part of your standard care either before or during your treatment) 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 64Cu-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 64Cu-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 your pancreatic cancer will discuss the findings with you. The imaging team is always available to answer your questions as well.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 75 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 involvement will last for approximately 6 months and your medical records may be followed for up to 2 years**:**

- Your active participation is limited to 1 or 2 imaging days. Each imaging day will be 3-7 hours in length.
- You will receive a follow up phone call at least 24 hours after your imaging visit(s)
- The study will follow your treatment progress through your medical record for up to 2 years after you start chemotherapy or receive surgery.

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,, 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 from the CT scanner

Radiation Exposure: This study will expose you to radiation from the injection of the radioactive drug 64Cu-DOTA-ECL1i and from CT scanning used as part of the PET/CT scan. Because of your condition, which may limit your life expectancy, there is little or no risk to you from the radiation exposure in this study. If you would like more information about radiation exposure, please see the "Radiation Fact Sheet" located at http://hrpo.wustl.edu or ask the study staff for a copy.
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. 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 compensated is broken down into $100 for each imaging time point and $50 for the blood draws. Overnight hotel stay(s) may be available if needed.

- **The total amount you will receive is $250**
- **If you return for follow up imaging you will receive a total of $500,**

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.

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 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. 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. Sharing this information will allow 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.

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.

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.

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.

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 researchers 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 at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 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: 03/20/25.

_____ _____
(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)