**Consent and Authorization Document**

**Dual-Tracer Theranostic PET/CT**

**Study Arms 1 and 2: FDG + DOTATATE in Neuroendocrine Tumors**

**Principal Investigator:** **Jeffrey Yap, PhD**

**Address:** **Huntsman Cancer Institute**
**2000 Circle of Hope**
**Salt Lake City, UT 84112**

**Phone #:** **801-585-0255**

This document may contain words and information that you do not understand. Please ask your study doctor or study staff to explain anything that is not clear to you. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

Once you know about the study, you will make a decision about whether to take part. If you decide to take part, you'll be asked to sign this form. Your decision to take part in this study is voluntary, which means you are free to decide to join this study or not to join this study.

**BACKGROUND**
You are being asked to participate in this research study because you have been diagnosed with neuroendocrine tumor (NET). This study is being conducted by Jeffrey Yap, PhD at the Huntsman Cancer Institute at the University of Utah under a grant 2R44CA257522 from the National Cancer Institute to the sponsor, MultiFunctional Imaging LLC.

The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:
- The main goal of a research study is to gain new knowledge to help patients in the future.
- The main goal of regular medical care is to help each patient.
- This study will include having 2 PET/CT scans on separate days. Each visit will require about 2 to 3 hours of your time. A catheter will be placed in your arm to will inject a radiopharmaceutical in your vein with a risk of bruising, discomfort and pain, and in rare cases a chance of infection. This will also involve a risk from radiation exposure that is considered to be small and comparable to other every day risks.

- During the study, we may learn something about your health that could help you and your doctors make decisions about your healthcare. The images and results from these scans will be shared with your doctors.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

**Purpose of the Study**

Patients diagnosed with neuroendocrine tumor (NET) will often receive a PET/CT scan. Here PET stands for Positron Emission Tomography, and a PET/CT scan combines a PET scan with a CT scan. PET scans can be done with different "tracers", and each makes a different kind of image. One of these tracers is called "FDG" (actually F18-fluorodeoxyglucose), and another is called "DOTATATE." There are currently 2 FDA-approved versions of DOTATATE; one is Cu64-DOTATATE (DETECTNET™) and the other is Ga68-DOTATATE (NETSPOT™).

Patients with NET will often get either an FDG-PET/CT scan or a DOTATATE-PET/CT scan in order to determine how advanced the disease is and to see if the disease has spread to other sites of the body. These scans can also help predict if treatment with a drug called Lutathera™ will be the best course of therapy. Currently, patients typically only receive one of these PET/CT scans, and the doctor must choose whether to use FDG or DOTATATE for this scan. However, it is known that FDG may give better images for some patients, and that DOTATATE may give better images for other patients.

This study is acquiring FDG and DOTATATE PET/CT images on separate days in order to develop a method that will allow for images of both FDG and DOTATATE to be obtained from a single PET/CT scan in the same day, which may provide the best images for all NET patients with the convenience of a single visit.

If you choose to participate in this study, then you will receive two research PET/CT scans: one with FDG, and one with DOTATATE. If you are in the first arm of the study, you will receive one PET/CT scan with FDG and one PET/CT scan with Cu64-DOTATATE. If you are in the second arm of the study, you will receive one PET/CT scan with FDG and one PET/CT scan with Ga68-DOTATATE. You will not be charged for these research PET/CT scans. The information gathered from this study could allow future patients with neuroendocrine tumors to get more efficient and effective diagnosis and treatment.

**STUDY PROCEDURES**

Your participation for this study will consist of a screening visit and two imaging sessions: one for an FDG-PET/CT scan, and one for a DOTATATE-PET/CT scan. Each imaging session will be performed on a different day.

**Screening Visit**

Before the study starts, you will be asked to sign this informed consent form, and a member of the Study Staff will ask you about your general health history, treatments you have had for your cancer, if you take any over-the-counter or prescription medicines, vitamins, or herbs, and if you have any drug allergies. The Study Staff will also record information from your medical records including previous blood test results, procedures, treatments, and plans for your cancer treatment.

If you agree to participate in the study and you qualify for the study, then you will be scheduled for your research PET/CT scans. The Study Staff will tell you when and where the PET/CT scans will be performed.

**Day of FDG-PET/CT Scan**

You are encouraged not to eat or drink anything except plain water for at least 4 hours before the scan. You may take medications with plain water however; this is optional.

When you arrive at the scanner suite, a member of the Study Staff will ask you questions about any changes to your general health and medications since your screening visit.

The following tests will be performed before dosing:
- Measurement of your height and weight; and
- If you are female and not post menopausal for a minimum of one year, and not surgically sterile, then a pregnancy test will need to be performed within 48 hours prior to the research PET/CT scan.

The Study Staff will place an IV catheter (long, thin tube) into an accessible vein. You will receive the F18-FDG injection through the catheter, and then you will wait for about 60 minutes before the PET/CT scan can begin. You will then be taken to the scanner, and you will be asked to lie on your back on the scanning bed. The technologist will help you lay in the correct position with a blanket and pillow for comfort. When the scan starts, the bed will move slowly through the PET/CT scanner several times. The CT portion of the scan usually takes about 1 minute and sends X-rays through your body that are measured by the CT camera. The PET portion of the scan will begin immediately after the CT scan and will last about 50 minutes.

This entire visit should require approximately 2 to 3 hours of your time.

**Day of DOTATATE-PET/CT Scan**

It is okay to eat normally before the DOTATATE-PET/CT scan. When you arrive at the scanner suite, a member of the Study Staff will ask you questions about any changes to your general health and medications since your screening visit.

The following tests will be performed before dosing:
- Measurement of your height and weight; and

- If you are female and not post menopausal for a minimum of one year, and not surgically sterile, then a pregnancy test will need to be performed within 48 hours prior to the research PET/CT scan.

The Study Staff will place an IV catheter (long, thin tube) into an accessible vein. You will receive the Cu64-DOTATATE injection through the catheter, and then you will wait for about 45 minutes before the PET/CT scan can begin. You will then be taken to the scanner, and you will be asked to lie on your back on the scanning bed. The technologist will help you lay in the correct position with a blanket and pillow for comfort. When the scan starts, the bed will move slowly through the PET/CT scanner several times. The CT portion of the scan usually takes about 1 minute and sends X-rays through your body that are measured by the CT camera. The PET portion of the scan will begin immediately after the CT scan and will last about 50 minutes.

This entire visit should require approximately 2 to 3 hours of your time.

**RISKS**

Side effects are generally uncommon at the doses of FDG and DOTATATE used during a PET/CT study, however some people have experienced discomfort at the injection site.

**Risks related to radiation exposure from the F18-FDG and DOTATATE PET/CT scan(s):**

This research study involves exposure to radiation from 1 FDG-PET/CT scan and 1 DOTATATE-PET/CT scan. These scans are for the research study and are not considered part of your standard care. The risk from this radiation exposure is considered to be small and comparable to other every day risks. This amount does not include any radiation exposures that you may receive from other types of tests.

| If you are enrolled in this study, the excess radiation you will receive is about the same as a uniform whole-body dose of: | The amount of radiation that is **considered safe** for a **radiation worker** (e.g. doctor, nurse, scientist, etc.) to receive in one year: |
|---|---|
| 2.7 rem* for the FDG PET/CT scan<br>+<br>2.2 rem* for the DOTATATE-PET/CT scan | 5 rem* |
| = about 4.9 total rem* | |

***A "*rem*" is a unit of radiation dose.**

**Risks Related to Other Study Procedures**

On the day of the scans you will have an intravenous (IV) catheter placed in your arm. Like blood draws, there is a risk of bruising, discomfort and pain, and in rare cases a chance of infection.

You could experience some discomfort in lying on a scan table for approximately 1 hour for each scanning session. Our study staff will assist in making sure you feel comfortable prior to beginning each scan.

**Loss of Confidentiality**

Although all reasonable and appropriate steps will be taken to maintain the confidentiality of your identifiable health information, there is always a possibility that your identifiable health information will be disclosed accidentally.

**REPRODUCTIVE RISKS**

Animal reproduction studies have not been conducted with PET radiotracers. It is not known whether this radiopharmaceutical affects male fertility. You will be slightly radioactive for up to 24 hours after the injection and should avoid close contact with women who are able to have children, and with children, for 24 hours after the scan. Nursing mothers should interrupt breastfeeding for 12 hours after DOTATATE administration.

**UNFORESEEABLE RISKS**

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

**BENEFITS**

Taking part in this study will not directly benefit you but will hopefully help physicians to improve the care and management for patients who are diagnosed with neuroendocrine tumors. Possible benefits for future patients include a better method to combine the information collected from 2 separate FDG and DOTATATE PET/CT scans into a single imaging visit.

**ALTERNATIVE PROCEDURES**

If you decide not to enter this study, there are other choices available. You may continue with your standard treatment and not take part in this study. If you choose not to take part in this study, your health care and your relationship with the doctors will not be compromised in any way.

**PERSON TO CONTACT**

If you have questions, complaints or concerns about this study, you can contact Dr. Yap at 801-213-5650. If you think you may have been injured from being in this study, please call Dr. Yap at 801-213-5650. The University Hospital Operator can be reached at this number: 801-581-2121 available 24-hours a day. Please ask for the oncologist on call.

**Institutional Review Board:** Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.



**Research Participant Advocate:** You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

**RESEARCH-RELATED INJURY**

If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

**VOLUNTARY PARTICIPATION**

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide to withdraw from this study, please inform your Study Doctor right away.

**RIGHT OF INVESTIGATOR TO WITHDRAW**

Your participation in this study may be stopped at any time by the Study Doctor or the Sponsor without your consent for any reason, including:

- If it is in your best interest;
- If you do not consent to continue in the study after being told of changes in the research that may affect you;
- If you require a medication that is not allowed while participating in the study;
- If you develop a condition which may negatively affect your health;
- If you do not follow the study instructions given by the Study Staff;
- If you withdraw your consent to participate;
- If the Sponsor decides to suspend or terminate (end) the study or the participation of this site in the study; or
- Other unanticipated circumstances.



**COSTS AND COMPENSATION TO PARTICIPANTS**

Huntsman Cancer Institute will provide the research FDG-PET/CT and DOTATATE-PET/CT scans free of charge.

You or your insurance company will be billed in the usual manner for procedures, tests and treatment that are considered standard of care for your disease (routine treatment that you would receive even if you were not part of this study). This includes procedures such as routine medical care or need for additional imaging evaluation and possible additional biopsy procedures based on the FDG-PET/CT or DOTATATE-PET/CT imaging results. If you have private medical insurance, you should check with the insurance provider before agreeing to take part in this study to ensure that participating in this study will not affect your medical insurance coverage.

You will be responsible for co-payments, deductibles and/or other out of pocket expenses required by your insurance carrier for medications and procedures which are considered routine care for your disease or condition.

Patients who live more than 50 miles from Huntsman Cancer Hospital may be eligible for mileage reimbursement, and those that live more than 100 miles may be eligible for hotel reimbursement up to $55 per night.

In addition, a $50 stipend will be provided to participants for each PET/CT scan visit they attend. A total of $100 is possible if both scans are attended.

**NEW INFORMATION**

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

**NUMBER OF PARTICIPANTS**

We expect to enroll 50 participants in total at the University of Utah, Huntsman Cancer Institute.

**AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION**

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address telephone number, and email address;
- Related medical information about you like family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results; and
- All tests and procedures that will be done in the study.

**How we will protect and share your information:**

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  – Members of the research team and the University of Utah Health Sciences Center;
  – The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
  – Government agencies responsible to confirm research accuracy such as the United States Food and Drug Administration (FDA), and the National Cancer Institute (NCI) which is a part of the National Institute of Health (NIH),
  – Governmental agencies in other countries where the study drug may be considered for approval.

- If we share your identifying information with groups outside of the University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health Sciences Center.

**What if I decide to Not Participate after I sign the Consent and Authorization Form?**

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, imaging results from this study will only be released to study participants upon request, and only after the imaging has been interpreted by the study team, which could take several weeks following the completion of imaging.

**CONSENT**

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

**I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

_____
Participant's Name

_____ _____ _____
Participant's Signature Date Time

_____
Name of Person Obtaining Authorization and Consent

_____ _____ _____
Signature of Person Obtaining Authorization and Consent Date Time

**Information requested for federal grant reporting purposes (optional)**

**Sex/Gender**

- ❑ **Male**
- ❑ **Female**

**Ethnicity**

Do you consider yourself to be Hispanic or Latino? (see definition below)

**Hispanic or Latino.** A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race.

**Select one:**

- ❑ **Hispanic or Latino**
- ❑ **Not Hispanic or Latino**

**Race**

What race do you consider yourself to be?
SELECT ONE OR MORE OF THE FOLLOWING:

- ❑ **American Indian or Alaska Native.** A person having origins in any of the original peoples of North America (including, Central or South America) who maintains cultural identification through tribal affiliation or community recognition.
- ❑ **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- ❑ **Black or African American.** A person having origins in any of the black racial groups of Africa.
- ❑ **Native Hawaiian or other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- ❑ **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
- ❑ **Unknown.**

❑ **Check here if you do not wish to provide some or all of the above information.**