Patient Name: _____

DOB: ____ /_____ /_____

UCSF MRN: _____

NCT# 02177773

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

CC# 14453: Evaluation of Gallium-68 DOTA-TOC imaging of somatostatin receptor positive malignancies

WHAT IS THIS STUDY ABOUT?

This is a medical research study. Your study doctor, Dr. Thomas Hope, and his associates from the UCSF Department of Radiology will explain this study to you. Medical research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your friends, family, and health care team. If you have any questions, you may ask your study doctor.

You are being asked to participate in this study because you have been diagnosed with a type of neuroendocrine tumor

In this study we will be testing Gallium-68 DOTA-TOC imaging. DOTA-TOC binds to your tumor, and can be attached to Gallium (Gallium-68) in the laboratory to make Gallium-68 DOTA-TOC. When patients are given Gallium-68 DOTA-TOC, it binds to your tumor and can be seen using a PET scan. A PET scan uses a special camera to detect energy given off from Gallium-68, to make detailed pictures of areas where material accumulates in the body. The PET scan will be combined with either CT or MRI to make detailed pictures of body tissues and organs.

Gallium-68 DOTA-TOC is an experimental imaging agent that is not yet approved by the US Food and Drug Administration (FDA).

WHY IS THIS STUDY BEING DONE?

The purpose of this study is:

- To use PET imaging to measure how sensitive Gallium-68 DOTA-TOC is for tumor imaging after a small dose of Gallium-68 DOTA-TOC is given by vein.
- To find out the effects, good or bad, of Gallium-68 DOTA-TOC.
- To compare the Gallium-68 DOTA-TOC PET imaging against the current standard imaging methods that include Indium-111 Octreoscan, Iodine-123 MIBG and contrast enhanced CT and magnetic resonance imaging.

- This study receives funding from the Peterson Family Foundation.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 394 people over three years will be enrolled in this study.

WHAT WILL HAPPEN TO ME IF I TAKE PART IN THIS RESEARCH STUDY?

Before you begin the study...

To find out if you can be in the study, the following procedures with occur:

- **Medical chart review:** Your medical chart will be reviewed by the study doctors. Your most recent liver and kidney function tests will be reviewed as well.

- **Pregnancy testing**: Because the drugs in this study can affect a fetus, pregnant women may not participate in this study. If you are a female and have had your first menstrual period, a urine or blood test will be done to make sure you are not pregnant.

- **Physical Exam:** A physical exam will be conducted including a review of your medical history. Your blood pressure, heart rate and temperature will also be taken.

During the main part of this study...

If the screening procedures show that you can continue to be in the study, and you choose to take part, then you will have the following tests and procedures done. All study procedures will be done at UCSF China Basin Imaging Center in San Francisco, California. The study visit will take approximately 2 hours. Your treating physician will determine if you should be imaged using PET/MRI or PET/CT based on the need for a liver MRI.

- **Gallium-68 DOTA-TOC administration**: Your infusion will take about 1-2 minutes. This imaging dose is only large enough to be seen with a PET/CT scan. This small dose will not treat or kill tumor cells. Vital signs (blood pressure, heart rate and temperature) will be taken prior to injection and after injection.

PLEASE CHECK WHICH IMAGING MODALITY WILL BE USED (CT or MRI imaging):

- ☐ **PET/CT imaging**: A PET/CT scan will be done around 60 minutes after the injection of the Gallium-68 DOTA-TOC agent. The PET/CT scan will take 30 to 40 minutes to complete. The pictures taken will allow researchers to look for tumors cells that accumulate the imaging agent. You will be asked to lay still and may be asked to hold your breath for a few seconds. If you need it, you may be given some medicine,

such as lorazepam (Ativan), to keep from feeling anxious or nervous during the scan.

The PET/CT may involve contrast if you did not already have a CT scan performed as part of your routine examination. Contrast is a special dye that makes it easier for doctors to see different tissues in your body. Intravenous (IV) contrast material is given to you by injecting the contrast material into a line that is attached to a needle in your arm. After you have been given the contrast material, you will lie flat on a table that will move you into the PET/CT scan machine.

☐ **PET/MRI imaging**: A PET/MRI scan will be done around 60 minutes after the injection of the Gallium-68 DOTA-TOC agent. The PET/CT scan will take roughly 50 minutes to complete. The pictures taken will allow researchers to look for tumors cells that accumulate the imaging agent. You will be asked to lay still and may be asked to hold your breath for a few seconds. If you need it, you may be given some medicine, such as lorazepam (Ativan), to keep from feeling anxious or nervous during the scan.

The PET/MRI will involve contrast. Contrast is a special dye that makes it easier for doctors to see different tissues in your body. Intravenous (IV) contrast material is given to you by injecting the contrast material into a line that is attached to a needle in your arm. After you have been given the contrast material, you will lie flat on a table while being imaged by PET/MRI.

- **Follow-up Phone Call**: You will receive a phone about two weeks after the completion of the study to determine if you experienced any adverse events related to the study protocol after leaving the imaging facility.

HOW LONG WILL I BE IN THE STUDY?

Taking part in this study will take about one day or until you decide to withdraw your consent for participation in this study. Withdrawing your consent to participate in this study will not affect your medical care/treatment whatsoever, and your doctor will continue to follow you as a patient. You can stop taking part in this study at any time. If you decide to stop taking part in the study, we encourage you to talk to your medical team first.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely. The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

You may have side effects while on the study. Every one taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or serious. Your health care team may give you medicines to help lessen side effects. You should talk to your study doctor about any side effects you experience while taking part in the study. There also is a risk of death.

Risks and side effects related to Gallium-68 DOTA-TOC administration and imaging include:

- **Placement of venous catheter**: The placement of a venous catheter is associated with the development of bruising and infection. It may also be associated with a risk of bleeding.
- **Radiation risk from DOTA-TOC**: This research study involves exposure to radiation from the Ga-DOTA-TOC agent. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive from the DOTA-TOC administration will be 4.3 mSv, which is equivalent to 1.4 times the yearly natural background of radiation in the US (3 mSv).
- **Transient nausea and diarrhea**: patients have reported developing nausea and diarrhea after injection. In all cases this has resolved without intervention within 45 minutes.
- **Unknown Risks**: The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.
- **Risk of incidental findings**: If the study doctor finds any unanticipated information on the imaging study that may be important to your clinical care, this information will be provided to your oncologist. No formal report will be made based on the imaging study. Depending on the finding, further imaging studies, target biopsies or follow-up could be performed.

PLEASE CHECK WHICH IMAGING MODALITY WILL BE USED (CT or MRI imaging):

☐ Risks and side effects related to PET/CT imaging:

- **PET/CT scan risks**: Having a CT scan may mean some added discomfort for you. For some patients, having to lie still on the scanning table for the length of the procedure may cause some discomfort or pain. After the scan your arm may be a little bit sore or have some redness where the IV was placed in your arm.
- **Radiation risk from CT imaging**: PET/CT scans involve additiona radiation exposure and increases the risk of cumulative radiation. The amount of radiation associated with the CT scan will be up to 4.5 mSv. This is equivalent to 1.5 times the yearly natural background of radiation in the US (3 mSv). This radiation is in addition to the dose from the DOTA-TOC injection described above.
    - **Radiation Risk Summary**: This research study involves exposure to radiation. This radiation exposure is not necessary for your medical care and

is for research purposes only. The total amount of radiation that you could receive would be approximately 9 mSv, which is slightly more than the three times the yearly natural background of radiation in the US (3 mSv). This amount of radiation involves a low risk of cancer. However, the UCSF Radiation Safety Committee has reviewed the use of radiation in this research study and has designated this use as acceptable to obtain the benefits provided by the results of the study. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

- **Iodinated contrast risk**: In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction, from mild (itching, rash) to severe (difficulty breathing, shock, or rarely, death). The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The study doctors will ask you about any allergies or related conditions before the procedure. If you have any of these problems, you may not be allowed to have a CT scan with contrast. If you are taking metformin (or similar drugs by mouth to treat high blood sugar), such treatment will be stopped for 2-3 days around the time a scan is planned in order to avoid kidney side effects.

☐ Risks and side effects related to PET/MRI imaging:

- **PET/MRI scan risks**: MR imaging is safe; but accidents, injuries, and deaths have occurred during MRI procedures. These events are rare, especially if appropriate safety precautions are followed. More specifically:
    - **Metallic objects (implanted or internal)**: Study staff will determine if it is safe for you to enter the PET/MRI environment. It is extremely important that you answer their questions completely.
    - **Heating and burns**: In order to minimize the chances of warming or burns, padding may be placed between you and the bore wall of the magnet.
    - **Tingling sensation**: Discomforts associated with MRI may include a temporary tingling sensation in certain parts of the body including. This sensation is not expected to last long and is typically not painful.
    - **Noises**: Loud noises made by the scanner during imaging may cause discomfort. You will be provided with earplugs to minimize the noise. If the noise is uncomfortable, please ask the Scan Operator to discontinue the scan.
- **Gadolinium based contrast risk**: During the PET/MRI study, you will be injected with intravenous contrast that may contain gadolinium. The most common adverse reactions are nausea, feeling "hot", headaches and abnormal tastes. These agents also have known rare risks that include anaphylactic reaction (which is a severe allergic reaction) and a disease called nephrogenic systemic fibrosis (NSF). NSF can be prevented by not administering gadolinium based contrast agents to patients with renal disease.

- **Radiation risk summary** *(PET/MRI imaging only)*: This research study involves exposure to radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you could receive would be approximately 4.3 mSv, which is slightly more than the yearly natural background of radiation in the US (3 mSv). The use of radiation may involve a low risk of cancer and is required to obtain the desired research information. If your child is pregnant or breast feeding, she SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

For more information about risks and side effects, ask your study doctor.

ARE THERE BENEFITS TO BEING IN THE STUDY?

There may be a medical benefit to you. The information obtained from the Gallium-68 DOTA-TOC PET imaging may provide additional information about sites of your disease compared to conventional imaging agents. Your images will be reviewed by a radiologist and a report will be sent to your physician. These images will be available to your treating physician, and will be used in addition to conventional imaging studies to make clinical decisions. Additionally, the information learned from this study may benefit other patients with solid cancers in the future by improving the quality and availability of imaging agents.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Instead of being in this study, your option includes imaging using standard agents, either an In-111 Octreoscan scan or an I-123 MIBG scan.

Please talk to your doctor about these options.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The UCSF Committee on Human Research
- The UCSF Helen Diller Family Comprehensive Cancer Center
- The University of California
- The National Cancer Institute (NCI) and other governmental agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You and/or your health plan/insurance company will need to pay for some of the costs of treating your cancer in this study. The cost of the imaging will be charged to you or your health plan/insurance company. The PET study will cost between $3,000 and $5,000. Prior to the study being performed, your health plan/insurance company will be contacted to attempt to obtain preauthorization. If insurance authorization is not obtained, you will have the option to pay out of pocket for the imaging component of the study or undergo the standard of care Octreoscan study, which is likely to be covered by insurance. You will be notified of the insurance company pre-authorization decision prior to the imaging study taking place, and you will be told the cost you will be responsible for if insurance dose not provide authorization for the study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call **1-800-4-CANCER (1-800-422-6237)** and ask them to send you a free copy.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You will not be paid for taking part in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, Dr. Thomas Hope, if you feel that you have been injured because of taking part in this study. You can contact your study doctor [redacted].

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further

information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor, Dr. Thomas Hope [redacted]

For questions about your rights while taking part in this study, call the UCSF Committee on Human Research (a group of people who review the research to protect your rights) at (415) 476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent