IRB NUMBER: 16-19297
IRB APPROVAL DATE: 12/04/2020
IRB EXPIRATION DATE: 05/20/2021

Patient Name: _____

DOB: ____ /_____ /_____

UCSF MRN: _____

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

Evaluation of 18F-fluorocholine (FCH) for the detection of parathyroid adenomas in patients with hyperparathyroidism

WHAT IS THIS STUDY ABOUT?

This is a medical research study. Your study doctors, [redacted] from the UCSF Departments of Endocrine Surgery and 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 take part in this study because you have been diagnosed with an endocrine disorder called *hyperparathyroidism (HPT).* This study involves taking pictures of the neck and chest with a new investigational imaging agent (18F-Fluorocholine). If you decide to volunteer for this study, you will be asked to sign and date this form.

18F-Fluorocholine (FCH) 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 see if the investigational 18F-Fluorocholine (FCH) Positron Emitting Tomography (PET) scan might help doctors find the abnormal parathyroid gland causing HPT. A PET scan is a nuclear medicine imaging technique that produces images of how the body functions. In other words, PET scans take pictures of the cells and how they work in the body.

In this case we will look at the cells in the abnormal parathyroid glands using FCH. The FCH agent is an investigational radioligand. A radioligand is a molecule that carries a small amount of radioactive substance in to the body, where the PET scanner can pick up the radiation being released to create a picture from within the body. The low dose of radiation that it gives off from inside the body is picked up on PET scan images. The images show color where the FCH emits radiation so study doctors see where the abnormal gland is.

In this study will look at images from the neck and chest from a PET scan using the investigational radioligand FCH. FCH has been shown to collect in cells of abnormal parathyroids. The accumulation of FCH allows the study doctors to see the abnormal gland when taking pictures with the PET scanner. This study we will provide evidence to decide whether it should be used regularly for patients with HPT as well in the future.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 140 people will be enrolled in this study over a five-year period.

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:

- **Screening:** Inclusion and exclusion criteria will be reviewed to see if you are eligible for the study.

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 [redacted] in San Francisco, California, during a single study visit.

- **18F-fluorocholine (FCH) administration**: A venous catheter will be placed in your arm, and the FCH will be given by intravenous (IV) injection.
    - Your infusion will take about 1-2 minutes.

- **PET Imaging**: A PET scan will be done around 20 minutes after the injection of the FCH imaging agent. The pictures taken will allow researchers to look for cells that accumulate the imaging agent. During imaging you will be asked to lie still and may be asked to hold your breath for a few seconds. No CT or MRI contrast will be administered as part of this study.

- *Imaging will be performed by either PET/CT or PET/MRI, your endocrine surgeon will discuss with you which imaging test is most appropriate for your care*:

    ☐ **PET/MRI imaging**:
    - Imaging will be performed using a PET/MRI, which will take 50 to 60 minutes to complete. Prior to the PET/MRI scan you will be asked to remove all metal from your clothing, pockets, shoes, and person. You will be asked to wear clothing compatible with the PET/MRI environment. You will be provided with earplugs or headphones that you must wear during the entire

scan. Protective padding will be placed between your body and the inner walls of the scanner. During the scan you will hear loud sounds that are a normal part of the scan.

☐ **PET/CT imaging**:
- Imaging will be performed using a PET/CT, which will take 30 to 40 minutes to complete. Imaging of your whole body will be obtained. During imaging you will lay flat on a table inside the PET/CT machine.

HOW LONG WILL I BE IN THE STUDY?

Screening will take place within 60 days of the study. The imaging day will take roughly two hours to complete. 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.

<u>Risks and side effects related to the imaging procedures</u>:
- **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.
- **PET/MR scan risks (*MRI imaging only*)**: 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**: 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 certain PET/MRI scanning techniques may include a temporary tingling sensation in certain parts of the body including, but not limited to, the arms, legs, fingertips, and nose. This sensation is not expected to last long and is typically not painful.
- **Noises**: Discomforts associated with certain PET/MRI scanning techniques may include listening to loud noises made by the scanner during the scanning procedure. You will be provided with earplugs to minimize the noise. If the noise is uncomfortable for you, please ask the PET/MRI Scan Operator to discontinue the scan.
- **No know effects adverse effects of magnetic fields**: There is no evidence in scientific literature that individual or even frequent repeated exposures to high static magnetic fields poses a health concern.

- **Detection of new lesions and incidental findings**: The imaging may detect previously unknown lesions. A report will be created describing the imaging findings and will be added to your medical record. New unexpected findings may affect your care, and your referring clinician will discuss the results of this imaging study with you. These findings may lead to additional and unnecessary biopsies.
- **Unknown Risks**: The experimental imaging 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.

- **Radiation risks**: This research study involves exposure to radiation from FCH administrations and possible CT scans. 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 as a result of participating in this study will be a maximum of 6 mSv, or approximately 2 times the yearly natural background of radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation may involve a low, lifetime risk of cancer. 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.

ARE THERE BENEFITS TO BEING IN THE STUDY?

There may be a medical benefit to you. Your images will be reviewed by a radiologist and nuclear medicine physician and a report will be sent to your referring clinician. These images will be available to your treating physician, and the information obtained will be used in addition to conventional imaging to help localize your abnormal parathyroid prior to surgery. Additionally, the information learned from this study may benefit other patients with hyperparathyroidism in the future if FCH is demonstrated to have utility by improving the quality and availability of imaging agents.

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

You can choose to not enroll in this study. In this case you may be staged using standard of care imaging including MRI, CT, sestamibi SPECT/CT and ultrasound.

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 University of California
- 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?

The costs of all visits, treatments, and tests described above will be billed to you or your insurance carrier. The cost of the imaging study will be charged to you or your health plan/insurance company, with an estimated cost of $6,000 for PET/MRI and $4,000 for PET/CT. If your insurance company does not cover the cost of the study, you will be billed for the care your insurance will not cover. If your insurance company choses not to cover the cost of the scan, you may withdrawal from the study and have standard of care imaging. Issues related to the cost of this imaging study will be reviewed with your prior to enrollment by a study personnel. Financial counselors are available through the hospital accounting department to discuss this with you. If you have any questions in regards to billing and authorizations, please contact the radiology billing office (415) 514-8888.

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, [redacted], if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call [redacted] or by email [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 [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
_____	_____
Date	Witness/Interpreter – Only required if the participant is a non-English speaker