Thomas Jefferson University
Informed Consent Document for Human Subjects Research

Department: Radiology

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Medical Study Title: A Pilot Phase I Open Label Study of Cu-64-TP3805 PET Imaging for Detection of Prostate Cancer in Men with Persistently Elevated PSA

Lay Study Title: A research study to determine if a new imaging agent can improve the diagnosis of prostate cancer using a scanning technique

What Is Informed Consent?

You are being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a University committee that reviews, approves and monitors research involving humans. Before you can make a knowledgeable decision about whether to participate, you should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you make a decision is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form, once you understand the study and have decided to participate. If you don't understand something about the study or if you have questions, you should ask for an explanation before signing this form;
- Being given a copy of the signed and dated consent form to keep for your own records.

The type of study you are being asked to join is known as a pilot study. A pilot study is one that is done on a limited number of individuals in order to collect enough information to determine whether a larger scientifically rigorous study should or should not be undertaken.

What is the purpose of this study?

There are several tests used to detect prostate cancer and include digital rectal exam, a blood test for prostate specific antigen, and MRI. However, biopsies are still the only way to determine whether a lesion is prostate cancer. Unfortunately, many men with benign lesions undergo prostate biopsies to get a definitive result. Additionally, prostate biopsies take tiny pieces of tissue that may not be where the prostate cancer is located. There is a need for a non-invasive diagnostic test that can examine the whole prostate and identify lesions, as well as whether the lesions are cancer or not. This study is being done to see if a new imaging technique can detect prostate cancer more efficiently and minimize the number of unnecessary biopsies.

PET (positron emission tomography) imaging is a diagnostic test that creates images that provide information about the functioning of structures of the body. PET works by using a small amount of a radioactive material that is attached to a biological compound that is either found in the body or mimics one that is found in the body. The radioactive material is administered and travels and through the body emitting signals and eventually collecting in the organs targeted for examination. A scanner records these signals and transforms them into pictures depending on how much signal is emitted. A radiologist can then read those pictures.

Cu-64-TP3805 is an investigational PET agent that is being studied. The radioactive material [Cu-64] is attached to a molecule that looks like a hormone that binds to cancer cells. This molecule does not affect the cancer or normal cells. It is thought that the Cu-64-TP3805 will be taken up by prostate cancer lesions but not by noncancerous tissue and can therefore be used to detect prostate cancer. The purpose of this study is to determine whether PET imaging done with Cu-64-TP3805 can detect prostate cancer. You are being asked to participate in this study because you have a persistently elevated PSA and are scheduled for a biopsy

How many individuals will participate in the study and how long will the study last?

20patients will participate in this study being conducted only at Thomas Jefferson University. Your involvement in the study will last one day. The entire study will take about 1 year to complete.

What will I have to do during the study?

As part of this study, you will have a PET scan with the Cu-64-TP3805. For the PET imaging exam, a small amount of Cu-64-TP3805 will be injected into your bloodstream. After the injection, you will be asked to wait for about 90 minutes in a quiet room before the imaging begins. Your blood pressure, heart rate, and respiratory rate will be measured 10 minutes before the injection, 15 minutes post injection and while you are waiting in the quiet room and at the end of the scan prior to you leaving . You will then lie on a table that passes slowly through the scanner. The scanner resembles a CT scanner, but has a much larger opening. The PET imaging will take approximately 60 minutes. You will be contacted by telephone the next day to see how you are feeling and if you have any questions about the research.

You will provide two urine samples. One prior to injection of Cu-64 and the other after 90 minute uptake prior to the PET scan.. The samples will help us determine whether there are cells in your urine that may be able to help with early diagnosis and prognosis of your prostate cancer treatment.

The results of the PET images exams will be compared to other imaging tests you have had and the results of your surgery.

What are the risks or discomforts involved?

In a previous study of 44 subjects, the only side effect was a flushing (redness and warmth) of the face immediately after the injection of the Cu-64-TP3805 in 3 patients, which went away in a few minutes. Otherwise, there are no known side effects from TP3805. This research study involves exposure to radiation from the Cu-64-TP3805. The amount of radiation exposure that you will receive is about the same you would receive from having a CT (computed tomography) scan. The risk associated with the amount of radiation exposure that you will receive from taking

part in this study is felt to be low and comparable to everyday risks. Cu-64 (the radioactive material) is eliminated through urine in 24 hours and there are only traces in the body at 24 hours, but all of it will be expelled within the next 5 days. There is no risk significant radiation exposure to your family or anyone who lives with you. However you may prefer to urinate sitting down on the toilet and may consider to sleep alone for the first night after you have received the dose of radioactivity.

Risks associated with injection of agents include bleeding, discomfort from the needle stick, bruising, and the rare risk of infection or fainting.

You should call the study doctor as soon as possible at 215-503-7874, if during the course of this study; you develop any of these side effects or symptoms. If the PI Dr. Thakur , cannot be reached , please call Jefferson ER at 215-955-1280 The study doctor has told you that if your condition worsens, if side effects become very severe, or if it turns out that being in this study is not in your best interest, you will be taken out of the study.

It is possible that the imaging with Cu-64-TP3805 will identify other lesions that were not seen on any other imaging. Because this is an experimental technique, it will not be known whether the lesions are truly cancer. Therefore, if additional lesions are found, your treating doctor will be told about this information, but your doctor will not make any clinical decisions based on this information. Your doctor may request you to have additional tests to evaluate those lesions based on the results of the Cu-64-TP3805 imaging. This could lead to anxiety and/or added costs.

What are the risks to fetuses, infants and pregnant women?
If you are participating in this study, you should practice adequate birth control for 7 days after the administration of the Cu-64-TP3805 because investigational drugs may have adverse effects on sperm that could also adversely affect a fetus. If your partner becomes pregnant during the course of the study, the investigator may want to follow her through the pregnancy and receive information on the pregnancy outcome. She will be asked to sign a separate consent form or a form for release of medical information for that.

If you are a person in a same sex relationship, it is not necessary for you to practice birth control.

Are there alternatives to being in the study?
You do not have to participate in this study.

How will privacy and confidentiality (identity) be protected?
Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies you personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that you may see and review your TJU or Thomas Jefferson University Hospital medical records

at any time. However, in a research study, you may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

If you join this study, the following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel of Thomas Jefferson University, Jefferson University Physicians, and Thomas Jefferson University Hospitals, Inc. involved in this specific study, the University's Division of Human Subjects Protection and the Institutional Review Board (IRB), and your health insurance company (if necessary for billing for standard medical care).

Your PHI may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- The National Institutes of Health, which is providing funds to Thomas Jefferson University to conduct this research
- The Food and Drug Administration (FDA)
- A Data and Safety Monitoring Committee (DSMC)
- With any person or agency required by law.

The following information will be provided to the study sponsor and other entities noted above:
Study data for analysis: PET images, any other imaging examinations to evaluate your prostate, and the results of your surgery to determine the ability of PET scans done with Cu-64-TP3805 to detect prostate cancer.
Demographic data: Age and race to track enrollment statistics.

If you develop an illness or injury during the course of your participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study. Your PHI may be used indefinitely.

You may quit the study and revoke permission to use and share your PHI at any time by contacting the principal investigator, in writing, at: Dr. Mathew Thakur, 1020 Locust Street, Room 359, Philadelphia, PA, 19107. If you quit the study further collection of PHI will be stopped, but PHI that has already been collected may still be used.

The results of clinical tests and procedures performed as part of this research may be included in your medical records. The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

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, this Web site will include a summary of the results. You can search this Web site at any time.

What if I am injured as a result of being in this study?
In the event that you experience a research-related injury, necessary and available medical care (including hospitalization) will be provided. A research-related injury is a physical injury or

illness resulting to you that is directly caused by any procedure or treatment used in this study that is different from the treatment you would receive if you were not participating in a research study. If you are physically injured due to any substance or procedure properly given under the plan for this study, medical expenses for treating the injury will be billed to your insurance carrier. You should be aware that some costs may not be covered by insurance. There is no plan to provide compensation for loss of wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).

If you receive a bill related to a research-related injury that seems wrong, please discuss it with the study doctor or research coordinator.

Will I benefit from being in this study?
You will not benefit from being in this research, but we hope that what we learn may be helpful to future patients or society in general.

Will I be paid for being in this study?
You will receive payment for your participation in this study. Approximately 4 weeks after completing the PET imaging study, you will be mailed a check in the amount of $100.00.

Will I be told about any new findings?
Anything learned during the study, beneficial or not, that may affect your health or your willingness to continue in the study, will be told to you and explained.

Disclosure of Financial Interest
The sponsor of this clinical study, the National Institutes of Health, is paying Thomas Jefferson University to conduct this study.

Are there costs related to being in this study?
The Cu-64-TP3805 PET scan is being done purely as a part of this research and is being performed free of charge. Any other procedures, tests and doctor's charges that you may have are considered standard of care and will be billed to your health insurance carrier. These are charges that you would have whether or not you were participating in a research study. It is possible that your insurance company may deny payment. If that happens you may be responsible for some or all of these charges. The study doctor will explain to you which procedures, tests and doctor visits are considered standard of care.

If you receive a bill that you think is wrong, please discuss it with the study doctor or research coordinator.

Can I be removed from the study or quit the study?
Your decision to participate in this research study is entirely voluntary. You have been told what being in this study will involve, including the possible risks and benefits.

Your participation in this research project may be terminated by the study doctor without your consent for any reason that he/she feels is appropriate.

You may refuse to participate in this investigation or withdraw consent and quit this study without penalty and without affecting your ability to receive medical care at Thomas Jefferson University.

If you withdraw from this study, you may continue treatment with your Jefferson doctor, or you may seek treatment from another doctor of your choice.

Should you decide to withdraw from the study, please be sure to inform the study doctor. Additional tests or procedures may be needed to ensure your safety. The study doctor will explain why these tests or procedures are necessary.

CONTACT INFORMATION

Telephone number for questions about your rights as a research participant	The Jefferson Institutional Review Board	215-503-8966
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Dr. Mathew Thakur or any co-investigator listed at the beginning of this form	215-503-7874
If you have difficulty contacting the study staff	Call the Jefferson Office of Human Research	215-503-0203

If you want more information about the Jefferson Institutional Review Board or Jefferson's Human Research Protection Program, please visit our website at http://www.jefferson.edu/human_research/irb/index.cfm.

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Non-Waiver of Legal Rights Statement

By your permission to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.

In order to be in this research study, you must sign this consent form.

You affirm that you have read this consent form. You have been told that you will receive a copy.

Signatures:

_____(Date)
Your Name *(please print or type)*

_____(Date)
Your Signature

_____(Date)
Witness Signature

_____(Date)
Name of Person Conducting Consent Interview

_____(Date)
Signature of Person Conducting Consent Interview

_____(Date)
Signature of Principal Investigator or Co-Investigator

As Per University Counsel - Do Not Sign
This Consent Form After 3-1-18