Title of Study: The Role of ^{68}Ga PSMA-11 in Enhancing Diagnosis of Primary and Metastatic Prostate Cancer

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center

Key Information about this Study

The purpose of this research is to determine if a new radioactive imaging drug for positron emission tomography/ computed tomography (PET/CT) improves diagnosis of prostate cancer compared to standard imaging such as MRI, CT or bone scans. This imaging drug has been used extensively for investigational purposes in the United States and other countries.
Participants will have had a blood test for prostate specific antigen (PSA) which may be elevated and will have undergone an MRI of the pelvis which shows at least one site suspicious for cancer. Each participant in this research will undergo a single PET/ CT session with this imaging drug which will take approximately one hour. The results from the PET/CT will be compared to any other imaging and any pathology results that you may have from biopsy or surgery for prostate cancer. Results of the PET/CT will be discussed with your treating doctor.
Risks of the PET/CT include exposure to low levels of radiation during the scan. There may be discomfort or bleeding at the site of the intravenous injection of the imaging drug. Bruising at the injection site is possible as well.
You may not receive any personal benefits from being in this study.

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Neil M. Rofsky MD, Department of Radiology at The University of Texas Southwestern Medical Center.

Funding

The Department of Radiology at UT Southwestern Medical Center is funding this study. This department is providing money so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

This study is being performed to assess whether imaging with ^{68}Gallium Prostate Specific Membrane Antigen-11 (^{68}Ga PSMA-11) PET/CT can identify the site of prostate cancer and any metastasis that other imaging techniques have not identified. PSMA is a protein which is increased in most prostate cancer so this imaging agent will show where prostate tumors may be located.

You are asked to participate in this research study of ^{68}Ga PSMA-11 PET/CT because the levels of prostate specific antigen (PSA) in your blood may be elevated and your MRI identified at least one site suspicious for cancer. ^{68}Ga PSMA-11 PET/CT has been used in the US and other countries and preliminary results show that it can aid in locating prostate cancer. This study is being done to assess the ability of this imaging to identify primary tumors and possible metastasis that other imaging techniques have not identified.

The researchers hope to learn if ^{68}Ga PSMA-11 can help in the diagnosis of prostate cancer.

Investigational Use of Drug or Device
This study involves the use of an investigational radioactive drug called ^{68}Ga PSMA-11. "Investigational" means that the drug has not yet been approved by the U.S. Food & Drug Administration (FDA) for diagnosis or monitoring of prostate cancer.

This study will help find out what effects, good and/or bad, this drug has on people who use it. The safety of this drug in humans has been tested in prior research studies; however, some side effects may not yet be known.

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you have suspected prostate cancer.

How many people are expected to take part in this study?
This study will enroll approximately 20 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 2 visits with the researchers or study staff.
It will be necessary for you to return to the hospital/clinic once for your ^{68}Ga PSMA-11 PET/CT.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. Many of the procedures are described below as "**standard of care**" and would be done even if you do not take part in this research study. You will be told which ones are for "**research only**".

Screening Procedures
To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had.
You may also have to fill out certain forms or have the following exams, tests or procedures:

- A physical exam and medical history
- Vital signs; respiratory rate, heart rate, blood pressure, temperature, weight.
- The results of the blood tests done as part of your standard care will be used.
- Demographic information (age, sex, race/ethnic origin)
- The results of imaging tests done as standard of care will be used including imaging of the abdomen and pelvis (CT Abdomen and Pelvis or MR Abdomen Pelvis).

This visit will take approximately 60 minutes and may be done as part of a routine visit with your doctor.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and will discuss other possible options

Study Procedures - as a participant, you will undergo the following procedures:
You will meet initially with your doctor who will perform the above screening procedures. This visit will last approximately 60 minutes or will add approximately 60 min to your routine care visit. If you qualify to be included in the study you will return at a later date to have an injection of ^{68}Ga PSMA-11 followed by a PET/CT scan.
When you come for your PET/CT scan:

- Upon arrival at the Clinical PET Facility located on the 2nd floor of the Clements Imaging Building at UT Southwestern, you will have an opportunity to have questions answered regarding the procedure.
- An intravenous catheter (IV) will be placed in a vein in your arm by the imaging technologist or nurse, for the admission of the radioactive drug (^{68}Ga PSMA-11). There may be some discomfort from the IV catheter and the injection of ^{68}Ga PSMA-11.
- You will be asked to lie still inside a large, doughnut-shaped instrument, called PET/CT scanner, for a 30 minute scan. After the completion of this scan you will remain comfortably sitting in one of the facility's rooms.
- At 60 minutes after the injection of the drug, you will be encouraged to empty your bladder and you will be asked to lie still on the PET/CT scanner for a second whole body scan that will take approximately 15 – 20 minutes.
- You will be observed for the duration of your staying at the PET Center for any side effects after the injection.
- The IV catheter will be removed at the end of the PET/CT scan and a pressure bandage will be placed on the IV site. After this you will be free to leave.
- You will receive a follow-up call 24 hours after your injection to check up on you and make sure you are not having any reaction or side effects after the injection.

After you have completed the PET/CT scans you will follow-up with your doctor as you would otherwise do. Any subsequent treatment or imaging your doctor does is part of your routine clinical care and not part of the study.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. Any clinically relevant results of the research will be communicated to you. Clinically relevant means that the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable and it can be confirmed. In that case, we will attempt to notify you using the contact information you have provided.

If you do not want to be notified of any of these incidental findings, please initial below.

_____ Please do not notify me of any incidental findings obtained from this research.

Risks – "What are the risks of participation in the research?"

Risks from the specific research procedures (drug(s), interventions, or procedures)
Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.
The following section will describe the risks related to each your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

PET/CT Scan
The PET/CT Scan uses a radiotracer (^{68}Ga PSMA-11) to evaluate your prostate tumor. The PET/CT scan looks and feels like a CT scan and is performed in a donut shaped machine. Each of the two same day scans is quiet and lasts about 30 minutes. You may feel some discomfort and/or fatigue from lying still during imaging.

IV Catheter Insertion
There are some risks associated with the insertion of a small plastic tube (IV catheter) into the blood vessel which include pain, bruising, swelling, infection from the catheter and formation of blood clots around the catheter in the blood. Dizziness and fainting are also possible risks.

^{68}Ga PSMA-11
^{68}Ga PSMA-11 is a radioactive drug that carries a small amount of radiation that can be detected by the PET/CT Scan. Based on the findings obtained from preclinical evaluation and clinical testing in humans, no major side effects from the radioactive tracer are expected. Regulatory bodies (FDA) that oversee the use of drugs and radiotracers in the US and other countries have not approved the sale or use of ^{68}Ga PSMA-11 for human use during PET/CT, although they have allowed the use in this study. You will be closely monitored during and after the scan for allergic reactions such as breathing difficulty, rash, flushing, and all other possible symptoms.

Infusion risk
May cause discomfort, irritation, mild bruising, bleeding, leakage of drug solution, and rarely infection, nausea, and lightheadedness.

Risks of Radiation
Being part of this study will expose you to radiation that you may not receive as part of your standard care. The radiation you receive for your everyday care outweighs risks the radiation poses because it allows your doctor to provide appropriate medical care. The extra radiation you receive from this study may not help you in this way. However, everyone is exposed daily to a background of radiation from the earth, outer space, the food we eat, and the air we breathe. Some people may be exposed to larger amounts of radiation (up to about 15 times more than this natural and background each year) because of their jobs working with radiation. Regulations limit the amount of radiation these workers can receive each year to make sure their risks are low. The added radiation dose you will receive from this study is less than the yearly regulatory limit set to protect radiation workers in the U.S.

For more information about risks and side effects, ask one of the researchers or study staff.

There may be unforeseeable side effects that could be life threatening or fatal (could cause death).

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Reproductive Risks –

Concerns for sexually active men: Men should not father a baby while taking part in this study because we do not know how the study drugs/procedures could affect a man's sperm

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is to identify possible abnormalities that were not identified by standard of care imaging. There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you. Your other choices may include: not participating in this study or an alternative one.

Payments – Will there be any payments for participation?

No, you will not receive payment for participation in this study.

Costs – Will taking part in this study cost anything?

The sponsor will provide the ^{68}Ga PSMA-11 PET/CT free of charge during this study.
You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as standard of care imaging of your tumor and therapy. It is important to understand that some insurance companies do not cover some costs (for example, approved drugs used in a way different from the package instructions). If your insurance company does not cover these treatments or procedures, you will be required to pay for them.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Your demographic information (age, race, marital status, occupation)
- Your medical history including your cancer diagnosis obtained from your medical record
- Your imaging studies and blood work obtained at your diagnosis
- Your treatment history

We will get this information by asking you, asking your doctor, and reviewing your medical record at UT Southwestern.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Simmons Cancer Center Data Safety and Monitoring Board the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center.
- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the UT Southwestern Medical Center for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.
After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to Dr. Neil M. Rofsky, 5323 Harry Hines Blvd, Dallas, TX 75390. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:
Dr. Neil M. Rofsky at 214-648-7702 during normal business hours

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Witness / Interpreter Signature Section

Interpreter/witness (Interpreter signature required per hospital policies when physically present.)
I attest that I have interpreted the information in this consent form and it was explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of Interpreter	Signature of Interpreter	Date	Time AM PM

Witness Signature (required when interpreter is not physically present-e.g., Language Line is used):
By signing below:
I attest that the information in the consent form was accurately explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of witness	Signature of witness	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM