Participant Informed Consent for Clinical Research

Study title for participants: Prostate-Specific Membrane Antigen (PSMA) PET Scans in People Prostate Cancer

Official study title for internet search on http://www.ClinicalTrials.gov: Serial PSMA PET Imaging in the Assessment of Treatment Response in Patients with Progressive Prostate Cancer

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If you are the parent or legal guardian of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to your child, if the participant is a minor, or to a person with a cognitive impairment for whom you are the Legally Authorized Representative (LAR).

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have recently been diagnosed with prostate cancer or you have prostate cancer that has gotten worse after treatment.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered. See the *Where can I get more information?* section of this document for more information about research studies and for general information about cancer.

Why is this study being done?

This study is being done to answer the following question:

Are the Prostate-Specific Membrane Antigen (PSMA) positron emission tomography (PET) scans used in this study accurate and better at imaging your prostate cancer than the usual methods?

What is the usual approach to prostate cancer imaging?

People who are not in a study usually have standard imaging, such as computed tomography (CT) scans, or bone scans. These scans use radiation to take pictures of cancer. People may also have magnetic resonance imaging (MRI), which uses a magnetic field and radio waves to take pictures.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will have a PSMA PET scan 3 separate times: before you begin treatment for your prostate cancer, early during treatment, and at a later point during treatment. These scans will be done in addition to any prostate cancer imaging you have as part of your regular medical care.

The study team will do two types of PSMA PET scans during this study: one using ^{68}Ga PSMA and one using ^{18}FDCFPyL. ^{68}Ga PSMA and ^{18}FDCFPyL are substances that give off a small amount of radioactivity (also called radioactive tracers or agents) and target prostate cancer cells that contain a protein called prostate-specific membrane antigen (PSMA). The PET scanner detects the radioactivity from these tracers and makes images of your prostate cancer.

Your study doctor will tell you which type of scan you will receive. The type of scan will depend on your disease and what treatment you are going to receive as part of your regular medical care or as part of an additional research study.

Your participation in this study will be complete once all the PSMA scans required by the associated therapeutic protocol or other research project in which you are enrolled have been obtained (usually 3, but could be more than 3).

You will receive the results of your scans. However, this report will not be as detailed as reports given for prostate cancer imaging you have as part of your regular medical care. You should know that the meaning of the results of these research scans will not be clear while the research is ongoing.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

There is a risk that you could have side effects from the study approach. These side effects may be worse, and they may be different than you would have with the usual approach for imaging your cancer.

Some of the most common side effects that the study doctors know about are:

- ^{68}Ga PSMA: Infection at the injection site.

- ^{18}FDCFPyL: Infection at the injection site; feeling tired (fatigue), headache, and/or temporary taste changes that may affect the way foods normally taste.
- Radiation exposure (details on this risk are explained below in the *What risks can I expect from taking part in this study?* section)

There may be some risks that the study doctors do not yet know about.

Benefits
There is some evidence that PSMA PET scans are able to accurately image prostate cancer. However, we do not know if this will happen for all people with prostate cancer. This study may help the study doctors learn things that may help other people in the future.

If I decide to take part in this study, can I stop later?
Yes, you can decide to stop participating in the study at any time.

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

If you decide to stop, let the study doctor know as soon as possible. It's important that you stop safely.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?
Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?
The purpose of this study is to see whether ^{68}Ga PSMA and ^{18}FDCFPyL PET scans are accurate and work better or the same as the CT, bone, and MRI scans doctors usually use for imaging prostate cancer.

^{68}Ga PSMA or ^{18}FDCFPyL tracers are FDA approved.

Researchers think the ^{68}Ga PSMA and ^{18}FDCFPyL PET scans may be more effective than the usual approach at showing prostate cancer lesions. As compared to conventional imaging studies, such as

bone scan and computed tomography, these scans may more accurately show where the cancer is located in your body. Therefore, doctors may have improved options for diagnosing and treating cancer.

About 600 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

All study participants will get a PSMA PET scan before they begin treatment for their prostate cancer, during their treatment, and when they stop treatment. Some participants will get the ^{68}Ga PSMA PET scan at each of these times, and other participants will get the ^{18}FDCFPyL PET scan. Your study doctor will tell you which type you will receive. This decision is based on your disease and what treatment you are going to receive (either as part of your regular medical care or as part of an additional research study).

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in the study. This first part of the study is called screening. Most of the screening exams, tests, and procedures are part of the usual care that you would have if you were not in a study.

The tests and procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- PET scans and radiotracers (68Ga PSMA or 18FDCFPyL tracer) at the following times:
  - Within 6 weeks before beginning your treatment for prostate cancer
  - About 4 weeks after you have started your treatment
  - When you stop your treatment

During the study:

You will have 3 PET scans at the following times:

- Within 6 weeks before beginning your treatment for prostate cancer
- About 4 weeks after you have started your treatment
- When you stop your treatment

You will have the same type of scan (^{68}Ga PSMA or ^{18}FDCFPyL) each time. Your study doctor will tell you which type of scan you will get.

On the day of each scan, the study team will place an intravenous (IV—directly into the vein) catheter (hollow tube) in your arm. The study team will inject the tracer (either ^{68}Ga PSMA or ^{18}FDCFPyL) into this catheter. About 15 minutes following the administration of PSMA, 20mg of IV Furosemide (Lasix®) may be administered. Following the administration of the Lasix, you will need to consume about 1 liter of fluid prior to imaging. About 60-90 minutes after the injection, you will have a PET/CT scan. The scan itself will take about 30-40 minutes. Upon completion of imaging and at the discretion of the investigator, you may be asked to void and get back in the scanner for 1 additional image of the pelvis. This additional image allows investigator's to see an unobstructed view of the prostate/prostate bed.

The PET scans used in this study will not replace the imaging that is part of your regular medical care. They will be in addition to the imaging that is part of your regular medical care.

You will remain on study until 30 days after your last PSMA imaging timepoint required by your companion therapeutic protocol.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss

There is a risk that you could have side effects from the study approach.

Important information about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may be mild, and others may be very serious.

Important information about how you and the study doctor can make side effects less of a problem for you:

- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.

The tables below show the most common and the most serious side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible side effects of ^{68}Ga PSMA:

Rare, and serious In 100 people receiving ^{68}Ga PSMA, 4 or fewer may have:
• Infection at the injection site

Possible side effects of ^{18}FDCFPyL:

Rare, and serious In 100 people receiving ^{18}FDCFPyL, 4 or fewer may have:
• Feeling tired (fatigue) • Headache • Taste changes that may affect the way foods normally taste • Infection at the injection site

The PET scans that you will receive in this study will expose you to low amounts of radiation. Every day, people are exposed to low levels of radiation that comes from the sun and the environment. (This type

of radiation is called “background radiation.”) No one knows whether exposure to low amounts of radiation is harmful. However, scientists believe that exposure to too much radiation can be harmful, and may even cause a new cancer to develop.

The normal-organ radiation doses associated with the investigational imaging procedure(s) included in this protocol are comparable to those from standard-of-care diagnostic imaging studies. Each year, many thousands of patients routinely undergo similar diagnostic procedures and receive comparable radiation doses with no adverse effects, either short- or long-term.

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not father a baby while you are in this study. The tracers used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control or pregnancy prevention to use while you are in this study. You will need to continue to use these methods while completing the study.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments.
- Tell the study doctor about:
    - All medications and any supplements you are taking
    - Any side effects from these medications or supplements
    - Any doctor visits or hospital stays outside of this study
    - Whether you have been or are currently in another research study

Is there a conflict of interest for this study?

This study is being sponsored by Memorial Sloan Kettering Cancer Center and funded by Progenics Pharmaceuticals. Some of the investigators involved in this study receive extra money from Progenics Pharmaceuticals for work that is not part of this study. These activities may include consulting, advisory boards, giving speeches, or writing reports.

If you would like to know more about the steps MSK has taken to protect your best interests while you are in this study, please contact the MSK Patient Representative Department at 212-639-7202.

What are the costs of taking part in this study?

You will not be charged for PET scans and radiotracers (68Ga PSMA or 18FDCFPyL tracer) at the following times:

- Within 6 weeks before beginning your treatment for prostate cancer
- About 4 weeks after you have started your treatment
- When you stop your treatment

It is possible that the ^{68}Ga PSMA or ^{18}FDCFPyL tracer may not continue to be supplied while you are on the study. This possibility is unlikely, but if it occurs, your study doctor will talk with you about your options.

You and/or your health plan/insurance company will have to pay for all the other costs of treating your cancer while you are in this study, including the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

Ask the study doctor or nurse for help finding the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

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

This research may lead to the development of new tests, drugs, or other products for sale. If it does, you will not receive any payment from the sale of these products.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK. All requests for data sharing will be reviewed by MSK, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

In the future, your information (data) may be de-identified, which means that your data will be assigned a unique code, and the list that links the code to your name will be stored separately from your data. Your de-identified information may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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 any information that can identify you. At most, the web site will include a summary of the study results. You can search this web site at any time.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

Prostate-Specific Membrane Antigen (PSMA) PET Scans in People with Prostate Cancer

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)
- Other data such as deidentified images

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator: Heiko Schöder, MD and Deaglan McHugh, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- The company or organization that provides the funding for the study, Progenics Pharmaceuticals, Inc.
- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study procedure.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to your medical record at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent
I have fully explained this clinical research study to the participant or to his/her Legally Authorized Representative (LAR). In my judgment, and in that of the participant or his/her LAR, sufficient information, including risks and benefits, was provided for the participant or his/her LAR to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's (or Legally Authorized Representative's [LAR's)]) statement
I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant/LAR must personally sign and date		
Participant/LAR signature		**Date:**
Participant/LAR name (Print)		
LAR relationship to participant		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's (or LAR's) language, and I confirm that the consent discussion was appropriately interpreted for the participant (or LAR).
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____
(The name of the witness must be documented in the EMR.)

Interpreter (if required)
Name of interpreter (if present): _____
ID number (if phone interpreter): _____
(The interpreter's name or ID number must be documented in the EMR.)

The participant/Legally Authorized Representative must be provided with a **signed copy** of this form.