

RESEARCH CONSENT FORM

Protocol Title: Metabolic Imaging in the Diagnosis and Risk-Stratification of Prostate Cancer

Study No.: HP-00084316

Principal Investigator: Mohummad Siddiqui, MD

Version: 17 January 2020

Participant Name:

MR#:

You are invited to take part in a research study. Taking part in this study is voluntary. You do not have to be in this study. If you choose to take part, you can change your mind and leave the study at any time. Please read this consent form carefully before making your decision. It contains important information about the study and your role in it. If you have questions, you may ask them at any time. You may also discuss the study with your friends, family, or family doctor. Please be sure that all of your questions have been answered before signing this form. If you decide to take part, we will ask you to sign this consent form. You will receive a copy of the signed form to keep.



CONCISE SUMMARY

This study will assess a special type of MRI called **hyperpolarized C13 MRI (HP C13 MRI)**. We want to find out if HP C13 MRI is safe and effective when used in prostate cancer diagnosis. HP 13C MRI is also known as “metabolic MRI.” In addition to imaging the prostate, as a standard MRI does, HP 13C MRI can also show areas of abnormal metabolism within the prostate. Prostate cancer cells have a metabolism that is different from normal cells. We believe that imaging areas of abnormal metabolism will help us understand tumor activity.

If you take part in this study, you will have a metabolic MRI done for research purposes. This includes an IV injection of hyperpolarized 13C-pyruvate (HP 13C pyruvate). You also will have blood drawn. Next, you will have your standard care prostate biopsy or prostatectomy. The prostate biopsy or prostatectomy is part of your routine clinical care. However, this study involves collecting additional prostate tissue samples. In total, we will collect 2-6 additional tissue samples for study purposes.

The risks of this study are described in this form. For example, you may react to the HP 13C pyruvate injection. A reaction could cause you to feel hot, dizzy, or flushed, or to have a bad taste in your mouth. Another possible risk is for bleeding, bruising, or redness at the injection site.

If you are interested in learning more about this study, please continue to read below.

Glossary of words used in this consent form:

- **MRI** (magnetic resonance imaging): An MRI uses a magnet to create images of the body. MRI does not use x-ray or radiation.
- **HP 13C pyruvate**: This is a metabolic chemical that is easily seen on MRI. It can provide valuable information about cancer metabolism.
- **Prostatectomy**: The surgical removal of all or part of the prostate gland.
- **Endorectal coil**: A device placed into the rectum in order to get high quality images of the prostate and surrounding areas.
- **Biopsy**: This diagnostic test involves collecting cell or tissue samples. Doctors then examine the samples for signs of damage or disease.

PURPOSE OF STUDY

The purpose of this study is to assess using hyperpolarized 13C MRI to diagnosis prostate cancer. Specifically, the study will assess the following:

- how safe and feasible it is to use HP 13C MRI in prostate cancer diagnosis;
- how well HP 13C MRI works for diagnosing prostate cancer; and
- Whether HP 13C MRI works better than standard MRI imaging.

HP 13C MRI requires an injection of hyperpolarized 13C pyruvate (HP 13C pyruvate). HP 13C pyruvate is an experimental drug. This means it is not approved by the U.S.



Food and Drug Administration (FDA). However, the FDA is allowing us to use HP 13C pyruvate in this study.

We are asking you to take part in this study for one or more of the following reasons:

- You have a high PSA level, which may indicate prostate cancer.
- You had a digital rectal exam with abnormal findings.
 - OR –
- You have a known prostate tumor.

Up to 36 patients may take part in this study at the University of Maryland, Baltimore (UMB). Your role in this study may last up to 3 months.

PROCEDURES

Standard Care Procedures

Your doctor has already discussed your standard clinical care options with you. These options include either:

- MRI-targeted biopsy
 - OR –
- Surgery to remove the prostate gland and surrounding tissue (radical prostatectomy).

Both standard care options involve a standard MRI procedure. If you will be having surgery for your standard care, you will have the MRI done 3 months prior to your surgery date.

Research Study Procedures

In addition to your standard care MRI, if you take part in this study, you will also undergo an experimental HP13C MRI.

HP 13C MRI: The HP 13C MRI includes the following additional procedures. These procedures will be done for research study purposes:

- Injection of HP 13C pyruvate
- Insertion of an endorectal coil
- Collection of extra MR images

Your standard care MRI involves taking images of your prostate. To make the images clearer, you will have a contrast agent (dye) injected into your veins. The dye is FDA-approved and used routinely for MRI exams. Before the standard care MRI begins, you will have an endorectal coil inserted into your rectum. You will also receive an injection of HP 13C pyruvate into your veins. The coil and the HP 13C pyruvate will allow us to take images of the prostate, and to detect the metabolic signal from the prostate. As



soon as the metabolic MRI imaging is complete, we will remove the endorectal coil. You will then have a standard MRI procedure to take images for your clinical care.

Blood and Urine Samples: After informed consent, Up to 6 teaspoons of blood will be collected. If possible, we will collect the study blood samples while you are having blood drawn for your standard care. We will also ask you to provide a urine sample. If you are unable or unwilling to give blood or urine, we will not collect these samples.

Prostate Tissue Samples: If you are scheduled for a MRI-guided prostate biopsy, this procedure will be done as part of your standard care. During the biopsy procedure, 1 additional sample will be taken from each lesion biopsied. This is for research purposes. Up to 2 additional samples may be taken from sites outside of the MRI-detected lesions.

Prostate biopsy procedures: A typical prostate biopsy involves collecting about 14-17 tissue samples. For this study, we will collect 2-6 additional tissue samples for research purposes. We will collect samples for your clinical care first. This is to ensure that the research sample collection will not interfere with collecting samples for your clinical care. If there is any concern that there may not be enough tissue for clinical care, we will not collect any research samples. We will only collect research samples if we are certain it will not compromise your clinical care in any way. Also, if you are uncomfortable and do not want us to take research samples, we will not take them. It does not matter if you consented to the samples earlier. You can change your mind.

Prostatectomy: If you choose to have a prostatectomy, we will ensure that the research sample collection does not interfere with clinical care. If we are concerned that there is not enough tissue for clinical care, we will not collect any research samples.

Clinical staff will call you after your procedure to check for issues or concerns. You will also have follow-up visits scheduled based on your diagnosis and test results.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you agree be in this study, you will be responsible for taking part in the study procedures listed above. We will also expect you to follow the instructions of the study team.

POTENTIAL RISKS/DISCOMFORTS:

Risk of blood draws: Drawing blood involves the following minor risks:

- pain,
- bruising, and
- feeling faint,

In rare cases, there is a risk of fainting or of infection at the puncture site. To reduce these risks, staff will draw blood while you are comfortably seated or lying down. When



possible, we will collect blood samples for the study during blood draws for your routine care. This will prevent the need for another needle picture.

Risk of prostate tissue sample collection: Prostatectomy is done as standard care. Samples of prostate tissue will be taken from extra tissue in the pathology laboratory. There is no risk in the collection of extra tissue.

MRI risks: MRI does not use radiation and is safe for people who have passed a safety screening. If you take part in this study, you will be screened to ensure the MRI will be safe for you. You cannot take part in this study if you have a fear of enclosed spaces. You also cannot take part in the study if you have any metal objects, such as metal implants, in your body.

The MRI scanner makes a loud knocking sound. The knocking sound depends on the type of scan. You will be given ear protection for the scan.

Risk of MRI contrast agents: You will receive an injection of gadolinium-based contrast as part of your standard care. About 1 in 100 people who receive gadolinium-based contrast may notice the following side effects:

- discomfort,
- tingling or warmth in the lips,
- metallic taste in the mouth,
- tingling in the arm,
- nausea, or
- headache that lasts for a few minutes.

There is also a risk for minor pain, bleeding or bruising, or infection at the injection site. The risk of infection is rare.

There is a very rare risk of an allergic reaction to the contrast. A severe allergic reaction occurs in less than one in 300,000 people.

People with severe kidney failure who receive gadolinium based contrast are at risk of developing Nephrogenic Systemic Fibrosis/Nephrogenic Fibrosing Dermopathy (NSF/NFD). This disease causes fibrosis, a scarring of the skin and internal organs. NSF/NFD is a serious disease that can result in death. However, the contrast agent that we will use is associated with the lowest risk.

You should notify the study team or MRI staff if:

- you are known to be allergic to gadolinium
- you have kidney problems



Risk of MRI-guided prostate biopsies: You will have a MRI-guided prostate biopsy procedure be done as part of your standard care. During the biopsy procedure, 1 additional tissue sample will be taken for research purposes from each lesion sampled. During standard prostate biopsy procedures, about 14-17 biopsy samples are collected. The risk of additional biopsies is minimal

We will use a local nerve block to numb your prostate prior to the biopsy. You should not feel any more pain from the additional sample collection. In general, biopsies involve a risk for minor bleeding or infection. However, there is no evidence that risk for bleeding or infection will be greater if an extra 2-6 samples are taken in addition to the standard number of tissue samples. We will only take samples for research if we are certain that there is a minimal risk of interfering with clinical care. If we are concerned there may not be enough tissue for clinical care, we will not take any research samples. Also, if you are uncomfortable and do not want us to take research samples, we will not take them. It does not matter if you consented to the samples earlier. You can always change your mind.

Risk of pyruvate injection: There are no known risks from injection of pyruvate. However, it is possible that you may react to pyruvate injection. A reaction could involve the following effects:

- flushing,
- feeling hot,
- having a foul, metallic, or salty taste in your mouth, and
- feeling dizzy.

Risk of endorectal coil: The insertion of the endorectal coil may cause some discomfort. The coil we use for this study is a research device. However, its design is about the same as the coils used routinely for standard prostate MRIs.

Unknown risks: There may be risks to this study that are unknown at this time.

Risk for loss of confidentiality: Although we will make every effort to protect your privacy, there is always a risk that some of your information could be revealed. We will minimize this risk by storing study data securely on password-protected computers.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. There is no guarantee that you will benefit directly from taking part in this study. Information gained from this study may also help others in the future.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at UMB / UMMC will not be affected.



COSTS TO PARTICIPANTS

During this study, many of the tests and procedures you will have will be part of the standard care for treating your disease. Standard care tests and procedures are those that will be done whether or not you take part in the study. Your standard care will be billed to you and/or your insurance company. Certain other tests and procedures are considered routine costs for clinical trials. These routine costs will also be billed to your insurance.

Your insurance or health plan may not want to pay the cost of treating any study-related side effects. Before you decide to take part in this study, you may want to contact your insurance company so that you will know what is covered. Tests and procedures that are done solely for study purposes (not standard care or routine costs) will be paid for.

The study coordinator will give you a copy of your completed insurance pre-authorization form once we have received it. This form will contain details from your insurance carrier about which study procedures your insurance has agreed to cover.

PAYMENT TO PARTICIPANTS

You will not be paid to take part in this study. You will receive a parking voucher after you complete each of your research visits.

CONFIDENTIALITY AND ACCESS TO RECORDS

Everyone using study information will work to keep your personal information confidential. Efforts will be made to limit your personal information, including research study and medical records, to people who need to view this information. We cannot promise complete secrecy. The following groups may inspect and copy your study records or data:

- the study doctor and study team;
- the UMB Institutional Review Board (IRB) and other representatives of UMB;
- the U.S Food and Drug Administration (FDA) and other relevant government agencies.

Research monitors and auditors, the IRB, the FDA, and other regulatory agencies will have access to your medical records to verify the research procedures and date. By signing this document, you authorize this access. By law, these groups cannot disclose any identifiable information unless they are required to do so by law.

The data from the study may be published. However, you will not be identified by name.

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.



RIGHT TO WITHDRAW

Taking part in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. If you refuse to take part, or if you stop taking part in the study, you will face no penalty or loss of benefits to which you are otherwise entitled. You should contact your doctor if you decide to withdraw from the study so you can do so safely.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include any medical concern. If this were to happen, the study doctor would tell you and allow you to ask questions.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you



may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037



Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

Patient's Signature

Signature of Investigator or Designee
Obtaining Consent

Patient's Printed Name

Printed Name of Investigator or Designee
Obtaining Consent

Date

Date



Health Insurance Portability and Accountability Act (HIPAA)

***AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH***

Name of Study Participant: _____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: *Metabolic Imaging in the Diagnosis and Risk- Stratification of Prostate Cancer*

UMB IRB APPROVAL NUMBER: *HP-00064745*

Researcher's Name: *Mohummad Siddiqui, MD*

RESEARCHER'S CONTACT INFORMATION:

*Urology department
University of Maryland School of Medicine (UMSOM)
29 S Greene St | Suite 500 |
Baltimore MD 21201*

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Billing and payment information and the medical information required to justify it.*
- *Research tests/images*
- *Results of standard of care medical tests/procedures including any routine imaging*
- *Medical history*
- *Patient identification number (MRN), gender and birthdate*

Federal laws require this researcher to protect the privacy of this health information. He/she will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- *Dr. Mohummad Siddiqui and his research team.*
- *Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University Physicians, Inc. (UPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS)*
- *The Institutional Review Board (IRB), or any relevant governmental agency, such as the U.S. Food and Drug Administration.).*
- *Your health insurer to pay for covered treatments*



THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.

To revoke this Authorization, send a letter to this researcher stating your decision. He will stop collecting health information about you. This researcher might not allow you to continue in this study. He can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you/your child receive at:
 - University Physicians, Inc. (UPI)
 - University of Maryland Medical System (UMMS)It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, and UMMS
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him/her.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature: _____ Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.

