



MAGNETIC RESONANCE SCIENCE CENTER

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

CONSENT TO BE A CLINICAL SUBJECT with Gadolinium Contrast

Magnetic Resonance Imaging and Spectroscopy of the Prostate

PURPOSE AND BACKGROUND

John Kurhanewicz, PhD, Daniel Vigneron, PhD, and Susan Noworolski, PhD and their associates from the UCSF Departments of Radiology and Urology are conducting a research study to examine the combined role of anatomic imaging and metabolic characteristics of prostate cancer in individual patients. I am being asked to be in this study because I have been diagnosed with prostate cancer or I am suspected to have prostate cancer due to an elevated or rising PSA. Magnetic resonance techniques use magnetism and radio waves to non-invasively obtain pictures of body structure (MRI) and to measure concentrations of important chemicals within the body (MRSI). Some of the components of the 3.0 T MRI/MRSI exam are investigational and, therefore, not yet approved by the FDA. However, studies to date suggest that combined MRI/MRSI exams can improve the identification and characterization (location, size, and aggressiveness) of prostate cancer in individual patients. The purpose of this study is to determine if this modern imaging technique of combined MRI with gadolinium contrast and MRSI will be useful to physicians and patients with prostate cancer in making treatment decisions and examining how well various types of treatment work. Gadolinium enhanced MRI provides additional information about the development of blood vessels within a tumor which is critical to cancer growth and spread.

PROCEDURES

If I agree to participate in this study the following will happen:

1. A physician will refer me for this exam and my clinical prostate history and biopsy pathology results will be collected to determine my eligibility.
2. To determine if I can enter the study, I will be asked a number of questions concerning my health, lack of metallic implants, allergies to xylocaine or latex and absence of claustrophobia.
3. I will be asked to be on a light diet one day prior to study and to empty my bowels prior to study. A Fleets enema is also suggested from one to three hours prior to the study.
4. The exam will involve my lying flat on my back inside a magnet which is about 1 yard in diameter and 3 yards long. An endorectal probe may be lubricated with 2% xylocaine jelly, will be inserted in my rectum and positioned under my prostate. An external pelvic phased array coil will be tightly secured over the pelvis.



5. An injection in my arm of Gadolinium contrast will be performed by a urologist or nurse just as is done for many routine clinical exams. The injection of this compound may cause tumors to appear much brighter on the MR images. An I.V. (intravenous) line may be set up during or prior to the exam to allow the injection of this compound during an MR acquisition. I.V. access involves the placing of a small teflon catheter or small needle into one of the veins, preferably in the arm. A small amount of fluid, usually normal saline or dextrose 5% in water, is dripped in to allow easy access in giving the contrast compound.
6. The exam will be performed at the UCSF Department of Radiology Imaging Centers located either at the UCSF China Basin, Mission Bay or Parnassus campus. The exam will require approximately one hour to perform. I will be advised of the probable length of time in advance. Communication with doctors and technicians outside of the room while the exam is in progress will be possible by a microphone and loudspeaker. If I wish to be removed from the magnet, I can so indicate and this will be accomplished immediately.
7. During the imaging segment of these studies, a loud banging noise will come from the magnet. This may be uncomfortable and earplugs or stereo headphones will be provided to reduce the sound level.
9. I **will not** be exposed to harmful radiation during this exam.
10. **Tissue Analysis: (optional):** If I decide to go on for radical prostatectomy or have a future prostate biopsy at UCSF, tissue samples may be collected and studied using research techniques for tissue analysis such as: determination of tumor type and grade, molecular assays of cell growth by staining the tissue, gene expression, and high resolution nuclear magnetic resonance (NMR) spectroscopic analysis of the metabolic composition of the prostate tissue.

RISKS

1. There is a remote risk (< 1%) that my rectum could be perforated by the probe. However, in over 4000 exams completed to date at UCSF there has not been any incidence of rectal perforation.
2. Because the MR instrument attracts iron, there is a possibility that an iron containing object will accidentally fly into the magnet causing injury. Precautions have been made to prevent such an event from happening.
3. Another potential hazard of the exam is localized heating of the body due to the radio waves employed. There is a small risk (<5%) that you will experience warming in the pelvic area. If this becomes uncomfortable enough that you wish to discontinue the exam, you may communicate this to the technologist and the exam will be stopped. However, the MR scanner and the MR probes have been designed to reduce the chance of this happening.
4. There is a remote risk (<1%) that the perfluorocarbon liquid used to inflate the balloon endorectal coil could leak out of the double-walled latex balloon. The



balloon is designed to prevent this from happening and an additional precaution of performing an inflation check prior to insertion is done by the nurse. If the unexpected leak does occur, I will be asked to use a tap water enema, provided by the nurse, to cleanse the rectal area. Afterward, I will be phoned by the research nurse, once a week for one month, to note any symptoms that I experience.

5. While there are no other significant risks associated with MR imaging, I may be bothered by feelings of claustrophobia and by the sounds of the MR instrument during the exam.
6. The most common reactions to an injection of gadolinium contrast which occur in approximately 1% of all patients or lower are: a mild, brief headache, nausea, vomiting, hives and/or local burning or coldness felt at the injection site. Since the gadolinium is given by injection into the vein, cases of irritation of the vein (phlebitis or thrombophlebitis) have been reported in less than 1% of the patients. Rarely (less than 1% of the time) low blood pressure, lightheadedness, tachycardia, high blood pressure occur. Very rarely, patients are allergic to gadolinium. These allergic effects are most commonly hives and itchy eyes, but more severe, life-threatening reactions have been seen in 1 to 100,000 through 1 to 500,000 patients. Rarely (less than 1%) convulsions have occurred.
7. A rare, but serious reaction to gadolinium is nephrogenic sclerosing fibrosis (NSF), a condition associated with the injection of gadolinium contrast, which has been seen in patients with severe kidney disease. Symptoms of NSF are tightening or scarring of the skin and organ failure. In some cases it can be life threatening. There are no reports of NSF in patients with normal kidney function. Before you have your MRI study requiring an injection of gadolinium contrast, you will be asked if you have any conditions that could put you at risk to develop NSF: for example, a history of kidney disease or dialysis, diabetes, or high blood pressure. If you do have a history of a condition that could put you at risk for NSF, you will be asked to have a blood test in order to check the function of your kidneys. Based on your medical history and the results of the test, a doctor will decide whether it is safe for you to continue in the study.
8. The temporary placement of an intravenous line to deliver the Gadolinium may cause conventional discomfort when inserting the needle. Less frequent complications include infiltration of I.V. fluids under the skin, redness and pain. Much less frequent would be phlebitis, or an inflammation of the vein.
9. The risks of drawing blood include temporary discomfort from the needle stick and bruising.

TREATMENT OF INJURY

If I am injured as a result of being in this study, treatment will be available. The cost of such treatment may be covered by the University of California depending upon a number of factors. The University does not normally offer any other form of compensation for injury. For additional information I may call the office of the Committee on Human Research at (415) 476-1814.



COST

If I participate in this study as a prostate cancer patient the cost of the clinical MRI/MRSI staging exam will be covered by my health insurance or myself. A clinical radiology report summarizing MRI/MRSI findings will be made available to my doctors.

CONFIDENTIALITY

My records will be kept as confidential as is possible under law. No individual identifiers will be used in any reports or publications resulting from this study, but the data will be used in the interests of the research ongoing at this center. Additionally, the study doctors and staff may want to contact you or your health care providers to review and/or obtain medical records.

BENEFITS

My physician will receive a clinical report which will assess the location, size, and any spread of cancer outside the prostate. The accuracy of the MRI/MRSI exam with gadolinium in staging and localizing prostate cancer prior to and after therapy is still under investigation. The research data may provide no direct benefit to me, but the investigators may learn more about the use of these techniques in evaluating patients with prostate cancer because of my participation.

ALTERNATIVE

The alternative to participating in this study is to not participate. If I decline to participate, my medical care will not change in any way either now or in the future. The prostate MRI exam is available off study, if ordered by my physician.

QUESTIONS

I have spoken with either Dr. Kurhanewicz, Dr. Noworolski or one of their staff about this study and my questions were answered. If I have other questions, I may call (415) 353-9452.

CONSENT

I have been given a copy of this form and the Experimental Subject’s Bill of Rights to keep. Participation in this research is voluntary. I have the right to refuse or to withdraw at any time without jeopardy to my medical care.

Date: _____ Signature of Subject: _____
 Date: _____ Signature of Person Obtaining Consent _____

Please check one of the boxes below regarding use of future tissue samples:

I agree to allow tissue to be used for the additional metabolic and cellular analyses described above in the procedure section. Subject’s initials: _____



I do not agree to allow tissue to be used for the additional metabolic and cellular analyses described above in the procedure section. Subject's initials: _____

I do not and will not see a physician at UCSF so this does not apply to me. Subject's initials: _____

UCSF

EXPERIMENTAL SUBJECTS' BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told what the study is trying to find out,
2. To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes.
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be'
5. To be told of the other choices I have and how they may be better or worse than being in the study,
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study'
7. To be told what sort of medical treatment is available if any complications arise,
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study'
9. To receive a copy of the signed and dated consent form,
10. To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions, I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: 415.476.1814 from 8:00 am to 5:00 pm., Monday through Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, California 94143

University of California
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):
Magnetic Resonance Imaging and Spectroscopy of the Prostate

Principal Investigator:
John Kurhanewicz, Ph.D.

Sponsor/Funding Agency (if funded):
National Cancer institute (NCI) and
 National Institute of Health (NIH)

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California San Francisco (UCSF) or your health care provider cannot release your health information to the research team unless you give your permission. The research team includes the researchers and people hired by the University or the sponsor to do the research. If you decide to give your permission and to participate in the study, you must sign this form, as well as the Consent Form. This form describes the different ways that the researcher, research team and research sponsor may use your health information for the research study. The research team will use and protect your information as described in the attached Consent Form. Once your health information is released it may not be protected by these privacy laws and might be shared with others. However, other laws protecting your confidentiality may still apply. If you have questions, please ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing the University of California, San Francisco Medical Center and Cancer Center, your referring physician to this study exam, and your other prostate care providers listed by you to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records and information that can identify you. For example, Personal Health Information may include your name, address, phone number or social security number.

- | | | |
|--|--|---|
| <input type="checkbox"/> Entire Medical Record | <input checked="" type="checkbox"/> Radiology Reports | <input checked="" type="checkbox"/> Laboratory Reports |
| <input type="checkbox"/> Outpatient Clinic Records | <input type="checkbox"/> Radiology Images | Psychological Tests |
| <input checked="" type="checkbox"/> Progress Notes | <input checked="" type="checkbox"/> Diagnostic Imaging Reports | <input type="checkbox"/> Dental Records |
| <input checked="" type="checkbox"/> Consultations | <input checked="" type="checkbox"/> Operative Reports | <input checked="" type="checkbox"/> Discharge Summaries |
| <input checked="" type="checkbox"/> History & Physical Exams | <input checked="" type="checkbox"/> Pathology Reports | <input type="checkbox"/> Health Care Billing |
| <input type="checkbox"/> EKG | <input type="checkbox"/> Emergency Medicine Center Reports | |
| <input type="checkbox"/> Other: _____ | | |

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

I agree to the release of HIV/AIDS testing information.

I agree to the release of genetic testing information.

I agree to the release of information pertaining to mental health diagnosis or treatment as follows:

D. How will my Personal Health Information be used?

Your Personal Health Information may be released to these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC who are required by law to review the research;
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration, the research sponsor or the sponsor's representatives, or government agencies in other countries. These organizations and their representatives may see your Personal Health Information. They may not copy or take it from your medical records unless permitted or required by law.

E. How will my Personal Health Information be used in a research report?

If you agree to be in this study, the research team may fill out a research report. (This is sometimes called a "case report".) The research report will **not** include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care, and a tracking code. The research report will also include information the research team collects in the study. The research team and the research sponsor may use the research report and share it with others in the following ways:

1. To perform more research;
2. Share it with researchers in the U.S. or other countries;
3. Place it into research databases;
4. Use it to improve the design of future studies;
5. Use it to publish articles or for presentations to other researchers;
6. Share it with business partners of the sponsor; or
7. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over. Research reports can be used forever.

G. Can I cancel my permission?

You can cancel your permission at any time. You can do this in three ways. You can tell the researcher, write to the researcher, or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used. Also, if the law requires it, the sponsor and government agencies may look at your medical records to review the quality or safety of the study.

H. Signature

If you agree to the release of your Personal Health Information, please sign below. You will be given a signed copy of this form.

Name of Subject (print)

Signature of Subject

Date

Note: if the subject is a minor, an individual signing with an “X”, an adult incapable of giving consent, or is unable to read the authorization, fill out and attach the “special signatures” page (sections “I” and “J”).

University of California
Permission to Use Personal Health Information for Research

SPECIAL SIGNATURES PAGE

I. If the subject is a minor, or an individual signing with an “X”, or an adult incapable of giving consent (where IRB approved), the legally authorized representative or witness signs here:

Name of Legally Authorized Representative
or Witness to the “X” (print)

Relationship to the Subject

Signature of Representative or Witness

Date

J. If the subject is unable to read the authorization, the translator or reader and a witness sign here:

I have accurately and completely read this Authorization to _____
(subject’s name) in _____(language), the subject’s primary language.
The subject has verbally affirmed his/her Authorization to me and to the witness.

Name of Translator or Reader (print)

Signature of Translator or Reader

Date

Name of Witness (print)

Signature of Witness

Date