	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:
APPROVAL PERIOD Aug 25, 2017 – Feb 23, 2018 INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** **Pilot study of using multi-parametric magnetic resonance imaging for organ delineation and tumor response assessment of prostate cancer patients being treated with radiation therapy**	

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1. WHY IS THIS RESEARCH BEING DONE?

To make reading this consent form easier, the word "you" refers to you throughout the form.

You have been asked to take part in a research study. The study will help develop magnetic resonance imaging (MRI) for the field of Radiation Oncology. MRI is an imaging technique that uses magnetic fields to create images similar to computed tomography (CT) images. However, MRI does not use x-rays. MRI shows soft tissues, like prostate, much better than CT. MRI images give doctors important information for planning radiation therapy treatments for cancer patients.

The purpose of this study is to implement a new MRI technique called multi-parametric MRI. Multi-parametric MRI is imaging using standard MRI *and* functional MRI. Standard MRI takes a "snapshot" of your anatomy, while functional MRI looks at changes in your anatomy over time, like blood flow. Having both standard and functional MRI images may help doctors detect cancer, and determine its exact location. The MRI scanner that will be used in this study is approved by the Food and Drug Administration (FDA). It is commonly used for routine diagnostic procedures. The experimental part of this study is taking multi-parametric MRI scans before, during, and after radiation treatment. These additional MRI scans could help doctors assess how the radiation treatment is affecting the tumor, and different areas in the prostate.

A grant from the American Cancer Society is paying for this research study. There will be approximately 20 people participating in the study at Henry Ford Health System (HFHS).

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Your participation in this study will last six months. You will have four MRI imaging sessions: one before your radiation treatment begins, one in the middle of your radiation treatment, one at the end of your radiation treatment, and one 2-3 months after your radiation treatment. A calendar will be provided to you to help you keep track of your appointments and the locations. The screening procedure will also occur before the study. Screening is a standard procedure for any MRI, and is not experimental.

Screening Procedure

Before your MRI procedure, an MR technologist or nurse will ask you questions about your medical history. Specifically, you will be asked if you have metal or medical devices in your body, like a pacemaker. This is an important safety precaution before you may participate in the MRI study. You will be told about the imaging procedure and you can ask any questions you may have. The screening should take about 10 minutes. If you qualify for the study and agree to participate, the 2nd visit will happen either on the same day, or at a later scheduled time.

MR Imaging Procedure

As part of this study, you will undergo four MRI imaging sessions. Your doctor will decide the location of your imaging session. The imaging sessions will occur at the following time points:

1. 1-2 weeks before your radiation treatment begins.
2. In the middle of radiation treatment.
3. Within 1 week after you finish radiation therapy.
4. 2-3 months after you finish radiation therapy.

Before each MRI, the MR technologist or nurse will ask you questions about the presence of metal or medical devices in your body. This is to ensure your safety. You will be told about the imaging procedure and you can ask questions. The screening should take about 10 minutes of your time. You will be asked to change into a hospital gown. During the MRI scan, you will lie flat on the couch and be placed into a magnet. A loud knocking noise occurs during the scan, so you will be provided with ear plugs to block the sound. There is a 2-way intercom system that allows you to communicate with the MRI technician and researchers if necessary. Pelvic MR images will be taken to evaluate your prostate anatomy and function. The total examination will take between 30-45 minutes. This is a typical exam time for MRI.

Unlike many diagnostic imaging procedures, such as CT, MRI does not use any x-rays. Participating in this study will not expose you to any radiation. The MRI scanner is FDA approved for the MR scans you will receive.

3. WHAT ARE THE RISKS OF THE STUDY?

If you are currently involved in any other medical research studies, you should tell the person obtaining your consent. While you are in this study, you are at risk for the following side effects:

Likely: MRI poses some dangers to patients with certain medical devices (like a pacemaker) or metal fragments in the body.

Before the imaging study, the MR technologist will ask you questions about the presence medical devices, or metal, in your body. For safety purposes, you will be asked these questions 3 different times:

1. At the initial screening visit.
2. At the 2nd visit before you are dressed in your hospital gown.
3. Just before you enter the MRI area.

Objects containing certain types of metals may be attracted to the magnet and accelerated to high speeds. For this reason, you will be screened by MR technologist or nurse. You will also be asked to remove any metal objects on your person, like, your watch, jewelry, or keys.

Less Likely: A small percentage (less than 5%) of patients may become claustrophobic inside the magnet. Should this occur, the scan will be stopped. Certain techniques may produce a sensation of warmth. For a small number of patients, this may become uncomfortable. If this happens, the scan will be stopped.

Rare but serious: A magnetic field that changes over time will cause a current in a conductor. In rare situations, this could lead to nerve stimulation in your arms and legs. If you or the MR technologist see or feel signs of stimulation, the scan will be stopped.

This study uses contrast agents, which add the following additional risks:

Likely: You may feel pain at the injection site.

Less Likely: You may have a metallic taste in your mouth, tingling in your arm, headache, or nausea.

Rare but serious: You may have an allergic reaction. Very few people are allergic to MRI contrast and have itching after it is given. Less than 1 person out of 300,000 will have a severe allergic reaction that requires medical treatment. Nephrogenic Systemic Fibrosis (NSF) is a rare condition where the skin gets thicker and limits the motion of your body. Burning, itching, and pain are also symptoms of this disorder.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

You will be given digital copies of your images on a CD if you request them. You may keep them or share them with your doctor. Since this is a pilot study, the MR images will not be used for your standard clinical care. However, others may be helped by what researchers learn from this study. By volunteering, you will be

helping Henry Ford Health System researchers develop the best imaging protocols for radiation therapy. Eventually this may help develop new radiation treatment planning techniques. While you will receive no direct benefit from participating in this study, others may be helped by what is learned from this research.

5. WHAT OTHER OPTIONS ARE THERE?

Participation in this study is entirely voluntary and will not affect your treatment in any way. You can decide not to participate in the study and continue on with your treatment as planned. Talk to your doctor about your choices before you decide if you will take part in this study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:

- Your existing medical records.
- New health information created during this study.
- Health insurance and other billing information.

We may release this information to the following people:

- The Principal Investigator and his/her research associates.
- Government officials who oversee research (FDA)
- Vendors or researchers at other institutions, who are participating in the research.
- The sponsors of this research (American Cancer Society).

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

HFHS or others may publish the results of this study. However, no names, identifying pictures, or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will expire at the end of this research study.

You do not have to sign this consent to release your medical information. If you do, you may cancel it at any time. If you decide not to sign this consent or to cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

7. WHAT IF I AM INJURED?

If you are injured as a result of participating in this study, medical treatment is available to you. However, no federal, state, or other program will compensate you or pay for your medical care. If you are injured as a result of participating in this study, you and/or your medical insurance may have to pay for your medical care. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Ning Wen, PhD, or his staff member, has explained this research study to you and has offered to answer any questions. .

If you have questions about your rights as a research subject, you may contact the HFHS IRB (Internal Review Board) Coordinator at (313) 916-2024. The IRB is a group of people who review the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the *routine* medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. The MR imaging cost associated with this study will be paid by the research grant. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

There will be no compensation to you for your participation in this study.

13. CONSENT

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

Signature of Subject	Date	Time

Print Name of Subject

Witness to Signature	Date	Time

Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent	Date	Time