Protocol Title:

The Value of Advanced MR Imaging

In Gynecological Tumors and Benign Uterine Fibroids

DF/HCC Principal Research Doctor / Institution:

Dr. Clare Tempany / BWH Diagnostic Radiology

Main Consent

INTRODUCTION AND KEY INFORMATION

All research is voluntary. It is your choice whether you take part in this research or not.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

1. Why am I being invited to take part in a research study?

You are invited to take part in this research study, because you have been referred to Brigham and Women's Hospital/Dana-Farber Cancer Institute for one of the following reasons:

- you have been diagnosed with a gynecological tumor OR
- you are being examined for a possible gynecological tumor OR
- you are being evaluated for the treatment of benign uterine fibroid(s)

We are also asking you to take part in this research study because you are undergoing a standard of care Magnetic Resonance Imaging (MRI) of the pelvis as part of your clinical routine examinations.

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2. Why is this research being done?

Magnetic resonance imaging (MRI) is a safe and painless test that uses a magnetic field and radio waves to produce detailed images of the body's organs and structures. This research is being done to test new MRI methods called Magnetic Resonance Fingerprinting and Q-space Trajectory Imaging in gynecological abnormalities. The purpose of this research study is to evaluate if these new MRI methods can give additional information in characterizing gynecological tumors compared with conventional MRI.

3. What does this research study involve and how long will it last?

This research study involves new MRI methods in gynecological imaging. The new MRI methods are called Magnetic Resonance Fingerprinting (MR Fingerprinting) and Q-space Trajectory Imaging (QTI).

All research study participants will undergo standard of care pelvic MRI at Brigham and Women's Hospital as part of their clinical routine examination. New MRI method, MR Fingerprinting or QTI, will be supplementary and included along with the routine clinical MRI scan. This requires 10–15 minutes additional scanning time. No other procedures are required. Also for participants with benign uterine fibroid(s) no other research procedures will be performed apart from the MRI.

In other words, if you participate in this research study, the scanning time during your clinical routine MRI will be increased with an extra 10–15 minutes. No other procedures and no extra hospital visit are required.

It is expected that about 110 people will take part in this research study.

Information about you and your health is personal and private. Generally it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. In this research study, we ask for access to your medical records to collect information on the management and follow-up of the gynecological abnormality that you are now being examined for. The clinical data that will be evaluated includes laboratory test results, notes on clinical examinations and procedures, imaging, treatments,

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pathology results if biopsy or surgery is performed, and co-morbidities from your past medical history.

4. What are the risks to participating in this study?

There are risks to taking part in any research study. There are no added risks with the new MRI methods required by this study beyond the general risks of MRI testing. We outline those general risks below. The new MRI methods used in this study do not require the use of intravenous contrast agent.

Because the MRI machine acts like a large magnet, it could move objects containing iron in your body or the MRI room during your examination, which could possibly harm you. We will take precautions to prevent this from happening. You will be screened before you enter the room. Loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI.

Having an MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia (a “closed-in” feeling) and by the loud banging noise during the test. Temporary hearing loss has been reported from this loud noise. This is why we will ask you to wear protective earplugs.

5. Will being in this study benefit me in any way?

We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

No extra hospital visit is required to participate in this study. The only burden to you is to be extra 10–15 minutes in the MRI scanner during your clinical standard of care MRI exam. You will not be paid for taking part in this study.

6. What are my options?

If you decide to participate, please sign and date at the end of this form.

We will give you a copy and you can refer to this consent form at any time during the research study.

If you choose not to participate in this research study, you will undergo the same clinical standard of care MRI exam, but the new MRI method will then not be included.

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A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research is being done to test new imaging methods (MR Fingerprinting and QTI) in gynecological abnormalities. We want to evaluate whether these new imaging methods are useful in female pelvic MRI. MR Fingerprinting and QTI have earlier been studied in brain tumors and prostate cancer, but not in gynecological imaging.

In this research study, we are:

- Investigating the use of MR imaging in gynecological tumors on imaging quality and comparison of tumor or fibroid structures and normal anatomy
- Investigating whether new MRI methods could help in characterizing the tumor and give information about the expected outcome

B. WHAT OTHER OPTIONS ARE THERE?

Instead of being in this research study, you may decide not to participate. In this case you will undergo the standard of care pelvic MRI (where you were referred to by your treating physician) without the supplementary new MRI method.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

C. WHAT IS INVOLVED IN THE RESEARCH STUDY?

This research study will include a new MR imaging method along with the standard of care routine pelvic MRI where you were referred to by your treating physician. The routine pelvic MRI will be performed in the usual way and the radiologist will read your scan as usual. Adding a new MRI method along with the routine imaging will not interfere with the routine protocol in any way. It will, however, increase the scanning time with an extra 10–15 minutes.

Imaging will be performed using a standard MRI scanner at Brigham and Women's Hospital. You will be scheduled for a specific MRI scanner that is used for clinical imaging. Only one new MRI method, either MR Fingerprinting or QTI, will be used.

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Participants cannot choose which of the new methods is performed for investigational purposes. New MRI methods do not require any invasive procedures. However, contrast agent may be given intravenously related to the standard of care clinical routine MRI protocol.

Participating in this research study does not require extra hospital visits. Also, this study will not interfere in any ways with your treatment. However, we ask for access to your medical records to collect information on the management and follow-up of the gynecological abnormality that you are now being examined for. The clinical data that will be evaluated includes laboratory test results, notes on clinical examinations and procedures, imaging, received treatments, pathology results if biopsy or surgery is performed, and co-morbidities from your past medical history. Follow-up information will be collected from the medical records up to 4 years after participating in this research study. Treatment response is defined as complete, partial, stable or progressive based on cross-sectional imaging, and will be used along with the long-term follow-up data to compare MRI findings with the outcome.

D. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

Risks Associated with MRI Scans:
When having an MRI scan, you will lie still on a table that slides into a space slightly wider than your body. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow cylinder. If you feel uncomfortable in confined spaces, please tell your research doctor. Your doctor may give you a medication to make you feel more comfortable. As images are taken, a loud banging noise will be produced. Earplugs or headphones will be available if needed. The MRI can be stopped at any time at your request, but the scan may not be complete.

Possible side effects related to MRI exam:

Likely:
- Anxiety/destress
- Claustrophobia
- Discomfort

Rare, but serious:
- Injury related to the presence of metallic or surgical implants or metal pieces in the body and the MR magnet; it is important that

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you complete the MR screening process and document, and tell the MRI team about whether you have these before the MRI procedure.

E. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- You are a female and become pregnant or plan to become pregnant
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Participants with benign fibroid(s) may also inform their research doctor (interventional radiologist) if they wish to withdraw from the study. Leaving the research study will not affect your medical care outside of the research study.

It is important to note that although you may withdraw from study participation, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from study records. Additionally, the research doctor may consult public records after you have withdrawn from the study.

The protocol does not include provisions for the withdrawal/destruction of identifiable samples to be used for future research.

F. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid for participating in this study.

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G. WHO IS SUPPORTING THIS RESEARCH?

This is an academic study and is not supported by outside sponsors.

H. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to any additional costs to you or your insurance company. The routine clinical pelvic MRI where you are referred to by your treating physician is covered by you or your insurance company as usual. You will not be charged for the new MRI methods that are included into your routine pelvic MRI.

I. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

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If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

J. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research doctor or study staff as listed below:

Brigham and Women's Hospital, Department of Radiology
- Aida Kiviniemi, Research Fellow, tel. (617) 732-8772

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

K. RETURN OF RESEARCH RESULTS

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information gives results that do have meaning for your health, the researchers may contact you to let you know what they have found.

L. CLINICALTRIALS.GOV (CT.GOV)

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.

M. FUTURE USE OF DATA AND SPECIMENS

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Your personal information and/or biospecimens collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

N. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

O. GENETIC RESEARCH

This research will not involve genomic or germline testing.

P. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

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

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;

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- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes

of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

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

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

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Q. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

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To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

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Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate

To be completed by person obtaining consent:

Minor Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

☐ 1) The parent or legally authorized representative gave permission for the minor to participate.

☐ 1a) Parent or legally authorized representative is a non-English speaker and signed the translated Short Form in lieu of English consent document

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed name of Interpreter/Witness: _____

Date: _____

☐ 1b) Parent or legally authorized representative is physically unable to sign the consent form because:

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☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the parent or legally authorized representative who was given the opportunity to ask questions and who communicated agreement for the minor to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 1c) The parent or legally authorized representative did not give permission for the minor to participate

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