

Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates

OHRS 08.13.10

Protocol Title:

A ONE YEAR MRI SURVEILLANCE OF LOCALIZED PROSTATE CANCER

DF/HCC PRINCIPAL RESEARCH DOCTOR / INSTITUTION:

JEROME RICHIE, MD (BRIGHAM AND WOMEN'S HOSPITAL)

A. INTRODUCTION

You are invited to take part in a research study because you have prostate cancer which was confirmed to be localized by MRI (Magnetic Resonance Imaging) and you decided to postpone your treatment and get regular PSA tests and perhaps repeat biopsies (otherwise referred to as active surveillance).

This research study is a way of gaining new knowledge about our “active surveillance” program which we sometimes recommend for localized and slow-growing cancers. For the purposes of this research, you will be referred to as a “participant.”

It is expected that about 75 people will take part in this research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

If you decide to participate in this research study, certain questions will be asked of you or certain tests will be taken to see if you are eligible to be in the research study. These tests are called screening tests. The research study has certain requirements that must be met. If the screening tests show that you can be in the research study, you will be able to start on the study.

If the tests show that you cannot be in the research study, you will not be able to participate in this research study.

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>

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We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

Our active surveillance program uses MRI imaging to better understand the location and nature of the prostate cancer. The endorectal MRI examines difficult-to-biopsy areas and provides more precise measurements of the tumor. The pelvic MRI is used to direct prostate biopsies to cancer or suspicious areas.

In this research study, we are evaluating participants' acceptance of the MRI surveillance program, their urinary and sexual symptoms, physical activity and diet.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have other options which may include the following:

- Start a treatment, such as surgery, radiation therapy, or hormonal therapy
- Participate in the MRI-surveillance program without the questionnaires or another "active surveillance" program or another research study (see www.clinicaltrials.gov)
- Continue to monitor your cancer with your doctor

Please talk to the research doctor about your options before you decide whether you will take part in this research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Sometimes it is hard to keep track of all of the details and procedures that are part of a research study. We will describe them in this consent form and you can refer to this at any time during the research study.

After signing this consent form and before the research starts the research doctor will review your PSA results, pathology reports, ultrasound and MRI studies to find out if you can be in the research study.

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
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Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates

OHRS 08.13.10

If these tests show that you are eligible to participate, we will ask you to fill out the following questionnaires:

- medical history
- family history of cancer
- concomitant medications
- urinary function
- sexual function
- anxiety scale for prostate cancer
- physical activity
- food frequency questionnaire

Every 3 months, we would like you to come in for a follow-up visit and a PSA test

For the research study, we will ask you to fill out the following questionnaires:

- adverse events
- concomitant medications
- urinary function
- sexual function
- anxiety scale for prostate cancer
- physical activity
- food frequency questionnaire

At the 12 month visit, you will have a repeat prostate biopsy, using MRI imaging:

For the research study, we will ask you to fill out the 3-month questionnaires:

E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study for as long as you remain in the “active surveillance” program.

At the end of each year, your doctor will review your PSA tests, MRI results and prostate biopsies and may suggest that you stay on the “activate surveillance” program. You may then decide to continue to participate in the research study.

The research doctor may decide to take you off the research study for many reasons including if:

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>

Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates

OHRS 08.13.10

- Your PSA tests, prostate biopsies and MRI results show that your cancer has progressed
- It is considered to be in your best interest
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

If you are removed from the research study, the research doctor will explain to you why you were removed.

In addition, you can stop participating in the research study at any time. If you decide to stop participating in this research study, we encourage you to talk to the research doctor and your primary doctor first.

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

There are risks to taking part in any research study.

Risks Associated with Watchful Waiting

There is a risk that the prostate cancer extends, metastasizes, or rapidly grows between the 3-month visits.

Some participants may experience anxiety and distress while being on “active surveillance” and should speak with their doctors. For other participants, repeat PSA testing, MRI imaging and prostate biopsies may actually provide relief and reassurance.

Risks Associated with Prostate Biopsies:

The risks may include:

- Pain and discomfort.
- Minor bleeding at the biopsy site.
- Rarely, an infection at the biopsy site.

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>

Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
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OHRS 08.13.10

Risks Associated with MRI Scans:

When having an MRI (Magnetic Resonance Imaging) scan, you will lie still on a table that slides into a tunnel 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.

Risks Associated with Contrast Agents Used During Scans:

There is a small risk with using a contrast agent that is injected into a vein during the MRI. The contrast agent is a special dye that highlights organs, blood vessels or tissue to make them more visible. Depending on the type of contrast agent that is used, it may cause decreased kidney function or worsen kidney function in people who already have decreased kidney function. Therefore, we will monitor your kidney function closely while you participate in this study. If there is any change in your kidney function, we may have to remove you from the study.

Uncommonly, some people have allergic reactions (such as hives and itching) to the contrast agent. Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction and death) are rare.

Non-Physical Risks:

The questionnaires used in this study may be upsetting. If you find the questionnaires upsetting, you may speak with the research doctor or ask to be referred for additional emotional support.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

Taking part in this research study may or may not make your health better. We hope the information learned from this research study will help doctors learn more about our “watchful waiting program” as a management option for low-risk prostate cancer in the future.

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>

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Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates

OHRS 08.13.10

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being 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. Leaving the research study will not affect your medical care outside of the research study.

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.

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

There is no plan or policy to provide you compensation for participating in this research study.

J. WHAT ARE THE COSTS?

The clinical visits will be longer and this could result in higher parking costs but we can mail the questionnaires to your home.

You and your insurance company will be responsible for the cost of PSA testing, MRI imaging, and prostate biopsies that are considered standard "active surveillance" care.

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

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

Providing your care does not mean that DF/HCC or the research Investigators are at fault, or that there was wrongdoing. There are no plans for DF/HCC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

Page 6 of 11

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>

Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
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OHRS 08.13.10

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 Investigator's name and phone number are listed in this consent form.

L. WHAT ABOUT 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.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file.

The results of this research study may be published. You will not be identified in publications without your permission.

M. 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

- Jerome Richie, MD (617) 732-6674

24-hour contact: Jean-Francois Caubet (617) 372 7124

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (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.

N. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana Farber/Harvard Cancer Center (DF/HCC) and its affiliated research Investigators, 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

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>

Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
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OHRS 08.13.10

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
- 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;
- 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
- Other reasons may include for intervention, 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.

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

- DF/HCC and its affiliated research Investigators 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.

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
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Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates

OHRS 08.13.10

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 on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, and its subcontractors
- Other research Investigators 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.
- 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 Investigators 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

Page 9 of 11

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>

Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates

OHRS 08.13.10

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 intervention or payment for your intervention, 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?"

O. DOCUMENTATION OF CONSENT

My signature below indicates my willingness to participate in this research study and my understanding that I can withdraw at any time.

Signature of Participant

Date

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date).

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

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

☐ Participant 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, in the participant's language, the researcher's

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>

Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates

OHRS 08.13.10

presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____

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

☐ gave permission for the adult participant to participate

☐ did not give permission for the adult participant to participate

Signature of Individual obtaining consent: _____

Printed name of above: _____

Date: _____

DFCI Protocol Number: <u>11-340</u>	Date DFCI IRB Approved this Consent Form: <u>September 29, 2011</u>
Date Posted for Use: <u>September 30, 2011</u>	Date DFCI IRB Approval Expires: <u>September 28, 2012</u>