# Expanding an Active Surveillance Cohort to Improve Survivorship for Men With Favorable Risk Prostate Cancer

NCT Number: NCT05424783

Approval Date: May 27, 2022

# Permission to Take Part in a Human Research Study

**Title of Research Study:** Expanding an Active Surveillance Cohort to Improve Survivorship for Men with Favorable Risk Prostate Cancer

**Short Title: MRI And GPS Informing Choices for prostate cancer treatment (MAGIC)**

**Principal Investigator:** Adam B. Murphy MD, MBA, MSCI

**Co-Principal Investigator:** Daniel Moreira, MD

**Supported By:** United States Department of Defense

**Key Information:**
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

**Why am I being asked to take part in this research study?**
We are asking you to take part in this research study because you are a male who has been diagnosed with very low to favorable intermediate risk prostate cancer, and you are willing to consider active surveillance for treatment.. This study involves a series of questionnaires, a magnetic resonance imaging (i.e., MRI scan), a blood draw, and the use of your prostate biopsy sample. Research studies answer important questions that might help change or improve the way we do things in the future.

**What should I know about a research study?**
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**Why is this research being done?**
We want to find out if the MRI and the Genomic Prostate Score (GPS) affect treatment choices and if it affects how closely the cancer is monitored over a 2 year period relative to men treated in the past. The purpose of this study is to recruit 222 men considering active surveillance for treatment in the MAGIC Study to provide meaningful data on active surveillance in men served in publicly funded hospitals. Our long-term goal is to improve the safety and uptake of active surveillance in publicly funded hospitals for improved survivorship for all prostate cancer participants.

This study will compare results from men in this study to men previously recruited from the ENACT study that are on Active Surveillance to identify the factors that may affect the way the cancer is monitored.

**How long will the research last and what will I need to do?**
We expect that you will be actively involved in this research study for over a period of 6 months. We will follow you through the medical records for 2 years

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You will be asked to come to the study site 3 times.

The first 2 visits will take about 1 hour. The third visit will take 30-45 minutes.

1. Initial visit for consenting, medication review, and questionnaires during regular urology appointment (standard of care and research purposes)
2. Second visit for medication review and questionnaires (standard of care and research purposes)
3. Third visit for review of labs, blood draw, and medication review (standard of care and research purposes)

| Time Period | Screening Visit/Visit 1/Day 1 | Visit 2 Day 36 or Day 50 +/- 7 days | Visit 3 Day 180 +/- 14 days |
|---|---|---|---|
| **Informed[1] Consent** | X | | |
| | | | |
| | | | |
| **Physical exam** | X | X | X |
| **Vital signs** | X | X | X |
| | | | |
| **Con Meds** | X | X | X |
| | | | |
| **GPS assay** | X | | |
| | | | |
| **Blood draw/ PSA levels** | | | X |
| | | | |
| | | | |
| **Visit 1 Questionnaires** | X | | |
| **Visit 2 Questionnaires** | | X | |

These visits will take place during your regularly scheduled visits with your doctor.

MRI Test: You are having an MRI scan as part of your standard health care. This is to be sure there are no other areas of the prostate suspicious for cancer and takes approximately 30-45 minutes. The MRI is usually done with contrast dye.

GPS test: This is a standard of care test. Tissue samples from your diagnostic prostate biopsy will be tested for expression of 17 genes to provide a Genomic Prostate Score which measures tumor aggressiveness. This is considered standard of care and is in the 2021NCCN Guidelines for Prostate Cancer.

MRI and GPS results: Results will be provided at your post-biopsy visit, which is standard of care and would occur whether or not you participate in research.

Prostate Biopsy: This is a standard of care test and would occur whether or not you participate in research if Active Surveillance is chosen as your treatment choice.

Biopsy results: This is a standard of care visit where you will find out if your cancer has progressed.

Complete questionnaires: This is for research purposes and will take approximately 30-45 minutes.

Blood draw: This is for research purposes in Visit 3. You are not required to consent to the blood draw in order to take part in the main study.

We will use the blood for future prostate cancer research.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

**Is there any way being in this study could be bad for me?**
All procedures have possible risks. We will watch for any problems during the study procedures so that we can stop if necessary.

For this study, the main risks to know about are:

- The MRI scanner uses a very strong magnet, making it unsafe for people with metal on or in their body to have an MRI scan.
- The use of contrast dye may cause an allergic reaction.
- You might feel anxious in the small space of the MRI scanner. You will be able to stop the scan at any time.
- The MRI scanner makes loud noises. You will wear ear protection.
- Prostate Biopsy discomforts would occur whether or not you participate in research.
- Blood draw for the study. In rare cases, swelling and infection may occur at the site of the vein where the blood is sampled.
- You may feel emotionally uncomfortable, as we will ask questions about your medical history and diagnosis of prostate cancer.
- The Oncotype DX GPS test and MRI results give you and your doctor additional information that may influence your treatment.
- There may be a risk of loss of privacy.

More detailed information about the risks of this study can be found under **"What are the potential risks and discomforts of the study?" (Detailed Risks)"**

**Will being in this study help me any way?**
You may not benefit directly from participation in the research. You should not expect your

condition to improve as a result of participating in this research. However, receiving the Oncotype DX GPS test and MRI may assist you with making a treatment choice for your cancer.

We hope that your participation in this study may benefit other people in the future. You have a right to refuse to participate in this study at any time.

**What happens if I do not want to be in this research?**
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

If you decide not to enter this study, there is other care available to you including an MRI of the prostate or an Oncotype DX test outside of the study. The study doctor will discuss these with you. You do not have to be in this study to be treated for prostate cancer.

**Detailed Information:**
The rest of this document includes detailed information about this study (in addition to the information listed above).

**Whom can I talk to?**
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (312) 908-7963 from 9am to 5pm on Monday through Friday.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

**How many people will be studied?**
We expect 40 people from the University of Illinois Hospital (UI Health)/University of Illinois at Chicago (UIC), 89 people from John H. Stroger Jr. Hospital of Cook County, and 93 people from Jesse Brown VA Medical Center will be in this research study out of 222 people total in the entire study.

**What happens if I say "Yes, I want to be in this research"?**
While Northwestern University is the data coordinating center, this research will be performed at University of Illinois at Chicago, Cook County Health, and Jesse Brown VA. The MRI test will take place in the radiology departments at each recruiting site.

If you agree to be in the study, you will be asked to do the following procedures:

You will need to come to the study site 3 times over the next 6 months (at date of recruitment, 3 months later and 6 months after the date of recruitment). Each of those visits will take between 30 minutes and 1 hour. The Study procedures are:

At Visit 1 (the first visit with your doctor after your biopsy) you will:

1. Discuss the results of your prostate biopsy with your doctor
2. Review the study with members of the research team
3. Complete and sign this consent form
4. Have your MRI scheduled
5. Extra (leftover) tissue from your biopsy will be used to perform research test that measures your GPS.
6. Complete questionnaires
7. Allow researchers to review your medical record and collect information on your medical history, such as pathology reports, lab reports, medication, and current illnesses.
8. Receive a $20 stipend

At Visit 2 (the second visit with your doctor after your biopsy) you will:

1. Discuss all treatment options with your doctor. You and your doctor will also review the results from your Oncotype DX lab test and MRI.
2. Make a decision on your treatment for prostate cancer.
3. Complete questionnaires
4. Receive a $20 stipend

At Visit 3 (Final Visit), which occurs after your treatment, you will:

1. Review your PSA labs with your doctor
2. Provide a blood sample (approximately 25 ml)
3. Schedule follow up visit and repeat Active Surveillance biopsy, if applicable
4. Complete questionnaires if not fully completed at Visit 2
5. Receive a $20 stipend

During this study, Dr. Adam Murphy and his research team will collect information about you for the purposes of this research. We will explain why we need this information.

Biopsy results: A positive diagnosis of prostate cancer will be communicated by your urologist doctor that had performed your biopsy. This visit will signify the beginning of the study.

Medical history: prior prostate biopsy, prior diagnosis of prostate cancer, MRI incompatible implanted medical devices, anatomy incompatible with transrectal biopsy. This information will help your doctor to evaluate if you can participate in the study.

Demographics and social history: This information will help researchers understand the background of the individuals participating in this research study.

MRI test: The MRI test will have different settings to verify the areas of identified prostate cancer.

Oncotype DX Genomic Prostate Score test: Leftover tissue from your biopsy will be used to perform a genetic test to measure your Genomic Prostate Score, which can identify men with higher likelihood of having aggressive prostate tumors.

Follow up: Participants will be followed by medical records for up to 2 years from the date of

enrollment. They will be tracked for future PSA tests, prostate exams, imaging studies, genomics tests, prostate biopsies, treatments, and radical prostatectomy pathology findings, and for evidence of tumor progression or post-treatment biochemical recurrence.

**What happens if I say "Yes", but I change my mind later?**
You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can provide advice about how to leave the study. If you choose to no longer be in the study and you do not want any of your future information to be used, you must inform the researchers in writing at the address provided. The researchers may use your information that was collected prior to your written notice.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, class standing (for students enrolled in a class at NU), or your present or future employment (for employees at NU or its affiliates).

**Detailed Risks: Is there any way being in this study could be bad for me?**
The procedures in this study may cause all, some, or none of the risks listed below:

Blood Draw/Venipuncture: The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the overlying skin and infection, and a rare risk of fainting. Care will be taken to reduce these risks.

Risks of the prostate MRI with Gadolinium-based contrast dye

Some people cannot have an MRI because they have some type of metal in their body. For instance, if you have a heart pacemaker, artificial heart valves, metal implants such as metal ear implants, bullet pieces, chemotherapy or insulin pumps or any other metal such as metal clips or rings, you cannot have an MRI. During this test, you will lie in a small, enclosed area inside a large magnetic tube. Some people are scared or anxious in small places (claustrophobic). The MRI scanner makes loud banging noises while taking a measurement, so either earplugs or specially designed headphones will be used to reduce the noise.

We have switched the Gadolinium-based contrast dye we use to Gadavist, which is safer than most gadolinium-based contrast dyes. Some people have allergic reactions to Gadavist. The dose for Gadavist (i.e., gadobutrol) to be given is 0.1mmol/kg through a peripheral vein at a rate of 2 ml/second for prostate MRI and is within FDA approved guidelines. If you experience shortness of breath or itching, please tell your technologist to stop the MRI. If you are on dialysis, you will need to have your prostate MRI done on the day of your dialysis before dialysis in order to remove the contrast dye from your system. We can do the MRI without the Gadavist also. You will be asked if you have any history of kidney problems or have had a kidney and/or liver transplant.
Deposits of Gadolinium-based dyes remain in the brain of some patients who have undergone MRI scans with gadolinium-based dyes for a prolonged time after the last administration. Deposits of gadolinium-based dyes have also been reported in skin and bone. It is unknown whether these Gadolinium deposits are harmful or can have serious health effects.

The dose and frequency of the contrast dye we are giving you is standard. We do not expect any additional risk to be posed to you beyond those already described above.

You should avoid receiving additional Gadolinium-based contrast dye within 24 hours before or after the dose given in this research study.

Your participation may make you feel emotionally uncomfortable, as we will ask questions about your medical history. Some of the questions we ask may be upsetting or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

You may experience mild to severe anxiety or nervousness during the MRI test that requires cancellation of the procedure. Although unlikely, it is possible that spots seen on the MRI scan are falsely positive, which will lead to biopsies of areas of the prostate that are not cancer.

Risks and discomforts from the prostate biopsy would occur whether or not you participate in the research and includes: blood in the urine, blood in the semen, and blood of the toilet paper after a bowel movement for 1-2 days.

There may be risks from the study that are not known at this time.

Questionnaires: Some of the questions may make you feel uncomfortable or remind you of unpleasant aspects of your condition. You may skip any questions you do not wish to answer.

A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

While we believe that the risks to you and your family are very low, we are not able to know all of the risks from taking part in genetic research studies. Your privacy will be protected to the fullest extent possible. Certain health concerns that affect you and your blood relatives might be found as inherited traits are studied. Even though your genes are unique, you share some of the same genes with your blood relatives. In addition, there may be undue stress, anxiety, or embarrassment resulting from inadvertent disclosure of information on family relationships, ethnic heritage, or potentially stigmatizing conditions.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. For example, life insurance companies may charge a higher rate based on this information. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease that is being tested in this research study.

**Will it cost me anything to participate in this research study?**
You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

## Permission to Take Part in a Human Research Study

**What happens to the information collected for the research?**
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- The sponsor of the research study, The US Department of Defense.
- Northwestern University (lead investigation site).
- USAMRMC Office of Research Protections, or
- Human Research Protection Office (HRPO)

A possible risk of the study is that your participation in the study or information about you and your health might become known to individuals outside the study. Your health information will be stored on a secured HIPAA compliant database to prevent access by unauthorized personnel.

Your study information will be given to Dr. Adam Murphy at Northwestern University in a format that will not contain any information that can be used to identify individual participants and will only be shared via secured methods.

Your individual data will be assigned a registration number. This number will be used in place of your name and any other personal identifying information on all study questionnaires and blood samples. Personal information about you that will be stored on a Northwestern secure database are your name and registration number, date of registration, age, sex, and race. Only authorized study personnel will have access to information linking personal identifying information to your registration numbers. Data sent to institutions outside of Northwestern will only know you by your registration number. All paper and electronic study materials will be kept in locked cabinets or password protected computers in locked offices.

When the results of the study are published or discussed in conferences, no one will know that you were in the study.

**Data Sharing**
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Can I be removed from the research without my OK?**
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include that the researchers or the

sponsor believe it is in your best interests to no longer continue participating in the research study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

**What else do I need to know?**
If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you agree to take part in this research study, we will pay you $60 total for your time and effort.

You will receive $20 for each completed study visit. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of $60 cash. You will receive your payment immediately after each visit via cash. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service (IRS).

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. There are no plans to compensate you for any of these developments.

**HIPAA Authorization**
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that 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. Your health information we may collect and use for this research includes:

- Results of physical examinations

- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information (such as hospital associated charges, and billing codes based on diagnosis and procedures done)
- Results of other imaging studies
- Questionnaire responses
- Prostate cancer treatments, if applicable
- The results of your prostate biopsy
- Currently used medications and supplements

During this study, you may be coming to a recruiting site for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the recruitment sites' computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both the recruitment sites' clinical records and in the study records.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): U.S. Department of Defense, the Human Research Protection Office, the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- The National Cancer Institute, who is sponsoring the study, and their contractors and partners.
- Clinical affiliates, including but not limited to those of Northwestern University, Jesse Brown VA, Cook County Health and University of Illinois at Chicago. Your participation in this clinical study may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to

you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Adam B. Murphy MD
Northwestern University
Department of Urology
303 E. Chicago Avenue
Tarry Bldg. 16-729
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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**Optional Elements:**

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

| I agree | I disagree | |
|---|---|---|
| _____ | _____ | The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study. |
| _____ | _____ | The researcher may retain any leftover blood, DNA or tissue samples taken during the study. These samples may be used for other research not related to this study. These samples will be retained in non-identifiable form, meaning that there will be no information associated with the blood, DNA or samples that will allow anyone to readily ascertain my identity. |

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent