NCT04396808

TITLE: Genomics in Michigan to AdJust Outcomes in prostate canceR (G-MAJOR): A randomized controlled multi-center study for men with newly diagnosed favorable risk prostate cancer.

PROTOCOL NO.: 2019.132

WCG IRB Protocol #20201568

HUM00173277

IRB approved 7/25/2025

CONSENT
TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THE STUDY

TITLE: Genomics in Michigan to AdJust Outcomes in prostate canceR (G-MAJOR): A randomized controlled multi-center study for men with newly diagnosed favorable risk prostate cancer.

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SPONSOR: Health and Human Services, Department of-National Institutes of Health

INVESTIGATOR: Todd Matthew Morgan, MD
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United States

STUDY-RELATED PHONE NUMBER(S): 734-764-4060 (24 Hours)

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your participation in this study. If you decide to take part in this study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

Clinical trial of molecular diagnostic products:
Your prostate biopsy will be tested using one of three Gene Expression Classifiers (GEC) tests to see if the results of these tests will help your doctor make decisions about your treatment.

Your health-related information along with prostate biopsy sample will be collected for this research study.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but information gained in this study may help future patients who are diagnosed with prostate cancer. More information will be provided later in this document.

We expect the amount of time you will actively participate in the study will be approximately 90 days, then transition into study follow-up for three years after receiving the study intervention (GEC Testing) or no GEC testing.

You can decide not to be in this study. This is not a treatment study; your option is to not participate. If you choose to not participate in this study, you can still receive these tests and standard treatment for your prostate cancer from your doctor.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
You are invited to participate in a research study being conducted by the Michigan Urological Surgery Improvement Collaborative because you have newly diagnosed prostate cancer and have undergone a diagnostic prostate biopsy. The purpose of this research is to understand the effect of Gene Expression Classifiers (GEC) tests on shared decision making about treatment for your prostate cancer and to determine whether these GEC tests help physicians and patients like yourself decide on appropriate treatment. GEC testing will be performed with Prolaris, Genomic Prostate Score (GPS), or Decipher tests. Because all prostate cancers are not the same, getting a GEC test may give your doctor additional information about your cancer. If so, this would help your doctor determine how aggressive your cancer is and help you and your doctor make decisions about your treatment.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you decide not to be in the study or leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? Men age 18 and over, who have been diagnosed with prostate cancer. Participants must have undergone a prostate biopsy within the past 9 months and have not received any treatments for their prostate cancer. Having previously collected prostate biopsy samples is a study requirement.

3.2 How many people are expected to take part in this study? We expect about 900 subjects to take part at all sites in this study. About 500 subjects will take part in the study at the University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Study Visits:

The study team will explain the research study and answer any questions you have about the study. If you still want to participate in the study the study team will request you sign the consent form prior to any activities occurring that pertain to the study. Once your consent is obtained, the study team will look through your medical chart, ask you questions, and begin scheduling tests and procedures to determine if you are eligible for the study. The study team will inform you of the types of tests and procedures required before the study begins.

Once it is determined you are eligible to enter the study, tests and procedures done at your study visits as part of your regular cancer care will continue, but some may be done more often because you are participating in this research study. Also, some of the tests or procedures may have to be repeated if, for example, they were done too long ago or the results are not normal.

Some tests and procedures may be done that are not part of your regular cancer care and are being done only for this research study. Tests and procedures that are performed more often or are not part of your standard cancer care will be identified below as “Research”.

Refer to the study calendar at the end of this section for information about what to expect during each study visit.

Before you can begin the study (Screening Period):

You will need to have certain exams, tests, or procedures to find out if you can be in the study. This is called the screening period. If you have had some of them recently, they may not need to be repeated. The screening tests and procedures do not have to be completed in one day and you are allowed to take breaks if you have multiple procedures in one day. The following tests or procedures will be performed as part of screening:

- You will be asked questions about your medical history and disease symptoms
- You will be asked to sign the informed consent document
- Your biopsy sample will have a grade classification performed

Enrollment into Study:

- Once you are enrolled into to the study, you will be randomized to a GEC testing group or the control group.
- If you are in the GEC testing group, they will test your prostate biopsy specimen within 2 months of enrollment with the GEC Test and provide you and your study doctor with the results.

Baseline:

- You will complete a Quality of Life (QOL) questionnaire and the data will be entered into the MUSIC registry

3 months, 6 months, 1 year, 2 years and 3 years:

- You will complete a Quality of Life (QOL) questionnaire and the data will be entered into the MUSIC registry.

Year 1, 2 and 3:

- •A repeat biopsy for patients on active surveillance as standard of care (as indicated).
- •PSA, treatment, and pathology data capture.
- If the surveys are not finished within the designated timeframe, a coordinator from either your site or the coordinating site, the University of Michigan, will contact you to provide a reminder to complete them.

Time and Events Table

Research plan	Pre-study	Enrollment	Baseline	3 Months	6 Months	Year 1	Year 2	Year 3
		Date of Randomization				+/- 12 weeks	+/- 12 weeks	+/- 12 weeks
Assessment for eligibility	X							
Informed Consent	X							
Grade Classification	X							
Randomization		X						
GEC test		Test ordered within 2 months of enrollment						
Management Plan finalized for AS patients, date of surgery for RP patients, radiation start date for RT patients			X					
Grade Reclassification						As indicated	As indicated	As indicated
QOL questionnaire			When entered in the MUSIC registry	X Between 2.5 and 5.5 months	X Between 5.5 and 11.5 months	X Between 11.5 and 23.5 months	X Between 23.5 and 35.5 months	X Between 35.5 and 48 months
Repeat biopsy for patients on active surveillance as standard of care						As indicated	As indicated	As indicated
PSA, treatment, and pathology data capture						X	X	X

This is a randomized study. Participants of the study will be randomly assigned to two groups, a GEC testing group and a control (the Other) group. If you are in the GEC testing group, we will have your prostate biopsy specimen tested with one of the 3 GEC Tests and provide you and your study doctor with the results. Your study doctor will

then review with you the GEC test results and the Cancer of the Prostate Risk Assessment (ASKMUSIC) scoring results from your sample. If you are in the other group, your doctor will only review the ASKMUSIC results with you; GEC test results will not be provided to you or your physician. Neither you nor your treating physician can choose which group you are assigned to. The GEC tests are available to your physician regardless of your participation in this study. These tests are considered experimental in this research. Once you and your physician have decided on a treatment plan, regular visits with your treating physician(s) will occur as required for your treatment.

The frequency and type of interaction with your treating physician(s) is at the discretion of you and your physician.

In addition, for all patients in the study demographic information and clinical information related to diseases and treatments you currently have or have had in the past will be collected and entered into the investigator's research database through the Michigan Urological Surgery Improvement Collaborative. Your cancer tissue may be used for future discovery of genes and their products that may help in diagnosing, preventing, or treating cancer and other diseases. These studies will use your pathology and clinical data to help with this discovery process. If information collected on you in this study is shared with collaborators, identifiable information (e.g., your name, your hospital number) will be removed so that the collaborator cannot identify you by looking at this data. All your medical information will be stored on a secure server that is protected by passwords and institutional firewalls. Paper copies of your medical information will be stored in a locked cabinet.

This study will follow the course of your decided treatment for 3 years.

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the clinic for visits and complete telephone visits with the study doctor or study staff when requested.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

What happens during study visits?
After you sign this form, the study doctor or study staff will do the things listed below when you come in for study visits or complete visits by phone. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

- Demographic Questions: Ask you to give personal information, such as: your date of birth, ethnicity, and type of insurance plan you use.
- Health and Medication Questions: Ask you to answer questions about your health, your medical history, and the medications you take.

4.2 How much of my time will be needed to take part in this study? To take part in this study, you will only need to see your doctor as you would for your regular and/or prostate cancer care. There may be one additional follow-up visit or phone call to discuss the results of the GEC test or ASKMUSIC score. There also may be 1-2 additional contacts either by phone calls, email or mail during the study in order to confirm whether any additional treatments have taken place. The telephone calls will last about five minutes.

4.3 When will my participation in the study be over? The study is expected to be open for enrollment for up to 4 years. Your active participation in the study is expected to last up to 90 days. You will then transition into a study follow-up for three years after receiving the study intervention (GEC Testing) or no GEC testing.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information may be shared with Michigan Urological Surgery Improvement Collaborative, Myriad Genetics (Prolaris), MDx Health (Genomic Prostate Score), or Decipher Biosciences (Decipher).

With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens will be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed on this form about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

This study involves existing predictive tools (ASKMUSIC) and are available tissue markers (Prolaris, GPS and Decipher). Possible risks include:

- The use of the predictive biomarker GEC test results could impact the way you and your doctor select your treatment options. Even though you will be using these predictors, the treatment you choose may prove ineffective for you.
- Loss of confidentiality

Your regular medical care will not change for this study. This study should not involve any physical risk to you.

You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Talk to your study doctor about this and any other concerns you have about the study.

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

- Health insurance companies and group health plans may not request your genetic information that we obtain 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 obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

As with any research study, there may be additional risks that are unknown or unexpected.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any direct personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have? This is not a treatment study; your option is to not participate. If you choose to not participate in this study, you can still receive these tests and standard treatment for your prostate cancer from your doctor.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
If you decide to leave the study early, please notify someone on the study team. They will instruct you on how to stop the study safely and you will be advised whether any additional tests may need to be done for your safety.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in the contact section below.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in this form or call your health plan's **medical reviewer**.

8.2 Will I be paid or given anything for taking part in this study?
No. You will not be paid for taking part in this study.

8.3 Who could profit or financially benefit from the study results?
The company whose products are being studied: Decipher Biosciences (Decipher), MDx Health (GPS) and Myriad Genetics (Prolaris)

Residual tissue may be used for future translational research.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my privacy?
University of Michigan has rules to protect information about you. Federal and state laws also protect your privacy. Upon enrolling in this study, you will be assigned a unique identification number. All records related to the study will use this identification number instead of your name or other personally identifying information whenever possible. 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.

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 study treatment for your disease, but you may access this information only after the study is completed. To request this information, please contact the researchers listed in Section 10 "Contact Information" (below).

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.) and dental records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University of Michigan, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UHMS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.
- Your information may be given to the Institutional Review Board, a group of people who independently review research.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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.

University of Michigan policies require that private information about you be protected. This is especially true for your personal health information.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described earlier it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and may be redisclosed without your permission.

You may withdraw your permission to use your information at any time. If you withdraw your permission, no new information will be collected about you. The researchers may still use and disclose any information collected up until you withdrew your permission.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University of Michigan and government officials make sure that the study was conducted properly

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed on the first page of this document. If you withdraw your permission, you may no longer be eligible to participate in this study.

Information about a Certificate of Confidentiality for this research:
University of Michigan and Dr. Morgan has received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about subjects collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, the subject may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Please contact the research listed on the first page of this document to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (number that begins HUM that is located on the front page or bottom of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

You may also express a concern about a study by contacting the Institutional Review Board listed below.
This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify):

12. SIGNATURES

_____

Subject's Printed Name

_____

Subject's Signature Date

_____

Print Name of Person Obtaining Consent

_____ _____ _____

Signature of Person Obtaining Consent Date Time