THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Neoadjuvant Dietary Intervention in Intermediate Risk Prostate Cancer 2020-0673

Study Chair: Dr. Justin Gregg

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

You are being asked to take part in this study because you have been diagnosed with prostate cancer and have decided to have surgery to remove the prostate glands and the lymph nodes as treatment for the prostate cancer.

The goal of this research study is to learn if diet changes can be done before surgery in patients with intermediate risk prostate cancer. Researchers want to study the effects of diet changes on the overall health of prostate cancer patients.

This is an investigational study. The results of this study will be compared to the results of another study in which patients were not told to change their diet and were not given meals and snacks (described below).

Changing your diet before surgery may help to improve your overall health. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

Your participation in the study will consist of 8 visits over about a 3 month period. Of these 8 visits, five (5) are due to this study specifically. Other visits are part of your

standard care, but some study-specific tests may be done. If you cannot come to the clinic for some of these visits, you may be able to have virtual visits (such as through Zoom). This will be discussed with you.

All snacks and meals provided as part of this study will be provided at no cost to you.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to change your diet outside of this study. Your doctor can discuss other options with you. You may choose to have standard of care surgery without participating in this study.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following tests will help the doctor decide if you are eligible:

- You will have a physical exam.
- Blood (about 1 tablespoon) will be drawn for routine tests, including tests to check your prostate specific antigen (PSA) and the level of fat in your blood.
- Blood (about 2-3 tablespoons) will be drawn for research tests. You must fast (have nothing to eat or drink except water) for at least 8 hours for this draw. In this study, research tests refer to immune system testing, checking the level of fat in the blood, and biomarker testing. Biomarkers are found in the blood/tissue and may be related to your response to the diet changes.
- Urine will be collected and banked (stored) for future research related to cancer. You will complete a food diary about the types of food you have eaten in the last 7 days.
- You will complete questionnaires about diet and exercise. It should take about 45-60 minutes to complete these questionnaires.
- A stool sample will be collected for microbiome testing (a type of testing that checks for certain bacteria and microorganisms in the stool). The study staff will give you instructions on how to collect this sample.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Up to 10 participants will be enrolled in this study, although up to 40 participants may complete the screening tests to find the 10 participants to enroll in the study. All will take part at MD Anderson. If you are screened and are found to be not eligible to take part in this study, the data and samples collected from you during screening will be used.

Study Diet Changes

If you are found to be eligible to take part in this study, you will be provided with meals and snacks over a 4-week period before your scheduled surgery. You should eat these snacks and meals for every meal/snack for at least 6 days of each week. 1 day each week, you will be allowed to eat whatever you want. You will pick up these meals at MD

Anderson and bring them home with you, and/or the meals will be sent to your home. The study team will discuss this with you.

The food provided to you will be rich in vegetables, legumes (such as beans), nuts, and fish. It is very important that you tell the study staff about any food allergies you may have. Food will be prepared by chefs and given to you with instructions each week.

Study Visit

During the 4 weeks before your scheduled surgery:

- A member of the study staff will call you and ask you and ask you questions about your diet, how often you eat, the size of your portions, and so on. This will be done at least 1 time each week. It should take about 15 minutes to complete the interview. At the end of the interview, you will be sent a link and a secure username and password so that you can complete this same information every day during the study. You will also fill out a diary of what you eat each day. The study team will go over this with you, if you have any questions.
- During Week 4 (the last week of the diet), a stool sample will be collected for microbiome testing. You will be mailed a stool collection kit with all supplies and instructions needed, including a pre-paid envelope to return the sample to MD Anderson.

At your pre-surgery visit (about 2 weeks before your surgery):

- You will have a physical exam.
- Blood (about 1 tablespoon) will be drawn for research tests.

On day of your surgery, you will sign a separate consent form explaining the surgery and its risks. In addition, as part of this study:

- Blood (about 2-3 tablespoons) will be drawn for research tests. You must fast for at least 8 hours before this blood draw.
- Urine will be collected and banked for future research related to cancer.
- During the surgery, some of the tumor and normal (non-cancerous) tissue in the prostate will be collected, along with fat from around the prostate and small bits of fat that are incidentally removed from where the cut is made in your abdomen to remove your prostate. This tissue will be stored by MD Anderson for use in future research and for research as it relates to this study.

Follow-Up

Within 4-8 weeks after your surgery, you will return to clinic for a follow-up visit. At this visit:

- Blood (about 2-3 tablespoons) will be drawn for research tests. You must fast for at least 8 hours before this blood draw.
- You will fill out a questionnaire about your food. This should take about 15-30 minutes to complete.
- A stool sample will be collected for microbiome testing.

Other Instructions

You should tell your doctor about any medications you are taking at the screening visit and tell the study doctor before you start a new medication or if you stop taking a medication while you are in the study.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

The **diet** in this study may cause an allergic reaction, depending on your food allergies. If you have any food allergies, it is very important that you tell the study tam. The diet may also cause some stomach discomfort as you change to a different way of eating. You may crave foods that are not allowed during the study which may make you feel uncomfortable or frustrated.

Providing a **stool sample** may make you feel embarrassed or uncomfortable.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this

research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Justin Gregg, at 713-792-3250) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson, and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood, stool, and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and

community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Genetic Research
Samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

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 deciding 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. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - any future sponsors/supporters of the study

- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

The results of this study may be published in a medical journal and shown at medical meetings. You will not be identified (by name or any other means, such as photographs) in any of these publications.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION