Official Title:	**W**eight management **A**imed to **R**educe **R**isk and **I**mprove **O**utcomes from **R**adical Prostatectomy (WARRIOR)
NCT Number:	NCT03261271
Approval Date:	September 3, 2019

RESEARCH CONSENT FORM

Weight management **A**imed to **R**educe **R**isk and **I**mprove **O**utcomes from **R**adical Prostatectomy

WARRIOR

Funding Source: The American Cancer Society

You are being asked to join a research study. Participating in research is different from getting standard medical care. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to before deciding about this research.

You can ask questions now or at any time during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

This research study will take place at KUMC with Jill Hamilton-Reeves, PhD, RD, CSO, as the lead researcher. About 40 people will be in the study at KUMC.

Why am I being asked to take part in this study?

You are being asked to take part in this study because you are an overweight or obese man who has been diagnosed with prostate cancer and will undergo a prostatectomy in the next four months.

Why is this study being done?

Compared to healthy weight men, those who are overweight at the time of their prostate cancer surgery are more likely to have their cancer come back. Fat tissue makes signals that allow cancer to grow and spread beyond the prostate, and overweight men have higher levels of these signals. One of the signals is a harmful immune cell that reduces the ability of the immune system to keep cancer in check. We think that helping men lose weight before their prostate cancer is removed will help weaken the cancer before surgery and keep it from spreading. Keeping that weight off may also help prevent the spread of cancer, improve how long men with prostate cancer survive, and improve their quality of life.

What is being tested in this study?

This study is testing how a weight management program affects substances in the body called biomarkers that can show the presence or severity of cancer, compared to a standardized diet and exercise educational flyer. Researchers also want to see how weight management affects weight loss, the amount of fat in the body, and quality of life in prostate cancer survivors. Researchers know that diet and lifestyle affect the microbial population in the gut. This population is referred to as the microbiome. This study will also look at fecal samples to identify changes in the microbiome in men with prostate cancer.

How long will I be in the study?

You will be in the study for up to 5 years. You will be actively participating in the study activities for about 10 months. Depending on which group you are assigned to, you will be asked to come to the study site at the KU – Clinical Research Center located at 4350 Shawnee Mission Parkway, Fairway, KS 66205 at least three times. The study team will review your medical record for up to 5 years after enrollment to monitor your weight and if your cancer returns. The study team may also contact you by phone to get this information.

What will I be asked to do?

If you agree to participate in this study you will be asked to read and sign this consent form before any study procedures are performed. You will be given a copy of the signed consent form to keep.

You will be randomly assigned (like rolling the dice) to one of 2 groups. A computer will decide which group you are in.

> Group 1 will participate in a weight loss program for at least 4 weeks (and up to 16 weeks) before their prostatectomy, and a weight maintenance program for 6 months after their surgery.
>
> Group 2 will receive a standardized educational flyer about a healthy diet and exercise.

Both groups will have their height and weight measured, have blood drawn for laboratory testing, provide a fecal sample for laboratory testing, and have a special scan to determine their body composition three times during the study: a Baseline visit, 1 week before surgery, and 6 months after surgery. People in both groups will be asked to complete questionnaires about their quality of life and symptoms at these visits, and answer questions about the food/drink they have consumed over several 24-hour periods.

Below you will find a schedule of events that lists all the procedures that will happen in the study. Following the table is a description of each procedure.

	Enrollment	Baseline	Weight Loss Program (Group 1)	Surgery	1 Week Pre-Surge	Weight Maintenance Program (Group 1)	6 Months Post-Surgery	Annual Follow-up
			4-16 weeks before surgery					*1 through 5 years*
ALL PARTICIPANTS								
Medical history	X	X			X		X	
Height & weight, vital signs collected		X			X		X	
iDXA scan		X			X		X	
Blood drawn for laboratory testing		X			X		X	
Provide fecal sample and mail sample in the provided kit		X			X		X	
Questionnaires		X					X	X (mailed)
24-hour food recall, phone calls		X (plus call in ~1 week)			X (plus call in		X (plus call in ~1 week)	
Prostate tissue collected				X				
Medical record review								X
Phone call from study team								X
Survey about quality of life		X					X	X
GROUP ONE ONLY PROCEDURES								
Weight program orientation	X							
Diet & Exercise plan	X							
Individual coaching sessions			Weekly					
Group support sessions						Every 6 weeks (4 total)		
Phone check-in			Weekly			Weekly		
Diet & Exercise monitoring			Every day			Every day		
GROUP TWO ONLY PROCEDURES								
Receive diet/exercise educational material	X							
Length of study visit (hours)		2		*N/A*	2		2	

Procedures for All Participants

Medical History: You will be asked questions about your health, medical history, current medication use, and whether you smoke or use tobacco.

Height & Weight, Vital Signs Collected: Your height, weight, and vital signs (blood pressure, temperature, and heart rate) will be measured and the results recorded for the study. Your waist, and hip circumferences will be measured using a flexible measuring tape.

iDXA Scan: Your body composition will be assessed using a iDXA scan. This scan will determine your current levels of body fat, lean tissue, and bone density. You will be asked to lie very still during the scan. This test will last about 15 minutes.

Blood drawn for laboratory testing: About 3 tablespoons of blood will be collected from a vein in your arm at three of the study visits. A total of about 9 tablespoons of blood will be drawn over the entire study. This blood will be tested for substances in your blood called biomarkers.

Fecal sample collection for laboratory testing: At three of the study visits, you will be provided with a kit to collect a fecal sample in the privacy of your home. You will mail the fecal sample to our lab. Postage will be provided.

Questionnaires: You will be asked to complete quality of life questionnaires, which will ask you questions on things like how difficult or easy certain tasks are to complete, if you are experiencing pain, and if you feel tired.

24-hour food recall, phone calls: At each visit, you will be asked to remember and write down everything you have had to eat or drink for the previous 24 hours. A member of the study team will ask questions about how the food you ate was prepared, amount eaten, and help you remember any commonly forgotten foods. During the week around the baseline visit, 1 week before your surgery, and 6 months after your surgery, a member of the study team will call you and ask you to complete another 24-hour food recall. You will be provided with a Food Amounts booklet to help with these calls. Please refer to the Food Amounts Booklet during these calls. These calls should take about 30 minutes each.

Prostate tissue collected: On the day of your surgery, the study team will collect tissue samples of your prostate and prostate cancer before it is sent to pathology, strictly for study testing.

Medical record review: For up to 5 years following your final study visit, the study team will periodically review your medical record to update your current weight, and PSA values from your regular doctor's appointments. Your information will be put into a computer database along with information about other people who join this study. The database will be kept at KUMC indefinitely. The database will only be used by approved persons.

Phone call from study team: If the study team is not able to collect all the information they need from your medical record they will contact you by phone to ask you questions about how you are feeling and whether your cancer has returned.

Receive diet/exercise educational material: Participants in both groups will receive a book, "Dr. Walsh's Guide to Surviving Prostate Cancer" by Patrick C. Walsh and Janet Farrar Worthington. They will also be given the American Institute for Cancer Research downloadable booklet, "Heal Well, A Cancer Nutrition Guide".

Procedures for Group One only

If you decide to join the study and are assigned to Group One, you will be given a Garmin Vivofit accelerometer that you will wear on your wrist. You may earn the the ability to keep the Vivofit if you complete the study. You will need to download the LST AtHome and the Garmin Connect applications to your mobile device. A compatible device with internet connectivity is required to use the apps and for study participation. If you do not own a compatible device, the research team may issue you one, but the device will need to be returned at study completion. You will also be asked to sign an additional user agreement for those items. If you are using a device provided by the research team, the apps will already be loaded for you.

In order to activate the apps, you will need to complete an electronic registration process through the study app or the study web portal. Registration will include entering your name, address, phone number, email address, date of birth, and gender. In addition to this information, the Garmin Connect app will collect your height and weight. The research team will show you how to use the apps once installed.

Weight Program orientation:
The weight loss and weight management program will be explained to you. You will begin the weight loss program up to 16 weeks before your prostatectomy. Following your surgery, you will begin the weight maintenance portion of the program. Dietary instruction will shift to encourage lifestyle changes to maintain a healthy weight long- term. You will not be prohibited from continuing to lose weight if you so desire, and the study team will use clinical judgment in nutritional coaching.

You will be asked to complete several tasks via the LST app or web portal. These tasks include: recording what you eat and how much you exercise. The app will also sync with your accelerometer and scale to show your daily weight and steps.

Diet & Exercise plan: The study nutritionist will tailor a diet to your needs that focuses on less red, processed, or charred meat, more produce, and less sugar. You will be asked to follow the diet plan designed by the nutritionist. The diet plan will consist of 5 prepackaged meal replacements supplied by the study in addition to lean proteins and greens which you will need to purchase. The study team will provide a list of meal replacement options and a meal guide. The meal replacements will be provided by a third

party called Medifast®. The meal replacements will be delivered directly to your home. You will be required to provide your address to Medifast® in order to participate. If you have dietary restrictions, please let the study team know. Egg-free, fish-free, gluten-free, kosher, lactose-free, milk-free, peanut-free, tree nut-free, shellfish-free, wheat-free, and vegetarian-friendly options are available.

The study nutritionist will tailor a plan for increasing your physical activity and adapting it to your current lifestyle. You will be asked to follow the exercise plan designed by the nutritionist. You will choose your own activities based on what you find most convenient and enjoyable. After your surgery you will continue to follow your exercise plan with the exception of any heavy lifting. You should refrain from lifting anything over 15 pounds until you are cleared by your surgeon.

Individual coaching sessions: You will have weekly one-on-one coaching sessions with the study nutritionist during the weight loss phase. Coaching sessions will be offered in-person or by videoconference. A compatible device with internet connectivity is required to use videoconferencing. The videoconferencing will be through Zoom Videoconferencing, Inc. You will receive a link to the videoconferencing from the study team via email.

Group coaching sessions: You will have group coaching sessions with a nutritionist every 6 weeks during the weight maintenance phase. You will learn how to gradually introduce conventional foods into your diet instead of having to rely on the meal replacements. The sessions will include cooking demonstrations to learn how to prepare meals with foods you can find in the grocery store. The study team will provide a weight maintenance meal plan to guide you. You will have the group sessions with other study participants and your spouse/significant other or caregiver is invited to attend as well. You will check in with your nutritionist briefly before or after the group session. This will be done privately, and your weight and height will be measured. The sessions will be held at the KU – Clinical Research Center. You may choose to join the sessions through videoconferencing. You and your spouse/significant other or caregiver will be asked to maintain confidentiality of the group and not disclose the information discussed in your meetings. The study team will organize lighthearted competitions between study participants to encourage meeting diet and exercise goals. The winners will be rewarded with small prizes and group recognition.

Phone check-in: You will receive weekly phone calls and/or secure messages from the study team through the LST AtHome app, an app designed by LifeScience Technologies. You will be asked to report your weight and if you are having any difficulties following the program.

Diet & exercise monitoring: You will be asked to keep track of your diet, daily weight and physical activity in LST AtHomeapp. A scale to measure your daily weight will be issued to you, but the scale will need to be returned at study completion. LST AtHome will store your diet and exercise data securely, and the study team will be able to view it. You will

be given a Garmin Vivofit accelerometer to keep track of your physical activity. You will wear it on your wrist and sync it daily, it will automatically upload your data into the LST AtHome app. In order to process your data, Garmin will receive limited information about you including your email address, gender, age, weight, and height. You will keep a log of your diet, daily weight, and exercise in the LST AtHome app.

Procedures for Group 2 only

Receive diet/exercise educational material: If you decide to join the study and are assigned to Group 2, you will receive a book titled "Dr. Patrick Walsh's Guide to Surviving Prostate Cancer" by Patrick C. Walsh and Janet Farrar Worthington. You will also be given the American Institute for Cancer Research downloadable booklet, "Heal Well, A Cancer Nutrition Guide".

What are the possible risks or discomforts?
Any risks associated with your standard care medical treatment for your prostatectomy will be addressed in separate hospital consent forms.

The weight management program may cause side effects or other problems. The researchers will be checking your medical information during the study to watch for side effects. However, you should tell the research team about anything that is bothering you or any changes in your health since the last visit. The researchers may be able to take steps to reduce side effects. You may experience none, some, or all of the side effects listed below.

Exercise risks
There are certain risks and discomforts that may be associated with exercise that include temporary shortness of breath, muscle fatigue, muscle soreness, sweating, and physical discomfort. Also, there exists the possibility of an undiagnosed medical problem that may surface during exercise. These include abnormal blood pressure response, fainting, irregular, fast, or slow heart rate, and in rare instances, heart attack, stroke, or death. The study team will work with you to gradually increase your physical activity levels to minimize these risks.

Blood draw risks
During the study you will have blood drawn for laboratory tests. The risks of drawing blood from a vein may include bleeding, infection, and a slight bruising at the site that is used for the blood draw. This will be minimized by careful and clean techniques.

Radiation risks
You will be exposed to radiation in this study from three iDXA scans. This radiation exposure is not needed for your medical care. You are exposed to radiation every day. This radiation comes from the sun and the earth. It is called background radiation. The amount of radiation you receive in this study is less than or equal to the amount that you would receive in six days from background radiation exposure. The risk from this radiation

exposure is very low.

Questionnaire risks
There is a risk of feeling uncomfortable while answering some of the questions in the questionnaires. If you feel uncomfortable at any time, you may skip a question or stop answering questions altogether.

Food allergy risks
There may be allergic risks for the prepackaged meals. Do not consume any meals that contain food products that you are allergic to.

Wearable device risks
There is the possibility of minor skin irritation associated with wearable devices. We recommend taking it off occasionally, not wearing it too tightly, and keeping it clean and dry.

The use of technology as part of this research project can present risk(s). It is possible that private data from a mobile device may be intercepted during transmission. It is possible that your data could be accessed by others should you lose your mobile device or lend the device to other people. It is highly recommended that you set up a password on your own phone and/or electronic device to help prevent unauthorized access to your device and research data. It is also recommended that a remote disable feature be set up on your device in case it is lost or stolen. Some additional risks are related to a loss of confidentiality especially when using electronic devices to transmit, store, and access data. There is some possibility that others may see your open webpage or smartphone communications.

Group coaching session risks
It is possible that confidentiality of the group sessions would not be maintained as other subjects may disclose information heard during a meeting.

Possibility of unknown risks
There may be other risks of the study that are not yet known.

Are there benefits to being in this study?
You may or may not benefit from this study. If the intervention is effective, you may lose weight and benefit from participation. Researchers hope that the information from this research study may be useful in the treatment of other patients with prostate cancer.

Will it cost anything to be in the study?
The study will pay for all study-related medical services provided during this study. These services include the iDXA body composition measurements, study-related blood work and prostate tissue testing, coaching sessions, meal replacements, and the use of the accelerometer during the study as listed in this consent form.

Any other medical visits and procedures you have that are unrelated to the study will be billed to your insurance through normal hospital billing practices. This includes the cost of your prostate surgery and hospitalization, any blood or tissue testing not related to the study, and care you receive for your cancer. Your insurance may not cover some or all of the services if you are part of a research study. Pre-Certification is not a guarantee of payment. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study.

You can still be in the study even if your insurance denies coverage for your routine medical treatment or if you are uninsured. The hospital has a financial assistance program which it makes available to all patients who quality. If you do not qualify for financial assistance you will be responsible for all bills that are not payable by the study. The study staff will be able to provide more information to you.

Data collected through the mobile applications in this study will count against your existing mobile data plan. You may want to change the settings on the app to only use Wi-Fi connections to limit the impact this data collection has on your data plan.

Will I get paid to participate in the study?
You will receive $50.00 for each completed visit of the three study visits. You may receive up to $150.00 if you complete all study visits. If your participation in this study ends early, you will be paid only for the visits you have completed. If the research team has issued a scale to you, you are to return the scale at the last study visit. If you do not do so, you will not receive your last payment of $50.00.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available in approximately 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call the Study Coordinator, Misty Bechtel, at 913-945-5037..

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments from participating in research studies are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

If you complete the study in Group One, you will be given the Garmin Vivofit as yours to keep.

This study includes providing specimens to the researcher. The specimens will belong to the University of Kansas Medical Center. There are no plans for you to profit from new products that are developed from research on your specimens.

What happens if I get hurt or sick during the study?
If you experience harm and require immediate medical attention, you should call 911. If you experience a side effect or other problem that does not require immediate medical attention, you should contact Dr. Holzbeierlein at 913-588-3118. If it is after 5:00 p.m., a holiday, or a weekend, you should call the operator at 913-588-5000 and ask for the urology attending physician on call. Please tell that physician that you are in a research study. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care, and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

Do I have to be in the study?
Being in research is voluntary. You can choose whether or not to participate. Even if you decide not to join the study, you can still come to KUMC for services and treatment.

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

What other choices do I have?
You can choose not to be in the study. You can talk to your doctor about other weight loss options.

How will my privacy be protected?
The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record. You may be identified by information such as name, address, phone number, date of birth, or other identifiers. Your health information will be used at KUMC by Dr. Hamilton-Reeves, members of the research team, the University of Kansas Hospital Medical Record Department, the KUMC Research Institute, and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. By signing this form, you are giving Dr. Hamilton-Reeves and the research team permission to share information about you with persons or groups outside KUMC. Your information will be shared with representatives of Quest Diagnostics, the laboratory that processes the blood samples, LifeScience Technologies, Inc., Medifast®, Garmin International, Inc., Carematix, Zoom Video Communications, Inc., and U.S. agencies that oversee human research (if a study audit is performed). These groups or agencies may make copies of study records for auditing purposes. The purpose for using and sharing your information is to make sure the study is done properly and to evaluate the safety and effectiveness of the intervention.

The HIPAA privacy law may not apply to everyone who receives your health information. Your information might not be protected by HIPAA if persons outside KUMC disclose it. In some cases, there may be other laws that protect your information from improper use.

Your permission to use and share your health information will not expire unless you cancel it. Any research information that is placed in your medical record will be kept indefinitely.

While you are participating in this study, you may see and copy any study information that is placed in your KUMC medical record. However, some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Can I stop being in the study?

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. You might be asked to come back for a final study visit. You should continue to see your primary care physician or oncologist for your cancer treatment.

You have the right to cancel your permission for researchers to us your health information. If you want to cancel your permission, please write to Dr. Hamilton-Reeves. The mailing address is Jill Hamilton-Reeves, PhD, RD, CSO, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side

effect of the intervention. They may use and share information that was gathered before they received your cancellation.

Could my participation be stopped early?
This study might be stopped, without your consent, by the investigator if it is in your best interest or if you do not follow the study requirements.

The investigator will not be obligated to provide you with any treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Who can I talk to about the study?
Before you sign this form, Dr. Hamilton-Reeves or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

CONSENT
Dr. Hamilton-Reeves or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

OPTIONAL EMAIL You can choose to sign up for emails about this study. The messages will remind you about your study appointments and give you other information that might be helpful during the study. You are not required to give your email address in order to be in the study. If you decide to receive messages when the study starts, you can still change your mind later.

I want to receive study communication by email (check one):

❑ Yes
❑ No
❑ Email_____(your email address)

_____ _____ _____
(Date) Time (Printed Name of Participant)

_____
(Signature of Participant)

OPTIONAL SAMPLE STORAGE AND FUTURE USE

You are being asked to allow any leftover blood samples, fecal samples and, prostate tissue samples to be stored for future research. If you agree, your samples will be used for future research studies involving prostate cancer or nutrition.

Some of the future research might include genetic testing. DNA is found inside all the cells in your body including those in your blood and is the code for how we inherit certain traits. You can think of DNA as a book of instructions (called genes) that your body uses to know how to build you the way you are. There are instructions for things such as eye and hair color, certain diseases, and also instructions that tell your body how to react to medicines. By looking at your genes, the researchers could learn more about prostate cancer and possible treatments.

The samples will be stored at Dr. Hamilton-Reeves' research laboratory at KUMC. Your samples will be stored by a unique code and no personal identifying information will be included with them. Your samples will be stored indefinitely. The list that links the code to your name will be kept separate from the samples and information. The samples will belong to KUMC.

There is a small risk that if people other than the researchers were given your genetic facts, they could misuse them. If genetic information was given to employers or insurers it could affect your ability to get a job or be insured. Misuse could cause problems for family members. In order to minimize these risks, your genetic information will be kept confidential.

Genetic Information Nondiscrimination Act (GINA)

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 decisions to hire, promote, or fire you or when setting the terms of your employment. The GINA protections do not help you if you work for a company with less than 15 employees.

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.

The information about the uses and disclosures of your health information for the main study also apply to this additional testing. You may choose not to participate in optional sample storage and future use, while still participating in the main study.

You may also withdraw your consent to store your samples for future research at any time and have your samples destroyed. If you want to cancel your permission, please write to Dr. Hamilton-Reeves at University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. The researchers may use and share information that was gathered before they received your cancellation.

You and your doctor will not receive the results of future testing. The results will not be put in your medical record. The researchers may publish the results of the additional testing. If they do, they will only discuss group results. Your name will not be used in any publication or presentation.

Participation in this optional research is voluntary and you do not have to participate in this portion of the research to be in the main study. Please mark your choice "Yes" or "No" below. If you have any questions you can talk to the investigator or the study team.

☐ Yes, I agree to allow the investigator to store my leftover blood, fecal and prostate tissue samples for future research on prostate cancer or nutrition.

☐ No, I do not agree to allow the investigator to store my leftover blood, fecal and prostate tissue samples for future research on prostate cancer or nutrition.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

OPTIONAL Peer Mentorship

Some participants benefit from contacting other participants in the study. You may choose to receive phone numbers from current or past participants who agree to be contacted to talk about the study. You may also choose to provide your phone number to future participants. The study team does not monitor these calls and the peer mentorship is offered as a way for participants to share their experience and tips for what worked for them.

Would you like to be mentored or act as a mentor?

☐ Yes, I would like a contact list of phone numbers so that I may reach out to past or current study participants for mentorship.

☐ Yes, I am willing to be contacted by other participants wanting mentorship.
Phone number:

☐ No, I do not want to participate in peer mentorship or be contacted by other study participants

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date