Official Title: A Phase 2 Double-blind, Placebo-controlled Study of the Effects of Muscadine Grape Extract in Men With Prostate Cancer on Androgen Deprivation Therapy '

NCT03496805

IRB Approval Date: 06/03/2025

Participant Name: _____ Date:_____

Title of Study*: Phase 2 Double-blind, Placebo-controlled Study of the Effects of Muscadine Grape Extract in Men with Biochemically Recurrent Prostate Cancer on Androgen Deprivation Therapy* IRB# 19-012 IRBNet# 1575432

Principal Investigator: Michael Goodman, M.D. VA Facility: W.G Bill Hefner VAMC

To be a current and valid informed consent, this form must contain an IRB Stamp that indicates the current approval and expiration dates of this form on page 1. If this form does not contain the current IRB stamp, please notify the person that gave you this form.

Please read this form carefully. It tells you important information about a voluntary research study. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Salisbury VAMC's Institutional Review Board, please call the research office at [redacted].

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being asked to be in this study because you have been diagnosed with prostate cancer and are receiving androgen deprivation therapy (ADT). This is a research study being funded by an anonymous private donor.. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate.. You may also discuss the study with your friends and family.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study we hope to learn if Muscudine Grape Extract (MGE) helps to decrease fatigue or other side effects of androgen deprivation therapy (ADT) and/or slows down the growth of your cancer.

You will participate in the study for 12 months. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

To participate in this study, we require that you take the pills provided. Muscadine grape extract is an investigational drug. This means it has not been approved by the U.S. Food and Drug Administration (FDA). Drugs and devices that do not have approval by the FDA cannot be sold or prescribed by your physician.

About 160 people at Wake Forest University, W.G. Hefner VA Medical Center, and one other site will be in this study. In order to identify the 160 participants needed, we may need to screen as many as 170, because some people will not qualify to be included in the study. Locally at the W.G Bill Hefner VA Medical Center, 80 participants will be enrolled.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY? DO YOU HAVE TO TAKE PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people with prostate cancer in the future. The benefits of participating in this study may be a decrease in fatigue or other side effects of adt and/or slowing of the growth of your cancer. Based on experience with muscadine grape extract in animals and other research studies, researchers believe the components of the muscadine grape may contain agents that benefit people with cancer. Because individuals respond differently to therapy, no one knows in advance if it will be helpful in your particular case.

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

Standard-of-care procedures for treating men with prostate cancer with a rising PSA after surgery or radiation are either continued observation with regular monitoring of PSA or initiation of ADT. If you and your treating physician are considering this study, that means you have decided to start ADT.

If you participate in this study, you will continue to receive standard treatment with ADT. Possible ADT-related side effects include fatigue, loss of muscle mass, weight gain, loss of interest in sexual activity, hot flashes, and mood changes. The goal of this study is to determine if treatment with MGE (in addition to ADT) helps with your fatigue and quality of life while you are receiving standard prostate cancer treatment.

The alternative to participation in this study is to NOT participate in this study, in which case you will continue to follow up with your doctor who is managing your prostate cancer.

Participant Name: _____ Date:_____

Title of Study*: Phase 2 Double-blind, Placebo-controlled Study of the Effects of Muscadine Grape Extract in Men with Biochemically Recurrent Prostate Cancer on Androgen Deprivation Therapy* IRB# 19-012

Principal Investigator: Michael Goodman, M.D. VA Facility: W.G Bill Hefner VAMC

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The benefits of participating in this study may be a decrease in fatigue or a decrease in other side effects of ADT. It may potentially slow the growth of your cancer. There is no guarantee that you will receive the muscadine grape extract. You will be randomized and have a 50% chance of receiving the investigational drug or a placebo. There are no guarantees that taking the medication will help you**.**

Your participation in this study is completely voluntary. Refusal to take part in this study will involve no penalty or loss of benefits to which you are otherwise entitled.

You may withdraw from this study at any time and still receive the same standard of care that you would otherwise have received.

For data already collected prior to the participant's withdrawal, the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data. Specimens already used cannot be withdrawn.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

If you take part in this study, you will be randomized to one of two study groups. Randomization means that you are put into a group by chance. You have a one in two (50%) chance of being placed into either group. Half of the people in this study will receive the muscadine grape extract, the other half will receive a placebo, a placebo is an inactive substance. Neither you nor the investigator will know which study drug (muscadine grape extract or placebo) you are receiving. This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency.

Regardless of which group you are assigned to, we will collect data from your medical record about your health and medicines, and ask you survey questions about how you are feeling. This will include questions about your symptoms, fatigue, general well-being and quality of life. The surveys may take up to 30 minutes to complete. You will take four pills twice daily for the duration of your participation in the study. You will be asked to report any side effects that you feel. You will have regular study appointments every 3 months for 1 year. You will be asked about concerns or symptoms at each in person visit and by phone 6 weeks after your first visit.

Participant Name: _____ Date:_____

Title of Study*: Phase 2 Double-blind, Placebo-controlled Study of the Effects of Muscadine Grape Extract in Men with Biochemically Recurrent Prostate Cancer on Androgen Deprivation Therapy* IRB# 19-012

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To measure your physical functioning, you will be asked to complete a short physical function performance battery (SPPB) and a 6 minute walk test. During the SPPB you will be asked to complete a balance test, a gait speed test, and a chair stand test. During the 6 minute walk test you will be asked to walk back and forth from one end of a long hallway to the other at your own pace while attempting to walk as long a distance as possible in six minutes. You will complete these tests at your baseline, 6 and 12 month visits.

You will have blood drawn and give a urine sample to determine the amount of muscadine grape extract components in your blood and urine as well as measure inflammation or growth factors that might be affected by the grape extract. To accomplish this, about 4 tablespoons of blood will be drawn at your baseline visit and then at 6 and 12 months. Part of the blood sample taken at your baseline visit will be processed to provide DNA. DNA, or deoxyribonucleic acid, stores and transmits inherited traits, such as eye color or blood type. As part of this research project, your DNA will be studied in an effort to find out if there are genes that contribute to medical conditions that are part of this study. Because we do not know how the results of this DNA study relate to your individual health, the results of the research will not be given to you or your doctor without your permission. These results will also not be placed in your medical records. Blood and urine will be collected at your baseline, 6 and 12 months visits. Blood for DNA studies will be collected only once, at baseline.

You may use other therapies prescribed to you to treat symptoms while participating in this study.

We can send copies of your test results to your primary care physician or any physician of your choice. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study test/exams to your? primary care physician?

[ ] No [ ] Yes

Participant Name: _____ Date:_____

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WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Being in this study involves some risks to you. You should discuss the risks of being in this study with the study staff. Potential risks and side effects related to taking muscadine grape extract may include:

- Excess gas
- Indigestion
- Diarrhea
- Nausea
- Abdominal pain
- Constipation

Because muscadine grape extract use in the treatment of cancer is investigational, there may be other side effects that we cannot predict. Please tell the research team about all the medications, vitamins and supplements you are taking. This may help avoid or minimize additional side effects, interactions and other risks. It is unlikely but possible that you may experience an allergic reaction to the study drug. Allergic reactions may involve itching, rash, or in severe cases, difficulty breathing and changes in blood pressure or other symptoms. Alert the study team if you have any known allergies. Although very unlikely, there may be a risk of death from taking muscadine grape extract.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Potential risk and side effects related to the SPPB and the 6 minute walk test may include muscle or joint soreness following the tests. These symptoms usually go away quickly and are typically not serious. There is also slight risk of falling during the walking portion of testing.

From blood draws, you may experience:
• Discomfort
• Bruising and/or bleeding where the needle is inserted
• Occasionally some people become dizzy lightheaded or feel faint
• Infection may occur on rare occasions
• Frequent donation of blood can result in low iron in your blood (iron deficient anemia)

If you experience side effects that you think might be related to the muscadine grape pills that are intolerable, at any point during the study you can call Dr. Michael Goodman or his study team for assistance (phone number [redacted]).

REPRODUCTIVE RISKS AND OTHER ISSUES TO PARTICIPATING IN RESEARCH

Due to unknown risks and potential harm to the unborn fetus, sexually active participants must use a reliable method of birth control while participating in this study. Reliable methods of birth control include abstinence (not having sex), or vasectomy An acceptable, although less reliable, method involves the careful use of condoms with spermicide. Reliable methods of birth control for your partner include: oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation. An acceptable, although less reliable, method involves the careful use of spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

There are times when we might have to show your records to other people. Your research records may be reviewed by Salisbury VA staff who are responsible for the safe conduct of this research. Other than Wake Forest Medical Center there is a possibility that the Food and Drug Administration (FDA) and other research oversight entities such as the Office for Human Research Protections (OHRP), Office of Research Oversight (ORO), Office of the Inspector General (OIG), the Government Accountability Office (GAO), (insert names and/or agencies such as CROs, other sponsors, etc., including those who may receive information for reimbursement), may inspect the records. We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

Participant Name: _____ Date:_____

Title of Study*: Phase 2 Double-blind, Placebo-controlled Study of the Effects of Muscadine Grape Extract in Men with Biochemically Recurrent Prostate Cancer on Androgen Deprivation Therapy* IRB# 19-012

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Study team members leaving will no longer have access to the research data, and will be instructed of this fact. In addition, if the team member is leaving the service line and/or VA employment their research keys will be taken back to ensure that there is no access to the hard copy research records. Further, the team member's access to electronic research files will be disabled. In the event that there is a theft or loss of data, or storage media, or unauthorized access of sensitive data or storage devices, the VA Research Service, Information Security Officer (ISO) and Privacy Officer (PO) will be notified immediately (within 1 hour).

- If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law. Your medical records will be maintained according to this Medical Center's requirements.

- Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in this research study. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

  The original copy of this consent form will be placed in my research record and scanned into my medical record**.**

What about My Health Information?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information (PHI). The information we will collect for this research study includes: demographics, medical history, medicines used, vital signs, analysis of your blood, review of exsisting cancer-related imaging, surveys about your quality of life, questions about the effects the study pills may have on you, short physical performance battery, and 6 minute walk test.

If this research study involves the diagnosis or treatment of a medical condition, then PHI collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

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As part of this study, we will monitor the status of your cancer diagnosis and treatment. To do so, we will need to obtain medical information concerning your cancer diagnosis and treatment from your medical record. If you receive treatment for your prostate cancer at any other facility, with your authorization, we will need to request copies of information about your cancer diagnosis and treatment. At that time, we will be required by the hospital to submit a current medical record release form to obtain this information.

Your PHI and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the W.G. Bill Hefner IRB; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries. Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.F

If required by law or court order, we might also have to share your PHI with a judge, law enforcement officer, government agencies, or others. If your PHI is shared with any of these groups it may no longer be protected by federal or state privacy rules.

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Any PHI collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your PHI in the research records until all activities in the study are completely finished.

You can tell Dr. Michael Goodman that you want to take away your permission to use and share your PHI at any time by sending a letter to this address:

Dr. Michael Goodman
[redacted]

However, if you take away permission to use your phi, you will not be able to remain in the study. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study. By signing this form you give us permission to use your phi for this study. If you choose to participate in this study, your medical record at wake forest university baptist medical center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this medical center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial is 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.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of W.G, Bill Hefner VA Medical Center. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study

Participant Name: _____ Date:_____

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WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY? WILL YOU BE PAID FOR PARTICIPATING?

Study costs that include any study medications, lab tests, and procedures which are directly related to the study will be paid for by study funds. You will have some standard medical tests done at the beginning of the study that will be billed to your insurance, such as CT scans and routine blood draws, but this would happen regardless of your decision to participate in this study. Neither you nor your insurance company will be billed for the muscadine grape extract or placebo pills used in this study.

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

You will be paid a $10.00 gift card at the completion of each study visit. If you complete all 5 scheduled study visits, you will be paid a total of $50.00 in gift cards. Thus, if you withdraw from the study for any reason prior to study completion, you will not receive further compensation.The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.
If you have any side effects after taking the study drug or are injured during the study, then tell your study doctor as soon as possible. Your study doctor will make sure you receive medical treatment. If side effects or other physical injuries are caused by the study drug, the study sponsor will pay for the reasonable costs of medical treatment if:

- You took the study drug and followed the study doctor's instructions on how to take the study drug
- You did not cause your own injury
- You told your study doctor as soon as possible; and
- You followed the study doctor's medical advice.

The study sponsor will only pay for the medical costs that are not covered by other programs. You will not be paid for lost wages or other losses. The study sponsor will not make any other payment to you, but you do not give up any legal rights by signing this form and may have other legal options. By paying for your medical treatment, the study sponsor or anyone else does not admit fault.

Participant Name: _____ Date:_____

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Principal Investigator: Michael Goodman, M.D. VA Facility: W.G Bill Hefner VAMC

- If you have an illness or are injured as a result of your participation in this VA approved research study you should contact the Principal Investigator(s). You will be treated for the illness or injury at no cost. However, no additional compensation is available.

- If you have any questions about your rights as a research subject or about the conduct of this study that have not been answered by the Principal Investigator, you should contact the Chairperson of the Institutional Review Board at [redacted] or current extension, or the Research Compliance Officer at [redacted] or current extension.

No promises have been given to you since the results and the risks of a research study are not always known in advance. However, we will take every reasonable safety measure we can to protect your well-being. You have not released this institution from liability for negligence.

Emergency and ongoing medical treatment will be provided as needed.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

There may be various reasons why you are taken out of the study. For example, you may need other treatment, you may have health issues that require you to leave the study, you are not able to follow study instructions, or the study may be stopped. Also, there may be a change in the study that could end your participation. The reason will be explained to you by the study doctor.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, and concerns about the research or related matters. Please contact Michael Goodman, MD at: [redacted] or you can contact the research nursing staff at [redacted] **during business hours or the Emergency Department at** [redacted] **after hours, for emergencies ONLY.**

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB) chairperson at [redacted] or the Research Compliance Officer at [redacted], ext. [redacted]. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call these individuals if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

Participant Name: _____ Date:_____

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WHO COULD PROFIT FROM THE STUDY RESULTS?

This study is being sponsored by the Chronic Disease Research Fund of WFUHS, established by a private donor to conduct research on muscadine grape extract and cancer. WFUHS has a financial interest in the muscadine grape extract. This means that WFUHS could financially profit from the results of the study if the extract is licensed for use related to this research.

FINANCIAL STATEMENT
This study is being sponsored by a grant from an anonymous private donor.The Principal Investigator (Michael Goodman, MD), and the Co-Principal Investigators, Richard Williams,MD and Amy Franklin, PA-C of this study receive none of their salary from this research study.

HOW WILL MY GENETIC INFORMATION BE PROTECTED?

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this study.
- Health insurance companies and group health plans may not use your genetic information obtained from this study when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this study 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. It also does not prohibit discrimination on the basis of already known genetic disease.

HOW RESEARCH DATA WILL BE PROTECTED AND SECURED

All research records are kept in locked cabinets at W.G Bill Hefner VA Medical Center in Room C129 on the 2nd floor of the Oncology Hematology Clinic located in building 21. Study Coordinators and Research Staff have access to cabinets.

There are rules that are approved by the National Archives and Records Administration and published in the VHA Records Control Schedule (RCS

10-1) about how long your research records are kept. Your research records may be destroyed 6 years after the end of the VA fiscal year (September 30th) in which the study is closed.

STORAGE OF BIOLOGICAL TISSUE

If you agree to participate in this study, we will bank any unused blood to use for future research related to inflammation and prostate cancer. Your sample will be obtained at at the VA. The sample will be stored in the Hypertension Core Laboratory and it will be used by researchers approved by Dr. Michael Goodman. An Institutional Review Board (IRB) must also approve any future research study using your sample.

The choice to let your blood sample be kept for future use is up to you. No matter what you decide to do, it will not affect your care in this study. If you decide now that your blood sample can be kept for research, you can change your mind at any time. Just contact your study investigator, Dr. Michael Goodman at [redacted] and let him know that you do not want your blood sample used and it will no longer be used for research. Otherwise, the blood sample may be kept until it is used or it is destroyed.
In the future, people who do research may need to know more about your health. While the study investigator may give reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to being contacted in the future. If there are any optional sub-studies or future contact provisions of the study, list them here.

____Yes, I am willing to have my blood stored for future research.
____No, I do not want to participate in the storage of tissue samples

Your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be an assigned number and only the research team will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

If you gave consent for the specimen(s) to be used in future research by the W.G. Bill Hefner VA Medical Center Research Department or its research partners, an Institutional Review Board (IRB) will review and approve each new study. The IRB may require that you be contacted for your consent prior to the use of the specimen(s) in a new study if it decides such consent is required for your protection.

Participant Name: _____ Date:_____

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You have the right to withdraw your consent in the future and have your unused specimen destroyed. You need to notify the investigator of your decision. If you decide to remove identifiers from your specimen(s), you will not be able to withdraw your specimen later because it cannot be linked back to you.

Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have or have had read to me all of the above statements. The study has been explained to me and I have had the opportunity to ask questions about the study, and my questions have been answered. I know I can ask questions about the study at any time during the study. I have been told of the risks or discomforts and possible benefits of this study. I have been told of alternative choices of treatment available to me.

I understand that I do not have to participate in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my record will not be revealed unless required by law.

If you have any questions, concerns or complaints about the research or if you want to discuss a problem, get information or offer input you should contact the Chairperson of the Institutional Review Board at [redacted] or current extension, or the Research Compliance Officer at [redacted] or current extension.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent may also be put in your medical record.

Participant Name: _____ Date:_____

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I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Person obtaining consent	_____ Signature of Person obtaining consent	_____ Date