Nitrite Supplementation to Mitigate Fatigability and Increase Function in Long COVID Patients

NCT05618574

October 28, 2024

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: _____

Principal Investigator: _____ VAMC: Pittsburgh (646)

LAY TITLE: Nitrite Supplement to Reduce Fatigue and Increase Function in Long COVID Patients

KEY ELEMENTS:

This is a research study to find out if Nitrate-rich Beetroot Juice provides clinical changes in fatigue and endurance for Veterans affected by long COVID. Dietary nitrate is converted to nitrite through a non-enzymatic process and nitric oxide (NO) by symbiotic bacteria in the oral cavity and stomach.

Your participation in this study is voluntary.

When you enroll and are deemed eligible for this study, you will be assigned to one of two groups. One group drinks Nitrate-rich Beetroot Juice once each day for 14 days and the other group drinks a nitrate depleted cranberry beverage placebo once daily for 14 days. You will not know which group you are assigned to. Both groups will be encouraged to receive physical therapy 2-3 times a week. The physical therapy is part of the regular care provided in Long COVID program. If you are not part of the Long Covid Program, the study physician can refer you to physical therapy as part of your regular care. You will also receive 3 telephone calls from the research team over this period to make sure you have no problems or concerns.

You will have assessments of physical function, skeletal muscle, and blood before and after the 14-day juice intervention completed by a research staff member. This will include a needle biopsy of the muscle from the side of your thigh. The blood draw and needle biopsy assessments will occur approximately 2 days before or after the physical function assessments.

There are risks to this study that are described in this document. Some risks include: hypotension (low blood pressure), dry mouth, nausea, stomach pain, vomiting, flushing, rapid heart rate, headache, dizziness, seizure, coma, abnormal rapid breathing, difficulty breathing, and changes in the blood that can cause too little oxygen being delivered to cells and bluish discoloration of the skin. The study team will call you during the time you are consuming the study beverage/placebo to ensure these risks are recognized and addressed if any occur.

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You may or may not directly benefit from participating in this study. You may, however, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of Nitrate-rich Beetroot juice for Long COVID.

If you do not participate in this study, you will receive all the standard care from the Long COVID and/or Primary Care clinic, including medical oversight, physical therapy and complementary approaches (nutrition, sleep) that are available to all Long COVID patients.

If you are interested in learning more about this study, please continue reading below.

STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call the study coordinator at or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call [redacted] Principal Investigator at [redacted] during normal working hours.

In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

The study coordinator can also be contacted at [redacted] to forward you to someone who can assist you with this issue. After hours or on weekends please call [redacted] and inform the research operator that you are a research subject from the Pittsburgh VA in Nitrite Supplementation to Mitigate Fatigability and Increase Function in Long COVID Patients and need to speak with [redacted]. Then give the operator a telephone number where you can be reached. The operator will get in touch with [redacted] or another person listed below who will call you back.

Principal Investigator:
[redacted]

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[redacted]

Co-Investigators:

[redacted]

[redacted]

[redacted]

[redacted]

STUDY SPONSOR:
This study is sponsored by Veterans Health Administration's program on Rehabilitation Research and Development. Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY:
The purpose of this research study is to find out if Nitrate-Rich Beetroot Juice provides clinical changes in fatigue and endurance for Veterans affected by Long COVID.

You are being asked to participate in this research study because you have survived an episode of COVID-19 and now have symptoms of long-COVID.

Long COVID is common among survivors of initial COVID-19 infection. Long COVID is associated with progressive declines in function and well-being. Symptoms include fatigue and weakness. COVID-related changes in muscle may contribute to symptoms and risks of Long COVID. In the study, we will assess the benefits of Nitrate-rich Beetroot Juice to improve muscle health and physical function.

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This is a single-site study with active recruitment at the VA Pittsburgh Healthcare System and VA Hospital H J Heinz Campus. We will enroll 30 Veterans with long COVID at the VA Pittsburgh, comparing 15 who consume two weeks of daily Nitrate-rich Beetroot Juice versus 15 Veterans who consume a Nitrate-depleted placebo.

The main aims of the study are to measure your physical function (cardiorespiratory fitness, which is measured using a stress test) and the sense of fatigue that develops during walking. In addition, blood tests and skeletal muscle biopsy assessments will be used to assess your skeletal muscle energy function. Muscle and serum samples will be stored in deidentified fashion in the Veterans Health biorepository at University Drive to facilitate the analyses for this investigation and others that may be approved over the next 3 years. After 3 years, any remaining tissue samples will be discarded.

The Nitrate-rich Beetroot Juice beverage is a food product. For this study, it is being studied as a dietary supplement, but it is not FDA approved for medical treatment of long covid or other diseases.

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 website will include a summary of the results. You can search this Web site at any time.

DESCRIPTION OF THE RESEARCH STUDY:
If you decide to participate in this research study, this is what will happen:

CONSENT

You will first sign the informed consent and then go through a series of screening measure to insure you qualify for the study to ensure your fatigue from covid diagnosis. Eligible veterans will move on to baseline testing.

A study staff member will read over the consent and answer any questions you may have. A physician within the Long COVID clinic or a study physician will also answer any medical questions or concerns you may have about the study. Once all study details have been explained and questions have been

answered, you will sign the consent if you are interested in participating in this study. All eligible veterans will move on to baseline testing.

BASELINE

Your baseline evaluation will occur on two separate days.

Functional Baseline Testing: This will take about 90 minutes. We will administer questionnaires about your sleep, nutrition, fatigue, alcohol use, and quality of life that will take about 15 minutes. There are also several assessments that will include: fatigability, an exercise stress test (on a treadmill), 400-meter corridor walk test where you will walk around cones for 400 meters, and a short performance physical battery test in which we test strength and balance. For the exercise stress test, you will walk on a treadmill at increasing speeds and inclines until you are too tired to continue. We will give you an exam before and closely monitor you to make sure you are safe. If you are a female under the age of 55 and able to become pregnant, we will ask you to complete a pregnancy test.

Lab Baseline Testing: This will take about 90 minutes. We will perform a blood draw, a muscle needle biopsy, and you will receive your study beverage.

The blood draw (about 2 tablespoons) will take about 5 minutes.

The muscle needle biopsy will take about 45 minutes. We will also monitor you for 15-30 minutes after to make sure there is no bleeding or other concerns and that you are stable. During the muscle needle biopsy, study staff will obtain approximately the size of the tip of a pencil or pen from your vastus lateralis (thigh muscle). The procedure includes using first cleaning the site with an appropriate antiseptic and shaving the skin if necessary. A local anesthetic of 10ml of Xylocaine at 1% will be injected into your thigh will be used to numb the biopsy location. The muscle biopsy needle will be insert through your numb skin and into the muscle to take your sample. You might feel a slight pinch. Sterile gauze will be placed over the incision site using firm pressure. The incision will then be closed with Steri-Strips and a sterile dressing. The dressing should remain on for a total of 5 days to allow for proper healing. The leg will then be wrapped with a pressure dressing and an ice pack.

Lab assessments may occur before the functional assessments during baseline and post-intervention timepoints if the visits are approximately 48 hours apart. If you opt out of doing the muscle biopsies, the blood draws can occur during the functional assessment.

The samples will be stored in a repository at the VA. A portion of the samples will be sent to the University of Pittsburgh for analysis. The samples will be coded with a unique study ID number and will not contain any personal identifiers.

There is the chance that unanticipated findings may be found during the physical examinations, the stress test, or other evaluations of the study; if that happens, we will let you know, and then reach out to your doctor. If you do not have a primary care doctor, we will refer you to one within the VA system. Please note that we are not specifically looking for any medical problem so it is unlikely we will find any underlying problems.

Study staff will place an order with the VA pharmacy for your study beverage (nitrate-rich beetroot juice or nitrate-free cranberry placebo) depending on which group you are assigned to. The study staff member will then pick up the study beverage and give you your assigned package of beverages. This process will take roughly 10 minutes.

RANDOMIZATION

At the end of the baseline assessment, a computer program will randomly assign you (like a flip of a coin) to be in either Study Group 1, a nitrate-rich beetroot juice or Study Group 2, nitrate-depleted cranberry beverage placebo.

INTERVENTION

No matter which group you are placed, you will be encouraged to go to 2-3 physical therapy sessions a week for 2 weeks as part of the usual care within the Long COVID or Primary Care clinics. Additionally, we will call you 3 separate times to see how you are doing during the intervention. During the first

intervention call, you will be asked how the muscle biopsy site is healing. If you are having pain or other symptoms, you may be asked to come in for further evaluation. The total length of your participation in this study is approximately 2-3 weeks.

1. Study Group 1, Nitrate-Rich Beetroot Juice:
   If assigned to study group 1, you will receive a nitrate-rich beetroot juice beverage once daily for 14 days. Research study staff will assist in transitioning into physical therapy, if you choose, as part of the usual care in the Long COVID unit or your regular clinical care and will call you 3 separate times during the 2-week intervention to check your health and wellbeing.

2. Study Group 2, Nitrate Depleted Cranberry Placebo Beverage:
   If assigned to study group 2, you will receive a nitrate-depleted cranberry placebo beverage once daily for 14 days. Research study staff will assist in transitioning into physical therapy, if you choose, as part of the usual care in the Long COVID unit or your regular clinical care and will call you 3 separate times during the 2-week intervention to check your health and wellbeing.

   The study beverage will be consumed daily until the morning before the follow up physical assessments. Once the physical assessments are complete, you will consume the study beverage once you return home and continue daily consumption of the study beverage until the day prior of the blood draw and muscle biopsy.

FINAL FOLLOW-UP

The final follow-up consists of two separate visits, similar to your baseline visit. The first of which will be about 14 days after baseline. The next will be about two days after that.

The follow-up that takes place about 14 days after baseline is for functional assessments and to answer a questionnaire. The functional assessments must be conducted on site and will take 70 minutes. These are the same assessments as those completed at the baseline visit for; fatigability, an exercise stress test (on a treadmill), a 400-meter corridor walk test, a short performance physical battery test on strength and

balance. The exercise stress test will be conducted with you walking on a treadmill at increase speeds and inclines until you are too tired to continue. We will examine and closely monitor you to make sure you are safe. The questionnaire will be asked on site. It will be the same as one asked at your baseline visit. This portion will take about 5 minutes.

The second and final follow up is another muscle biopsy and blood draw that will occur approximately 2 days after the physical assessments. This visit must occur on site and will take about 80 minutes.

The blood draw (about 2 tablespoons) will take about 5 minutes.

The muscle needle biopsy will take about 45 minutes. We will also monitor you for 15-30 minutes after to make sure there is no bleeding or other concerns and that you are stable. During the muscle needle biopsy, study staff will obtain approximately the size of the tip of a pencil or pen from your vastus lateralis (thigh muscle). The procedure includes using first cleaning the site with an appropriate antiseptic and shaving the skin if necessary. A local anesthetic of 10ml of Xylocaine at 1% will be injected into your thigh will be used to numb the biopsy location. The muscle biopsy needle will be insert through your numb skin and into the muscle to take your sample. You might feel a slight pinch. Sterile gauze will be placed over the incision site using firm pressure. The incision will then be closed with Steri-Strips and a sterile dressing. The dressing should remain on for a total of 5 days to allow for proper healing. The leg will then be wrapped with a pressure dressing and an ice pack.

The samples will be stored in a repository at the VA. A portion of the samples will be sent to the University of Pittsburgh for analysis. The samples will be coded with a unique study ID number and will not contain any personal identifiers.

Your participation in the study will be complete after you complete all assessments and your final muscle biopsy site is checked 2-3 days after the biopsy to make sure the site is healing well. After study completion you will continue with your normal care.

RISKS AND BENEFITS:

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Title of Study: _____

Principal Investigator: _____ VAMC: Pittsburgh (646)

As with any experimental procedure, there may be adverse events or side effects that are currently unknown and certain of these unknown risks could be permanent, severe or life threatening.

The risks from study procedures include the following:

Inconvenience of completing four assessment visits: Two assessments at baseline and two assessments after the 14 intervention are face-to-face at the VA Pittsburgh Healthcare system. This may cause challenges regarding travel, scheduling, and time. We will try to reduce these inconveniences by working with you to find the best way to schedule these appointments.

Risk potential with nitrite therapy:
Some side-effects that may come with nitrite therapy are unlikely but include lightheadedness, dizziness, weakness; we will also survey subjects for flushing, increased heart rate, increased breathing rate, headache, shortness of breath, bluish color of skin or dry mouth, and stomach discomfort.

Since the start of the study, there was a reduction in beetroot juice dosage within the intervention group from 210ml to 140ml per day to alleviate some of the side effects. Bloating, stomach discomfort, and nausea were reported while taking the beetroot juice at 210ml. These changes will continue to provide physiological benefit while reducing the likelihood and severity of side effects.

Symptom-limited exercise testing (to assess cardiorespiratory fitness):
The exercise stimulus is associated with a 1 in 10,000 chance of significant untoward outcome (e.g., myocardial infarction, arrhythmia), including the possibility of death. However, all study subjects will have a physical exam immediately before exercise testing to best ensure that they can tolerate the test, and they will have a qualified staff performing the stress test to be sure they are maximally safe and well-cared for if any problems develop.

Muscle biopsies:
Muscle biopsies are associated with a chance of bleeding and associated bruising (about 1 in 100). Therefore, extra care will be used for anyone using medication that increase these risks. In these cases, the study physician approval will be required. If the primary physician feels it is safe, medicines such as

aspirin, warfarin, or novel oral anticoagulants will be held for 3-days before the muscle biopsy, and then subjects will restart these medications after the muscle biopsy. Thienopyridines will be held for 5 days. Approximately 10 ml, and no more than 20ml, of Xylocaine at 1% will be used with muscle biopsies. Neurological or cardiac risks are very rare with this quantity of Xylocaine. With any injection there is a very small chance inflammation and infection The muscle biopsy procedure is a sterile procedure utilizing sterile gloves, facemasks, sterile needle, tubing, and syringes. Biopsy site well then be cleaned with an appropriate antiseptic and skin may be shaved if necessary.

Peripheral blood sampling:
Blood samples will be obtained by qualified staff and will follow all clinical and/or research standards for collection, processing, and analysis. Risks are minimal and include mild bruising or infection. All blood tests will be performed under sterile conditions with experienced personnel to minimize risks.

Assessments: Walking and balance tests may be associated with a risk of falling. Falling during these tests may be associated with fractures. However, the research staff working with you has been trained to help prevent falls during these tests. The risk of falling during these tests is less than 1 in 200, and the risk of fracture secondary to a fall during the walking tests is less than 1 in 5,000.

Questionnaires: The questionnaires require people to answer questions about their daily activities, diet, fatigue, alcohol and substance use, mood, thinking ability and quality of life, and in some cases, could be a source of emotional distress or annoyance. You have the option to skip any question you don't feel comfortable answering.

PREGNANCY RISKS AND BIRTH CONTROL METHODS:

PREGNANCY RISKS
Participants in the study cannot/should not be or plan to be pregnant during the study. The safety of the nitrate-rich beetroot juice in pregnancy is not known. These supplements could cause harm and even death to a fetus. If you are pregnant, planning to become pregnant or nursing, you cannot take part in this study. If you should become pregnant during this study, you should stop taking the study supplement and tell the study doctor immediately. If you can become pregnant (not post-menopausal, have not had tubal ligation (tubes tied) or have not had your uterus or both ovaries removed), you must use an adequate

method of birth control. Adequate methods of birth control are hormones (birth control pills or Depo-Provera), an implantable contraception, an IUD (intrauterine device) or double barrier methods (such as a diaphragm plus condoms). If one of these cannot be used, using contraceptive foam and a condom are recommended. For childbearing women under the age of 55, urine pregnancy tests will be done during the first baseline assessment. We encourage all women enrolled in this study to use one of the effective birth control methods during treatment and for 1 month after treatment is stopped.

You may also experience some side effects related to the procedures/medications/treatments you receive that are not part of the research, but are considered standard of care for your condition. A description of these side effects should have been provided to you by your physician. If you have not received information regarding these side effects, please contact your physician.

You may possibly benefit from participating in this study. Direct benefits may include: increase in cardiorespiratory fitness, improvements in fatigability, and enhanced skeletal muscle mitochondrial respiration because the nitrate-rich beetroot juice is fast acting and you may see benefit within three hours after consuming. Acute benefits may occur from physical therapy alone. You will not directly benefit from participating in this study. You may however, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of how nitrite can be a therapeutic for long COVID patients.

You may not directly benefit from participating in the banking portion of this study. You may however, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of how nitrite can be a therapeutic for long COVID patients.

ALTERNATIVES TO PARTICIPATION:
You will receive all standard medical and associated care (physical therapy, support) provided by the Long Covid program or Primary Care clinic. You may be able to attain beetroot juice on your own. There may be other studies that you qualify for. Talk to your provider about such options.

NEW FINDINGS:

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You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate. The results of any significant findings during assessments will be given to you verbally and/or in writing.

INVESTIGATOR INITIATED WITHDRAWAL:
The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW:
Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

You have the right to be treated with respect, including respect for your decision to continue or stop being in the study. You are free to choose to stop being in the study at any time. To withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study.

Your doctor may also be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your doctor. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study. If you withdraw your consent, you may not be able to continue to participate in the research study, any data that was collected prior to that point will still be used.

Participants also have the right to withdraw any biospecimen samples which they provided for the study. With this, those biospecimen samples will be removed and destroyed to prevent them being used in future studies. If you withdraw your consent for such use, you may not be able to continue to participate in the research study.

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MEDICAL TREATMENT:
In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION:
If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable Federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS:
You or your insurance will not be charged for any costs related to the research. However, if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in Federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

You will receive payment for your time based on the number of visits you complete for the study. Study participants will be offered a $25 stipend for their participation in each assessment and a $100 stipend for each biopsy completed. The maximum amount you may receive is $250.
Payments for study participation:

- Baseline Assessment: $25
- Follow-up Assessment: $25
- Biopsy #1: $100
- Biopsy #2: $100
- **Total: $250**

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Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. If you are not able to receive payment through EFT, the Direct Express Debit MasterCard may be issued. The Direct Express Debit MasterCard is a prepaid debit card. Please refer to the flyer that study personnel has provided for more information about which services may require a fee if using your Direct Express Debit MasterCard. A member of the approved research study team will be accessing your medical record in order to obtain specific information (Social Security Number, address, etc.) to help complete VA Payment forms.

In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose. If you are a Veteran eligible for Beneficiary Travel, please speak with the research team to understand how research visits may impact your ability to receive Beneficiary Travel.

RECORD RETENTION:
Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

CONFIDENTIALITY AND USE AND DISCLOSURE OF DATA: There are rules to protect your private health information. Federal and State laws and the Federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization', for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including:

Information from your Health Records such as diagnoses, progress notes, medications, lab or radiology findings

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Specific information concerning:
Alcohol Abuse Drug Abuse

Demographic Information such as name, age, race, date of birth

Questionnaires

Blood and muscle biopsy specimens

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the:

Study Sponsor and Authorized Agents/Funding Source: VA Rehabilitation Research and Development

Academic Affiliate: The University of Pittsburgh: Shiva lab and Jurczak lab will receive specimens with study numbers. The Jurczak Lab at the University of Pittsburgh will store data about the muscle assessments, but the data will be stored without identifiers (only study number).

Compliance and Safety Monitors: Data Safety Monitoring Board (DSMB) if requested by the RR&D

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

A progress note stating you are participating in this study will be placed within your medical record.

In addition, Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government

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Accountability (GAO) may have access to your research records. Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under Federal laws and regulations.

Finally, you consent to the publication of the study results or release of the data when published, so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

Confidentiality risks and precautions to decrease risk:
Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.
Information collected as part of this study will be stored in a combination of paper and electronic records. Only staff associated with this study will have access to the data.

Your information will be stored in a locked cabinet or in a password-protected file on the limited access drive on a password-protected computer in a locked room that only approved study staff have access to. Hard copies will be stored in locked file cabinets in locked rooms. Your data will be provided to the University of Pittsburgh without any identifiable information. Any identifiable information collected will remain within the VA.

Future Use:
Future use is part of this study. By signing this form, you are authorizing and permitting uses and/or disclosures of your data and specimens for future research purposes (e.g., future studies) as described in this document. The VA (Research) has allocated -80 freezers for banking tissue. The Freezers will be located at aon the ground floor of the Research Office Building. Specimen will be stored indefinitely and will only be used by [redacted] study team for future research. Study staff performing the biopsies will have access to these specimens.

Revocation:

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You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at the address below. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

[redacted]

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time. Any study information that has been placed into a repository to be used for future research will not expire.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all the above. [redacted] or authorized representative has explained the study to you and answered all your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.
A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

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If you have any questions about your rights as a participant in this study, or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at [redacted].

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

_____	_____	_____
Subject's Signature	Subject (Print)	Date
_____	_____	_____
Investigator/Person Obtaining Consent*	Researcher (Print)	Date

**If person other than the Investigator is obtaining consent, he/she must be approved by the IRB to administer informed consent.*

Version Date 10/16/2024