Official Title: Progressive Activity-Based Rehabilitation in Veteran Cancer Survivors with Chronic Pain (Exercise Rehabilitation in Veteran Cancer Survivors)

NCT ID Number: NCT03621813

ICF Document Date: 06/02/2023

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date: _____

Title of Study: Progressive Activity-Based Rehabilitation in Veteran Cancer Survivors with Chronic Pain

Principal Investigator: [redacted]

VA Facility: Baltimore [redacted]

STUDY No: HP-00081388 v.8.0

SPONSOR: Department of Veterans Affairs

You are being asked to participate in a research study at the Veterans Affairs Maryland Health Care System (VAMHCS). Your participation in this research study is voluntary. You may choose not to participate now or at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to stop participating in this study, if you have questions or concerns at any time, or if you need to report an injury related to the research, please contact [redacted] during the day and [redacted] after hours.

PURPOSE OF STUDY

We will investigate the role of exercise to decrease a variety of different symptoms, including fatigue. The overall goal is to identify the reasons why exercise helps to manage these symptoms. A number of common symptoms as well as fatigue and weakness are associated with treatment for lung cancer and can result in reduced ability to function in daily life. Exercise has been shown to be helpful with a number of conditions in patients who do not have lung cancer. You qualify for the study because you have a history of lung cancer. A total of 50 participants will be enrolled.

PROCEDURES

As VA policies regarding infection control adjust over time to maintain a safe environment for in-person facility visits, we will adjust our policies to meet all guidelines. Infection mitigation policies that may be required as determined by the CDC and the VAMHCS include masking, social distancing, COVID-19 symptom and exposure screening, use of PPE and COVID testing if determined to be appropriate. After being consented you will undergo a screening medical history and physical exam to determine if you qualify to be in the research study. This screening will check if you meet the
eligibility requirements. It will also be used to help determine if it is safe for you to exercise. If you are a woman and have had a menstrual period within the last 12 months, we will ask you to collect urine so that we may test it for the pregnancy hormone BHCG. If the test indicates that

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

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Principal Investigator: [redacted]

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Schedule of Data Collection for All participants			
	Baseline	**6 weeks**	**Post-Intervention**
Informed Consent	**X**		
Medical History and examination	**X**	**Health updates**	**Health updates**
Quantitative Sensory Testing	**X**	**X**	**X**
Questionnaires	**X**	**X**	**X**
Treadmill or Bicycle Test (Optional)	**X**	**X**	**X**
Strength Tests	**X**	**X**	**X**
Physical Performance Testing	**X**	**X**	**X**
Body Composition	**X**	**X**	**X**
Activity Monitor	**X**	**X**	**X**
Blood Draw	**X**	**X**	**X**

you are pregnant, you will not be able to participate in this research. Your overall participation will involve approximately 20-24 weeks to complete all of the testing and study intervention.

You will participate in the study intervention for 12 weeks, which is divided into two 6–week periods. During the first 6 weeks that you are in the study, you will continue activities of regular life. A study team member will contact you each week to see how you are. During the second 6-week study period, you will attend supervised training twice a week, as well as perform the activities at home a third day of the week. Strict social distancing and COVID -19 precautions will be followed for these in person sessions. The training sessions begin with aerobic exercise of walking on a treadmill for 15-30 minutes. The intensity (how hard it is to do) will increase weekly as tolerated. Your heart rate will be measured during each session using a chest-strap heart rate monitor. You will use Thera-Bands for resistance exercise for legs, arms, and shoulders. When the exercises become easy, the next level of band difficulty will be used. The balance program includes exercises such as stepping, marching, squats, and leg raises. The total amount of time for each training session will be 60-75 minutes. You will have a heart-rate monitor and the Thera-bands along with instructions to take home for the at-home session that you do each week.

The following tests will be done at the beginning of the study (Baseline), before the 6-week exercise period begins, and after the exercise period is completed (Post-Intervention). All of

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

these study procedures are for research purposes only. All of these procedures take place at the Baltimore VAMHCS. Each testing period will be approximately 2-3 days and will take about 90 minutes each day. The number of visits needed to complete testing, order, and/or location of these tests may vary based on your availability, the availability of the staff, the availability of equipment/space, and your ability to complete the tests without fatigue or duress. It may be necessary to repeat one or more of the research tests. This may be required due to technical error, unexpected difficulties with measurements, or other unanticipated problems during the data collection and testing. Please note that it is possible that not all participants may complete all tests, meaning that you might not undergo all testing detailed in the following sections. Details on the procedures are as follows:

The results of these tests will be made available to you upon request. You will be advised of the finding of any tests that may have an effect on your medical care. With your permission, we will send the results of any test that may have an impact on your medical care to your health care provider(s).

Graded Exercise Treadmill Test or Bicycle Test (Optional) – If you decide to have a treadmill or bicycle exercise test, you may receive a COVID-19 test within 7 days prior to the scheduled exercise test. We will follow VA policies and procedures to determine if a test is needed for infection control purposes. If a COVID test is required prior to testing, a negative test result is required before proceeding with the exercise test. If results are positive, you will be referred to your primary care physician and the test will not be conducted. We will schedule the test, which will be conducted at the VA, for you. The test involves swabbing of the nose on both sides. Treadmill: you will be asked to walk on the treadmill for as long as you can. The speed and incline of the treadmill will be increased every few minutes until you feel that you can no longer continue or the clinician decides to stop the test. If you are having difficulty standing, walking or with balance you will be tested on a bicycle. Bicycle: you will be asked to sit on an exercise bicycle and pedal at a certain rate. The resistance will be increased every few minutes until you feel that you can no longer continue or the clinician decides to stop the test. For both the treadmill and bicycle tests, your heart rate and rhythm will be monitored by ECG. Your blood pressure will also be monitored during the test. You will wear a facemask to collect the air you breathe out. This will be done to see how much energy (oxygen) your body uses when you are walking up a hill.



Physical Performance Testing- You will have a series of tests to evaluate your walking and balance. For one test, you will be asked to cover as much distance as you can in 6 minutes. Another test will time how fast you can walk 10 meters at various speeds. You will also be asked to complete a series of activities that test your balance and function. These activities include walking up and down stairs and walking while completing various tasks like walking at various speeds, stepping over an object, and pivoting.

Strength Tests- This test will allow us to understand your muscular strength at the beginning and end of the study. You will be asked to lift the maximum weight possible using proper form after a warm up of several submaximal repetitions. You will be asked to lie, sit, and/or stand in various exercise machines and push your legs as hard as you can. The testing position is dependent on the muscle group being tested. The resistance that you push against and number of repetitions will be different depending on the test.

Questionnaires- you will complete questionnaires about your general health, fatigue, quality of life and symptoms related to neuropathy. The total time for surveys is expected to be 1 hour.

Body Composition Your body fat, muscle mass, and bone density will be evaluated using a whole body scan and single thigh scan with dual-energy x-ray absorptiometry (DXA). A spiral Computed Tomography (CT) scan of the abdomen and thigh will also be used to evaluate abdominal fat, and thigh fat and muscle.

Body circumferences from several body sites will be taken with a measuring tape.

Bio-electrical impedance analysis (BIA): this is a non-invasive test that will be done to estimate your body composition: the measurement of body fat in relation to lean body mass. You will stand on the device, which looks like a regular scale, and BIA results will be available in about 30 seconds.

Activity Monitor: You will be asked to wear an activity monitor on your waist or wrist for 5-7 days. You will be asked to keep a written record of your activity during this time.

Fasting Blood Draw: This test will be performed after an overnight fast. Blood collection by clinical study staff will be done at the same time you have other study procedures, such as surveys, administered. A blood sample of approximately 10 teaspoons will be drawn by placing a small needle in your arm to collect blood into several small tubes. The samples will be used to measure factors of metabolic health, inflammation, and neuropathic pain. Genetic tests may also

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

be performed on your blood samples to examine how genes play a role in the development of chronic neuropathic pain in hopes of finding new ways to treat or prevent this condition. Blood cells will be used to see if there are markers in your genes linked to pain. All samples will be coded to insure they remain unnamed and confidential. You will not be provided with the results of these genetic tests as they are research tests of unproven medical importance. You may participate in this research study even if you do not agree to genetic testing.

Please initial below to indicate whether or not you agree to have genetic tests run on your coded, unnamed, and confidential stored samples.

My samples can_____ can't_____ be tested for genes that affect inflammation and neuropathic pain.

Date: _____

You will have approximately 10 teaspoons of blood drawn at each of three testing time points for a total of 30 teaspoons if you complete the study. The first draw will occur on the day of your history and physical examination. Although we do not expect a problem with the collection of blood samples, should a problem arise, such as clotting or insufficient sample for analysis, we will draw up to an additional 80 mL across study participation.

Banked Specimens: While you are in this study, blood will be collected from you that may be useful for future research. As new testing methods become available, we may measure additional factors that influence metabolic health, inflammation, and neuropathic pain. These samples will be stored for an indefinite time period at the [redacted] BVAMC. All samples will be coded so that your name cannot be readily identified. However, your identity can be determined by matching the code on the sample with your name in the study file. Your samples will be used only for research and will not be sold or used for the production of commercial products. Your samples will not be used to generate a cell line for genetic testing. These samples will not be used to tell if you have other diseases or conditions. They will not be used to direct the treatment of your cancer, should it recur.

Reports about research done with your samples will be included in your study file and will be kept confidential. You or your medical care provider will not be provided with the results of these tests as these measurements are for research purposes only and are not of proven medical importance.

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

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Principal Investigator: [redacted]

VA Facility: Baltimore [redacted]

You have the opportunity to request that your samples be withdrawn from future use. To do so please inform [redacted]. in writing at Baltimore VAMC, [redacted] to request that your samples be destroyed. Data already collected from your samples may not be destroyed or removed from your study file.

Please initial below to indicate whether or not you agree to have your samples stored.

My samples can____ can't____ be stored as banked specimens. Date: _____

Registry: In the future, researchers may need more information about you, or may ask you if you are willing to participate in a new research study. With your permission, we may enter the information we obtained during your screening visit into a secure, password protected computerized registry. Information in the registry may be used as a source from which University of Maryland, Baltimore and Baltimore VA researchers working with us can contact participants for future recruitment into new IRB approved studies. Even if you agree to be re-contacted now, you may still change your mind about providing this information in the future. You may choose not to have your information entered into this registry and still participate in this research study.

Please initial below if we may or may not store your information and re-contact you.

_____ My information may be stored in the registry and I can be re-contacted.

_____ My information may not be stored in the registry and I cannot be re-contacted.

Date: _____

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible for following staff instructions and attending the scheduled testing and intervention visits. It is also your responsibility to notify the study staff of changes in your health status, symptoms, medications, and/or your ability to participate so that we can remove you from the study as early as possible.

POTENTIAL RISKS/DISCOMFORTS:

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

Graded Exercise Treadmill or Bicycle Test - The risks for exercise testing are minimal, but occasionally include chest pain, fainting, dizziness, irregular heartbeats, fatigue, muscle soreness, and falling. Handrail support and a spotter (person watching you) may be used to decrease the risk of falling. Serious complications such as heart attack or cardiac arrest occur in less than 1 in 10,000 tests. You can stop the test at any time. During the test, you will have your blood pressure and heart rate and rhythm monitored by a clinician. All personnel involved with this test are trained in CPR. A crash cart and emergency medications are available if needed.

Physical Performance Testing- There is a small risk of falling during the walking and balance tests. Ample rest periods are provided between tests to limit fatigue during testing.

Strength Testing- There is a small risk of fatigue, muscle strain, joint and/or muscle discomfort and soreness with strength testing. Ample rest periods are provided between tests to limit fatigue during testing. If you feel pain during the test, then the test will be stopped.

Body Composition Testing- The radiation dose which you will receive as a result of taking part in this study includes radiation from the DXA machine and the CT scan. Using the standard way of describing radiation dose, you will receive 386.1 mrem to your total body, 760.8 mrem to your bladder, 618.6 mrem to your ovaries/testes, and 438.3 mrem to your bone in one year. During your participation in this study other organs and tissues may receive lesser radiation doses. The University of Maryland (UMB) and VA Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being within the UMB/VA Radiation Safety Guidelines for research subjects of 3,000 mrem to any tissue in a 13-week period and 5,000 mrem in one year. The radiation dose you will receive is in the range of 300-5000 mrem, which is equivalent to the exposure limit of 5000 mrem per year that is established for radiation workers such as physicians and X-ray technologists who work with radiation and this level of exposure has never been associated with any definite adverse effects. Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care. Please advise your doctor if you have taken part in research studies at UMB or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include x-ray studies conducted in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine studies, e.g. thallium scan of your heart, and scans of your brain. Should any study-related problems occur, medical treatment will be provided.

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

There are no risks related to the BIA testing.

Activity Monitor: There are no risks to wearing an activity monitor.

Blood Draws- Common risks of drawing blood include bruising, bleeding, discomfort, and swelling. Rarely, fainting and possible infection at the injection site can occur. These risks are decreased by having skilled professionals perform the blood draws.

Exercise Training - To minimize your risk, a staff member who is trained in cardiopulmonary resuscitation (CPR) will be present at the training sessions. In addition, a medical provider is available by phone for all training sessions. For exercise sessions performed at the Baltimore VAMHCS training facilities an AED is available on site. If needed the 911 emergency medical system would be activated by the research team. If 911 is activated, you would be taken to the nearest available hospital for care.

Questionnaires – You may experience some psychological discomfort answering these questions about your wellbeing. Subjects will have the option to discuss any concerns during your study visits or contact the PI, medical oncologist co-investigator [redacted] or study staff at any time to discuss concerns.

Confidentiality: As with any scientific research study involving the collection of potentially sensitive medical information, participation in this study may involve risk of a breach in confidentiality. The study investigator has taken measures to minimize this risk. To minimize the risk of accidental disclosure of your private information (PHI) and to maintain the confidentiality of your data, names will be masked by assigning each a unique participant identifier number (PID#). Data will be stored in a secure location such as a locked cabinet and locked office. Electronic data will be password protected. Your research records will be kept confidential to the fullest extent permitted by law. Your name will not be used in any reports or publications. Research records will not be released to your health care provider(s) without your prior consent. Some of the research test results will be stored in the VA Computerized Patient Record System (CPRS). This data will be stored in accordance with federal regulations and cannot be deleted. The results stored in CPRS can be accessed by VA clinical personnel who are not affiliated with this research study.

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

Pregnancy: A pregnancy test will be performed as part of the study, and if positive you will not be able to participate. While in the study we ask that you use suitable birth control (female participants only) recommended by your healthcare provider.

Unforeseen Risk: There may be risks in this study which are not yet known.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. You may experience reduced symptoms and improved function, but there is no guarantee that you will receive direct benefit from your participation in this study.

ALTERNATIVES TO PARTICIPATION

Your alternative is to not take part in the study. If you choose not to take part, your healthcare will not be affected.

COSTS TO PARTICIPANTS

Transportation to the Baltimore VAMHCS is the only cost to you. Parking at the BVAMC and exercise facilities and all research tests are free to research participants.

PAYMENT TO PARTICIPANTS

You will receive a total of $220 in the form of cash over the course of your study participation to cover transportation and other incidental costs - $25 on the day of your study baseline testing, $25 at the 6- week testing period and $50 following study completion and final testing. You will also receive $20 per week for each of the six weeks you are exercising at a VA facility.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this part of the study, the VA Maryland Health Care System (VAMHCS) will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.



HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

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Principal Investigator: [redacted]

VA Facility: Baltimore [redacted]

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:
Dr. _____ at _____

and

AFTER HOURS:
Dr. _____ at _____.

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study will involve the collection of confidential information. As with any scientific research study involving the collection of potentially sensitive medical information, participation in this study may involve a risk of breach of confidentiality. The investigator and research staff will have access to your information, data, and samples. Your data and samples will be coded to protect your privacy. There may be some instances where your information cannot be coded such as the radiology reports or blood work done in the VA clinical laboratory. All study-related information will be stored in secure locations. Paper reports will be stored in locked cabinets in a locked room. Electronic data will be password protected.

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

Organizations that may inspect and copy your information include the IRB, regulatory auditors and monitors, the VAMHCS Office of Research Compliance, VA Office of Research & Development (ORD), VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP) and other representatives of this organization. The monitors, auditors, and the IRB will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.

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

Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential.

If you are a patient in the VAMHCS, the results of your CT and DXA scans and screening blood labs for this study may be included in your VA medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

A new 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.

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

•Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Withdrawal from this study will not result in any physical, social, economic, legal or psychological adverse consequences. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator [redacted]

A written withdrawal is requested, and should be sent to:

[redacted]
Baltimore, MD[redacted]

You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

If you withdraw from this study, already collected data may not be removed from the study database.

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

Participant Name: _____ Date: _____

Title of Study: Progressive Activity-Based Rehabilitation in Veteran Cancer Survivors with Chronic Pain

Principal Investigator: [redacted]

VA Facility: Baltimore [redacted]

CAN I BE REMOVED FROM THE RESEARCH?

Alice Ryan, PhD, the Principal Investigator can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff, or if Dr. Ryan decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, you may contac[redacted].

Please read the University's statement below.
The University of Maryland Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the UMB Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Human and Animal Research Protections Officer (HARPO). The contact information for the HARPO is:

VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 6582
Room 3D-158

The VAMHCS Human and Animal Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study: Progressive Activity-Based Rehabilitation in Veteran Cancer Survivors with Chronic Pain

Principal Investigator: [redacted]

VA Facility: Baltimore [redacted]

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

HP-00081388 UM IRB Approval Date 6/2/2023
Do Not Sign this Form after this Date 6/1/2024