Official Title: Vivo Heart: Home-Based Virtual Exercise Program for Older Adults with Cardiovascular Disease

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Vivo Heart: Home-Based Virtual Exercise Program for Older Adults with Cardiovascular Disease

Informed Consent Form to Participate in Research
Internal Medicine – Gerontology and Geriatric Medicine
Tina Brinkley, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to test the feasibility and effectiveness of a home-based virtual exercise training program for older adults with cardiovascular disease. The study will use Vivo – an online, live small group exercise program that is tailored to meet each participant's needs for building strength, flexibility, and balance.

You are invited to be in this study because you are between 60 and 80 years old and you meet other eligibility criteria for the study. Your participation in this research will last around 5 months and will involve phone interviews, online assessments, two visits to the Sticht Center for testing, weekly virtual group exercise and health education classes for 12 weeks and two individual meetings with a registered dietitian.

This study has a baseline testing visit to ensure your safety and eligibility. Once that is determined, you will do an online Vivo orientation and will be assigned to a small group (~4 to 6 participants) which will meet at a set time twice a week with a certified trainer for 45 minutes each time. You will also be asked to complete a third exercise session each week on your own which involves at least 30 minutes of moderate-intensity aerobic activity (such as walking or biking). In addition, you will attend weekly virtual group health education classes and individual nutrition consultations with the dietitian. You will also be given a blood pressure cuff and a smartwatch to use throughout the study to track your heart rate, physical activity, and other health indices.

All research studies involve some risks. A few risks involved in this study that you should be aware of are falls, muscle soreness and/or fatigue from exercises or physical testing, and loss of confidentiality. These risks are low. You may or may not benefit from participation in this study. The potential benefits are improved strength, aerobic capacity and physical function.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include talking with your doctor about safe exercise programs in your community that may fit your needs and goals. You will not lose any services, benefits, or rights you would normally have if you decide not to participate in this study.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Tina Brinkley, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, contact her at [redacted]. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study called Vivo Heart. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are between 60 and 80 years old, you have cardiovascular disease and you meet other eligibility criteria for the study.

Your participation is voluntary. Please take your time as you review this form and make your final decision about participating in this study. Ask the study staff to explain any words or information you do not understand. You may also discuss the study and this consent form with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to better understand the feasibility and effectiveness of a home-based virtual exercise training program for older adults with cardiovascular disease. The study will use Vivo – an online, live small group exercise program that uses exercises tailored to meet each participant's needs for building strength, flexibility, and balance.

The information learned from this study will help us know if a long-term study is feasible.

WHO IS SPONSORING THIS STUDY?

The National Institute on Aging and the Wake Forest Pepper Center are funding this study. Other than receiving support from these agencies to conduct the study, the researchers do not benefit financially from your participation.

NIH National Institute on Aging

HOW MANY PEOPLE WILL BE IN THIS STUDY?

Approximately 40 people will take part in this study. To identify these people, we may need to screen around 100 people.

HOW LONG WILL I BE IN THIS STUDY?

If you are eligible, you will be in this study for approximately five months. You can stop participating at any time.

WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this study by signing this consent form, you will be asked to complete one baseline clinic visit and an online orientation with Vivo staff to orient you

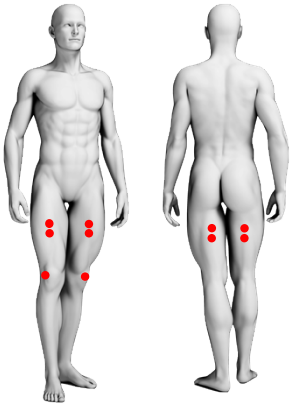
to the program. The program includes an online, live group exercise class twice a week, as well one individual aerobic exercise session and a health education class each week for 12 weeks. You will also meet virtually with a registered dietitian who will ask you about your eating habits in order to provide you with personalized healthy eating recommendations. You will be called monthly so we can see how you are doing and track any medication changes or health events since we last spoke. After you complete the program you will return to the clinic for a follow-up visit. The following sections describe the study visits where data is collected.

Baseline Visit

For this visit, we will ask you to come to the Sticht Center at Atrium Health Wake Forest Baptist in Winston-Salem where you will learn more details about the study and will be given time to ask questions and get satisfactory answers. You will then be asked to sign this informed consent form before any testing is done. After signing the consent form, we will:

- Measure your height, weight, blood pressure, pulse and hip and waist measurements.
- Ask you to answer questions about your health, demographics, energy level, mood, stress and physical activities.
- Ask you to complete a series of memory and thinking tasks. We will ask you questions and also ask you to complete a pencil and paper test asking you to match up numbers with symbols in a legend.
- Ask you to complete a series of physical function tests to measure your balance, walking speed over short (4 meters or 13 feet) and medium (80 meters or 262 feet) distances, ability to stand from a chair (stand up from a seated position in a chair 5 times), leg strength (walking up 4 stairs), and grip strength (squeezing a device as hard as you can).
- Ask you to complete an exercise stress test to measure your fitness level. You may take your medications as normal prior to this test. You should avoid alcohol for about 12 hours before and caffeine for about 3 hours before your visit. You will be asked not to exercise the day before or morning of testing. You will begin the test by walking slowly on a flat treadmill surface while breathing into a mouthpiece to measure your oxygen consumption. You will be asked to walk at your usual walking pace (determined from the 80-meter walking test) for five minutes. As the test progresses, the treadmill will gradually steepen to mimic walking up a hill and you will be asked to keep walking until you are too tired to continue. Your heart rate and rhythm will be monitored continuously with an electrocardiogram (ECG) using small sticky patches (electrodes) placed on your chest and abdomen. Your blood pressure will also be measured throughout the test. If you develop a pain in your chest or have particular patterns on the ECG, you will be asked to stop walking. All tests will be conducted by an experienced exercise physiologist and supervised and interpreted by our physicians. If your exercise test is abnormal, you will be instructed to follow up with your cardiologist. Following completion of this test, you will step off the treadmill and rest for ~20 minutes. During the next test, you will be asked to walk on the treadmill for 5 minutes at a standard slow pace of 1.5 miles per hour.

- Measure muscle activity in both legs during the exercise test (*if you consent to this optional test*). Two surface electrodes will be placed on the front of your thighs, two electrodes will be placed on the back of your thighs, and one electrode will be placed on each knee cap, as shown in the figure. Before placing the electrodes, we will use a tape measure and marker to locate specific muscles of interest in the thigh. The skin over the muscle will be cleaned using an alcohol wipe, and a razor may be used to remove hair, if necessary.



- Give you a welcome kit that includes resistance bands, a blood pressure cuff, a smartwatch, a tape measure and instructions about the assessments.
- Help you complete the online registration for Vivo and set up applications (apps) on your smartphone to sync with the blood pressure cuff and smartwatch provided by the study.

This visit will take approximately 3 hours.

Online Orientation by Vivo Staff

The orientation visit will be conducted virtually in your home by Vivo staff using a Zoom meeting (online video format). During this visit, you will receive information about the class format and expectations for the exercise program. Vivo staff will assess your physical space to ensure the safety of the surroundings. They will also complete an online screening assessment to confirm functional status. This assessment will include a chair stand test, arm curl test, walking test, step test, and balance test. This information will be used by the trainer to develop an exercise plan that is tailored to your individual needs. This online visit will take approximately 1 hour. You will be asked to complete a similar online visit with Vivo staff at the end of the study to do these same assessments and discuss any changes observed.

Vivo Heart Intervention/Program

The Vivo Heart intervention will last 12 weeks and will include each of the following components:

Group Exercise Classes on Zoom: You will meet virtually with a certified trainer and your assigned group (~4 to 6 participants) for 45 minutes twice a week. Each class incorporates stretching, balance, and dual-task exercises in addition to resistance training. Dual-task exercises combine cognitive and movement tasks, such as doing squats while counting backwards. The choice of exercises and the intensity is set based on your ability and your physical limitations.

Aerobic Exercise Session: You will be asked to exercise for 30 minutes on your own doing moderate-intensity aerobic activity (e.g., walking, biking). You will be asked to keep a written log of your activity.

Personalized Dietary Counseling: You will meet with a registered dietitian at the beginning of the study and again at the end of the study. The dietitian will ask you about your eating habits and will then review this information with you and provide healthy eating recommendations.

Health Education: You will attend weekly virtual educational classes led by a registered dietitian. These classes will be incorporated to provide support and general information on healthy lifestyle behaviors. Topics may include risk factor control, diabetes, hypertension, lipids, medications, aerobic exercise, strength training and flexibility, weight control, reading food nutrition labels, eating out, holiday eating, intimacy, stress, relaxation, cardiac symptoms, and cardiac interventions.

Blood Pressure and Heart Rate Monitoring: You will be asked to monitor your blood pressure and heart rate using a blood pressure cuff and smartwatch provided by the study. You will also be asked to record your blood pressure and heart rate before and after each exercise session in a written log.

Remote Activity Monitoring: You will be instructed to wear the smartwatch on your wrist continuously throughout the study. You will also be asked to download two apps (the Garmin Connect app and the Labfront Companion app) on your iOS/Apple or Android device to use with the smartwatch. You will receive a personalized code that enables you to anonymously log into the Labfront app without having to enter any personally-identifying information. These apps connect directly to the smartwatch via Bluetooth technology and send study data such as heart rate, activity, and other health indices to an encrypted Labfront cloud through an internet connection. Data travelling between the Labfront app and the system is encrypted with the use of various technologies that keep the data secure while it's being sent and ensures it can only be interpreted by the intended parties. You will need to sync your smartwatch with the apps on a regular basis (i.e., every 1-2 days) to make sure that your information is uploaded in a timely manner.

Monthly Phone Calls

You will be called by the clinic staff after months 1 and 2 to see how you are doing and ask about any medication changes or health events.

Follow-up Vist

You will be asked to return to the Sticht Center at Atrium Health Wake Forest Baptist to complete all the same study assessments as completed at the baseline visit. We will:

- Measure your height, weight, blood pressure, pulse and hip and waist measurements
- Ask you to answer questions about your health, energy level, mood, stress and physical activities
- Ask you to complete a series of memory and thinking tasks

- Ask you to complete a series of physical function tests
- Ask you to complete a treadmill exercise stress test
- Measure muscle activity during the exercise test
- Ask you to answer questions about your satisfaction with the Vivo Heart program

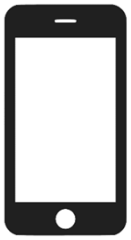
This visit will take approximately 3 hours.

AUDIO AND VIDEO RECORDING

As part of this study, you may be audio- and video-recorded during the cognitive testing and the virtual exercise sessions. This is to ensure the sessions are being conducted in a consistent way. You will not be able to inspect, review, or approve the recordings before they are used in this study.

HOW WILL I BE CONTACTED?

While you are participating in the study, you will be contacted by Gerontology Research Center staff and by Vivo staff.



You may be contacted in the following ways:

- Text messages
- Phone calls
- Email
- Through Zoom on your computer or iPad

I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided for the purposes of sending information and reminders and communicating with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

If you join this study, there may or may not be a direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating may include improving your strength, aerobic capacity and physical

function. You will also be informed about healthy eating and exercise behaviors that will enhance your lifestyle. You may request the results of certain tests that you can share with your doctor.

WHAT ARE THE RISKS OF BEING IN THIS STUDY?

Being in this study may involve some risk to you. You should discuss the potential risks of being in this study with the study investigators or staff. A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing safety and other data from this research throughout the study. Risks and side effects related to the exercise program and study procedures include:

Video Conferencing and Mobile Applications
While the devices themselves don't pose any risk, you may become frustrated with some of the technical aspects of the devices and applications you may be asked to use. You will be given time to learn with the study staff, but please reach out if you ever have any questions.

Exercise Stress Test
Exercise stress tests on a treadmill are common clinical procedures with minimal risks, including muscle strains or pulls, falls, or joint injury. There is also a small (1 in 10,000) risk of sudden death or serious cardiac event. To minimize these risks, you will be screened prior to testing to identify any safety concerns and to verify that you are able to safely exercise. During testing, blood pressure, heart rate and rhythm, and breathing will be continuously monitored by an exercise physiologist and physician trained in advanced cardiac life support. Tests will be stopped if the following problems occur: fainting, dizziness, chest pain, irregular heartbeat, or a heart attack. In case of an adverse event, a fully equipped code card is available on the unit.

Muscle Activity Measurements
In very rare occasions, surface electrodes can cause skin irritation. To avoid this risk, we will thoroughly clean your skin before electrode placement and use caution when taking them off.

Physical Function Tests
There is a slight risk of falls while participating in the physical function tests. However when possible, you will be positioned beside a wall that can be reached immediately if you feel that you are going to lose your balance. Additionally, the staff member conducting the test will stand next to you at all times. There is a small possibility that you may stumble, fall or aggravate one of your joints or muscles during the walking test. You will not be asked to conduct these tests if you have a pre-existing and serious leg injury.

Questionnaires
We will ask you some questions about your background, medical history, medications, memory, energy level, mood, stress, and physical activities. You may get frustrated or tired answering these questions. You can stop answering these questions at any time.

Home-based Virtual Exercise
You may experience some muscle or joint soreness as you begin to move your body in new ways. This can be lessened by modifying your intensity level, getting adequate rest and stretching.

Blood Pressure and Heart Rate Monitoring
You will be asked to monitor your blood pressure and heart rate before, during, and/or after exercise to ensure your safety. If skin irritation occurs from the cuff or smartwatch, please adjust the position of the wearable device and ask the trainer for tips.

Confidentiality
Taking part in this research study may involve providing information that you consider confidential or private. Efforts will be made to keep your information safe, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records. By participating in this study, you will use several technologies to help you stay in touch with your peers, trainers, and the study dietitian and to better understand your patterns of moving and eating. Any time you use this type of technology there is risk that others could view the data collected on these devices, including your daily activity patterns, heart rate information, blood pressure, your stress and energy levels, and perhaps where these devices are in the world. You should be comfortable with this possibility prior to participating in this study. We will work with you to take steps to minimize how easily this information could be related to you, such as creating an anonymous account for use with these devices.

There may be other side effects that we cannot predict. You should tell the research staff about any medical conditions you have, as this may avoid side effects, interactions, and other risks.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study; you do not have to participate. You do not have to be in this study to make lifestyle changes. You should talk to your doctor or other specialists in the community, such as a health coach or dietitian, about other choices you can make to have a healthier lifestyle.

WHAT IS THE COST TO JOIN THIS STUDY?

There may be some costs to you for taking part in this study. The study dietitian may recommend some healthy changes to your diet which may include new food items or supplements. You will be responsible for the costs of any dietary changes you choose to make. All study costs related directly to the study will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

You will be responsible for maintaining adequate Wi-Fi coverage during the study. We also expect that you will keep up with the monitoring devices provided by the study. If

lost or stolen, the device(s) may be replaced. We would not expect you to pay for a replacement, but we ask you to keep these devices in a safe place.

If you want to continue with the Vivo program after completing the Vivo Heart study, Vivo will offer 2 classes a week at a reduced rate for as long as you want to participate. This is completely optional and is not required to participate in this study.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. You will be able to keep all the equipment (blood pressure cuff, smartwatch, resistance bands and tape measure) provided to you at the beginning of the study as a thank you.

WHAT ABOUT MY HEALTH INFORMATION?

What is Protected Health Information (PHI)?

In this research study, any new information we collect from you and 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: your name, address, phone number, date of birth, medical history, and the information we receive during the intervention and clinic visits.

Will my PHI remain confidential?

We will make every effort to keep your PHI private. We will store records of your PHI in a cabinet in a locked office or on a password protected computer. Your identity and your PHI will not be shared unless: it is required by law; it is necessary to protect the safety of yourself or others; you give us permission to share it.

Who has access to my PHI?

Your PHI may be given to others during and after the study. This is for reasons such as carrying out the study, determining the results of the study, making sure the study is being done correctly, providing required reports, and getting approval for new products.

Some of the people, agencies and businesses that may receive and use your PHI are:

- Vivo investigators and staff
- National Institutes of Health (the funding agency)
- Investigators at other sites who are assisting with the research
- Laboratories, reading centers or analysis centers
- Other companies who are assisting with the research
- The IRB
- Department of Health and Human Services (DHHS)
- Representatives of Wake Forest University Health Sciences and Atrium Health Facilities
- Representatives from government agencies that review our study for safety

Some of these people, agencies and businesses may further share your PHI if they need to. Once they share your information, it may no longer be covered by federal or state privacy rules.

We may have to share your information if required by law or court order. If so, we might 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.

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

How long will you keep my PHI?

We will keep your PHI for at least two years after the study has ended, although by joining the study you are giving us permission to keep your information for as long as we need it. 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.

What about my medical record?

If you choose to be in this study, your medical record at Atrium Health Wake Forest Baptist will show that you are in a research study. Information about our research may also be included in your medical record. Only people who normally have access to your medical record (like your doctors or nurses) will be able to see this part of your medical record.

If you are not a patient of Atrium Health Wake Forest Baptist, a medical record will be created for you to make sure this important information is available to doctors in case of an emergency.

Any laboratory test result and other medical reports created by this study may be entered into the computer systems of Atrium Health Wake Forest Baptist. Like all your other information, we will keep this data as safe and private as possible. Only people who have been trained to keep your information safe will be able to see these results, but they may not be directly involved with this research study. For example, they might work at a blood laboratory that we partner with.

Do I have to share my PHI with you?

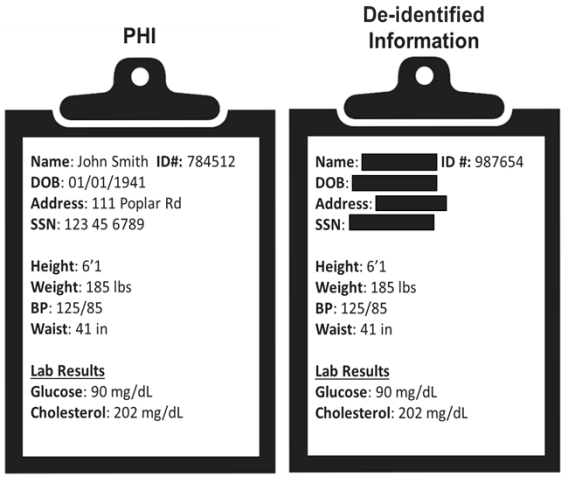
No. You can tell Dr. Tina Brinkley that you want to take away your permission to use and share your PHI at any time by sending a letter to this address:

Tina Brinkley, PhD
[redacted]

However, if you take away permission to use your PHI, you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the research study. By signing this form, you give us permission to use your PHI for this study.

What is de-identified information?

Your PHI may be used to create information that does not identify you. This de-identified information will not include anything that could identify you, such as your name, date of birth, address, or social security number. Your identity will be replaced with an ID number that cannot be linked back to you. Any publication or presentation that may result from this study will only report de-identified information. There is always some risk that even de-identified information might be re-identified.



Who has access to my de-identified information?

Your de-identified information will be shared in a few ways:

- Your de-identified information will be shared on secure websites and research databases. For example, a description of this study will be on http://www.ClinicalTrials.gov, as required by U.S. Law. This website does not include information that can identify you. At most, the website will include a summary of the study results; no individual results will be included. You can search this website at any time.
- We will share the results of this study at scientific meetings and we will publish the data in scientific journals. Lastly, your de-identified information will be shared with researchers in the future. Researchers want to study your data to make new discoveries and help cure diseases.

What is the difference between PHI and de-identified information?

De-identified information will not identify you in any way. Your identity will be replaced by an ID number that cannot be linked back to you. PHI will include things like your name and address but this information will be heavily protected.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will

not be disclosed unless it is authorized by you, required by law, or necessary to protect your safety or that of others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WHAT HAPPENS IF I GET INJURED OR SICK FROM BEING IN THIS STUDY?

Atrium Health Wake Forest Baptist maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the DHHS.
You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research-related injuries or to report a study related illness, adverse event, or injury you should call Tina Brinkley, at [redacted] or [redacted] if it is after hours and identify yourself as a Vivo Heart study participant.

DO I HAVE TO BE IN THE STUDY?

Being in this study is voluntary. You may choose to not take part or you may leave the study at any time, but if you are thinking about stopping the study, you should talk to the Vivo Heart study staff first. If you do not join the study or you leave the study at any time, your normal medical care will not be affected. We will always give you any new information we find that might make you want to stop being in the study. Also, if new information becomes available, the study doctor may stop your participation without your consent. If this happens the reasons will be explained.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about the study or you have an injury caused by the study, please call Tina Brinkley, PhD, at [redacted] or [redacted] if it is after hours and identify yourself as a Vivo Heart study participant. If you have concerns about your information privacy, your rights when you are in the study, or any problems you experience, you should call the IRB. The IRB is a group of people who review the research to protect your rights. You can call the Chairman of

the IRB at [redacted] or the Research Subject Advocate at [redacted]. You will be given a copy of this signed consent form.

PARTICIPANT'S STATEMENT OF CONSENT

I have had the opportunity and enough time to review the study information and ask questions about this study, and my questions have been answered. I understand the study, and I have been informed of the possible risks and benefits of taking part in this study. I agree to participate in this study.

Participant Name (Printed):_____

Participant Signature:_____

Date:_____Time:_____ am pm

Name of Person Obtaining Consent (Printed):_____

Signature of Person Obtaining Consent: _____

Date: _____Time:_____ am pm

Please review each question below and place your initials in the space that goes with your answer. You can still participate in this study even if you answer NO to any of the following questions.

AGREEMENT TO REPORT RESULTS TO YOUR DOCTOR

Do you agree to have medical results from your study tests or exams reported to your doctor if needed? _____ YES _____ NO

AGREEMENT TO CONTACT ME FOR FUTURE RESEARCH STUDIES

Do you agree to be contacted for future research studies? _____ YES _____ NO

AGREEMENT TO AUDIO/VIDEO RECORD ME FOR FUTURE STUDIES

Do you agree to allow audio/video recordings of you to be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB? You will not be able to inspect, review, or approve their future use.

_____ YES _____ NO, destroy them when no longer needed for this study

AGREEMENT TO THE OPTIONAL RECORDING OF MUSCLE ACTIVITY

Do you agree to have surface electrodes placed on your legs to record muscle activity during the treadmill exercise test. _____ YES _____ NO