Effects of 12-weeks of High-intensity Resistance Aerobic Circuit Exercise Training on Epigenetic Aging and Inflammation in Older HIV-infected Veterans

NCT04103593

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U.S. Department of Veterans Affairs
Atlanta VA Health Care System

Informed Consent Template Version 7-1-20

Consent to be a Research Subject

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 40 people who are being studied at the Atlanta VA Health Care System.

Why is this study being done?

The primary purpose of this study is to test if the exercise class provided by VA Clinical Video Telehealth (VTEL) improves fitness in older adults. The secondary purpose of this study is to test if this exercise changes biomarkers of aging in blood samples. Although exercise is beneficial, many people do not have access to a gym or exercise facility. Exercise is especially important in older adults since it improves aspects of aging.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will 1) complete tests before the exercise program; 2) exercise for 12 consecutive weeks in the exercise class 3 days a week; and 3) complete tests after the exercise program. Details on the tests and the exercise program are in the rest of this form. The exercise is unique because the exercise instructor will be at another VA. The exercise instructor will lead the class and supervise you through the video telehealth or VTEL.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. You may not benefit personally from this exercise. However, when exercise is consistently performed, it is reasonable to see improved stamina, strength, and overall wellbeing. You may also learn exercises that you can perform on your own after the program is over.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, the risks are similar to exercise in general. The most common risk is muscle and joint soreness. Others feel fatigue, especially early in the program. There is also a slight risk of loss of privacy or breach of confidentiality. A full list of expected risks, including their frequency and severity, is in the RISKS section of this document.

Alternatives to Joining This Study

You may start to exercise on your own or may continue your current level of activity.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this and talk about it with your family and friends. By signing this document, you agree to participate in this research study. Your decision to participate in this research study does not affect your medical care. You may change your mind and withdraw from the study at any time without penalty.

U.S. Department of Veterans Affairs
Atlanta VA Health Care System

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TITLE: Effects of 12-weeks of High-intensity Resistance Aerobic Circuit Exercise Training on Epigenetic Aging and Inflammation in Older HIV-infected Veterans

Sub-title: FIT-VET: Functional Interval Training for Veterans Exercising through Telehealth

PRINCIPAL INVESTIGATOR: Vincent Marconi, MD

SPONSOR'S NAME: The Office of Research and Development, Veterans Health Administration (VHA)

PURPOSE:
You are being asked to volunteer in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

The primary purpose of this study is to test if the exercise class provided by VTEL improves fitness in older adults. The secondary purpose of this study is to test if this exercise changes biomarkers of aging in blood samples. Your personal time involved with this research may be between 4 months to 1 year. If you agree to take part in this study, you will sign this Informed Consent Form before any study-related procedures are performed. We hope to have up to 80 Veterans at two VA sites and about 40 at the Atlanta VA Health Care System (AVAHCS).

CLINICALTRIALS.GOV:
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.

WHAT WILL I BE ASKED TO DO?:
At the first visit, you will have a physical exam done by one of the clinician investigators for this study to determine if you are eligible for this study. We will review your medical record for information about your health issues, including your HIV status, and the medications you are taking. We will look at your recent blood test results from your clinic doctor, including CD4 cell count (T-cell) and viral load. We will ask you about your medical problems, such as heart disease, sugar diabetes, high blood

pressure, and lung disease. We will ask you about your use of cigarettes, alcohol, and illicit drugs. A resting electrocardiogram (EKG) will be done. An EKG is a non-invasive exam for irregular heartbeats and signs of scar tissue in the heart.

If you qualify for the study, the visits are in 3 groups (Phases 1, 2, and 3) of research tests as described below:

Overview of Phases:

Phase 1: This phase of the study may take up to 5 weeks. Beginning tests include measure of your exercise fitness, muscle strength, and capacity to do routine daily activities (called physical function). These tests will be considered your baseline performance. The following tests will be scheduled over approximately 1-5 weeks and include: 1) exercise treadmill test; 2) blood draw; 3) DXA Scan (Dual-energy X-ray absorptiometry); 4) strength and endurance tests; 5) nutrition assessment; and 6) surveys. Based on the results from the tests during Phase 1, the investigator will decide if you can continue in the study and start Phase 2.

Phase 2: If you are cleared for Phase 2 by the research staff, then you will be assigned (by chance - like a flip of a coin) to be in either the Exercise Program or the Delayed Exercise Group. You will have a 50:50 chance of being placed in either group. Once you are placed in a group, you will be expected to stay in that assigned group until the end of Phase 3.

The Exercise Program consists of supervised VTEL exercise 3 times a week for a total of 12 weeks at the Atlanta VAMC facility.

*Those in the Exercise Program complete study participation after 12 weeks of Phase 2 exercise, and Phase 3 follow-up testing.

*Those in the Delayed Exercise Group complete study participation after 12 weeks of Phase 2 at their normal activity level (no exercise), and Phase 3 follow-up testing. They will be given the option to complete a home-based exercise program after testing at 12 weeks. If they choose to complete the exercises, they will go through another round of Phase 3 testing at 24 weeks, except without the nutrition assessments.

Phase 3: Repeat of the Phase 1 testing for follow-up.
Phase 4: At this time, the Delayed Exercise Group will be given the option to complete a 12-week home-based exercise program with weekly phone calls and 3 in-person group sessions. Phase 2 exercises followed by Phase 1 testing at week 24 timepoint, except without the nutritional assessments.

PLEASE NOTE ON SCHEDULING: All of the visits will be scheduled depending on your availability and the test facility schedule time at the Atlanta VAHSC. The order of the tests and visits may vary depending upon your availability and staff and equipment schedules. To remind you when a test is scheduled, the research staff will give you a phone call or send you a reminder letter.

Phase 1: Phase 1 is 1-5 weeks long.
Before the treadmill test a resting electrocardiogram (EKG) will be done. An EKG is a non-invasive exam for irregular heartbeats and signs of scar tissue in the heart. If your medical history, physical exam and EKG do not show any evidence of heart disease that would prevent you from exercising, then you will complete the treadmill test. This will take approximately 30-45 minutes.

Test 1: A 'exercise treadmill test' is a test to see how far you can walk on a treadmill that will first be like you are walking on flat ground and then after a few minutes it will be like walking up a slight hill.

The treadmill test will be done to test for symptoms of heart disease and to measure your level of exercise fitness. The treadmill test will be supervised by a clinician (physician or nurse practitioner) and an exercise physiologist. During the treadmill test, you will be asked to walk for approximately 10-15 minutes while breathing through a mouthpiece. The speed and tilt of the treadmill will be increased every few minutes for the duration of the test or until you cannot continue. The test will be stopped if you feel chest pain, shortness of breath, dizziness, or are too tired to continue. You may stop the test at any time. During the test, you will have your blood pressure, heart rate, rhythm and EKG checked by the research staff and research doctor. You may need to repeat a treadmill test if the first results show that the test was incomplete. You may need to first practice walking on a treadmill. A heart specialist (cardiologist) will make a final report on the test results. Participants with abnormal treadmill test results which suggest heart disease will be told of these findings. If you have an abnormal test, you will be advised to make an appointment to see your primary care physician or a cardiologist. The visit for the treadmill test will take about 45-60 minutes and will take place in the Atlanta VAMC.

Test 2: Two separate blood draws will be done to collect a small amount of blood to see if markers of inflammation, irritation and clotting factors, or in your blood are elevated. Approximately 60ml (about 4 tablespoons) will be collected over two blood draws. One of the blood draws will be done after you have fasted for 8 hours (which means no eating or drinking for 8 hours prior). If we cannot collect the entire blood sample during either of the lab visits, then you will be asked to reschedule one additional lab visit. Each blood draw will take approximately 10 minutes in the Atlanta VAHCS.

Test 3: A 'DXA Scan' will require you to lie comfortably on a large table for your body to be scanned to measure your body's amount of fat and muscle and the density of your bones. This is a fasting test (which means no eating or drinking for 8 hours prior) and will take approximately 30 minutes at the Atlanta VAHCS. If your results show you have low bone density and are at risk for a bone fracture, then you will be referred for follow-up with your primary care provider.

Test 4: Nutrition Assessment: You will be interviewed by a research staff member on three separate occasions. The interview will last about 15 minutes and will include a detailed discussion of what you ate and drank in the previous 24 hours. At least 1 of the three interviews will be done in person, and the other 2 can be over the phone, if that is convenient for you. This test is considered complete when all 3 interviews have been done.

Tests 5: Tests for muscle strength and capacity to do routine daily activities (called physical function) will be performed. The research staff will explain each test before they administer the test. These include tests of how long it takes you to get up from a chair 10 times, and the distance you can walk

for 2 minutes. Strength tests will include measure of arm curve. A research exercise technician will perform each of these tests. These tests will take approximately 60 minutes to complete at the Atlanta VAHCS. These tests will be performed by a VTEL visit, which means the Salem VAMC exercise physiologist will watch and instruct you through the VTEL screen as you complete these tests.

Test 6: Surveys: You will be asked to complete 4 different surveys or questionnaires. You can complete these paper surveys at home if you prefer. First, as part of Phase 1 and 3 testing, you will be asked to complete a 31-item survey which will ask you questions about how you feel, kind of things you are able to do, and symptoms you may have. The total time expected is 15 minutes. Then, during the exercise phase, you will complete three surveys after approximately 4 weeks of exercise sessions. These three surveys will ask you about: 1) your experience with the videoconferencing system; 2) difficulties you encountered during the exercise; and 3) how you felt about exercising with other people in an exercise class. The total time for all three of these surveys is 20 minutes.

Phase 2 - Phase 2 is 12 weeks long.

Exercise Program: After Phase 1 tests have been completed and if you met all the requirements, you will go to the VTEL Facility at the Atlanta VAHCS for the Exercise Program of this study. You will be asked to come to the VTEL Facility to exercise three times a week with a small group of other people in the study for about 1-2 hours. The size of your exercise group will depend on COVID safety practices in place at that time but will never be more than 5 individuals. It is possible that you will be the only participant in the room and the only other people you see will be on a VTEL screen.

Your Exercise Program will consist of high-intensity functional circuit fitness training (aerobic exercise) to improve your heart and lung function. All training sessions will be led by a research staff member from the Salem VAMC who is a qualified exercise physiologist. The classes will be televised over VTEL and you will follow along with the exercise on the screen and also be able to talk with the physiologist with the microphones provided.

Your heart rate and blood pressure will be monitored throughout the session using a Polar heart rate monitor. Which group of activities, how hard and long you exercise is different for each person and will depend on your heart rate and how comfortable you are during the exercise. You will start with a brief warm up and slowly beginning your activity during your planned session. The staff will help you adjust the activity to comfortably reach your target heart rate for the exercise session. You may slow down and stop to rest if you need to at any time. This Exercise Program is similar to one recommended by the American Heart Association.

The Delayed Exercise Group will have no exercise activities for the 12 weeks of Phase 2 and will not be required to visit the VTEL Facility. Participants in this group will continue their current daily activity level without any structured exercise.

Phase 3: Repeat all Phase 1 visits.

Phase 4: At this time, the delayed exercise group will be given the option to complete a 12-week home-based exercise program with weekly phone calls and 3 in-person group sessions and Phase 1 testing, except without nutritional assessments.

Delayed Entry Exercise Program: Only participants in the Delayed Exercise Group will be included in the delayed entry exercise program. This program is also 12-weeks in duration and includes functional fitness training (aerobic exercise) to improve your heart and lung function. But the exercises are performed at home while wearing a Garmin Vivosmart v5 which measures your heart rate. You will receive a list of exercises and other activities (like mowing the lawn) from the exercise physiologist. Each week you will have a goal for total number of minutes of exercise or activity. You will be able to choose how to meet that goal using any of the exercises or activities on your list. The only requirement is your sessions are at least 10 minutes long. You will use a Garmin Connect phone app installed on your personal phone with assistance from the research staff to upload or synch the heart rate information from the Garmin Vivosmart v5 to the Garmin Connect website. Once a week you will have a phone call with the exercise physiologist to review your exercise and activity. Every week the exercise physiologist will encourage you to spend more time and perform harder exercise or activities. The goal at the end of the 12-week program is meet the U.S. healthy activity guidelines: 150 minutes of moderately hard exercise/activity (average of 30 minutes 5x/week) -OR- 75 minutes of vigorous exercise/activity (average of 25 minutes 3x/week).

To help meet this goal, you will come to a small group session at the VTEL Facility at the Atlanta VAHCS once a month for three times (appropriately 4, 8, and 12 weeks). You will meet with a small group of other people in the study for about 1-2 hours. The size of your exercise group will depend on COVID safety practices in place at that time but will never be more than 5 individuals. An exercise physiologist will lead a discussion on exercise approaches and tips. At this time you will also receive an updated list of exercises and activities that meet your personal progress.

RISKS:
The following are risks of the research tests:

Exercise testing: For the treadmill test and physical function tests and fitness training, there is a small risk that you will fall, get chest pain, get short of breath, or become dizzy. The exercise technician will stop the test if you have any serious symptoms such as chest pain. There is a small risk of muscle strain or pulled muscles. We have taken care to minimize the risks. Participants will not do any of the exercise and physical function tests before receiving a medical evaluation. Participants with unstable medical problems will not be eligible to perform exercise testing or training. The exercise technician who will be doing these tests is trained in CPR. Emergency equipment and medications are available in the area where these tests are performed. A physician will be present and will supervise the treadmill test. If there is evidence of coronary artery disease or dangerous abnormal heart rhyme on the treadmill test, you will be referred for further medical evaluation and may not be eligibile to continue in the study. Other risks that are uncommon with exercise testing include musculoskeletal injury, or damage to a muscle or joint. Very uncommon risks include cardiovascular events, such as heart attack, stroke, ruptured intracranial aneurism, aortic dissection, and sudden death in very high-

risk populations. These risks will be minimized by the use of proper screening and strict adherence to study eligibility criteria, and providing direct oversight for all tests with qualified staff.

For the blood draws: It is possible that you may develop a bruise or swelling at the site of the blood draw. Very rarely, you may become light-headed during your blood drawn. The technique we will be using is likely to be similar to having your blood drawn in your doctor's office or at one of the VA clinics.

For the DXA: The total amount of radiation exposure is 20 mR (whole body = 1 mR, lumbar spine = 7 mR, hip = 7 mR, forearm = 5 mR). The radiation dose you will get in this study is the same or less than what an average person in the US receives from the environment each year. The main risk linked with radiation is the chance of getting cancer later in life. We think that the risk from the radiation exposure you will get in this study is small compared to other daily risks.

For the nutrition assessment: Risks associated with completing the nutrition assessment are minimal.

Tests of physical function: These tests involve a variety of timed walks and getting up from a chair. There is a small risk that adults will fall, get chest pain, short of breath or become dizzy during these tests.

Surveys: There are no physical risks to you. The inconvenience of the surveys is the time required to complete them. The surveys may be completed while you are waiting for your visit or in the privacy of your home. There is a small chance that the privacy of your surveys will not be maintained. Every effort will be made to prevent this from happening by asking you to complete the questions in a private area and by using a study number rather than your name on the paper.

Exercise Training:
There is a small risk of muscle strain or pulled muscles. Other risks that are uncommon with exercise training include musculoskeletal injury, or damage to a muscle or joint. We have taken care to minimize the risks. You will be taught proper stretching and exercise techniques to minimize this risk and discomfort. If persistent soreness does develop, you will stop exercise and be taught how to stretch and ice the sore muscle or joint to relieve the soreness. A personalized exercise program based on Phase 1 test results and monitoring by trained personnel limits the risk for these occurrences. The duration and difficulty (intensity) of the exercise is slowly increased over time to minimize problems with muscles, joints, fatigue, and shortness of breath. Very uncommon risks include cardiovascular events, such as heart attack, stroke, ruptured intracranial aneurism, aortic dissection, and sudden death in very high-risk populations. These risks will be minimized by the use of a medical evaluation which includes a history and physical exam, ECG, and treadmill test. Your maximum heart rate is recorded on your treadmill test and is used to make your personalized exercise program.

Because this is a group setting, other people participating in the exercise class or group will know that you are also HIV positive. Our research team will address you by your preferred name, and you will not be required to give any other identifying information.

BENEFITS:
You may not directly benefit from participating in this research study. However, the tests from this study may identify early heart disease or other medical conditions that may help your doctor improve your care. By participating in this study, you will contribute to a greater understanding of exercise fitness, strength, and physical function, and the benefits of exercise training for those infected with HIV. The knowledge from this study may also help to identify patients at risk for physical disability or heart disease in the future. You will be informed of any significant new findings during the course of the study which may affect your willingness to continue to participate.

COMPENSATION:
You will be reimbursed for time and travel at the following rates:
Compensation is per test completed. Multiple tests may occur at a single visit, depending on scheduling of staff and equipment.

Phase 1: At your first visit with the study staff, you will be reimbursed $20. At that time, you will complete a clinical history evaluation and physical exam, as well as an EKG. You will be reimbursed for each test of the following tests completed at the following rate:
exercise treadmill test ($50); physical function tests ($50); and DXA scan ($50). You will be reimbursed $25 per test for each of the two blood draws ($50 total), and $10 each for each of the three dietary recalls. If you complete all three tests, both blood draws, and the three dietary recalls, you will receive $230.These tests will be scheduled over a 1-5 week period.

Phase 2:
Exercise Program Group - for the 12 weeks of the Exercise Program you will be reimbursed $10 per session. You will not be reimbursed for sessions you do not complete. After completing 4 weeks of the exercise, you will receive a $50 completion bonus. You will receive a total of $360 if all 36 exercise sessions are completed. In total, you will receive $410 for completing the exercise.

The Delayed Exercise Program Group – for the 12 weeks of Phase 2 you will not be required to visit the VTEL Facility.

Phase 3: Repeat of the Phase 1 testing (9 tests) for follow-up. You will be reimbursed at the same rate for each test completed for a total of $230 for completing all 3 tests, both blood draws, and three dietary recalls. These tests will be scheduled over a 1-5 week period. Additionally, for completing the study, if you are in the exercise group, you will be compensated an additional $100 at this time.

Phase 4: Only participants in the Delayed Exercise Group who decide to enter the Exercise Program after their Phase 3 testing will be able to repeat testing, with the same reimbursement rate. You will be compensated a total of $200 for completing the treadmill test, DXA, physical function test, and two blood draws. Additionally, for completing the study, you will be compensated an additional $100 at this time.

SUMMARY OF TOTAL REIMBURSEMENT:

- For the participants in Exercise Program Group (with no required additional visits): After all completed visits (enrollment visit, Phase 1 baseline testing, Phase 2 Exercise Program for 12 weeks, Phase 3 follow-up testing, and $100 completion bonus), you will have been reimbursed for travel and time a sum up to $990. If you decide at any point during the study you no longer want to participate in the study, you will still be reimbursed in the amount listed above for each test and each exercise session that you have completed.

- For the participants in Delayed Exercise Group (with no required additional visits): After all completed visits (enrollment visit, Phase 1 baseline testing, Phase 2 waiting period without exercise for 12 weeks, and Phase 3 follow-up testing), you will have been reimbursed for a sum up to $480. If you desire, you will be able to begin exercising after Phase 3 testing is completed; you will be reimbursed for time or travel equivalent to the Phase 2 exercise group ($410). If you complete the Phase 4 testing, you will earn $200 for the tests at the above-mentioned rates, as well as a $100 completion bonus. The total potential compensation would be $1,190.

If the study staff finds that an additional visit is required for technical reasons to repeat a test, reimbursement will be at a rate equivalent to that test.

You will be reimbursed for each completed visit by an electronic funds transfer (EFT) to your bank account. If you prefer, a check can be mailed to you instead. It may take up to 4 to 6 weeks to receive the check. If you are reimbursed by direct deposit, Atlanta and Austin Financial Services Center are entities to whom your name, address, social security number, and bank account number will be disclosed. Your name, address, social security number, and amount of payment will be submitted to the Internal Revenue Service for tax reporting purposes for any financial compensation you receive per calendar year as a result of your participation in this research study.

Please note that we are required to complete a Form 1099 for any participant payments for research at the Atlanta VAHCS that total over $600/calendar year. To comply with this federal mandate the researchers are required to obtain your social security number to complete the form.

COSTS:
You will not be charged for any treatments or procedures that are part of this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

You will get necessary medical treatment if you get injured from being in this study. This requirement does not apply to:

(1) Treatment for injuries due to non-compliance by a subject with study procedures;

Or
(2) Research conducted for VA under a contract with an individual or a non-VA institution.

Care for VA research subjects with research-related injuries must be provided in VA medical facilities, except in the following situations:
(1) If VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility Directors shall contract for the needed care;
(2) If inpatient care must be provided to a non-Veteran research subject with a research-related injury, VA medical facility Directors may contract for such care; or
(3) If a research subject needs treatment in a medical emergency for a research-related injury, VA medical facility Directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

Subjects in VA-approved research cannot be charged, nor their insurance be billed, for research-related interventions or procedures that are required by the protocol.

If you believe you have been injured by this research, you should contact Dr. Vincent Marconi at 404-321-6111 x207592

ALTERNATIVES:
Your alternative is to not participate in this research study. If you choose not to participate in this research study, it will not affect the quality of medical care provided at the Atlanta VAHCS. If you change your mind about participation in research study, it will not affect your clinic visits. The clinic doctors will treat you as they normally would. Your participation in this research is voluntary. You can refuse any of the procedures if you are uncomfortable or change your mind.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED:
We will keep information about you, including any research records we create, strictly confidential to the extent required by law.

We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use a study number rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results. We may ask again if you are interested in participating in future study activities conducted by the Infectious Disease research team. People other than those doing this research study may have access to your medical and study records including:

- Salem Veterans Affairs Medical Center (SAMVAMC)
- Baltimore Veterans Affairs Medical Center (BVAMC)
- Yan Sun Laboratory at Emory University
- Pearce Laboratory at Emory University
- Departments of Veterans Affairs
- Rehabilitation Research and Development (RR&D)

- The Office for Human Research Protections
- The Government Accountability Office (GAO)
- VA Office of Research and Development (ORD)
- The Office of Research Oversight (ORO)
- Atlanta VA Research Compliance Office
- Foundation for Atlanta Veterans Education and Research (FAVER)
- The Inspector General
- Polar
- Emory University
- Emory University Institutional Review Board
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.

If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.

If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA):

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 your name, address, date of birth, and information from your medical records such as medical history, allergies, lab or radiology results, HIV status, medications, drug, alcohol or STD treatment, genetic test results or mental health treatment.

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 Salem Veterans Affairs Medical Center (SAMVAMC), Baltimore Veterans Affairs Medical Center (BVAMC), Yan Sun Laboratory, Pearce Laboratory, Departments of Veterans Affairs, Rehabilitation Research and Development (RR&D), The

Office for Human Research Protections, The Government Accountability Office (GAO), VA Office of Research and Development (ORD), The Office of Research Oversight (ORO), Atlanta VA Research Compliance Office, Foundation for Atlanta Veterans Education and Research (FAVER), The Inspector General, Polar, Emory University, Emory University Institutional Review Board, as well as any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above.

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.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. 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.

If you revoke this authorization, Dr. Vincent Marconi and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

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.

RESULTS:

If you are a patient in the Atlanta VAHCS the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

In general, we will not give you any individual results from the study of the samples or information you give us. If the test results could help you improve your health or prevent future risks to you, the research team will give you and your physician this.

WHO COULD PROFIT FROM THE STUDY RESULTS?

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

IDENTIFIABLE PRIVATE INFORMATION OR IDENTFIABLE SPECIMENS:

Identifiers will be removed from the biospecimens that are collected and given a study ID. After that removal, the deidentified specimens collected throughout the study will be stored for the use in future studies in a tissue bank maintained by one of the following institutions dependent upon storage

support availability: Atlanta Veterans Affairs Health System, Salem Veterans Affairs Medical Center (SAMVAMC), Baltimore Veterans Affairs Medical Center (BVAMC), or Yan Sun Laboratory at Emory University. Because the study key code will not be after the study closes, you will not be able to have specimen samples destroyed after the study has closed.

The data collected from you throughout the study will be sent and stored in a controlled-access database in a data repository maintained at the Salem Veterans Affairs Medical Center Your information will be coded with a study ID in the research database. A separate file with identifiable information and the study key code will be kept in a different location in a password protected file to protect your privacy. We may ask again if you are interested in participating in future study activities conducted by the Infectious Disease research team. At the completion of the study, this key code will be destroyed. If data is shared with other researchers, it will be done in such a way that you will not be identified.

The deidentified information and left-over samples could be used for future research studies or distributed to another investigator for future research studies relating to HIV/AIDS related diseases, exercise, or aging processes without additional informed consent from you or your legally authorized representative. Future studies by VA and/or non-VA investigators will undergo ethical review before the information and/or samples are used. Only researchers who apply for and get permission to use the data for a specific research project will be able to access the information.

All of your specimens used in research that is supported by this repository will be stored indefinitely at one of the following locations:

- Atlanta Veterans Affairs Health System
- Salem Veterans Affairs Medical Center (SAMVAMC)
- Baltimore Veterans Affairs Medical Center (BVAMC)
- Yan Sun Laboratory at Emory University

CONFLICT OF INTEREST: None

CONTACT PERSONS:
If you have any questions, concerns, or complaints about this study you can call a member of the study staff: Dr. Vincent Marconi at 404-321-6111 x207592

If you have been harmed from being in this study call: Dr. Vincent Marconi at 404-321-6111 x207592
If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

The Research Compliance Officer at (404) 321-6111 ext. 206964 or the Clinical Studies Center Manager at (404) 321-6111 ext. 206933.

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at (404) 712-0720 or toll free at 1-877-503-9797.

VOLUNTARY PARTICIPATION AND WITHDRAWAL:
The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue, if you do not follow study procedures as directed by the study doctors, or if the sponsor decides to end the study.

Your participation is voluntary, and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. For your safety, however, you should consider the study doctor's advice about how to go off the study treatment.

The study doctor or investigator may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions.

You are free to withdraw your consent at any time. 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. If you are an employee, your employment status will not be affected by your participation or non-participation in this study.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care for safety and medical reasons. If you agree, this data will be handled the same as research data.

Your participation will not affect the way you now pay for medical care at the Atlanta VAHCS. A written withdrawal sent to Dr. Vincent Marconi is required.

(Continued on the next page.)

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

RESEARCH PARTICIPANT'S SIGNATURE AND DATE:

_____
Research Participant's name

_____ _____
Research Participant's Signature Date

Contact for future studies
There may be additional research studies in the future that you may participate in. We would like to keep your contact information after the close of this study in order to contact you about future research.

_____YES, you may store my contact information after the close of the study.
(Initials)

_____NO, you may not store my contact information after the close of the study.
(Initials)