Official Title of Study:	The Impact of a Resistance Training Intervention on Blood Pressure Control in Older Adults With Sarcopenia (INERTIA)

NCT Number:	NCT04255745

Date of Document:	February 21, 2023
Document Type: Each Document must have a separate cover page. Each Document must be in **PDF/A*** format.	<u>Separate Documents:</u> ☐ Protocol ☐ Statistical Analysis Plan ☒ Informed Consent <u>Combined Document:</u> ☐ Protocol that includes Statistical Analysis Plan

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Effective: 2/21/2023
Expires: 1/24/2024
UIC Office for the Protection of Research Subjects

University of Illinois at Chicago
Research Information and Consent for Participation in Biomedical Research
The impact of a resistance training intervention on blood pressure control in older adults with Sarcopenia: The INERTIA Study

Principal Investigator/Researcher Name and Title: Deepika Laddu, PhD Assistant Professor
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Sponsor: NIH/NHLBI

About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	The purpose of this study is to better understand how muscle strength is related to blood pressure in older adults with significant muscle weakness (a condition known as sarcopenia). To determine this, we will conduct muscle strengthening exercise program to see if your muscles become stronger and if this results in lower blood pressure. One year later, we will look to see whether changes in your muscle strength effect your blood pressure.
	All subjects will undergo screening during visit 1 to confirm

WHAT WILL HAPPEN TO ME DURING THE STUDY?	eligibility. Participants who qualify will be randomly assigned (like flipping a coin) to one of two groups: 1.) a 12 week resistance training **exercise program** or, 2.) receive **exercise educational materials** for 12 weeks Participants in both groups will complete an activity questionnaire by mail/email, as well as undergo **4** study visits that will include: 1.) a DXA scan (like an x-ray) 2.) a blood draw 3.) measurements (like blood pressure and weight) 4.) balance and strength tests 5.) questionnaires As an optional part of this study, we will remove a small piece of fat tissue from your buttocks to get a closer look at how well blood is flowing through your arteries. As an optional part of this study, we will bank any blood and fat tissue that is left-over from this study (along with your health information) for future research studies.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	If you are found eligible after screening: Participants assigned to the exercise program will come to the study site **26** times as follows: 1) 24 exercise visits (2x/week for 12 weeks, 1 ½ hour each) 2) 1 mid-intervention visit (2 hours) 3.) 1 focus group discussion (1 hour) Participants assigned to receive the educational materials will receive 4 mailings total (once every 3 weeks for 12 weeks). All participants will complete **3** three-hour study visits at: baseline (day 1), post-intervention (week 17), and final (1 year), and **1** one-hour blood collection visit at baseline (day 2). As an optional part of this study, we will invite all participants following completion of the 12-week clinic visit to an exercise training session once a month until their 1 year visit (12 total optional sessions total)
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	We cannot promise any benefits to you or others from your taking part in this research. The study exercise program may work better than standard care for your condition, but we cannot promise this will happen.

WHAT ARE THE MAIN RISKS OF THE STUDY?	For this study, the most important side effects to know about are: • Minimal risk of a small amount of radiation exposure from the DXA • Side effects that are associated with exercising or the leg strength and endurance test include: - Fatigue and muscle soreness, exhaustion, and possible injury - Increased blood pressure - Some rare but serious risks that may be related to exercising include: sudden death related to the heart stopping, and heart attack • Risk associated with the blood draw and optional fat tissue removal includes: - Possible pain, bleeding, and infection - Possible bruising, temporary soreness at site - Possible allergic reaction to lidocaine (associated with optional fat tissue removal only) • Minimal risk of falling when performing balance and strength tests • Potential loss of privacy and confidentiality For details and a list of risks you should know about, please see the "What Are the Potential Risks and Discomforts of the Study" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You have the option to not participate in this study.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Dr. Deepika Laddu, Assistant Professor at 312-255-2135 or dladdu@uic.edu. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

Who may participate in the study?

You are being asked to participate in the research study because you are 60 years of age or older, have low muscle strength, and not physically active.

Approximately 150 subjects may be involved in this study at UIC.

What procedures are involved?
This research will be performed at the University of Illinois at Chicago ICOMPASS Laboratory located at 1919 West Taylor Street in Room 422, and at the Integrative Physiology Laboratory (IPL), located at 1640 W. Roosevelt Road in Suite 158.

The study procedures for all subjects are:

Screening (~10 minutes):
During the first study visit, you will undergo the following screening procedures to see if you qualify to participate in the research. If you are eligible, you will be asked to complete all Visit 1 study procedures below.

Grip Strength: A grip strength test gives us an idea of how strong (or weak) your muscles are. To do this test, we will ask you to squeeze as hard as you can on a hand grip device. We will ask you to do this two times with rest in between. If you meet the criteria for low muscle strength, we will be considered eligible and will be asked you to continue to the next stage of baseline testing. If you do not meet the criteria for low muscle strength, we will thank you for your time and your participation will cease.

Visit 1, Week 1 (~3 hour, including DXA scan):
Measurements: We will measure your weight, height, around your waist, blood pressure and heart rate.

DXA scan: As a secondary confirmation of sarcopenia, you will be undergo a Dual-energy X-ray absorptiometry (DXA) scan, which will determine the amount of muscle mass in your arms and legs. You may have had a DXA during a bone density testing for osteoporosis screening. During this test, you will lie on a table on your back for about 5 minutes while a scanner passes over your body.

Five time sit to stand test: You will be screened to determine the severity of sarcopenia by doing a five time sit to stand test. This test gives us an idea of how well and how strong your muscles are working and your overall balance while a simple task such rising and sitting down from chair. In this test, we will have you rise fully from a chair and sit back down five times as fast as you can, while being timed. You will repeat this two times. If you are determined to be sarcopenic, you will be invited to participate in the research study. If you are not-sarcopenic, we will thank you for your time, and your participation will cease.

Balance and Strength tests: You will be asked to perform a 6 meter- walking test, in which we will assess your speed. We will measure your strength using a hand grip test, in which you will squeeze the handles of a device for several times. We will also measure your muscle strength by having you do various exercises with a weighted machine or with hand-held weights. For

example, we may have you extend your knee several times against a weighted machine, pull down a weighted bar, or push a weight bar away from you while sitting down. Finally, we will examine your balance and mobility by having you sit and stand from a chair several times as well as stand toe to heel, and heel to heel.

Strength, Endurance and Equipment Education: During this visit, we will escort you over to the IPL to familiarize you with the exercise equipment so that you can practice using the proper technique.

We will also ask you to perform a series of strengthening tests (under supervision), including a knee extension, leg press, squat test, chest press, seated row or pull-down, shoulder press, and leg curl. These tests are referred to as one-repetition maximum, which represents the maximum weight that you able to lift to complete a given exercise. If you are assigned to the intervention group, this amount of weight will be used starting on day 1 of resistance training.

Questionnaires: We will ask you to complete 4 questionnaires: a medical questionnaire that also asks about medications you are currently taking, a questionnaire about depression, a physical activity questionnaire, and report on your ability to complete daily tasks such as bathing, carrying groceries or walking up stairs.

Visit 2, Week 2 (~1 hour): Blood collection and optional equipment education day
Blood draw: We will draw approximately 2 tablespoons of blood from a vein in your arm. The blood will be used to measure your levels of cholesterol, insulin, blood sugar, and interleukin-6 (a measure of inflammation). We ask that you take all prescribed medications as normal and to drink plenty of water. Since the results of the blood test are for research purposes only, they will not be shared with you.

During this visit, we also provide you the option to return back to the IPL to familiarize yourself with the exercise equipment before starting the program. This session is optional to make sure that you are comfortable with the equipment but is not necessary to continue with the program since the exercise sessions will be supervised.

After completing these Visit 1 and 2 tests, we will randomly assign you to either the exercise intervention group (a 12 week nationally recommended resistance training program) or to a control group that will receive education material and at-home tutorials by mail over the course of 12 weeks. You will not have the option to choose which group you will get. You will have a 50% chance of being assigned to either group.

The study procedures for the exercise intervention group are:

Exercise Intervention: Visit 3-27, Weeks 3-16 (1hr, 30min each)
Visits 3 through 27 will include the 12-week exercise intervention. You will be asked to come to the IPL twice a week to undergo supervised muscle-strengthening exercise. Each session will begin with a 10-minute warm-up, which will include low-intensity treadmill walking, light stretching and flexibility exercises. Additionally, we will measure your blood pressure and heart rate before, one time during, and immediately after the exercise session.

Next, we will begin progressive resistance training (as recommended by the American Heart Association), and will include exercises targeting a variety of muscle groups. The exercises will include: seated leg press, chest press, shoulder press, pull down (upper back), triceps extension, knee extension, knee flexion, bicep curl, and calf-raises.

During the resistance training, you will start out with 1 to 2 sets of each exercise (with 10-15 repetitions per set at one-third to one half of your one-repetition maximum). Once you are comfortable at this level, we will gradually increase the weight load and resistance (the number of repetitions will be decreased at this point). In addition to measuring your performance, we will also ask you about how hard you think the exercise, which may range from "this exercise is easy to do" to "this exercise is very, very hard".

All exercise testing will be monitored by a qualified exercise physiologist and research personnel. We will end each session with a 5-minute cool-down, including stretching, and flexibility exercises. We will provide post workout snacks and water throughout the 12-week intervention.

Mid-Exercise Intervention Evaluation: Visit 16, Week 8 (2 hours)
After you have completed half of the exercise program, we will like to examine your progress. During this visit, we will ask you to perform the same one-repetition maximum test you did during one of your familiarization visits during **week 1,** which will give us an idea if the exercise program is strengthening your muscles**.** We will also measure your blood pressure, and have you repeat the DXA scan, balance and strength tests you did during **visit 1**.

Post-Intervention: Visit 28, Week 17 (3 hours):
After the intervention is complete, you will repeat all the tests performed during **visit 1.** A blood draw will be included in this visit.

Focus Group Discussion: Visit 29 Week 18 (1 hour):
We will ask you to participate in an open discussion (focus group) to provide feedback about the exercise study and tell us what things motivated or hindered your participation, as well as what you might change in a future study.

Final: Visit 30, ~Week 69 (3 hours):
One year after completing the intervention, we will ask you to come back to the ICOMPASS laboratory to repeat all the tests performed during **visit 1.** A blood draw will be included in this visit.

The study procedures for the control group are:
If you are assigned to receive education material by mail or email, you will receive materials from the National Institutes on Aging (NIA) Go4Life® every 3 weeks, for a total of 12 weeks. The materials include non-specific at-home exercises focused on endurance, balance, strengthening, and flexibility with minimal equipment and items commonly found at home. You will be instructed to perform the exercises on your own for 12 weeks.
With each exercise mailing, we will include an exercise log which we ask that you fill out with

the type of exercise performed and for how long each day, along with any comments you may wish to share. We ask that you complete the exercise log for every day exercise is performed (regardless of whether it is from the exercise materials we provide you or other exercise, or if no exercises performed), and return to the ICOMPASS laboratory using the pre-stamped envelope we provide. We will give you the dates to return the filled out exercise logs, which will be approximately once every month (3 total).

In addition, you will complete three 3-hour study visits at: baseline (day 1), post-intervention (week 17), and final (1 year). The visits will include all the same tests that are performed above listed under Visit 1 including: a DXA scan, measurements, balance and strength tests, questionnaires, and a blood draw.

For all subjects:

- You will receive a reminder phone call, or text, prior to each of your study visit.
- At week 38 we will mail/email you a questionnaire to reassess your physical activity
- After completion of the 12 week program, you will receive a follow-up call once a month to see how you are doing, if you are continuing to exercise, and what types of exercises you are doing, and how often you are doing these exercises.

Optional: Exercise Session visits one time per month (~1 hour; 12 total sessions)**:**
Following completion of the 12 week clinic visit up until the 1-year clinic visit, you will be given the option to return to our exercise gym to complete a resistance training exercise session on your own, once a month for a total of 12 sessions. The purpose of these optional exercise sessions are to help you to start or continue to do exercises that will strengthen your muscles and improve your ability to function day to day. A trainer will be present to answer any questions and make sure you are performing the exercises safely, but they will not provide a formal exercise plan or provide any one-on-one training. Additionally, we will measure your grip strength and blood pressure during these visits. These sessions are optional.

Optional: Removal of Fat Tissue to test Microvascular Function (~1 hour): During Visit 2 and again at Visit 28.
The purpose of this optional procedure is to examine how your muscles influence the ability of the smallest arteries (type of blood vessel) in the body to pump blood to your heart. We refer to this process as evaluating your microvascular function. The procedure is associated with minimal discomfort or risk. To do this, we will numb a small region of the buttocks region with a medicine (anesthetic, lidocaine) that will decrease the likelihood of pain. We will then remove a small amount (1-2 ml or less than half of a teaspoon) of fat that is located right beneath the skin. In the case that enough fat cannot be removed, we may suction out the fat with a small needle (syringe) from the same site. After, we will close up the site that was cut with Steristrips (a type of dressing used to close small cuts) and cover with a waterproof bandage. We ask that you keep the area dry for 24-48 hours after which the bandage can be removed. The Steristrips will remain in place until they spontaneously fall off which may be in approximately 4-5 days.

What we will do with the fat sample: We will take the sample fat tissue and remove the small arteries in our laboratory and test how well they pump blood under different types of "blood

pressures". This will allow us to see how well and how efficient your arteries are working to pump blood to the heart and throughout the body when you have low, normal, or high blood pressure.

This procedure is optional. You can still be involved in the study and chose not to participate in this optional procedure.

☐ I agree to participate in the microvascular function testing which will involve removal of a small amount of fat tissue and will allow for a better understanding of how muscle is related to blood pressure.
Initials _____.

☐ I **do not** agree to participate in the microvascular function testing which will involve removal of a small amount of fat tissue and will allow for a better understanding of how muscle is related to blood pressure
Initials _____.

Does the study involve data and/or tissue banking?

As an optional part of this research study, we are requesting to bank (store long-term) any left-over blood and fat tissue from this study (along with some of your health information) for future research studies on obesity, cardiovascular disease or inflammation being conducted by the principal investigator, Dr. Deepika Laddu. If you agree, the following information will be stored indefinitely on a secure (password protected) computer in the Department of Physical Therapy at UIC: the study arm you are place in (exercise intervention or control group), your age, race/ethnicity, diagnosis of sarcopenia, results from balance, hand grip and muscle strength tests, sex/gender, blood test results (including cholesterol, insulin, blood sugar, and IL-6), results from microvascular testing (if you elect for this option), weight, height and body mass index (amount of body fat and muscle). Your participation in the data/blood and tissue banking is optional and will not affect your involvement in the main study (should you choose not to participate.) The blood and tissue samples and health information will be stored coded in the UIC College of Applied Health Sciences, until the end study when key to the code is destroyed so they will be completely de-identified (without any link to your identity). Only Dr. Laddu and approved study personnel will have access to them.

Please select one below:

☐ I agree to allow my blood and fat tissue and health information to be kept by Dr. Deepika Laddu, in the Department of Physical Therapy, at the University of Illinois at Chicago for future research to learn more about how to prevent, detect, or treat musculoskeletal conditions and high blood pressure.
Initials _____.

☐ I **do not** agree to allow my blood and fat tissue and health information to be kept by Dr. Deepika Laddu, in the Department of Physical Therapy, at the University of Illinois at

Chicago for future research to learn more about how to prevent, detect, or treat musculoskeletal conditions and high blood pressure.
Initials _____.

☐ I agree to allow the researchers to contact me about future research..
Initials _____.

☐ I **do not** agree to allow the researchers to contact me about future research.
Initials _____.

Will I receive my results from the study?

All results from this study are for research purposes only. As part of this study, we will provide you a copy of the DXA scan to keep for your own records. However, we cannot provide any medical advice concerning the results of the scan. We may learn things about you from this study which could be important to your health or treatment. If this happens, this information will be shared with you. For example, we may find that you have low bone mineral density from the DXA scan results. If this is the case, we will notify you in person, however, we cannot provide any advice, nor will we share results with your physician regarding this finding. You may need to meet with experts to help you learn more about your study results. The study will not cover the costs of any follow-up actions.

What are the potential risks and discomforts of the study?

- Blood draw: There may be temporary discomfort from the needle stick, bruising, excessive bleeding, and rarely, infection. Risks will be minimized by use of sterile technique and applying sustained pressure to the site.

- DXA: minimal risk, involves a small amount of radiation. The radiation exposure from this research is about 90 microsievert (9 millirem, mrem, total for 3 scans). This research study will give you the same amount of radiation as you would get from living in a high altitude city such as Denver for 4 days, or taking 1 airplane flights from New York to Los Angeles. The radiation dose we have discussed is what you will receive from this study only. Importantly, this exposure will not add to the risk of the research.

- Minimal risk of falling or possible injury when performing the four tests of balance and strength.

- Exercise, muscle strength assessments and endurance tests: you may experience some fatigue and muscle soreness, exhaustion, and possible injury; Increased blood pressure. Rare incidences of exercise-related sudden death related to the heart stopping, and heart attack.

- Questionnaires: you may feel uncomfortable providing any personal information. If you are uncomfortable, we will advise you to skip any questions that you do not wish to answer.

- Focus group questions: You may feel uncomfortable, shy, or nervous speaking in front of other participants.

- A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

- Optional Fat Removal Procedure: There is a risk of infection or excessive bleeding with fat removal. However, these will be minimized using sterile technique and pressure, and all procedures will be performed by a physician or advanced practice nurse. It is possible that temporary soreness, bruising, or bleeding could occur at the incision site. This will be minimized with an ice pack administered 10-20 minutes following the procedure.
- It is also possible to develop an allergic reaction to lidocaine which is the medicine that will be used to numb and reduce pain before removing the fat tissue. The reaction could range from minor itching and a rash to severe respiratory arrest and death. However, this is a possibility with all medications and unlikely since a very small amount will be used. We will perform the procedure if you report having no known history of an allergic reaction to lidocaine or other pain numbing medicines.

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The National Institutes of Health, the sponsor of the research.

A possible risk of the study is that your participation in the study or information about you and your health might become known to individuals outside the study. Your research data, and specimens will be stored coded, on a password protected computer, in a locked office to prevent access by unauthorized personnel. Your study information will be given to the co-investigators in a coded format.

Your individual data will be stripped of all direct and indirect identifiers at the end of the study.

When the results of the study are published or discussed in conferences, no one will know that you were in the study.

A description of this study 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.

Focus Groups or Group Discussions:
Although we ask everyone in the group to respect everyone's privacy and confidentiality, and not to identify anyone in the group or repeat what is said during the group discussion, please remember that other members of the group may accidentally disclose what was said.

What if I am injured as a result of my participation?
If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Laddu at telephone number (312) 355-2135.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of UIC.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research study?
There are no costs to you for participating in this research study.
Will I be reimbursed for any of my expenses or paid for my participation in this research study?
You will receive up to $25 for each completed clinic visit (see table below). You will only receive compensation after the measurements for the specified visit has been completed. If you do not finish the study, you will be compensated for the visits you have completed. If you are assigned to the exercise intervention and complete all exercise session and clinic visits, you will receive a total of $225. If you are assigned to the group that receives educational materials only and complete all clinic visits, you will receive a total of $100.

Visit	Compensation Amount	Payment type
Education and exercise Group – total $100 if all three visits are completed		
Baseline testing (Clinic visit 1 and visit 2)	$25 will be received	**Cash, check or GC**
Post-intervention testing (Clinic visit 28)	$25 will be received	**Cash, check or GC**
1-year testing (Clinic visit 30)	$50 will be received	**Cash, check or GC**
Exercise participants only (may receive up to an additional $125 if 24 sessions are completed)		
Completion of 4 sessions	$20 will be received	**Cash, check or GC**
Completion at 8 sessions	Additional $20 will be received	**Cash, check or GC**
Completion at 12 sessions	Additional $20 will be received	**Cash, check or GC**
Completion of 16 sessions	Additional $20 will be received	**Cash, check or GC**
Completion of 24 sessions	Additional $45 will be received	**Cash, check or GC**

For example: if 8 sessions total are completed, you will be awarded $40; if you complete 16 sessions total, you will be awarded $80

Optional fat biopsy: if you opt in for the optional fat biopsy procedure, you may receive additional $10 compensation for providing a biopsy prior to starting the intervention (baseline) and $10 after completing the 12 week intervention by cash/check (up to $20 total if baseline and post intervention biopsies are provide).

All cash or checks can be picked up 1919 W. Taylor St. in either Room 443 or the ICOMPASS laboratory, Room 422; alternatively, the check can be mailed to you if you are unable to pick up the check in person.

In addition, we may reimburse for transportation to/from the University for study-related visits using the bus/train/PACE pick up throughout the study.

We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service (IRS).

Additionally, as a token of our appreciation for your continued participation, we will also hold a raffle. If you are in the intervention group, you may receive up to 6 raffle tickets for attending and completing exercise training sessions over the 12 weeks. If you are in the control group, you may receive up to 6 raffle tickets for returning completed exercise logs over the 12 weeks. The raffle tickets will be entered in the raffle box. One raffle ticket will be drawn every month over the 12 weeks for a prize. Raffle prizes may include a water bottle, t-shirt, coffee mug; resistance band, $5 Walgreens gift card, etc.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Can I withdraw or be removed from the study?
If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty.

For your safety, you should consider the researcher's advice about how to leave the study. If you leave the study before the final planned study visit, the researcher may ask you to complete the final steps, such as the reassessment of visit 1 tests, and provide reasoning as to why you wish to leave.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You were to object to any future changes that may be made in the study plan.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Laddu in writing at the address on the first page. Dr. Laddu may still use your information that was collected prior to your written notice.

Remember:
Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research study. I will be given a copy of the signed and dated form.

_____ _____
Signature Date

_____
Printed Name

_____ _____
Signature of Person Obtaining Consent Date (must be same as subject's)

_____
Printed Name of Person Obtaining Consent