ID: E1813-R Multimodal Exercise and Weight Loss in Older Obese Veterans with Dysmobility

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Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date: _____

Title of Study: Multi-modal exercise and weight loss in older veterans with dysmobility

Principal Investigator: Leslie Katzel, MD, PhD, 410-605-7248 VA Facility: Baltimore 512

STUDY No: HP-00069566
Study consent form version #8

SPONSOR: Veterans Health Administration

Your participation in this research study is voluntary. You may ask questions about this study at any time. Please read the information below carefully before making a decision about whether to participate in this research study.

In this form, VAMHCS means the VA Maryland Health Care System. All testing and procedures will take place at the VAMHCS.

PURPOSE OF STUDY

Obesity is a major risk factor for mobility problems in older adults and many older adults use a walking aid to help with their mobility. The use of a walking aid changes normal walking patterns and makes walking harder, leading people to have more functional problems. The purpose of this study is to test the effects of 3 months of a multi-modal balance intervention (MMBI) with supervised weight loss on fitness, functional performance, balance, and economy of gait. You will be one of 240 participants in the VAMHCS. Your participation in this study is voluntary. The research will be conducted at the VAMHCS. The entire study will take approximately 4 years to complete. Your participation in the study will last up to 24 months. The study procedures are outlined below.

PROCEDURES

Visit #1: Screening visit (Phase 1)
Strict social distancing and COVID -19 precautions will be followed for all in person visits. You will be required to wear a face mask at all times during your visits to the VA including during testing and exercise training. Prior to all in person visits you will be contacted by the study staff using the standard COVID-19 Screening Tool. In addition, whenever possible, participants reporting to a VA facility should use Screen Pass as the preferred method of on-site screening. You will be provided with a handout detailing these COVID-19 screening procedures. This first visit will take approximately 2 hours and will occur at the Baltimore VA Medical Center (BVAMC) Geriatric Research, Education and Clinical Center (GRECC). It might take an

additional visit to perform these tests. If you agree to participate, during the first visit you will complete the following:

Consent (Approximately 30 minutes): Prior to the first in person visit, you will be mailed a consent form and HIPAA authorization form. During the visit for the consent process, we will review all the details of the research program in a private setting. You will be given enough time to have your questions answered, concerns addressed or clarified, and time provided for you to consider whether or not you wish to participate. A copy of this typed and signed consent form will be given to you.

Screening (Approximately 90 minutes): After you provide your written consent, at this first visit, a medical history and physical examination will be performed. A resting electrocardiogram (EKG – electrical reading of the heart) will be performed and we will measure your height and weight. In addition, a brief test of memory, thinking, and concentration will be performed. You will also be asked questions about your ability to complete different activities during the day ("activities of daily living"). If you receive your health care at the VA we will also access your medical file to obtain additional information about your medical history and medications. We will also assess your usual walking speed across a certain distance to determine how fast or slow you walk. If you were enrolled in this study before the COVID-19 pandemic and it has been a while since we have been in contact with you, we will review your medical history and medications before you resume participation in the study.

You will have blood drawn to make sure you are eligible for this study. Prior to this blood draw you will be asked to fast (not eat or drink anything except for water and your usual medications) for 12 hours. You may, however, take your medicines with water. Approximately 20 cc, which is equal to 4 teaspoons of blood, will be drawn to measure blood-based levels of blood sugar (if you are diabetic), cell counts, and cholesterol. Additionally, approximately 40 cc, which is equal to eight teaspoons of blood, will be drawn to check measures of inflammation in the body and we will also be storing these bloods for future research. These samples will be stored until the completion of the study at the Division of Gerontology at the BVAMC. The tubes containing your blood samples will be coded so that your name cannot be readily identified. However, your identity can be determined by matching the code on the sample with your name in the study file. Your blood samples will be used only for research and will not be sold or used for the production of commercial products. Your samples will not be used to generate cells for genetic testing. In this future research, we will measure risk factors for stroke, difficulties in thinking and memory,

and poor physical function. As new laboratory techniques become available, we may measure additional factors that influence risk of these problems. Reports about the research done with your stored blood samples will be included in your study file and will be kept confidential. You will not be provided with the results of these tests as these measurements are for research purposes only and are not done as part of medical care. You have the opportunity to request that your samples be withdrawn from future use. To do so, please inform Dr. Katzel at 410-605-7248 to request that your samples be destroyed.
After your blood is drawn, you will be given a light meal. If new medical abnormalities are detected during this visit, we will tell you and with your permission, results will be forwarded to your primary doctor.

Visit #2: Baseline testing (Phase 2)
If you are eligible for the study after the initial screening, you will return for your baseline testing (before you start the training program). This baseline visit will last approximately 4 hours and will occur at the Baltimore VA Medical Center (BVAMC) Geriatric Research, Education and Clinical Center (GRECC) and/or the BVAMC Annex at 209 W. Fayette Street and/or the Geriatric Wellness Center at the Loch Raven VA Medical Center at 3901 the Alameda. It might take an additional visit to perform these tests. Depending upon your schedule, some of these tests listed under phase 2 might be performed at phase 1. The order in which the tests will be completed will vary. There is flexibility in the timing of these assessments depending upon your schedule and the study staff's schedule.

The tests that will be done during this phase of the study are as follows: 1) vital signs; 2) physical function testing; 3) questionnaires; 4) lateral mobility and balance tests; 5) lower extremity strength tests; and 6) body composition scans.

You may be asked to repeat one or more of the research tests, should it be required, if the sample that was collected is not enough to study, or an unexpected problem occurs during the test (for example, with our equipment). Also, a test may be eliminated on an individual basis based on medical judgement. The results of all tests will be made available to you at the completion of your participation in the study. However, you will be immediately informed of any abnormal test results that have a direct effect on your health. The order of these tests may vary.

1) Vital signs: We will measure your vital signs (blood pressure, weight, heart rate), and ask you about your mediations. You may eat, drink, and take medications as usual before these measurements.

2) Physical function tests: you will be asked to perform a number of tests of physical performance. These tests will be administered by the study staff and each test will be explained to you. These include tests of balance, how quickly you can stand up from a chair, and the time it takes for you to walk various distances. One of these walking tests involves walking continuously for six minutes. You may also be asked to wear a small device, called a QTug, above both your knees about the size of a deck of cards. This will give us information on how you walk. We will measure your grip strength. We will also take measurements of different body circumferences. This testing will take about 45 to 60 minutes.

3) Questionnaires: you will be asked to complete, in private, forms about your feelings about your ability to complete different activities during your day ("activities of daily living"), your levels of physical activities, an assessment of your learning and memory, and your feelings of function and disability. These questionnaires will take about 10 minutes.

4) Lateral mobility and balance tests: we will measure how good your balance is by assessing your ability to change directions while stepping and getting up from a chair and walking. You may again be asked to wear the small QTug device above your knees during this test. This testing will take about 10 minutes.

5) Lower extremity strength tests: we will measure your leg and hip strength using either a Biodex Dynamometer or Keiser equipment. We will measure the amount of weight you can move one time with your legs from both standing and seated positions. You will be asked to perform movements several times per joint and leg. This testing will take approximately 60 to 90 minutes.

6) Body composition scans: we will use two x-ray tests to measure the amount of your muscle and fat:

Computerized tomography scan (CT scan): you will have CT scans of the abdomen and thigh. CT scans are painless, but do involve exposure to low doses of x-rays. You will lie on a large machine and your lower body will pass through a large ring. Your head will not be

enclosed. The CT scan takes about 20 minutes to complete. They will measure the muscle, fat, and bone tissues in your legs and belly.

Dual x-ray absorptiometry scan (DXA scan): you will lie comfortably on the large DXA machine while your body is scanned to determine total body fat and muscle mass. In addition, the DXA will measure bone density (how solid your bones are). This is a painless test, but it involves exposure to low-level radiation. The DXA and CT scans might not be performed, based on the availability of testing times in radiology. This will take about 30 minutes to complete.

Food questionnaires: You will also complete 3 24-hour food recalls that will be reviewed by the study dietician and analyzed for nutritional content.

Initial Intervention Phase (Phase 3)
This phase will last 3 months. The exercise program includes two components: center-based one-on-one supervised training sessions at either the BVAMC Annex located at 209 W. Fayette Street or the Loch Raven VA Medical Center Geriatric Wellness Center facility located at 3901 The Alameda and a home tele-health exercise program. The center-based sessions initially will be once a week or once every other week and consist of balance exercises (about 30 minutes), a supervised obstacle course (about 10 minutes), and lower body and core body strength exercises (about 20 minutes). You will start exercise at a very low level. Over the three months of the training, the exercises will gradually increase in difficulty to challenge you. Each in person session will be monitored to ensure your safety, including measurements of heart rate, blood pressure, and blood sugar (if you are diabetic), and how hard you feel you are working. The number of in person sessions will be tapered over the three months. Strict social distancing and COVID -19 precautions will be followed for these in person sessions. In addition to the in-person sessions, you will exercise two or three times a week via tele-health video sessions. These group exercise classes will be led by exercise physiologists and will include some of the exercises that you perform in the center-based sessions. You will also be encouraged to walk on your own. You will also attend nutrition sessions once a week via telehealth. You will receive individual dietary recommendations, based on your food preferences, designed to produce about a 5 to 10% weight loss over the first three months of the study. You will also be encouraged to take over the counter supplements based on guidelines specific for older adults. You will receive guidance on nutrition education, portion control, and weight management skills. You will be asked to keep weight and food diaries to monitor your progress.

3 month Testing (Phase 4)

Three months after beginning your participation in the intervention phase, you will undergo repeat testing. The order in which the tests will be completed will vary. There is flexibility in the timing of these assessments depending upon your schedule and the study staff's schedule. In addition, some of the testing might be done remotely via telehealth or telephone to further reduce in person visits.

Maintenance Phase Training (Phase 5)
This is optional. You can continue with the telehealth exercise sessions and nutrition sessions. This phase of the study will another three months.

6 month Testing (Phase 6)
At the end of six months of training you will undergo repeat functional testing. The order in which the tests will be completed will vary. There is flexibility in the timing of these assessments depending upon your schedule and the study staff's schedule.

Retention Phase (Phase 7)
For this optional phase, you will be provided a home exercise program and you may attend monthly video nutrition classes to aid in the maintenance of weight loss.

12 and 24 month Testing (Phase 8)
At the end of the retention phase, you will be asked to complete the functional testing and questionnaires. There is flexibility in the timing of these assessments depending upon your schedule and the study staff's schedule.

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

___ Yes, my information may be stored in the registry and I may be re-contacted for information

___ No, my information may not be stored in the registry and I may not be re-contacted for information.

Subject initials _____ Date _____

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

If you choose to participate in this study, you will be responsible for attending the scheduled exercise and/or nutrition sessions and testing visits and for notifying study staff of changes in your health status, symptoms, and/or medication regiment.

POTENTIAL RISKS/DISCOMFORTS:

There are potential risks involved with your participation in several of the study procedures; however, the procedures have been planned by the investigators to minimize your discomfort and the danger of any major complication. Before you participate in any aspect of this research, the procedure will be explained to you in detail and you may refuse at any time. Risks associated with different portions of the protocol are described below:

COVID-19: In this COVID-19 pandemic, there is a small chance that you will become infected with COVID-19 due to your participation in the in-person visits to the facility. We have taken extensive steps in accordance with CDC guidance and local VA policies to minimize this risk. We will follow VAMHCS guidelines as they pertain to patient screening and access to VA facilities. All participants will be called the day before their appointments and pre-screened over the phone using the standard COVID-19 Screening Tool. You will be pre-scheduled for exercise and may only attend during your scheduled appointment slot. Any positive phone screens or in person screens will result in cancellation of your appointment, and you will be referred back to your health care provider for further instructions and follow-up. You must wear a face mask at all times when you are in the facilities, including during your exercise session. Staff will extensively clean the equipment as per VA policies. You will be provided with an information sheet detailing all of the COVID-19 procedures. If you do not follow the COVID-19 infection guidelines, you will be withdrawn from the study.

Blood sampling: Blood tests will be performed that will require blood to be drawn from a vein in your arm. Blood draws will be performed by a trained phlebotomist or research nurse. Bruising

and infection are possible but unlikely complications of this blood draw procedure. The total amount of blood to be drawn during your participation in this research program is approximately 130 cc or 26 tsp.

Questionnaires: The questionnaires are used as part of standard medical evaluations and are of minimal risk. You will be able to answer the questions privately.

Tests of Physical Performance, Balance, and Gait Assessments: Tests of physical performance, lateral mobility and balance, and gait assessments will be performed at the Baltimore VA Medical Center and/or the BVAMC Annex and/or the Loch Raven Geriatric Wellness Center. These tests involve a variety of timed walks, getting up from a chair, and tests of balance. There are no known risk to wearing the QTug during these tests. There is a small risk that you will fall, get chest pain, get short of breath, or become dizzy during these tests. The exercise technician will stop the test if you have any significant symptoms such as chest pain. There is a small risk of muscle strain or pulled muscles in the measurements of strength. We have performed >1000 tests of functional performance without complication. We have taken care to minimize such risks. None of the tests of physical performance will be performed prior to you receiving a medical evaluation. Patients with unstable medical conditions will be excluded. The exercise technician who will be administering these tests is trained in CPR.

Strength Testing: Tests of strength will be performed at the Baltimore VA Medical Center and/or the BVAMC Annex and/or the Loch Raven Geriatric Wellness Center. There is a small risk of tenderness or swelling around the joints or muscles during testing. You may also experience some muscle soreness, but the risk of more serious injury such as a muscle sprain is small. The exercise technician will teach you the proper way to do the exercise and will also watch over you during your testing. The exercise technician will stop you if you have any significant symptoms such as chest pain, dizziness, arm, or leg pain.

Body Composition Testing: The radiation dose which you will receive as a result of taking part in this study includes radiation from the DXA machine and the CT scan. Using the standard way of describing radiation dose, in the 1st year you will receive 378 mrem to your total body, 723 mrem to your bladder, 603 mrem to your ovaries/testes, and 483 mrem to your spleen in one year. In the 2nd year you will receive 126 mrem to your total body, 241 mrem to your bladder, 201 mrem to your ovaries/testes, and 161 mrem to your spleen. The total amount of radiation dose you will receive if you complete the study is 504 mrem to your total body, 964 mrem to

your bladder, 804 mrem to your ovaries/testes, and 644 mrem to your spleen over 2 years. During your participation in this study other organs and tissues may receive lesser radiation doses. Please be aware that this radiation exposure is necessary for research purposes only, and is not essential for your medical care. The University of Maryland (UMB) and VA Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being within the UMB/VA Radiation Safety Guidelines for research subjects of 3,000 mrem to any tissue in a 13-week period and 5,000 mrem in one year. The radiation dose you will receive to your total body, bladder, ovaries/testes, spleen, liver, bone, and kidneys is in the range of 300-5000 mrem, which is equivalent to the exposure limit of 5000 mrem per year that is established for radiation workers such as physicians and X-ray technologists who work with radiation and this level of exposure has never been associated with any definite adverse effects. The radiation dose to all other organs and tissues is in the range of 0-300 mrem, which is equivalent to the level of natural background radiation that you would be exposed to each year living in this area of the country. Background radiation levels will vary from place to place, but this level of exposure has never been associated with any definite adverse effects. Thus, the risk to you, if any, is estimated to be small. Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care. Please advise your doctor if you have taken part in research studies at UMB or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include x-ray studies conducted in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine studies, e.g. thallium scan of your heart, and scans of your brain. Should any study-related problems occur, medical treatment will be provided.

Exercise Training: Exercise training is associated with the risk of cardiovascular complications such as chest pain, heart attack, or sudden death, and complications related to stress and strains of muscles, twisted ankles, or falls. This risk is increased in people who have heart disease, poor circulation to the legs, or stroke. The risk of heart attack in these people is one in 300,000 hours of exercise, and risk of death is one in 800,000 hours of exercise. The risk is lower if you do not have evidence of heart disease. In over 1,000,000 miles of walking or jogging, there has been only one fatal event at the Cooper Exercise Clinic in Dallas, Texas (a large exercise clinic for heart disease patients). Due to the nature of the training required to improve balance, there is a risk of stumbling or falling during the balance training portion of the exercise session. To minimize this fall risk, trained exercise physiologists will be stationed appropriately to assist you during the balance training. Exercise specialists will teach you the proper way to do the exercises

and will watch over you while you exercise. To minimize exercise training risks, you will first undergo a medical evaluation and a screening exercise treadmill test. Your heart rate and blood pressure will be assessed by exercise physiologists trained in CPR before and after each exercise session, or more frequently if indicated. If blood pressure or heart rate go too high, or you develop an irregular heart rate, chest pain or leg cramps, the training will be stopped immediately. A clinical provider is on call and can be reached by phone for consult in case of any problems. An AED is available on site and should there be any unanticipated medical emergencies, staff can initiate emergency care by calling 911. If 911 is activated, you will be taken to the nearest available hospital for care. We believe that it is highly unlikely that you will develop a medical emergency that would require the 911 system to be activated as in more than 27 years of training more than 1000 research subjects, we have had only 1 subject who had a heart attack during training.
Muscle soreness and injury can also occur during testing and training, but you will be taught proper stretching and exercise techniques to minimize this risk. If soreness does develop, you will stop exercise and be taught to stretch and ice the sore muscles to relieve the soreness. However, monitoring by trained personnel during exercise training limits your risk for these things to happen.

Confidentiality: As with any scientific research study involving the collection of potentially sensitive medical information, participation in this study may involve a risk of a breach in confidentiality. Study investigators have taken measures to minimize this risk. We will store data in a secure location such as a locked office and locked cabinet, and electronic data will be password protected and stored on VAMHCS computers.

Privacy: Loss of privacy is a risk of participation in this research. The investigators have taken steps to protect your privacy. All research testing activities will be conducted in a private examination/interview area, away from public traffic, where only the member(s) of the study research team may see or hear you. Only members of the study research team will interact with you or have access to you during these study activities. However, the other study participants in your exercise or nutrition group will know that you are participating in the study with them.

In addition to these risks, there may be risks in this study which are not yet known.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. The potential benefits of participating in this study may be: learning about your risk factors for heart disease and obtaining a comprehensive evaluation of your physical fitness. The tests performed will help you to know how healthy you are compared to others your age. You will learn about your physical fitness, functional performance level, and whether or not you have an immediate health concern. The benefits of exercise may include improvements in your physical function. In addition, exercise training may lower your risk for heart disease and mortality, and may also decrease symptoms of depression, as well as improve your feelings of well-being. The scientifically documented benefits of increased physical fitness on general health outweigh the risks of study participation.

ALTERNATIVES TO PARTICIPATION

You may choose not to participate in this study or withdraw at any time without penalty or health risk. If you choose not to take part, your healthcare at the VAMHCS will not be affected. You will not lose any VA or other benefit to which you are entitled. You could pursue exercise programs and/or nutrition classes outside of this research study. Other nutrition education or physical activity programs may be available in your area and may include non-VA hospital, physician, or private physical activity programs for a fee. Physical activity programs without a fee also may be available. If circumstances develop which cause you to be removed from the study, efforts will be made to offer your alternatives. The sponsor may stop the study at any time or stop the Investigator's participation.

COSTS TO PARTICIPANTS

You will not be charged for any treatments or procedures that are performed for research purposes in this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study. The only cost to you is transportation to the Baltimore VAMC and the Baltimore VAMC Annex and the Loch Raven Geriatric Wellness Center. Parking at the medical center, annex, and Loch Raven VA medical center and all research tests are free to participants. Some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payments will continue to apply to medical care and services provided by VA that are not part of this study.

PAYMENT TO PARTICIPANTS

You may be reimbursed up to $250 for participation in this study. This will help you to pay for your transportation costs to come for your research visits. Payments will be spread out over the course of the study. If you stop the study early, you will be paid only for the portions of the study

you have completed. You will be paid $50 after the completion of baseline testing, 3 month testing, 6 month testing, 12 and 24 month testing.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

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

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: Dr. Leslie I. Katzel, MD, PhD at 410-605-7248.

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

CONFIDENTIALITY AND ACCESS TO RECORDS

As with any scientific research study involving the collection of potentially sensitive medical information, participation in this study may involve a risk of breach in confidentiality. Study Investigators have taken extensive measures to minimize this risk. All research data will be stored together in secure locations.

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the VA Office of Research and Development (ORD), the VAMHCS Office of Research Compliance, VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS), and other representatives of this organization. The monitors, auditors, IRB, the Food and Drug Administration, will be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access. Your research records will be stored at the VAMHCS.

Participant Name: _____ Date:_____

Title of Study: Multi-modal exercise and weight loss in older veterans with dysmobility

Principal Investigator: Leslie Katzel, MD, PhD, 410-605-7248 VA Facility: Baltimore 512

A description of this clinical trial will be available on http://www. ClinicalTrials.gov, as required by US Law. This web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.
The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect stations of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use, and Disclose Protected Health Information for Research." However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.
If you are a patient in the VAMHCS, 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. You will receive a results packet summarizing your testing results at the end of your participation in the study. The research staff will be available to explain your results to you.

If you are enrolled in this study, HP-00069566, you are taking place in a study that is similar to another study in the GRECC, HP-00060757 (Improving Balance and Mobility in Older Veterans, PI Leslie Katzel, MD, PhD). Testing procedures and training are similar between the two studies. Therefore, with your permission, we are asking to share your testing data with HP-00060757 for a more comprehensive look at different participant populations doing the same tests.

____Yes, my results can be used for both studies

____No, my results can't be used for both studies

Subject initials: _____ Date: _____

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Leslie I. Katzel at 410-605-7248.

There are no adverse consequences (physical, social, economic, legal, or psychological) if you decide to withdraw from this research. However, a written withdrawal is requested. It should be sent to the investigator, Leslie I. Katzel, at the following address: 10 N. Greene Street (BT/18/GR), Baltimore, MD 21201. If you withdraw from this study, already collected data may not be removed from the study database. You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include not following study-related direction from the investigator or if the person in charge decides that your participation in the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

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

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, you may contact Dr. Leslie I. Katzel, MD, PhD at 410-605-7248.

Please read the University's statement below.

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

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

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

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

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

VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56512
Room 3D-158

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

Participant Name: _____ Date: _____

Title of Study: Multi-modal exercise and weight loss in older veterans with dysmobility

Principal Investigator: Leslie Katzel, MD, PhD, 410-605-7248 VA Facility: Baltimore 512

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date: _____

Title of Study: Multi-modal exercise and weight loss in older veterans with dysmobility

Principal Investigator: Leslie Katzel, MD, PhD, 410-605-7248 VA Facility: Baltimore 512

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

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

_____
Participant's Signature

Date: _____

_____
Investigator or Designee Obtaining Consent Signature

Date: _____