Wake Forest®
School of Medicine

Section of Gerontology & Geriatric Medicine

UPLIFT (Utilizing Protein During Weight Loss to Impact Physical Function)
Informed Consent Form to Participate in Research
Denise Houston, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research study is to help determine the appropriate diet composition (i.e., amount of protein, carbohydrate, and fat) to preserve muscle mass and improve physical function and weight loss maintenance in older adults. Your participation in this research will involve 7 assessment visits over the 20-22 month study period.

Participation in this study will involve a 6-month weight loss intervention with diet sessions once per week and exercise sessions 3 times per week. You will be asked to prepare your own meals from the meal plans provided and consume either a protein or a carbohydrate supplement. Some participants will be asked to continue consuming the supplement for an additional 12 months during the weight maintenance phase. Assessments include vital signs (weight, height, blood pressure); a blood draw; questionnaires on your medical history, physical and mental abilities; an exercise stress test; and physical function tasks such as hand and leg strength, balance and walking. You will also be asked to have a DXA or bone density scan and a CT scan. All research studies involve some risks. The risks with physical function testing and exercise include muscle strains or pulls and a risk of falling. Risks will be minimized by having experienced/trained staff conducting all assessments/exercise sessions. The DXA and CT scans involve exposure to radiation. Please read the risk section for more information about risks. If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study include receiving information about your health including your blood sugar, cholesterol, body composition and bone density, and physical function. These tests will help you to know how healthy you are compared to others your age.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Classes and testing procedures similar to those offered in this study are available in the community and usually involve a charge to participants. You will not lose any service, benefits, or rights you would normally have it you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Denise Houston, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are 65-85 years old, fit the height and weight requirement, and have expressed interest in participating in an 18-month intervention weight loss study. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

This study is being conducted to help determine the appropriate diet composition (i.e., amount of protein, carbohydrate, and fat) to preserve muscle mass and improve physical function and weight loss maintenance in older adults.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 225 people will take part in this study at Wake Forest Baptist Medical Center. In order to identify these potential 225 participants, we may need to screen as many as 600 because some people will not qualify for the study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study by signing this consent form, you will be asked to come to the Wake Forest Baptist Medical Center to complete two screening visits to see if you qualify for the study. If you qualify, you will then complete two more testing visits before beginning a 6-month weight loss program followed by a 12-month weight maintenance phase. You will also be asked to complete one testing visits after the first 6 months of the weight loss program, one testing visit at 12-months, and one testing visits at the completion of the 18-month intervention. Your involvement in the study will last 20-22 months due to the scheduling of study testing visits occurring before and after the 18 month intervention. The details about all study visits and procedures are provided below. We will make every effort to follow the visit procedures in the order they are outlined below; however, it may be necessary at times to make changes to accommodate different schedules.

Screening Visit (SV1)

You will be asked to come to the Wake Forest Baptist Medical Center (or Piedmont Plaza I) in the morning having fasted for at least 8 hours prior to your appointment time, with nothing to eat or drink except water. At this visit, you will learn more details about the study and you will be given time to ask questions and get satisfactory answers. Then, you will be asked to sign this informed consent and a HIPAA authorization form. After signing the consent form, we will:

- Measure your height and weight to calculate your BMI and waist circumference to determine eligibility
- Measure your blood pressure and pulse rate
- Ask you to do series of physical performance tests including balance tests, chair rise (stand up from a seated position in a chair 5 times), a narrow walk test, and a short-distance (4-meters or 13-feet) walking speed test to determine your eligibility
- Ask you questions about your memory and mood

- Draw blood (about 1 tablespoon) from a vein in your arm to test your blood sugar, blood counts, and your liver and kidney function
- Provide you with a light snack
- Ask you questions about various physical activities that you have done recently
- Ask you to answer questions about your background, medical history, medications and dietary supplements, and readiness to begin a weight loss program
- Ask you to record everything you eat and drink for four days (4-day food record)

This visit will take approximately 2 – 3 hours to complete. If you continue to qualify at the end of the visit, you will be scheduled for Screening Visit 2. If you do not qualify, we will send you a letter with the results of the lab work so that you may share them with your doctor if you would like.

Screening Visit 2 (SV2)
Approximately one week later you will be asked to come to the Wake Forest Baptist Medical Center and we will:

- Review your medications and changes in your health
- Measure your weight
- Ask you to do an exercise test on a treadmill while breathing through an oxygen collection mask and while hooked up to an electrocardiogram (ECG). Your blood pressure will also be monitored during this test.
- Determine the amount of bone, fat and muscle you have using a DXA (dual energy x-ray absorptiometry) scan (more details provided in the Risks Section of this form)
- Measure your waist, hip and thigh using a tape measure
- Allow you to sample or taste the supplements that will be used in the study
- Ask you to return your 4-day food record

This visit will take approximately 1 ½ – 2 ½ hours to complete. If you continue to qualify, you will be scheduled for Baseline Visit 1. If you do not qualify, we will send you a letter explaining why you did not qualify.

Baseline Visit 1 (BV1)
Approximately one week later you will be asked to come to the Wake Forest Baptist Medical Center and we will:

- Review your medications and changes in your health
- Measure your weight
- Perform a series of CT scans of your abdomen, hip and thigh that provide images to measure the location and amount of body fat in your abdomen and thigh and the bone density of your spine, hip, and femur (more details provided in the Risks Section of this form)
- Ask you to answer questions about your physical and mental energy levels and quality-of-life
- Ask you to complete a memory task
- Ask you to answer a series of questions about your ability to perform different physical activities on either a laptop or iPad

- Ask you to do a series of physical tests including testing your leg strength on a chair-like device, testing your grip strength by gripping a device with your hands, and a longer walk test (about ¼ mile)
- Provide you with a collection bottle to collect a 24-hour urine sample prior to your next visit

This visit will take approximately 3 – 4 hours.

Baseline Visit 2 (BV2)
Approximately one week later you will be asked to come to the Wake Forest Baptist Medical Center having fasted for at least 8 hours prior to your appointment time, with nothing to eat or drink except water. At this visit we will:

- Review your medications and changes in your health
- Measure your weight, blood pressure and pulse
- Measure the number of calories your body uses at rest (resting metabolic rate, RMR; more details provided in the Risks Section of this form)
- Measure the stiffness of your arteries
- Draw blood (up to 4 tablespoons) from a vein in your arm to measure lipids (total, LDL, and HDL cholesterol, and triglycerides), insulin, and glucose, and blood for storage
- Ask you questions about what you ate and drank in the past 24 hours (you will also be asked questions about what you ate or drank in the past 24 hours over the telephone on two separate occasions before your next visit, each phone call taking approximately 20-40 minutes). Due to scheduling, this may occur starting at BV1 for some participants. Those participants will be given instructions and all interviews will occur over the phone.
- Provide you with a light snack
- Ask you to return your completed 24-hour urine sample to measure kidney function, the amount of protein in your urine, and for storage

This visit will take approximately 2 – 3 hours.

Randomization
At the end of baseline testing, you will be randomly assigned to one of the three study groups described below. Randomization means that you are put into a group by chance, such as flipping a coin. You will have a one in three chance of being placed in any of the three groups. You must agree to be in any of the groups and you may not pick or change the group that you are placed in. You will participate in one of these three groups for a total of 18 months before the final testing visits are conducted. All three groups will participate in a 6-month weight loss and exercise program at the Wake Forest Baptist Medical Center.

The three study groups are:
1. Recommended Protein Diet for 18 months
2. Higher Protein Diet for 6 months; and then the Recommended Protein Diet for 12 months
3. Higher Protein Diet for 18 months

- All participants will be enrolled in a 6-month weight loss and exercise program to help them reduce their weight with a goal of achieving a 10% weight loss. All participants will be asked to prepare their own meals from the meal plans provided and consume either a protein or a carbohydrate supplement with their morning and midday meal or afternoon snack during the 6-month weight loss program. The protein and carbohydrate supplement will be provided throughout the duration of the study. You will also receive a study shaker bottle to assist you in preparing your supplement as directed by the dietitian.

- You will meet with a registered dietitian/study staff weekly: three times a month in a group setting and once a month individually. Group classes and individual sessions may be conducted virtually (via WebEx or phone) if conditions warrant (e.g., restrictions on in-person research and/or stay at home orders are put in place due to COVID-19). You will be provided with an individualized meal plan and instructed on food selection, portion sizes, relapse prevention, and self-monitoring techniques. Your weight will be measured weekly. You will be asked to keep track of everything you eat and drink on a daily basis in a log book provided. The diet sessions will last approximately 45 minutes to an hour.

- You will also participate in a supervised, center-based exercise program using treadmills three days a week for the first 6 weeks during the 6 month weight loss program. All center-based sessions will be supervised by trained exercise interventionists. You will go through an orientation session where the equipment will be demonstrated. You will warm-up by walking for 3-5 minutes at a slow pace and the sessions will end with a cool-down period of light stretching. The exercise will progress to a longer time or a harder intensity each week for the first few weeks until you reach your target range. You will record you heart rate and treadmill speed/grade during the exercise sessions. After the first 6 weeks of the 6-month weight loss intervention, you will continue center-based exercise one to two days a week and exercise on your own one to two days a week for a total of three days a week of combined center- and home-based exercise (with the option of transitioning to all home-based exercise if conditions warrant – e.g., restrictions on in-person research and/or stay at home orders are put in place due to COVID-19). You will be asked to keep exercise logs detailing your home-based exercise sessions. The exercise sessions will last approximately 45 minutes to an hour.

- After the six-month weight loss program, those in the Higher Protein Diet group for 18 months will be asked to continue consuming the supplement during the 12-month weight maintenance phase for a total of 18 months. All participants will be invited to quarterly presentations on various health-related topics during the 12-month weight maintenance program and an individual diet counseling session with the registered dietitian approximately 6 months after the completion of the 6-month weight loss intervention.

- If you are not already taking a calcium and/or vitamin D supplement, the study dietitian will advise you to take a calcium (500-1000mg/day) and/or vitamin D (800 IU/day) supplement to ensure you are getting proper nutrition throughout the length of the study.

- During the first 6 months of the study, you will be asked to maintain your current physical activity levels outside of your structured UPLIFT exercise sessions and be asked not to start any new physical activities or change the frequency or intensity of any physical activity you may currently be doing. During the last 12 months of the study, the study staff will provide you with recommendations for maintaining a physical activity program on your own.

6-month Follow Up (FV1/2)

Approximately 6 months after you started the weight loss intervention you will be asked to come to the Wake Forest Baptist Medical Center having fasted for at least 8 hours prior to your appointment time, with nothing to eat or drink except water. At this visit we will:

- Review your medications and changes in your health
- Measure your weight, blood pressure and pulse
- Measure the number of calories your body uses at rest (resting metabolic rate, RMR; more details provided in the Risks Section of this form)
- Measure the stiffness of your arteries
- Draw blood (up to 4 tablespoons) from a vein in your arm to measure lipids (total, LDL, and HDL cholesterol, and triglycerides), insulin, glucose, blood counts, liver and kidney function, and blood for storage
- Provide you with a light snack
- Determine the amount of bone, fat and muscle you have using a DXA (dual energy x-ray absorptiometry) scan (more details provided in the Risks Section of this form)
- Measure your waist, hip and thigh using a tape measure
- Ask you a series of questions about various activities you have done over the last 4 weeks and questions about your physical and mental energy levels and quality-of-life (these questionnaires may be done over the phone to reduce in-person visit time)
- Ask you to answer a series of questions about your ability to perform different physical activities on either a laptop or iPad
- Ask you to complete a memory task
- Ask you to do a series of physical tests including testing your leg strength on a chair-like device, balance tests, chair rise (stand up from a seated position in a chair 5 times), and a short-distance (4-meters or 13-feet) walking speed test, a narrow walk test, a longer walk test (about 1/4 mile) and testing your grip strength by gripping a device with your hands
- Perform a series of CT scans of your chest, abdomen, hip and thigh that provides images to measure the location and amount of body fat in your chest, abdomen, and thigh and the bone density of your spine, hip, and femur (more details provided in the Risks Section of this form)
- Provide you with a collection bottle to collect a 24-hour urine sample
- Ask you to return your completed 24-hour urine sample following your visit to measure kidney function, the amount of protein in your urine, and for storage
- You will also be asked questions about what you ate or drank in the past 24 hours over the telephone on three separate occasions over the next couple of weeks, each phone call taking approximately 20-40 minutes

This visit will take approximately 4 hours.

12-month Follow Up (FV3)

Approximately 12 months after you started the weight loss intervention you will be asked to come to the Wake Forest Baptist Medical Center. At this visit we will:

- Review your medications and changes in your health
- Measure your weight, blood pressure and pulse
- Ask you to do a series of physical tests including testing your leg strength on a chair-like device, balance tests, chair rise (stand up from a seated position in a chair 5 times), and a short-distance (4-meters or 13-feet) walking speed test, a narrow walk test, a longer walk test (about ¼ mile) and testing your grip strength by gripping a device with your hands
- Ask you a series of questions about various activities you have done over the last 4 weeks and questions about your physical and mental energy levels and quality-of-life (these questionnaires may be done over the phone to reduce in-person visit time)
- Ask you to answer a series of questions about your ability to perform different physical activities on either a laptop or iPad

This visit will take approximately 2 – 3 hours.

18-month Follow Up (FV4/5)

Approximately 18 months after you started the weight loss intervention you will be asked to come to the Wake Forest Baptist Medical Center having fasted for at least 8 hours prior to your appointment time, with nothing to eat or drink except water. At this visit we will:

- Review your medications and changes in your health
- Measure your weight, blood pressure and pulse
- Draw blood (up to 4 tablespoons) from a vein in your arm to measure lipids (total, LDL, and HDL cholesterol, and triglycerides), insulin, glucose, blood counts, liver and kidney function, and blood for storage
- Provide you with a light snack
- Determine the amount of bone, fat and muscle you have using a DXA (dual energy x-ray absorptiometry) scan (more details provided in the Risks Section of this form)
- Measure your waist, hip and thigh using a tape measure
- Ask you a series of questions about various activities you have done over the last 4 weeks and questions about your physical and mental energy levels and quality-of-life (these questionnaires may be done over the phone to reduce in-person visit time)
- Ask you to answer a series of questions about your ability to perform different physical activities on either a laptop or iPad
- Ask you to complete a memory task
- Ask you to do a series of physical tests including testing your leg strength on a chair-like device, balance tests, chair rise (stand up from a seated position in a chair 5 times), and a short-distance (4-meters or 13-feet) walking speed test, a narrow walk test, a longer walk test (about ¼ mile) and testing your grip strength by gripping a device with your hands
- Perform a series of CT scans of your abdomen, hip and thigh that provides images to measure the location and amount of body fat in your abdomen and thigh and the bone density of your spine, hip, and femur (more details provided in the Risks Section of this form)
- Provide you with a collection bottle to collect a 24-hour urine sample prior to your visit

- Ask you to bring your completed 24-hour urine sample to measure kidney function, the amount of protein in your urine, and for storage
- You will also be asked questions about what you ate or drank in the past 24 hours over the telephone on three separate occasions over the next couple of weeks, each phone call taking approximately 20-40 minutes

This visit will take approximately 3.5 – 4 hours.

Once we receive the results of your lab work, your individual results will be mailed to you. We will also let you know which group (protein or carbohydrate) you were in.

On rare occasions, you may be asked to repeat one of the assessments after a visit. You will only be asked to repeat an assessment if the results from the first assessment were inconclusive or abnormal. This would be for your safety as well as to ensure data quality for the study. This will most commonly occur with abnormal laboratory values. In the event of any inconclusive or abnormal results, you will be notified and a repeat assessment scheduled as soon as possible.

You will have approximately 1 tablespoon of blood withdrawn from a vein at Screening Visit 1 and up to 4 tablespoons drawn at your Baseline Visit, 6-month Follow Up Visit, and 18-month Follow Up Visit. The total amount of blood withdrawn during the study will be approximately 13 tablespoons.

Storage of Biological Tissue

If you agree to participate in this study, we will draw about 3 tablespoons of blood from a vein in your arm and 2 tablespoons of urine to use for future research. These samples will be kept and may be used in future research to learn more about other diseases. Your samples will be obtained in the Geriatrics Department at Wake Forest University Baptist Medical Center. The samples will be stored in the Geriatrics Lab and it will be given only to researchers approved by Dr. Denise Houston. An Institutional Review Board (IRB) must also approve any future research study using your tissue samples. In order to participate in this study, you must be willing to provide these samples for future research.

Your blood and urine samples will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

The research that may be performed with your blood and urine samples is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your blood and urine will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood and urine samples will not affect your care.

Your blood and urine samples will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

How Long Will I Be in the Study?

You will be in the study for about 20-22 months to complete all study visits and the 18 month intervention. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying include:

Physical Function Testing

There is a small risk of injury during the muscle strength testing and physical performance testing, such as muscle strains or pulls, falls, or joint injury. However, these tests have been performed in large study populations with no significant adverse events reported. Risks will be minimized by having experienced/trained staff conducting these assessments. A warm-up and range of motion practice will be conducted before maximal strength testing. In addition, if a participant reports pain, dizziness, lightheadedness or other medical problem during the test, the test will be terminated.

Radiation Exposure

This research study involves exposure to radiation from the DXA (1-10 mRem each) and CT (137-255 mRem each) scans. The risk of these procedures is small and is similar to that received from clinical x-ray and nuclear medicine studies. The amount of radiation exposure that you will receive from these procedures is equivalent to a uniform whole body exposure of 1860 millirem. This is equal to 37% the yearly radiation exposure limit allowed for a radiation worker (5000 mrem). The risk from this radiation exposure is considered to be comparable to other every day risks.

Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care. The Wake Forest University/Baptist Medical Center's 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 necessary to obtain the research information desired. The potential long-term risk from these radiation doses is uncertain, but these doses have never been associated with any definite adverse effects. Thus, the risk to you, if any, is estimated to be slight.

The CT scans are being conducted only for the purpose of research. It is a different test than what is used in the clinical setting to detect or discover medical conditions. It is not a substitute for a clinical CT scan. Research personnel will analyze the scans only for the specified research findings. These scans will not be analyzed until the study has ended; however, if we should happen to see an abnormal finding that may be harmful to your health, we will notify you.

Unexpected findings on the limited research scan will occasionally allow early discovery of a medical condition for which you may need treatment. They may also cause undue worry or result in additional testing, sometimes costly, which may or may not benefit your health.

If you participate in this study, you will be exposed to amounts of radiation above what you would normally receive in daily life. To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure.

Blood Draw

Blood samples will be drawn from a vein in your arm at four separate visits after an overnight fast. Participants may experience temporary pain, bruising, bleeding and a small risk of infection, fainting or dizziness during the blood sample collection process. Blood will be drawn only by trained and experienced phlebotomists who will minimize the discomfort as much as possible. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

Resting Metabolic Rate

The number of calories you burn at rest will be measured before and after the 6-month weight loss program using a metabolic rate test. For this test, you will rest quietly for up to 30 minutes, and a mask will be placed over your nose and mouth. You are able to see and breathe through this mask. Based on the air you breathe in and out, your resting metabolic rate is calculated. Some participants begin to feel claustrophobic when the mask is placed over the nose and mouth. Should this occur we will remove the mask and stop the test.

Weight Loss

There are no known serious risks associated with using caloric restriction to lose weight. Changes in usual bowel function (diarrhea and/or constipation) may occur when beginning the new diet due to differences between this diet and your usual diet. Under conditions of rapid weight loss (more than 5 pounds per week), there is a very small chance of developing gallbladder disease. Risks of weight loss at any age include the loss of lean (muscle and bone) tissue along with fat loss. However, the clinical impact of this muscle and bone loss is not known. In older adults, this decrease in muscle mass and bone density with weight loss may result in increased risk for sarcopenia and/or osteopenia/osteoporosis. Since most older adults with obesity have a higher muscle mass and bone density, this risk is lessened by excluding individuals who are non-obese and less likely to benefit from weight loss and excluding those with an increased risk for sarcopenia or osteoporosis. Procedures to minimize loss of muscle and bone during the weight loss intervention include prescription of a caloric deficit that does not result in excessively rapid weight loss (e.g., >2 lb/week), inclusion of increased weight-bearing activity (exercise intervention), and incorporating dietary recommendations and meal plans that include the current Recommended Dietary Allowance (RDA) for protein, calcium, and vitamin D.

High Protein Diet

The risks of the higher protein diet intervention are minimal, but may include a worsening of

existing kidney problems. However, we will not enroll individuals with evidence of preexisting impaired kidney function (persons with stage 4 or higher chronic kidney disease) for whom a diet with a higher protein level is contraindicated.

Exercise Program

The risks of the exercise program are minimal, but may include musculoskeletal complications and muscle soreness in the early phases of the training. This will be minimized since all exercise sessions during the first 6 weeks of the 6-month weight loss intervention and up to two exercise sessions a week for the remainder of the 6-month weight loss intervention will be center-based (unless conditions arise that necessitate a transition to all home-based exercise – e.g., restrictions on in-person research and/or stay at home orders are put in place due to COVID-19) and supervised by trained exercise interventionists, who will instruct participants in the proper exercise techniques and footwear. Procedures to minimize injury include warm-up and cool-down activities that include large muscle movements and stretching. Participants will begin with an easier exercise stimulus and will gradually increase in intensity over several weeks. Exercise physiologists or trained study staff, trained in cardiac life support, will supervise all center-based exercise sessions and practice codes are conducted quarterly. Tips on how to safely exercise in a home-based setting will be reviewed by the exercise interventionist during the first 6 weeks of center-based exercise.

Exercise treadmill test

This test requires you to breathe through a mouthpiece while exercising so that we can analyze the air you breathe out to calculate your fitness level. Electrodes will be placed on your chest to obtain an electrocardiogram (ECG) tracing. An exercise technician will monitor your heart rate, rhythm, blood pressure, and fitness level during the test. A doctor will be on call and ready to respond immediately to any emergency. The test will be stopped when you become exhausted, if you have chest pains, if your blood pressure rises too high, or if your ECG becomes abnormal. Exercise testing is a common procedure with minimal risks, but the test will be stopped if problems occur. These possible risks include fainting, dizziness, chest pain, irregular heartbeats, or a heart attack, although the latter is extremely rare in people with no history of heart disease. Your blood pressure, heart rate, rhythm, and breathing will be closely monitored by an exercise technician trained in CPR. In addition, we will monitor your blood oxygen level before and after this test.

Arterial Stiffness Testing

To measure how stiff your blood vessels are, you will complete a series of tests while sitting in a chair or lying down quietly for up to 15 minutes. During these tests we will place a blood pressure cuff on your upper arm to obtain information about your pulse. As the cuff inflates, the pressure might be uncomfortable but should only last a few seconds.

Confidentiality

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure

and allowing only authorized people to have access to research records, will be made to keep your information safe.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study include receiving information about your risk factors for heart disease including cholesterol, blood pressure, blood sugar, body fat amount and location, and physical function status. A possible benefit is that by losing weight and increasing your physical activity you may reduce your risk for diabetes and heart disease, and you may increase your physical function. Because individuals respond differently to diet and exercise, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

Classes and testing procedures similar to those offered in this study are available in the community and usually involve a charge to participants.

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

There are some costs to you for taking part in this study. The costs related to food to follow the individualized meal plan during the 6-month weight loss program and if you chose to start a calcium and/or vitamin D supplement will be your responsibility. All study costs, including any study medications (protein and carbohydrate supplements) and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified. Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, my inspect research records and learn your identity if this study falls under its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires

disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Aging at the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by National Institute on Aging at the National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.
You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related

illness, adverse event, or injury you should call Denise Houston, PhD, at [redacted] during normal business hours or [redacted] after hours and identify yourself as an UPLIFT study participant.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, and information from study visits, phone calls, surveys, and physical examinations.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Denise Houston that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Denise Houston, PhD
[redacted]

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

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because:

- your study doctor feels it is in your best interest;
- you may not be following the instructions properly;
- you do not later consent to any future changes that may be made in the study plan;
- or for any other reason.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Denise Houston, PhD, at [redacted] during normal business hours or [redacted] after hours and identify yourself as an UPLIFT study participant.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted]. You will be given a copy of this signed consent form.

Signatures

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm