Title:Empowered With Movement to Prevent Obesity and Weight Regain
NCT:NCT02923674
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Wake Forest®
School of Medicine

# Informed Consent Form to Participate in Research

**Wake Forest School of Medicine**
**Department of Internal Medicine**
**Section on Gerontology and Geriatric Medicine**

## Title: Empowered with Movement to Prevent Obesity and Weight Regain (EMPOWER)

**Principal Investigators:** Barbara J. Nicklas, PhD, and W. Jack Rejeski, PhD

**Participant Name:** _____

**INTRODUCTION**
You are invited to be in this research study being conducted at Wake Forest School of Medicine. Research studies are designed to gain scientific knowledge that may help other people in the future. You are asked to take part in this study because you are 65-85 years old, fit the health and weight requirements, and because you are interested in participating. Your participation is entirely voluntary. Please take your time making your decision as to whether or not you wish to participate. Please ask the study staff to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your doctor, friends, and family.

**WHY IS THIS STUDY BEING DONE?**
This study will help determine the appropriate type, amount and intensity of physical activity most beneficial for preventing weight regain after weight loss in older adults.

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**
A total of up to 189 people will take part in this study. To identify this number of participants, we may need to screen as many as 500 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, your involvement will last 18-24 months. The intervention lasts 18 months, but your involvement could last up to 24 months due to scheduled testing visits occurring before and after intervention. We will first ask that you come to Wake Forest Baptist Medical Center to complete two screening visits to see if you qualify for the study. If you qualify, you will be asked to complete another testing visit before beginning a 9-month weight loss program followed by a 9-month weight loss maintenance phase. You will also be asked to complete two testing visits after the first 6 months of the weight loss program, one visit after the entire 9-month weight loss program, and two visits at 18 months after completion of the maintenance phase. This is a total of 8 testing visits. The details about all study visits and tests are provided below. We will try to conduct these visits in the order they are outlined below; however, it may be

necessary to make changes to accommodate scheduling.

***Visit 1 (V1)- Screening***

Before this visit, we will ask you to fast for at least 8 hours prior to your appointment, having had nothing to eat or drink except water. We will also ask you to refrain from exercise and drinking alcohol 8 hours prior to this visit. At this visit you will learn more details about the study and you will be given time to ask questions and get satisfactory answers. You will then be asked to sign this informed consent form. After signing the consent form, we will:

- Measure your height and weight, blood pressure and pulse,
- Draw blood (about 1½ tablespoons) from a vein in your arm to test your blood cell counts, lipids, insulin and sugar levels, vitamin D levels, and liver and kidney function,
- Provide you with a light snack,
- Ask you to answer questions about your health background, medical history, medications, feelings, and memory.
- Ask you to record everything you eat and drink for four days (4-day food record)

This visit will take approximately 1½ -2 hours. If you continue to qualify for the study, you will be scheduled for a second screening visit.

***Visit 2 (V2)- Screening***

At this visit we will:

- 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),
- 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,
- Provide you with an activity monitor to wear for 1-week to record your activity level,
- Begin your 1-week Daily Questions period and provide instruction on how to use the study website (see below for more information)
- Ask you to answer questions about your physical and mental energy levels, food habits, motivation, and quality-of-life,
- Ask you to complete a memory task.

This visit will take approximately 2½ to 3 hours. If you continue to qualify for the study, you will be scheduled for the next testing visit.

***Visit 3 (V3)- Baseline***

Before this visit, we will ask you to fast for at least 8 hours prior to your appointment, having had nothing to eat or drink except water. We will also ask you to refrain from exercise and drinking alcohol 8 hours prior to this visit. At this visit, we will:

- Ask you to return the activity monitor, and measure your weight,
- Measure the number of calories your body uses at rest (resting metabolic rate; more details provided in the Risks Section of this form),
- Draw blood (about 1 1/2 tablespoons) from a vein in your arm to store for future tests (more information in the Storage of Biological Tissue section)
- Ask you to answer questions about your food cravings, then provide you with a light snack,

- Ask you to do series of physical performance tests to measure your balance, chair rise time, usual walking speed, grip strength and a short walking test on a treadmill,
- Ask you to complete a long-distance walking test while wearing an activity monitor.

This visit will take approximately 2 ½ - 3 hours.

***Randomization***

At the end of Visit 3, you will be randomly assigned to one of the study groups listed below. You will have a 1 in 3 (equal) 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 your assigned group for a total of 18 months before the final testing visits are conducted.

The groups are:

- Diet with structured exercise (mostly walking) at a moderate-intensity level (Diet+Exercise)
- Diet with increased light-intensity physical activity and decreased sedentary behavior throughout the day (Diet+Daily Activity)
- Diet with structured exercise and increased daily activity (Diet+Exercise+Daily Activity)

***Study groups (interventions)***

Throughout the entire 18 months of the study intervention you will be provided with an activity monitor, a small device that gives information about your activity level, to wear. You will receive this device and training before you start your weekly group class. At the completion of the study, you will be allowed to keep you monitor.

In addition, this study will use a website designed to help and motivate you to change your physical activity behavior. You will access this website with a smartphone, which we may provide for you if you do not have an Apple iphone or Android smartphone. This website will also provide you with visual feedback on how your activity program is progressing and will be monitored by a study staff member. You will receive individual training on how to use these tools and you will set up individual goals with a study staff member. If you need a study smartphone, it will be dispensed to you at V2 with instructions and training. At the completion of the study, you will be asked to return the phone and it will be deactivated. If you receive a phone from the study, it will be for study use only.

***Diet Program*—**Everyone in the study will undergo a 9-month dietary weight loss program followed by a 9-month weight loss maintenance phase. Throughout the study you will be given a prescribed calorie level and education/coaching designed to reach and maintain a 10% weight loss goal. You will be asked to record your food and beverage intake on a regular basis.

During the first 6 months of weight loss, you will meet weekly in a group setting for approximately one hour with other study participants and a study staff member; you may also be asked to meet with a staff member individually as needed. During the next 3 months of weight loss, the number of group meetings will decline to 2 per month, with individual sessions as needed. These sessions will focus on nutrition, motivation for sticking with the prescribed calorie level, and how to overcome barriers.

During the 9-month maintenance phase (months 10-18) you will receive a monthly email or phone call from a study staff member to ask if you had any changes in your health or medications.

***Exercise Program*—**Participants in the Diet+Exercise or the Diet+Exercise+Daily Activity groups will participate in a formal exercise program. This program involves participation in aerobic exercise (mostly walking) for 4-5 days per week. Supervised exercise will start slowly with sessions first lasting approximately 30 minutes and then gradually increasing to last a little over an hour. For the first 6 months, you will be asked to come to our exercise center for 3 days per week and you will be asked to exercise at home for the other 2 days per week with guidance from the study staff. For the next 3 months of the program (months 7-9), the number of days you exercise at our center will be reduced to 1-2 days per week and your home exercise will increase to 3-4 days per week.

During the 9-month maintenance phase (months 10-18), we will ask you to continue to use the activity monitor and study website as needed to continue your home-based exercise for 5-6 days per week. You will receive a monthly email or phone call from a study staff member to ask if you had any changes in your health or medications.

***Daily Activity Program*—**Participants in the Diet+Daily Activity or the Diet+Exercise+Daily Activity groups will be taught and encouraged to increase light activity during the day and to reduce the amount of time spent sitting or lying down during the day. The monitor provided to you will alert you with periodic reminders to stand up and move around and will work with the website to provide feedback to you on how your activity level is progressing each day. Your progress in meeting these goals and overcoming barriers will be discussed with study staff during the group meetings that occur weekly during the first 6 months and biweekly for months 7-9.

During the 9-month maintenance phase (months 10-18), we will ask you to continue to use the activity monitor and website as needed to continue to reduce the time you spend sitting and lying down. You will receive a monthly email or phone call from a study staff member to ask if you had any changes in your health or medications.

***Visit 4 (V4) after 6 months of weight loss program***

Before this visit, we will ask you to fast for at least 8 hours prior to your appointment, having had nothing to eat or drink except water. We will also ask you to refrain from exercise and drinking alcohol 12 hours prior to this visit. At this visit, we will:

- Measure your weight,
- Measure the number of calories your body uses at rest (resting metabolic rate),
- Draw blood (about 2½ tablespoons) from a vein in your arm to test your lipids, insulin and sugar levels, and to store blood for future tests,
- Ask you to answer questions about your food cravings,
- Provide you with a light snack,
- Ask you to do series of physical performance tests to measure your balance, chair rise time, usual walking speed, grip strength and a short walking test on a treadmill,

- Ask you to complete a long-distance walking test while wearing an activity monitor,
- Provide you with an activity monitor to wear for 1-week to record your activity level.

This visit takes approximately 2-2½ hours.

***Visit 5 (V5) after 6 months of weight loss program***

At this visit we will:

- Ask you to return the activity monitor, and 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),
- Determine the amount of bone, fat and muscle you have using a DXA (dual energy x-ray absorptiometry) scan,
- Measure your waist, hip and thigh using a tape measure,
- Ask you to answer questions about your physical and mental energy levels, food habits, motivation, and quality-of-life.

This visit takes approximately 1 ½ -2 hours.

***Visit 6 (V6) after 9 months of weight loss program***

At this visit we will:

- Measure your weight,
- Complete 2 questionnaires on the study's intervention and use of technology.
- Provide you with an activity monitor to wear for 1-week to record your activity level.

This visit takes approximately 30 minutes.

***Visit 7 (V7) and Visit 8 (V8) after 18 months of study participation***

Before this visit, we will ask you to fast for at least 8 hours prior to your appointment, having had nothing to eat or drink except water. We will also ask you to refrain from exercise and drinking alcohol 12 hours prior to this visit. At this visit, we will:

- Measure your weight,
- Measure the number of calories your body uses at rest (resting metabolic rate),
- Draw blood (about 2½ tablespoons) from a vein in your arm to test your lipids, insulin and sugar levels, and to store blood for future tests,
- Ask you to answer questions about your food cravings,
- Provide you with a light snack,
- Ask you to do series of physical performance tests to measure your balance, chair rise time, usual walking speed, and grip strength,
- Determine the amount of bone, fat and muscle you have using a DXA (dual energy x-ray absorptiometry) scan,
- Measure your waist, hip and thigh using a tape measure,
- Ask you to answer questions about your physical and mental energy levels, food habits, motivation, quality-of-life and on the study's intervention and use of technology (We will call you to complete these questionnaires on the phone before or after your visit),
- Ask you to complete a long-distance walking test while wearing an activity monitor,
- Provide you with an activity monitor to wear for 1-week to record your activity level and mail back

This visit takes approximately 3 hours.

As part of this research study, you will potentially be audiotaped during your first introduction to the study-specific program for your mobile phone. This is being done to ensure we are able to capture your feedback appropriately and so that we may continue to improve the application for easier use. You understand that you may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the audiotapes before they are used in this study. The audiotapes will be destroyed once their use in this study is finished.

**Daily Questions**

FOLLOWING VISIT 2 AND VISIT 6 YOU WILL BEGIN A WEEKLONG *DAILY QUESTIONS* PERIOD THAT WILL ALIGN WITH THE ONE-WEEK ACTIVITY MONITOR PERIOD. THESE DAILY ASSESSMENTS ARE COMPLETED ON A SMARTPHONE DEVICE. IF YOU ALREADY HAVE AN APPLE IPHONE OR ANDROID SMARTPHONE, THE STUDY INVESTIGATORS WILL WORK WITH YOU TO BE SURE THAT THE PHONE WORKS WITH OUR PROGRAM, AND WE MAY SUPPLY A PHONE FOR YOU IF YOU DO NOT ALREADY HAVE ONE. DURING THESE SESSIONS WE WILL WORK WITH YOU TO BE SURE THAT YOU ARE COMFORTABLE USING THE PHONE TO ANSWER THE DAILY SURVEY QUESTIONS AND TO ACCESS THE STUDY WEBSITE. ADDITIONALLY, STUDY PROMPTS WILL COME TO YOU AS TEXT MESSAGES, WHICH YOU WILL BE FAMILIARIZED WITH DURING VISIT 2.

You will answer four very brief sets of questions each day for one week. This includes one assessment that you will complete after waking in the morning, one that you will complete right before bed, and two for which you will receive prompts at random times throughout the day. As you become comfortable with the questions, these sets will take as little as one minute to complete, and they assess your daily sleep quality, mood, energy level, food cravings, and hunger, which may allow us to make future programs even more effective.

**Storage of Biological Tissue**

If you agree, you will have approximately 2½ tablespoons of blood drawn from an arm vein at V1, V3, V4 and V7. The total amount of blood taken during the study will be approximately 7½ tablespoons. Approximately 4 tablespoons of this blood will be processed and stored for future research to learn more about other diseases. Your blood sample will be stored in the Geriatrics laboratory at Wake Forest School of Medicine (WFSM) and it will be given only to researchers approved by the study PI (Barbara Nicklas, PhD). An Institutional Review Board (IRB) must also approve any future research study using your blood sample.

Your blood sample 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 regulations. The unique identifier will be a randomly assigned number. Your name, address, social security number, or other identifying information will not be disclosed to

future researchers who may use your sample unless permission is given by the Principal Investigator.

The research that may be performed with your blood sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the 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 will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood sample will not affect your care.

Your blood sample 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 potential future research.

Do you agree to have this blood drawn and stored for future research?

Yes_____ No_____ Participant Initials _____ Date_____

**HOW LONG WILL I BE IN THE STUDY?**

You will be in the study for anywhere from 1½ to 2 years, depending on the scheduling of the testing visits. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the study investigators or study staff first to learn more about potential health or safety consequences. You will also be encouraged to attend assessment visits even if you are no longer actively participating in your study group (intervention).

**WHAT ARE THE RISKS OF THE STUDY?**

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

1. Diet Program

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. When you lose weight you may lose some lean muscle and bone along with fat tissue. This is monitored by the DXA scan. The registered dietitian will guide you on making healthy choices to help minimize this natural occurrence.

2. Exercise and Daily Activity Programs

The risks of the exercise programs are minimal, but may include fainting, dizziness, irregular heartbeat, chest pain, heart attack, or extremely rarely, sudden death, and

stresses and strains of muscles, twisted ankles, or falls. Fall prevention will be discussed and emphasized and center-based exercise classes will be closely supervised by study staff who will instruct you in proper exercise techniques.
There is also a possibility of increased episodes of low (hypoglycemia) or high (hyperglycemia) blood sugar especially during or after the moderate-intensity exercise, in people with diabetes mellitus. We will reduce this risk by discussing signs and symptoms of low/high blood sugar for you to be aware of and we will have easily digestible snacks, glucose tablets, and juice in the exercise center for your use if this occurs. If you are on insulin or a similar medication to help control your blood sugar, we will also encourage you to check your blood glucose level before exercise. If it is less than 100 mg/dl, we will ask you to consume a higher carbohydrate snack prior to exercise. In some cases, we may ask you to consult with your physician about reducing your medication dose prior to beginning an exercise bout.

3. Resting metabolic rate (RMR) test
The number of calories you burn at rest will be measured using a metabolic rate test. For this test, you will lie comfortably on a bed for 30-45 minutes, and a mask will be placed over your nose and mouth. You are able to breathe through this mask. Some participants begin to feel claustrophobic when the mask is placed over the nose and mouth. Should this occur we will stop the test.

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

5. 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. If you are diabetic, we will take your blood glucose before and after the test for safety.

6. Body measurements and radiation
A dual energy X-ray absorptiometry machine (DXA) will measure the amount of your muscle, bone and fat. We will conduct three scans (whole body, hip and spine). This

machine uses photons (energy) which scan across your body while you are lying quietly on a padded table for the duration of each scan (5-10 min), for a total of up to 30 minutes. You will be lying down the whole time and will not be able to get up until the scan is complete.

This research study involves exposure to radiation from DXA 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 45 millirem. This is equal to 0.15 times of the amount of natural background radiation that the average person in the United States receives each year (300 millirem).

The risk of these procedures is small. Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care. Wake Forest Baptist Health'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 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 scan. Research personnel will analyze the scan only for the specified research findings. 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 (such as osteoporosis) 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 that are no different from 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 the study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure.

7. Blood sampling

You will have approximately 2½ tablespoons of blood drawn from an arm vein at V1, V4 and V7 an 1 ½ tablespoons of blood drawn at V3. If you agreed to have blood stored for future research, the total amount of blood taken during the study will be approximately 7½ tablespoons over 4 study visits- V1, V3, V4 and V7. (Approximately 4 tablespoons of this blood will be processed and stored for future research and 2 ½ tablespoons drawn and processed immediately for study measures.) You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally, some people become lightheaded or feel faint. Infection may occur on rare occasions.

8. Confidentiality: 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.

**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, fitness level, body fat amount and location, and physical fitness status. These tests will help you to know how healthy you are and whether or not you have an immediate health concern. A possible benefit is that by losing weight you may reduce your risk for diabetes and heart disease and may improve your physical ability. However, because individuals respond differently to diet, no one can know in advance if it will be helpful in your particular case.

**WHAT OTHER CHOICES ARE THERE?**

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

**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, how you respond to study activities or procedures, laboratory and other test results, and information from study visits, phone calls, surveys, and physical examinations.

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. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research,

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center.

3) Study sponsor or other government agencies that oversee research

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 be destroyed. 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 the study PI 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:

Barbara Nicklas, PhD


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.

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 THE COSTS?**

There are no costs to you for taking part in this study. All study costs, including any 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.

Please note that although we are able to provide the study website to you for free, there may be small costs associated with receiving text messages from your wireless carrier.

You will receive a parking voucher that will cover the cost of parking for each of your

visits.

**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 The National Institute on Aging (NIA). The sponsor is providing money or other support to Wake Forest Baptist Health 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 Barbara Nicklas, PhD, at [redacted] during normal business hours or [redacted] after hours and identify yourself as a EMPOWER study participant.

**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, Barbara Nicklas, PhD, at [redacted] during normal business hours or [redacted] after hours and identify yourself as a EMPOWER 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



WFU School of Medicine
Institutional Review Board
IRB Number: IRB00035300
Meeting Date Approved 8/3/2020
Version Valid Until: 4/8/2021