Title of Study: Prescribed Exercise to Reduce Recidivism After Weight Loss Pilot (PREVAIL-P) study*:*
Clinical Trials ID: NCT03685123
Document date: 11-27-18

Consent to Take Part in Research that has Potentially Greater than Minimal Risk

Information You Should Think About Before Agreeing to Take Part in This Research

Title of Research Study: Prescribed Exercise to Reduce Recidivism After Weight Loss Pilot (PREVAIL-P) study

Sponsor/Funding Source: National Institue of Health
Sponsor Protocol #: TBD

Principal Investigator: Damon L. Swift
Institution, Department or Division: East Carolina University/ Department of Kinesiology
Address: 388 Ward Sports Medicine Building
Telephone #: 252-737-1338

Participant Full Name: _____Date of Birth: _____
Please PRINT clearly

Researchers at East Carolina University (ECU) study diseases, health problems, environmental problems, behavior problems and the human condition. Our goal is to try to find better ways to improve lives. To do this, we need help from people willing to take part in research.

This form explains why this research is being done, what will happen during the research, and what you will need to do if you decide to volunteer to take part in this research

- The person who is in charge of this research is called the Principal Investigator.
- The person explaining the research to you may be someone other than the Principal Investigator.
- Others who may be asking you to take part in this research include:
  - Damon Swift, Ph.D.
- There may be other research staff members who perform some of the procedures.
- You may have questions that this form does not answer.
- If you have questions, feel free to ask those questions to the person explaining the study, as you go along.
- You may also have questions later; feel free to ask those questions, as you think of them.
- There is no time limit for asking questions about this research.
- Take your time and think about the information that is provided.
- If you want, have a friend or family member go over this form with you before you decide.
- If you choose to be in the study, then you will be asked to sign this form when you feel you understand the information provided.
- If you do not want to take part in the study, tell the person explaining the research that you do not want to sign this form.

You do not have to take part in this research study. That decision is yours and it is okay to decide not to volunteer.

Why is this research being done?

The purpose of this research study is to understand how different levels of exercise affects your weight and risk factors for heart disease after weight loss. We are asking you to take part in this research.
However, the decision is yours to make. By doing this research, we hope to learn how effective the current weight maintenance guidelines for physical activity (200-300 minutes per week) are for maintaining weight and improvements in heart disease risk factors compared to lower levels of exercise (~150 minutes per week). Currently, it is well established that after you lose weight that having a high level of physical activity is important for maintaining that weight loss. However, many previous study have not used accurate methodology for measuring physical activity levels.

We will study 39 overweight and obese adults. Individuals will participate in an OPTIFAST weight loss program for 10 weeks and supervised exercise training at ECU. Those participants that are successful in losing at least 7% of their body weight will be randomized to: 1) Exercise training consistent with the minimum physical activity recommendations or 2) Exercise levels consistent with the weight maintenance recommendations. This study will take place in the Human Performance Laboratory (HPL), the Fitness Instruction Testing and Training (FITT) Center of East Carolina University, the East Carolina Heart Institute (ECHI), Ward Sports Medicine Building and VIDANT Wellness Center.

Why am I being invited to take part in this research?

You are being invited to take part in this research because you are an adult between the ages of 18-65 years old, and not currently in an exercise training program. If you volunteer to take part in this study, you will be one of about 39 people to do so.

Are there reasons I should not take part in this research?

Several factors may make you ineligible for the present study. You should not volunteer for this study if you have been diagnosed with type 1 or 2 diabetes, have had a previous heart attack or stroke, have significant joint problems/injuries, or are already participating in an exercise/nutritional program. Due to the fact that this study will involve supervised exercise training in our facility, you will be not eligible for this study if you plan to be away from the Pitt County area for more than 2 weeks in the next 3 months. Lastly, you should not volunteer for this study if you are pregnant or trying to become pregnant.

What other choices do I have if I do not take part in this research?

You have the choice of not taking part in this research study.

Where is the research going to take place and how long will it last?

The research procedures will be conducted at East Carolina Heart Institute (ECHI) and the Fitness Instruction Testing and Training (FITT) building at East Carolina University, Ward Sports Medicine building, and VIDANT wellness Center. A summary of the time demands of this study by visits are shown below. This study will take approximately 117 hours.

Visit	Location	Time hours
Screening visit 1 (SV1)	ECHI or FTT	1.5
Screening visit 2 (SV2)	ECHI or FTT	0.5 hours
Baseline visit 1	ECHI	3.5 hours
Baseline visit 2	Ward Sports Medicine	1.5 hours
Mid study visit 1	ECHI	3.5 hours
Mid study visit 2	Ward Sports Medicine	1.5 hours
Follow-up visit 1	ECHI	3.5 hours
Follow-up visit 2	Ward Sports Medicine	1.5 hours
Weight loss/Exercise Training	VIDANT Wellness Center/FITT or ECHI	100 hours

What will I be asked to do?

The following procedures will be done strictly for research purposes

1. Eligibility Criteria:
    a. You may be eligible for the present study if you meet the following criteria:
        i. Age (18-65 yrs. of age)
        ii. Body Mass Index between 25-45 kg/m^2 with elevated waist circumference (above 102 cm men or 88 cm for women)
        iii. Not currently participating in exercise training program or have a low physical activity level

    b. You will NOT be eligible for this study if you meet the following criteria:
        i. You have had a previous heart attack or a significant heart-related condition
        ii. You have been diagnosed with type 1, type 2 diabetes or taking diabetes medication
        iii. Your resting blood pressure levels is excessively high
        iv. You have other medical conditions that are life threatening, aggravated by exercise training, or deemed by the research team to be above the safety limits of this study
        v. You plan to be away from Pitt County more than 2 weeks in the next 3 months
        vi. You are currently participating in an exercise training program or a weight loss program
        vii. If you have had previous gastric bypass or weight loss surgery
        viii. If you currently have thyroid conditions or taking medication for your thyroid
        ix. You are currently pregnant or have plans to become pregnant over the next 6 months
        x. Not fulfilling study requirements during the screening process
        xi. You are currently participating or have plans to engage in dieting or a weight loss program over the next 6 months
        xii. You have had bariatric or gastric banding surgery
        xiii. You are currently taking weight loss medications
        xiv. If you have sickle cell anemia or fragile veins

xv. You do not have a smart phone
xvi. Serious medical conditions such as cancer, respiratory, gastrointestinal, neuromuscular, neurological, HIV or psychiatric conditions.

c. Below, we have described the information and assessments that will be performed at each of the study visits and during the intervention.
   i. Screening visit 1:
      1. We will ask and record your name, address, contact information, ethnic/racial identification information, and other demographic information.
      2. Medical history: You will be asked questions about your medical history and current medication by a member of the study staff. We will ask that you bring in your medication bottles for confirmation of medication and dosage.
      3. Height: Research staff will use a device (called a stadiometer) to measure your height
      4. Weight: Your weight will be measured on a scale
      5. Waist circumference: A simple measurement will be made around your waist using a flexible measuring tape.
      6. Blood pressure: Your blood pressure will be evaluated in the seated position
      7. We will have you meet with the study staff to discuss any major barrier for study completion (adequate time for an exercise training study, time away from Pitt County area, and other major factors that could adversely affect adequate participation levels in the study). You will be asked to identify potential times based on your schedule that you will be able to exercise, and potential back-up times. We will also ask you questions about your time commitments (e.g. work, church, extra-curricular, child-care) and questions evaluating whether you have enough time to participate in this study.
      8. Exercise/Weight loss calendar: We will ask you to identify specific weekly times when you would be able to come to exercise sessions and the weight loss class
      9. Accelerometry (actigraph): You will be given a device called an actigraph accelerometery, which will measure the number of steps that you walk. You will be asked to wear this over the course of one week.
      10. Accelerometry (activpal): You will be asked to wear a small device similar to a pedometer attached to your thigh using Tegadem for 7 days. This device will measure the amount of time you sit and your physical activity levels.

   ii. Screening visit 2: During this visit, you will return the accelerometers (actigraph and activpal) to a study staff member. The study nurse will draw your blood to check your glucose, insulin and cholesterol levels and to make sure that you are healthy enough to participate in the study (e.g. normal kidney/liver function, etc.). A drop of blood will also be used to conduct a pregnancy test if you are a female who is premenopausal.

iii. Baseline visit 1 (ECHI): During this visit, we will do several measurements to assess your weight, distance around your waist, arterial stiffness, resting metabolic rate, and the ability of your body to metabolize glucose (e.g. sugar). You will also fill out questionnaires about your quality of life and your diet during this visit. The order of the tests may vary from below to accommodate the clinical schedule or for logistical reasons. You will be asked to come to your visit fasted for the last 24 hours, but to drink plenty of water.

1. Weight: We will measure your weight with you wearing only in a hospital gown with only undergarments underneath. You will be asked to use the bathroom and void prior to this measurement.
2. Waist circumference: A simple measurement will be made around your waist using a flexible measuring tape.
3. Aortic stiffness/blood pressure: This test measures how flexible/stiff a blood vessel called the aorta (large blood vessel leading out of you heart) is. In addition, this machine will measure the blood pressure within your arm and estimate the blood pressure in your heart. However, this test is done non-invasively. You will sit in a chair and rest for approximately 5 minutes. A blood pressure cuff will be placed around your bicep connected to a machine. The machine will take 4 blood pressures (separated by about 1 minute). You will be asked to sit in the chair and not move during the evaluation.
4. Resting metabolic rate: This test evaluates how much energy your body uses at rest. You will lay on a hospital bed for 15 minutes. After this a canopy will be placed over your head, which will be connected to a machine called a metabolic cart. The assessment will last approximately 30 minutes long.
5. Pulse wave velocity: This test measures how stiff your arteries are from your neck to your leg. A study staff member will feel for a pulse in your carotid artery (a blood vessel in your neck) and the femoral artery (a blood vessel on your inner thigh). A thigh blood pressure cuff will be placed on your leg. The research staff will measure the distance between your carotid artery to the top of your sternum, your carotid artery to the thigh blood pressure cuff, and your femoral artery to the thigh blood pressure cuff. After this the blood pressure cuff on your thigh will tighten around your thigh and a probe (a machine that is designed to measure your pulse) will be placed against your carotid artery. The pressure used should feel similar to feeling for your pulse at your neck. The researcher will hold the probe on your carotid artery until valid measurements are obtained.
6. Blood draw for lipoprotein analysis, c-reactive protein, lipids, glucose, insulin, and the study archive: Study personnel will place an intravenous (IV) catheter (small flexible tube) in your arm. This will be used during the oral glucose tolerance test (discussed below) to draw your blood. Prior to the oral glucose tolerance test, study personnel will draw your blood for lipoprotein analysis (size and number of your cholesterol particles), c-reactive protein (an inflammatory marker) and the study archive (2.0 tablespoons).

7. Oral Glucose Tolerance Test (OGTT) visits: An oral glucose tolerance test measures the changes in glucose and insulin after ingestion of a 75g a sugary glucose solution. Blood samples will be drawn from an intravenous (IV) catheter (small flexible tube) placed in your arm at min 0, 30, 60, 90 120. Five blood draws will be taken in total, one before the sugary drink (min 0) and then four every 30 min after. The total amount of blood drawn for the OGTT will be approximately 2.5 tablespoons.
8. Food frequency questionnaire: You will be asked to fill out a questionnaire about your eating habits.
9. Quality of Life Survey: You will be asked to fill out the SF-36 survey, which will collect information about your overall wellbeing and functional health.

iv. Baseline visit 2 (Ward Sports Medicine Building): During this visit, we will measure your body composition and fitness level. In addition, you will see a doctor who will do a brief medical exam and review your resting and exercise EKGs (electrical activity of your heart).
    1. Physical exam: You will receive a medical exam from a study physician to ensure adequate health for the study (prior to exercise testing).
    2. DEXA scan: A DEXA scan will be conducted to determine your body composition (the amount of muscle and fat in your body). The scanning method will require you to lie quietly on the scanning table for approximately 10 minutes. The scan will subject you to a very low dose of radiation, approximately 5-10% of the exposure of a typical chest x-ray.
    3. Exercise stress test: An exercise stress test will be conducted to determine your fitness level. During this test, you will wear a mouthpiece so the gases you breathe out can be collected for analysis of oxygen consumption. You will begin by walking on the treadmill at a slow speed for 2 minutes. Thereafter, the inclination will be increased every two minutes until you feel exhausted to the point you can no longer continue. The starting speed and incline will be adjusted with the goal of reaching exhaustion within 8-12 minutes.

v. Mid-intervention visit 1: The procedures will be the same as baseline visit 1. In brief, we will repeat the weight, waist circumference, aortic stiffness/blood pressure, pulsewave velocity, blood draw (lipoprotein analysis, c-reactive protein, lipids, glucose, insulin), oral glucose tolerance, food frequency questionnaire and quality of life.

vi. Mid-intervention visit 2: The procedures will be similar to baseline visit 2. In brief, you will repeat the DEXA scan and fitness test.

vii. Follow-up visit 1: The procedures will be the same as baseline visit 1. In brief, we will repeat the weight, waist circumference, aortic stiffness/blood pressure, pulsewave velocity, blood draw (lipoprotein analysis, c-reactive protein and the study archive), oral glucose tolerance, food frequency questionnaire and quality of life.

viii. Follow-up visit 2: The procedures will be similar to mid-intervention 2. In brief, we will repeat you DEXA scan and fitness test.

The study procedures are strictly for research purposes only. You should continue to see your primary care physician for ongoing care.

d. Study intervention:

i. You will participate in a 10 week OPTIFAST weight loss program at VIDANT Wellness. The study will pay for your participation in this program. However, you will need to have clearance from your primary care physician to do the OPTIFAST program. While going to weight loss classes, you will be asked to exercise at ECU 2-3 times a week. During your time in the study, you will wear an actigraph accelerometer (watch on your wrist) that will measure the amount of steps you walk and the intensity of your physical activity. You will wear this watch every day during the intervention. You will be asked to wear this device at all times (including sleeping) unless you are showering or participating in water related activities (e.g. swimming).

ii. OPTIFAST program (VIDANT WELLNESS): OPTIFAST is a comprehensive medically supervised weight loss program that combines lifestyle education and medical monitoring with portion-controlled, nutritionally-balanced meal replacement products (shakes, bars and soups) over the course of 10 weeks. The major goal of the OPTIFAST program for the study is for you to lose at least 7% of your body weight. While involved in the OPTIFAST program, participants will also perform supervised exercise training at ECU to increase your likelihood of reaching the weight loss goals of the study (described below). A nutritionist will guide you on your calorie goals for each week and you will consume OPTIFAST products (supplied through the study resources). You will attend a class once a week at VIDANT Wellness center where you will be weighed weekly, fill out a questionnaire about OPTIFAST products consumed and you will listen to a didactic session on weight management. During the time you are in the OPTIFAST program, you will document your food intake daily through my Fitness Pal App on your smartphone and wear an accelerometer that documents your physical activity levels.

iii. Randomization: After completion of the baseline visit and obtaining at least 7% weight loss, you will be randomized to a study group for the next 16 weeks. You will either be randomized to a group that exercises at: 1) the minimum physical activity recommendations or 2) the weight maintenance guidelines. Randomization means that the study group you will participate in will be randomly determined (i.e. like flipping a coin). Neither you nor the research staff will be able to change the group you are assigned.

iv. Exercise training:

1. Exercise training will be performed predominately on the treadmill. You will need to come to ECU to exercise and you will be supervised by study staff while you exercise. In addition, you will be asked to wear a heart rate monitor that measures how fast your heart beats during the exercise session.

2. During the time you are in the OPTIFAST program (shown above), you will exercise 2-3 times a week at ECU, which will be supervised by research staff.

3. After randomization to study groups:
    a. The physical activity recommendations group will exercise approximately 2-3 days per week supervised by research staff
    b. The weight maintenance recommendations group will exercise 4-5 days per week supervised by research staff
    c. In the event of travel or unexpected circumstances, participants will be allowed to exercise on their own and document this using a Fitbit. If this is needed, you will receive instructions from research staff about how to do this.

What possible harms or discomforts might I experience if I take part in the research?

There is a chance this research may not help your condition. Right now, we do not know for sure it will help. If it does not help, your condition/disease may get worse. There are always risks (the chance of harm) when taking part in research. We know about the following risks or discomforts you may experience if you choose to volunteer for this study. These are called side effects. The following side effects are known to occur in some people:

Risks associated with the exercise testing and training protocols are as follows:

- Exercise:
    - Light headiness or dizziness during or following exercise (rare, 1 to 4 out of 100 people)
    - Ventricular arrhythmia which is an abnormal heartbeat (rare, 1 to 4 out of 100 people)
    - Falls associated with exercising on equipment: There is also a slight risk that a person could fall off the treadmill while exercising. To reduce this risk, qualified personnel will supervise all participants while they are exercising at the fitness center (rare, 1 to 4 out of 100 people)
- Musculoskeletal injury (occasional, 5 out of 100 people): Joint and muscle-related injuries can occur with exercise training. Many, but not all musculoskeletal injuries get better with rest.
- Muscle soreness (common, 90 out of 100 people) is to be expected during the first few weeks of the exercise-training program. This soreness is a normal response to the increase in physical activity, and should lessen over the course of the exercise-training program.
- Death (very rare, fewer than 1 in 10,000 deaths in patients who are known to, or suspected of , having heart disease) The risk is expectedly much smaller in a group of people without known heart disease or diabetes. To minimize this risk, we will have heart (ECG) monitoring during exercise stress tests.
- Blood Draw: the total amount of blood drawn (12.5 tablespoons) is negligible. There is an extremely small risk of local hematoma or infection associated with insertion of intravenous catheters. Bruising at the site of the blood draw can occur.

- DEXA Scan: There is a negligible risk associated with the DEXA scan method of determining body composition. You will be exposed to a very low dose of radiation that is equivalent to approximately 5-10% of what you would be exposed to during a typical chest x-ray.
- Oral Glucose Tolerance Test: You may feel some pain during the insertion of the plastic catheter into your arm. Possible risks associated with the test are nausea, bruising, and a small chance of infection. To minimize risk, the procedure will be performed using sterile techniques by qualified personnel in ECHI.
- Pulse Wave Velocity and aortic stiffness: Mild discomfort during the tightening of the blood pressure cuff on the arm and thigh.
- Resting metabolic rate: Claustrophobia from the canopy placed over your head during the measurement

Additionally, there may be unforeseen risks involved with this and all research studies.

There is always a chance that you may experience some discomfort or harm when taking part in a research study, this study is no different. We will do everything possible to keep you from being harmed. There may be other risks or side effects that occur which we do not know about at this time.

It is important for you to tell us as quickly as possible if you experience any discomfort, harm or side effect as a result of taking part in this study.

Are there any reasons I might want to withdraw from the research or you might take me out of the research?

During the study, information about this research may become available that would be important to you. This includes information that, once learned, might cause you to change your mind about wanting to be in the study. We will tell you about this kind of information as soon as possible. This might include information about the side effects that are caused by taking part in this study. If that happens, we can tell you about these new side effects and let you decide whether you want to continue to take part in the research.

There may be reasons we would need to take you out of the study, even if you want to stay in the study. Some of these reasons include:

- It is not safe for you to stay in the study;
- The side effects are so severe that we need to stop the study or take you out of the study to decrease the risk of harm to you;
- You do not or cannot take your medicine properly; or
- You do not or cannot come for your study visits as scheduled**.**

If we find that the research might harm you or that it is not providing enough of a benefit to justify the risks you are taking, we will notify you and discontinue the study.

What are the possible benefits I may experience from taking part in this research?

We do not know if you will get any benefits by taking part in this study. There may be no personal benefit from your participation but the information gained by doing this research may help others in the future. You may benefit from the valuable information obtained from this research such as health-related information (e.g. weight, waist circumference, exercise testing) and the opportunity to participate in supervised exercise training. The results of this study may provide insight regarding whether exercise training and increasing physical activity provides more health benefits compared to exercise training alone. The risks are considered minimal compared to the benefits.

Will I be paid for taking part in this research?

We will pay you for the time you volunteer while being in this study. If you complete all visits for the study and participate in an adequate amount of exercise training (>75% adherence), we will pay you up to $500 for your time.

You will receive 2 payments for the study if you complete this study. The first payment will include money based on baseline visit 1, baseline visit 2, mid-intervention visit 1, mid-intervention visit 2, and exercise training week 1-12. This payment will occur at week 17 in the intervention ($200, on the condition that all visits are completed and adequate exercise adherence). The second payment will be made after the completion of the entire study ($300). Participants who start the intervention, but withdraw prior to completion of the study or have low exercise adherence (<75%) will receive $25 for exercise training portion of the study. In addition, these participants will be compensated for a prorated amount based on the study visits that they complete.

During the research study, we may also raffle for incentive items (e.g. mug, tee shirt) to help encourage adherence during the intervention.

Visit	**Payment**
Baseline visit 1	$50.00
Baseline visit 2	$25.00
Mid-intervention visit 1	$50.00
Mid-intervention visit 2	$25.00
Exercise training (week 1-10) with >75% adherence to exercise	$50.00
Follow-up visit 1	$50.00
Follow-up visit 2	$25.00
Exercise training (week 11-26) with >75% adherence	$125.00

What will it cost me to take part in this research?

It will not cost you any money to be part of the research. The sponsor of this research will pay the costs of will pay the costs of all research related testing performed in this study.

However, you will be expected to pay for the cost of transportation to and from the testing facility. In addition, you may need to purchase appropriate exercise attire (e.g. work-out clothes, sneakers, etc.). Lastly, you will need your primary care physician's clearance to be in the OPTIFAST program. Therefore, you may need to have a doctor's visit for this purpose. Any fees associated with obtaining this clearance will not be paid for by the study.

Who will know that I took part in this research and learn personal information about me?

To do this research, ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff.

- Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections
- The ECU University & Medical Center Institutional Review Board (UMCIRB) and the staff who have responsibility for overseeing your welfare during this research, and other ECU office staff who oversee this research.

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

How will you keep the information you collect about me secure and how long will you keep it?

Any paper data collection will be stored in a locked file cabinet in locked room (office, or training facility) within the FITT building. The key to that cabinet will be kept in a different room. All electronic data will be kept in secure databases (stored on the departmental drive space), with access restricted to study staff. The codes to the de-identified data will be kept separately. Access to the data files within the database will require user name and password information. All data sources will be stored for at least 6 years following study completion.

Data from the present study may be utilized by researchers at ECU or other institutions for future research to write research papers, support grant applications or other research-related activities. In this case, a dataset will be provided which will not include information that will identify you (i.e. information such as name, address, etc. will not be included in the dataset).

What if I decide I do not want to continue in this research?

Taking part in this study is voluntary. If you decide you no longer want to be in this research after it has started, you may stop at any time. You will not be penalized or criticized for stopping. You will not lose any benefits that you should normally receive by quitting.

What if I get sick or hurt while I am in this research?

If you need emergency care:
Call 911 for help. It is important that you tell the doctors, the hospital or emergency room staff that you are taking part in a research study and the name of the Principal Investigator. If possible, take a copy of this consent form with you when you go.

Call the principal investigator as soon as you can. He/she needs to know that you are hurt or ill. Call Damon Swift, Ph.D. at 252-737-1338.

If you do NOT need emergency care, but have been hurt or get sick:
Contact Call Damon Swift, Ph.D. at 252-737-1338. Call the principal investigator as soon as you can. As necessary, go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If necessary, the Principal Investigator or your regular doctor can assist you in identifying the appropriate place to get care.

If you are harmed while taking part in this study:

If you believe you have been hurt or if you get sick because of something that is done during the study, you should call Damon Swift, Ph.D. at 252-737-1338 immediately. There are procedures in place to help attend to your injuries or provide care for you. Costs associated with this care will be billed in the ordinary manner, to you or your insurance company. However, some insurance companies will not pay bills that are related to research costs. You should check with your insurance about this. Medical costs that result from research-related harm may also not qualify for payments through Medicare, or Medicaid. You should talk to the Principal Investigator about this, if you have concerns.

Who should I contact if I have questions?

The people conducting this study will be available to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator, Damon Swift, Ph.D. at **252-737-1338** (days) or **434-825-5762 (weekends)**

If you have questions about your rights as someone taking part in research, you may call the ECU Office of Research Integrity & Compliance (ORIC) at phone number 252-744-2914 (days). If you would like to report a complaint or concern about this research study, you may call the Director of ORIC, at 252-744-1971

Is there anything else I should know?

Most people outside the research team will not see your name on your research record. This includes people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I understand that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

Participant's Name (PRINT)	**Signature**	**Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

Person Obtaining Consent (PRINT)	**Signature**	**Date**

FUTURE TESTING OF BLOOD SAMPLES

Upon termination of this study, the blood samples collected for this study will be stored for up to 10 years to research scientific questions. These research questions are yet to be identified, but will likely address risk factors for heart disease, type 2 diabetes, obesity, and aging. It is possible that other indicators of health may be measured in these samples. You will continue to be the owner of the samples and retain the right to have the sample material destroyed at any time during this study by contacting the study principal investigator. During this study the samples will be stored with number identifiers only; however, the number identifier will be linked to a specific name and will be kept on file in the possession of the principal investigator. The linked file will be encrypted with password protection and stored on a password protected computer. A backup file will be made and will be encrypted with password protection. No other individuals outside the research team will have access to these identifying materials unless the principal investigator is required by law to provide such identifying information. Data will not be publicly available and participants will not be identified or linked to the samples in publication. If a commercial product is developed from this research project, you will not profit financially from such a product.

Your consent to have future testing of your blood samples is a required for the present study. Therefore, if you do not consent to future testing of your blood samples, you will not be eligible for the present study.

CONSENT TO PARTICIPATE IN FUTURE TESTING OF BLOOD SAMPLES

I certify that I have read all of the above, asked questions and received answers concerning areas I did not understand, and have received satisfactory answers to these questions. I willingly give my consent for participation in this research study. (A copy of this consent form will be given to the person signing as the subject or as the subject's authorized representative.)

_____

Participant's Name (PRINT) **Signature** **Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

_____

Person Obtaining Consent (PRINT) **Signature** **Date**