UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Resveratrol to Enhance Vitality and Vigor in Elders (REVIVE)

3. Who do you call if you have questions about this research study?

Principal Investigator: Stephen Anton, PhD, at 352-273-7514

Other research staff: Study Coordinator at 352-273-9212

Medical safety officer (physician who monitors participant safety and determines appropriate course of action for handling adverse events): Bhanuprasad Sandesara, MD, at 412-607-3914 (cell)

4. Who is paying for this research study?

The sponsor of this study is the National Institutes of Health: National Center for Complementary and Integrative Health. The study product (ReserveAge capsules containing resveratrol) and placebo (capsules containing vegetable cellulose) is provided by the company ReserveAge Organics.

5. Why is this research study being done?

The primary purpose of this research study is to examine the effects that resveratrol, a compound found in red wine and dark-skinned grapes, has on the function of mitochondria (cells' energy producing components) within the leg muscles of moderate functioning older adults.

In a recently completed pilot study, we observed that 12 weeks of use of resveratrol (1000 mg/day) was well tolerated and had the following beneficial effects in overweight, adults older than 65 years of age: (1) increased muscle metabolism at rest, (2) enhanced speed of thought process, and (3)improvements in walking speed in 40% of participants.

This study is also looking at the effects of resveratrol on changes in physical function, and exploring the connection that changes in cells' function have with changes in physical function. You are being invited to be a participant in the REVIVE study because you are 65 years of age or older and have met the initial study criteria through the telephone pre-screening.

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

No procedures in this study will be part of your normal clinical care. Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. These tests may need to be repeated if required for your medical care in the future.

7. What will be done only because you are in this research study?

Overview: The study product, ReserveAge Resveratrol capsules contains Organic French Red Grape & Vine, Muscadine USDA Certified Organic Red Grape & Seed, Organic French Red Grape and vine and wild natural Japanese Knotweed. The active compound in ReserveAge Resveratrol is resveratrol. Resveratrol occurs naturally in grapes, peanuts, and a number of other plants. Placebo capsules contain vegetable cellulose (edible fiber made of vegetables). For simplicity we will call ReserveAge capsules containing resveratrol "resveratrol" and capsules containing vegetable cellulose "placebo".

All study participants will be randomly (like flipping a coin) divided into three (3) groups: participants in one group will be taking 1000 mg of resveratrol/day, the second group participants will be taking 1500 mg of resveratrol/day and participants in the third group will be taking placebo ("sugar pill"). Participants in all groups will take three pills each day, with breakfast, lunch, and dinner. The Principal Investigator or the study team will not have control over what group you will be in. All capsules, 1000 mg resveratrol/day, 1500 mg resveratrol/day and placebo look the same, so the investigator and the study team, just like you will not know what you group you are in and if you are taking resveratrol or placebo.

Please see timeline for evaluations and procedures to be conducted and performed in the chart at the bottom of this section.

Phone Pre-screening Interview: An initial telephone pre-screening indicated that you may be eligible to participate in the study.

The first study visit ("Screening visit") will further determine if you are eligible to participate. Should you be eligible to participate in the study, you will be asked to participate in a daily resveratrol or placebo supplementation program for approximately 90 days. You will be asked to come to our research clinic during your study participation for assessments and ensure your wellbeing: Baseline Visits 1 and 2, 30-day and 60-day Visits, and 90-day Visits 1 and 2. You will also be asked to return to the clinic for three additional visits to monitor your safety. The first follow-up visit will occur approximately 10 days after your Baseline Visit 2 (Biopsy Visit), the

second follow-up visit will take place approximately 10 days after you 90-day Visit 2 (Biopsy Visit), and the third Follow-up Visit will occur approximately 30 days after your 90-day Visit 2. You can see the study's schedule at the end of this form.

Details regarding the tests to be conducted during this screening visit and other study visits (if you are eligible) are described below. Visits will take place at the University of Florida's Institute on Aging-Clinical Translational Research Building (IoA-CTRB), 2004 Mowry Rd, Gainesville, FL 32611.

Screening Visit: Approximately 1.5 to 2 hours long.

Written Consent: After discussion about the study with the study team member and reading this consent form, you will have opportunity to ask as many questions as you would like. During this process, the study team member will make sure that you are informed of what the study involves, and you will be asked to sign this consent form. A copy of the signed consent form will be provided to you for your records

Blood Draw: You were asked to fast before your appointment because blood will be collected during this visit. After we draw your blood we will provide a snack for you before you continue with your visit procedures We will collect approximately 2 tablespoons of blood from a small vein in your arm or hand. The purpose of this blood draw is to determine levels of certain compounds in your blood that will help us determine your eligibility. Should you remain eligible after completing the rest of the screening battery, you will be called to inform you of your eligibility status based on these tests.

Questionnaires: You will be asked questions about your medical history and medications as well as your mood. You will also be asked to complete short test of memory and reasoning.

Physical Measurements: We will take measurements of your height, body weight, waist circumference, pulse, and blood pressure.

Physical Exam: A licensed health care provider will perform a brief physical exam to determine if you are safe to continue with the study. This exam will include a review of your medical history, medications, and measurement of your height, blood pressure, pulse, weight, and waist circumference. Your blood pressure and heart rate will be measured in the seated position following 5 minutes of rest (sitting quietly in a chair).

Tests of physical performance: You will be asked to complete tests of your physical ability. You will perform tests of your physical ability that include:

1. Walking at your usual pace for a distance of 13 feet (4 meters) two (2) separate times
2. Standing from a sitting position, without using your arms. If you are able to perform this task, you will be to stand up from and sit down on chair five (5) times as fast you as can

3. Maintaining your balance while standing in three (3) different positions, 1) with your feet together, 2) with the heel of one beside the big toe of the other foot, and 3) the heel of one foot in front of and touching the toes of the other foot

You will be monitored and assisted as necessary in the event that you are unable to keep your balance.

Baseline Visit 1: Should you be eligible for the study based on the results of your screening visit, you will be asked to return to the clinic for the first baseline study visit. This visit is expected to take 2 to 3 hours and will include:

- Update your medical history and ask you questions about any adverse experiences you may have had since last visit
- Measurement of pulse and blood pressure
- Measurement of body weight and waist circumference
- Collection of fasting blood samples
- Questions about your health
- Tests of physical performance, including:
    - Walking as fast and far as you can for 6 minutes
    - Walking at your usual pace for a distance of 13 feet (4 meters) two (2) separate times
    - Standing from a sitting position, without using your arms. If you are able to perform this task, you will be to stand up from and sit down on chair five (5) times as fast you as can.
    - Maintaining your balance while standing in three (3) different positions, 1) with your feet together, 2) with the heel of one foot beside the big toe of the other foot, and 3) the heel of one foot in front of and touch the toes of the other foot.
    - Assessment of lower-body muscle strength and endurance
- Dr Anton and other researchers would like to store some of your leftover samples for future research. This is discussed in details in a separate consent form. It is up to you to agree or disagree to store some of your samples and your decision will not affect your participation in the REVIVE study.

_____I AGREE to discuss opportunity for some of my samples to be used in future research (please initial)

_____ I DO NOT AGREE to discuss opportunity for some of my samples to be used in future research (please initial)

Activity Monitor: You will also be asked to wear an Activity Monitor during a typical seven day period to assess your baseline physical activity habits. This monitor is worn on your hip during the day and night. You will be asked to return this monitor at your Baseline Visit 2.

Baseline Visit 2 (Muscle Biopsy): Approximately 2 hours long.

Please wear shorts for this visit. If you come to the visit not wearing shorts, disposable shorts will be provided for you for your comfort.

Vital Signs: Measurement of pulse and blood pressure before collection of the muscle tissue sample.

Medical History update: Update your medical history and ask you questions about any adverse experiences you may have had since last visit

Muscle Tissue Sample (Biopsy): A muscle biopsy is the removal of a small piece of muscle tissue for analysis. The study team is looking to collect a muscle sample with as little amount of fat as possible; total volume of muscle collected will not exceed a size of pencil eraser.

- You will have a biopsy of the muscle on the outside of your thigh, approximately 4-6 inches above your knee. The procedure to collect muscle samples will be performed by a licensed healthcare provider with experience conducting the procedure.
- You will be seated on the exam table in a separate room located in the Institute of Aging research center. If you prefer, you can lie down on the exam table.
- Biopsy area will be prepared: shaved (if necessary) and cleaned with non-iodine antiseptic.
- The study physician will inject a numbing medicine (anesthetic) into the biopsy area using a small needle. Before the area becomes numb, the anesthetic may burn or sting a bit when injected.
- Approximately 8-12 minutes will pass to let anesthetic take effect so it would make the biopsy site numb.
- The study physician will make a small (less than 1/4 inch) incision on the numb area of the skin.
- A needle of a size of pen refill will be inserted into the muscle through the incision in the skin. A syringe that provides suction will be connected to the needle and is used to aid collection of the sample. When the needle is removed from your muscle, a small piece of tissue will remain in the needle.
- During the procedure you may feel pressure as the needle is inserted into the muscle. You might feel discomfort, but pain occurs rarely. You should notify the physician if you have any pain during the procedure.
- If the sample taken is of poor quality (e.g. it contains too much fatty tissue) or too small for analysis, we will ask if we can insert the needle in the same incision site for a second try.

- When collection of the sample is complete, the physician will apply pressure on the area where biopsy was done.
- After making sure that bleeding (if any) has stopped, steri-strips or special liquid glue will be used to close the skin incision, and antibiotic cream will be applied on and around incision site.
- Gauze and a special bandage will be placed on the biopsy area.

Vital Signs: Measurement of pulse and blood pressure after procedure.

Instructions and follow-up after Muscle Biopsy: You will receive detailed instruction on how to care for the biopsy site: the study team member will discuss this with you and you will receive biopsy site care instruction sheet. Also, the study team member will call you following the procedure and will do a brief 10 minute phone interview regarding any problems that you may be having related to the procedure. In addition, we would like to ask you to come for a follow-up visit (described below) to make sure that biopsy site is healing well.

Randomization: If you are eligible and it is safe for you to continue with the study, you will be randomly assigned, much like a flip of a coin, to one of three conditions: (1) resveratrol (1000 mg/day) (2) resveratrol (1500 mg/day) or (3) placebo (vegetable cellulose).

A placebo is a substance that looks like and is given in the same way as an experimental treatment but contains no medicine, for example a sugar pill. A placebo is used in research studies to show what effect a treatment has compared with taking nothing at all. If you are assigned to receive placebo, you will not receive the benefits of the resveratrol, if there are any, nor will you be exposed to its risks, which are described below under "What are the possible discomforts and risks?" Studies have shown, however, that about 1 in 3 persons who take a placebo do improve, if only for a short time.

You and the principal investigator and other study team members conducting this study will not know whether you are receiving placebo or resveratrol, but that information is available if it is needed. Also, you will have a 66% chance of receiving one of the two different dose levels of resveratrol and a 33% chance of receiving placebo. In the remainder of the description of what will be done, both the resveratrol and the placebo will be called "study drug capsules."

You will be provided with a supply of the study drug capsules of at least 30 days and will be asked to return any remaining study drug capsules to the clinic at your next appointment, approximately 30 days from this visit. You will be asked to orally consume one study drug capsule following each of your main meals (i.e. breakfast, lunch and dinner) with a glass of water.

10-Day Post-Biopsy Visit: Approximately 30 minutes to 1 hour long.

- Measurement of pulse and blood pressure
- Update your medical history and ask you questions about any adverse experiences you may have had since last visit
- The area where the muscle sample was collected will be checked to make sure that there are no post-biopsy complications
- Collection of fasting blood samples

30-Day & 60-Day Visits: Each approximately 1 hour long.

- Collection of fasting blood samples
- Measurement of pulse and blood pressure
- Measurement of weight and waist circumference
- Update your medical history and ask you questions about any adverse experiences you may have had since your last visit
- Counting of any remaining study drug capsules that were not taken since last visit

Providing you with study drug capsules needed until your next study visit

90-Day Visit 1: This visit will be similar to your Baseline Visit 1 and will last approximately 2-3 hours.

- Measurement of pulse and blood pressure
- Measurement of body weight and waist circumference
- Collection of fasting blood samples
- Update your medical history and ask you questions about any adverse experiences you may have had since last visit
- Counting of any remaining study drug capsules that were not taken since last visit
- Tests of physical performance, including:
    - Walking as fast and far as you can for 6 minutes
    - Walking at your usual pace for a distance of 13 feet (4 meters) two (2) separate times
    - Standing from a sitting position, without using your arms. If you are able to perform this task, you will be to stand up from and sit down on chair five (5) times as fast you as can
    - Maintaining your balance while standing in three (3) different positions, 1) with your feet together, 2) with the heel of one beside the big toe of the other foot, and 3) the heel of one foot in front of and touching the toes of the other foot
    - Assessment of lower-body muscle strength and endurance
- You will receive an Activity Monitor to wear for seven days, and will be asked to return this monitor at your 90-Day Visit 2.

90-Day Visit 2 (Muscle Biopsy): This visit will be similar to your Baseline Visit 2 and will last approximately 1.5 to 2 hours.

- Procedure to collect muscle tissue sample (as described in Baseline Visit 2)
- Counting of any remaining study drug capsules that were not taken since last visit.

10-Day Post-Biopsy & 30-Day Follow up Visits: Each approximately 30 minutes to 1 hour long.

- Measurement of pulse and blood pressure
- Collection of fasting blood samples
- Update your medical history and ask you questions about any adverse experiences you may have had since last visit
- During 10 day Follow-Up Visit, area where the muscle sample was collected will be checked to make sure that there are no post-biopsy complications

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

If you qualify for the study, your expected participation in the study is approximately five (5) months – though it may be longer if conflicts arise in scheduling of assessment visits.

9. How many people are expected to take part in this research study?

We expect that approximately 600 people will be screened and 60 individuals will participate in the full study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

There are some possible discomforts and risks associated with participating in the study.

Physical Performance Tests: There is a risk of losing your balance and falling associated with the physical performance testing. A fall also places you at risk of a bone fracture. We will minimize this risk by: (1) safely escorting you to chairs should you become unsteady; and (2) being at your side should you need assistance.

Blood Draw: The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure.

Resveratrol: The potential risks associated with resveratrol supplementation are not fully known at the present time. Resveratrol is similar to the synthetic estrogen and may have estrogenic activity. Resveratrol might also interact with blood thinners such as warfarin, and non-steroidal, anti-inflammatory medications, thereby increasing the risk for bleeding. A potential risk could be increased gastrointestinal discomfort and/ or headaches. Adverse effects of resveratrol have not been reported at doses of 1000 mg/day, 1500 mg/day and 2000 mg/day; however, long-term side effects are not known. In our resveratrol pilot study which was conducted on older adults, resveratrol supplementation at doses of 300 mg/day and 1000 mg/day had minimal effects on results of blood tests of older adults, and there were no big differences in the number of participants reporting adverse or toxic events (e.g. headaches) between group taking 300 mg or 1000 mg of resveratrol a day.

Muscle Biopsy: The potential risks of muscle biopsy include mild muscle soreness, swelling, infection, bleeding, and possible temporary localized numbness at biopsy site or other areas of the body. Minute nerve damage causing injury to a small number of muscle fibers (<0.01%) could occur but no observable or measurable changes in muscle strength or muscle function have been reported. The potential for mild soreness and swelling is 50%, but no reports of restricted activity have ever been described. To minimize the risk of bruising, pressure dressings will be applied and only disposable and sterile materials will be utilized during the procedure. It is possible for the muscle biopsy procedure to leave a small scar that may or may not fade with time. Some people may be sensitive or allergic to the local anesthetics, and the study team should be informed if you have such an allergy or sensitivity. Please alert the study team if you are aware of any allergies or sensitivities to local anesthetics such as lidocaine. Some people may feel dizzy or feel faint during or after the muscle biopsy procedure. We will provide a place for you to sit and rest after the procedure.

Personal Information: Taking part in this research 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.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

Potential benefits of this study to you include learning information about your health and overall physical function.

11b. How could others possibly benefit from this study?

Others will gain knowledge on the possible health benefits associated with resveratrol, a dietary supplement that is widely available.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

Dr. Anton, the Principal Investigator, is a paid consultant for ReBody LLC which is owned by Reserveage Organics that makes the resveratrol product that will be used in the study. Please feel free to ask any questions you may have about this matter.

12. What other choices do you have if you do not want to be in this study?

If you do not wish to be in this study, please tell a study team member and do not sign this form. The study product being tested (i.e., resveratrol) is currently available at many health food stores.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw, no further information will be collected. Information already collected from you may be used to complete the study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The Principal Investigator feels it is necessary for your health or safety. You will be informed if this decision is made and the reason for this decision.
- New information suggests that taking part in the research study may not be in your best interests.
- The sponsor or the Principal Investigator has decided to stop the study for any other reason.

You may also be withdrawn from the study if you do not follow the instructions given to you by the Principal Investigator or the study team.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Drugs, Devices

The study drug (Resveratrol or Placebo) and an activity monitor will be provided at no cost to you while you are participating in this study.

The Sponsor will pay for all activities required as part of your participation in this study as described above in the question *"What Will Be Done Only Because You Are In This Research Study*". If you receive a bill for these services, please contact Dr. Stephen Anton at 352-273-7514 or the study coordinator at 352-273-9212.

15. Will you be paid for taking part in this study?

Yes. You will be paid up to $700 in gift cards if you complete the entire study. You will receive gift cards compensation for the completion of the study visits as following:

Baseline Visit 1 - $75

Baseline Visit 2 (Biopsy) - $150

10-day Post-Biopsy Visit - $50

30-day Visit - $50

60-day Visit - $50

90-day Visit 1 - $75

90-day Visit 2 (Biopsy) - $150

10-day Post-Biopsy Visit - $50

30-day Follow-up Visit - $50

If you live 20 miles outside of the University of Florida's Health Science Center we will compensate you a $20 gas card for each visit you attend.

The study drug (resveratrol or placebo) will be provided at no cost to you while you are participating in this study.

If you are paid for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more, the University must report the amount you received to the Internal Revenue Service (IRS).

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Stephen Anton at 352-273-7514 or Dr. Bhanuprasad Sandesara at 412-607-3914 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- First and last name
- Contact information
- Date of birth
- Social security number for compensation
- Information about your health status such as weight and height
- Complete past medical history to determine eligibility criteria
- Physical Examination to determine study eligibility criteria
- Medications you are taking
- Laboratory test results
- Answers to health questionnaires
- Physical performance test results

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or

other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To determine if you are eligible for the study.
- To determine the effects of resveratrol supplementation on changes in the functioning of the mitochondria within your muscle cells over a 90-day period.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- Other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States and governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .

- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study, which is the time when the study has been closed with University of Florida's IRB.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator. Please send you revocation letter to Dr. Anton, University of Florida, P.O. Box 112610, Gainesville, FL 32610.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date

REVIVE Study timeline for tests, evaluations, and procedures

Assessment	Phone Pre-Screen	Screening Visit	Baseline Visit 1	Baseline Visit 2	10 days Post-Biopsy Visit	30-Day Visit	60-Day Visit	90-Day Visit 1	90-Day Visit 2	10 days Post-Biopsy Visit	Follow-up 30 Day
Telephone interview pre-screening	X										
Informed Consent		X									
Informed Consent for Data/ Tissue Bank (optional)			X								
Medical History		X									
Medical History update			X	X	X	X	X	X	X	X	X
Height		X									
Weight/Girth Measurement		X	X			X	X	X			
Vitals (blood pressure + heart rate)		X	X	X	X	X	X	X	X	X	X
Physical Exam		X									
Memory and Concentration Tests		X									
Blood Draw		X	X		X	X	X	X		X	X
Short Physical Performance Battery (SPPB)		X						X			
6 min walk test			X					X			
Physical Activity Monitor			X					X			
Biodex (knee extension and flexion)			X					X			
Muscle Biopsy				X					X		
Randomization				X							
Product Dispense				X		X	X				
Product Compliance						X	X	X			
Adverse Event Assessment			X	X	X	X	X	X	X	X	X