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. Write Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Time Course Adaptations Using Deuterated Creatine (D_3Cr) Method: A Pilot Study **(D3Cr Study)**

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

Principal Investigator: Todd Manini, Ph.D. (office: 352-273-5914; cell: 352-275-8670)

Other research staff can be contacted: Phone: (352) 294-5800
Anoop Balachandran, Ph.D
Coordinator: 352-273-9212

4. Who is paying for this research study?

The sponsor of this study is University of Florida's Pepper Older Americans Independence Center (OAIC) that is funded by the National Institute of Health (NIH)

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. 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.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to

- Study a promising new method to measure muscle in older adults before and after a strength exercise and successful aging health education program
- Understand the correlation between muscle and function (leg strength, balance, walking speed and so forth) in older adults.

Study duration is approximately 16 weeks (including screening visits).

b) What is involved with your participation, and what are the procedures to be followed in the research?

Participants in this study will be randomized into either an exercise (resistance training) group or a Successful Aging Health Education group.

c) What are the likely risks or discomforts to you?

The risks of the resistance exercise training are minimal since all exercise sessions are supervised by trained exercise interventionist who instruct participants in the proper exercise techniques.

d) What are the likely benefits to you or to others from the research?

You will receive health and medical screening examinations and the results will be discussed with you. Participation in the intervention groups has the potential to improve your health, body composition, and quality of life.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

The option if you do not want to participate in this study is to do nothing.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

You are being asked to be in this research study because you told us you were interested in participating.

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)?

Your clinical care will continue as normal even if you do not participate in this research study. Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems.

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

Brief Overview: After an initial screening visit to determine if you **qualify** for the study, you will be randomly assigned (coin flip) to either of the two groups: A strength training group or a successful aging health education group for a total study duration of **14 weeks**.

- **Strength exercise training:** The strength exercise training program will comprise of upper body and lower body strength exercises using strength training machines. You will be training **3 days/week (40-55 minutes)** for 14 weeks and the sessions will be supervised by our study staff. To reduce chances of injury, exercises will be light at first and will slowly increase in difficulty based on your feedback. Study staff will tailor the program to your individual abilities. The program will also include a warm-up and cool down period.
- **Successful Aging Health Education:** The successful aging will attend stretching and health lectures as a group **once every 2 weeks** for 14 weeks for **40-55 minutes**. The topics might include, medication management, disease management (e.g. Blood pressure, diabetes, arthritis, dementia, pain management, diet) and other health related matters.

Baseline, Week 8 and Week 15: All eligible participants will be tested at three time points as shown in the table below. The tests will take approximately 2-3 hours.

Table 1: Study visits and assessments

Schedule of Events	Training Intervention								
				Preparatory Phase		Training Phase			
	Phone scr.	Scr. Visit	Baseline	**Week 1**	Week 2	**Week 8**	Week 11	Week 14	**Post-Test**
Screening									
Basic eligibility phone screening	X								
Short consent		X							
Informed consent			X						
Physical exam, Medical History, Height			X						
Body weight, height & Vitals			X			X			X
Interventions									
Resistance Training				←	—	—	—	→	
Successful Aging Health education				←	—	—	—	→	
Assessments									
Body composition scan				X		X			X
D3Cr Dosing & Collection			X	X		X			X
Physical Ability Test		X				X			X
Functional Tests			X			X			X
Questionnaires			X			X			X

Description of tests and procedures

1. **Medical History:** You will be asked questions about your medical history as well as your physical activity habits for your baseline visit.
2. **Physical exam.** A medical professional will give you a physical exam for your baseline visit. He or she will review your medical history and ask you questions about your health. This exam will help us know that it is safe for you to do the study activities at baseline.
3. **Measurements.** Measurements of your height, body weight, waist circumference, blood pressure, and heart rate will be taken.

Tests

All tests will be conducted 3 times during the study- at Baseline, Week 8 and at Week 15 as shown in the **Table 1.**

1. **Muscle mass:** Muscle mass will be measured at baseline, Week 8 and at post-test as shown in the Table. Two tests will be used to measure muscle mass. The measurement is sensitive to what you eat so we will ask you to come fasted in the morning. Water is allowed.

- D3-Cr (Deuterated Creatine): You will ingest a deuterated (non-radioactive) creatine capsule. Creatine is a natural substance in your muscles and is consumed in abundance when eating meat. It is not considered a drug or supplement and is safe for consumption. The muscle mass is estimated from the labeled creatine in the urine sample. You will be asked to return to the Institute on Aging to give a fasted, morning urine sample 2-3 days later.
- Body composition scan: You will be asked to lie on a table while a special X-ray machine scans your body. The machine, called DEXA (Dual-energy X-ray Absorptiometry, uses very low dose x-rays to measure bone, lean and fat mass. The scan takes less than 10-15 minutes to complete.

2. **Physical Ability Test:** The physical ability test has four parts. You will be asked to:

   1. Walk a short distance (about 4 feet)
   2. Stand up from a chair 5 times without using your arms
   3. Stand in 3 different positions while keeping your balance
   4. You will be asked to stand up from a chair and walk around a cone and sit back on the chair

Functional Tests

3. **Hand grip and Leg strength:** Grip strength is measured using a grip strength instrument and leg strength using a leg strength machine called Biodex.
4. **Walking Test:** You will be asked to walk 400 meters at a normal pace without help from an assistive device (e.g. cane or walker) or another person.

   - **Gait Analysis**: We will ask participants to walk across a carpet that contains sensors arranged in a grid pattern to collect step length, stride frequency and so forth.

5. **Energy consumption:** To calculate energy consumption we will sample your breath through a mask placed over your mouth and be fitted with a portable electronic unit. You will wear the unit while you do the following daily tasks lasting about 6-8 minutes each.:

   - Mopping: Mop a 200 sqft room using mop and water
   - Lifting: Lift chairs and transfer across a 200 sq ft room
   - 6 min walk test will include walking at a rapid pace around 2 cones 20 m apart wearing the portable metabolic unit.

6. **Balance** will be measured using the Timed Up and Go test which is widely used to examine balance.
7. **Questionnaires:** You will be asked questions about your physical function (ability to move around and carry everyday tasks), quality of life, mindfulness, and pain using both paper and computer based questionnaires.

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.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

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?

Your expected participation length is up to **6 months**

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

We will screen 534 people. We expect 24 older persons to complete the 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?

Walking tests: The 400-meter and 6 minute walk tests may be associated with the risk of falling or development of chest. Rarely, falling during the 400-meter walk test may result in a fracture. Similar to the walking tests, completion of the SPPB may be associated with the risk of falling or development of chest. Rarely, falling during the SPPB test may result in a fracture.

To minimize these risks, research staff are trained in the conduct of all physical performance tests and certified by before they work with study participants. Study staff are instructed **NOT** to perform these tests if they feel that testing is unsafe or if you are concerned about a specific test.

Questionnaires: There are some risks associated with questionnaire administration. Sensitive information collected for this study includes lifestyle factors (e.g., alcohol use) and personal health information (PHI). Participation includes a risk of loss of confidentiality of this information. To minimize risk, questionnaire data are collected in secure spaces where the interview cannot be overheard. Also, you can decline to answer questions that are uncomfortable or concerning.

DXA: This research study involves exposure to radiation from x-rays. You will receive three DEXA scan during this study. The radiation exposure from one DEXA scan is equal to about 3 millirems, which is comparable to about 4 days of natural

background radiation to which people in the United States are exposed to during their lives. The risk from this radiation exposure is considered to be low when compared to other every day risks

Resistance Training: The risks of the resistance exercise training are minimal, but may include the following:

- Difficulty breathing and/or shortness of breath
- Muscle, joint strains and soreness
- Soft tissue injury, falls and fractures
- Increasing intraocular and systemic pressures associated with use of the Valsalva maneuver to levels that may cause injury (detached retina, hernia, conjunctival hemorrhage), which is greatly reduced by instruction in proper exercise technique.
- Hernia
- Exacerbation of arthritis or other joint conditions
- Lumbar disk hernia
- A small increase in the risk of sudden death, stroke, and acute MI occurring during a bout of vigorous exercise has been reported, especially in previously sedentary individuals.
- Orthostatic hypotension
- Triggering of an asthma episode

These risks are minimized since all exercise sessions are supervised by trained exercise interventionist who instruct participants in the proper exercise techniques, including instructions to breathe normally during the exercise. Procedures to minimize injury include warm-up and cool-down activities that include large muscle movements and stretching. We have also built in a preparatory phase so that participants have enough time to learn proper exercise technique and gradually increase their training volume and intensity.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of

information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

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

- You will receive health and medical screening examinations and the results will be discussed with you. For example, bone density and muscle mass results.
- You will have the opportunity to participate in a **professionally supervised** strength training program or stretching plus health education program.
- Participation in these activities has the potential to improve your health, body composition, and quality of life.
- Also, you will receive an **individualized report** of your strength, muscle mass, fat percentage, bone density and physical function in comparison with other older adults in your age group and gender at the end of the intervention.

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

- The results of the study will help validate a new tool to measure muscle mass in older adults that will have a number of potential uses, ranging from detecting muscle loss in both health and disease to assessing the benefit of various interventions to increase muscle mass.
- It will also help us better understand the specific role of muscle to prevent or delaying disability in older adults.

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.

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.

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 in final data analyses

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

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

At the discretion of the Principal Investigator, participants may be discontinued early from this study due to unanticipated circumstances. The investigator and the sponsor reserve the right to terminate the study and discontinue your participation at any time for any reason in order to ensure your safety.

Some possible reasons for withdrawing you from the study:

- failure to follow study instructions
- your physician feels it is unsafe for you to participate
- the investigator decides that continuation could be harmful to you
- you need treatment not allowed in the study
- the study is canceled
- other administrative reason

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?
The Sponsor will pay for or provide all services and activities required as part of your participation in this study. There will be no cost to you. If you receive a bill for these services, please contact Anoop Balachandran at 352-273-8962.

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

You will be paid **$100.00 dollars** as compensation for the study after each assessment visit: Baseline Visit $25, Week 8 Visit $25 and Post-Testing Visit $50.

If you are paid more than $75 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 as required by law. You are responsible for paying income taxes on any payments provided by the study. If the

payments total $600 or more or you are a nonresident alien, payment will be processed through the University of Florida
Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

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 routinely 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 one of the research team members listed in question 3 of this form 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:

- Vital signs
- Results of your body measures
- Name, address and contact information
- Questionnaires
- Your social security number for compensation purposes
- The medical history you provide us to help evaluate your eligibility or continued participation in the study
- List of medications you are taking

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 and safe to be in the study.
- To determine changes in muscle and function in response to exercise

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 governmental agencies that 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.
- Other professionals at other institutions who are involved in this research

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

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.

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 _____