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?

Time to Eat Study - Pilot

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

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

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

4. Who is paying for this research study?

The sponsor of this study is the University of Florida Institute on Aging.

5. Why is this research study being done?

The purpose of this research study is to conduct a pilot study to assess the feasibility of a time restricted feeding intervention within the older sedentary population.

You are being asked to be in this research study because you are age 65 or older, are generally healthy and have reported that you are sedentary and have difficulty with mobility.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website 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 part of this research study will be done as part of your normal clinical care. The study does not interfere with your normal clinical care and your normal clinical care will not be interrupted whether you participate in the study or not. Participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence current or future health care you receive.

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

You will be asked to fast for a target of 16 hours per day for a period of 4 weeks. The first week will involve of a ramp up to a full 16-hour fasting period (Days 1-3 fast for at least 12 hours per day, Days 4-6 fast for at least 14 hours per day). You will be allowed to consume calorie-free beverages, tea, black coffee, and sugar-free gum during the time which you are fasting. You will also be encouraged to drink plenty of water during the time which you are fasting. You will be asked to record the time of first and final food or drink consumption each day.

Screening/Baseline Visit (clinic visit)

At this visit, you will be asked to do the following:

- Informed Consent review and discussion
- Review of your medical history
- Measurement of your height, weight, and waist circumference

- A 4-meter walk test (about 13 feet)
- Measurement of your vital signs

*If you consent to the study and are eligible for the study based on the screening criteria, the following items will *also* be completed at the Screening/Baseline visit:

- Fasting blood collection (about 1/2 tablespoon) for lab tests
- Montreal Cognitive Assessment (MoCA)
- A measure of your grip strength
- A 6-minute walk test
- Questionnaires about fatigue levels
- You will be given an activity monitor to wear for the duration of the 4 week intervention period
- You will be given a Food Intake Time diary to record the times of both the first and last instances of calorie consumption (food or drinks containing calories) for each day. You will also be given a diary to record the time you wake up and go to sleep each day.

This visit should last approximately 2 hours.

Week 1, Week 2 and Week 3 (phone visit)

At the end of week 1, week 2, and week 3, a study staff member will contact you by phone. During these phone contacts, study staff will review your food diary and ask you to report the time in which you ate your first and last meal each day. Study staff will also ask you about any changes to your health since your last study contact.

These calls should take less than 30 minutes. We may call you more often if you need additional support in following the fasting schedule.

Week 4 (clinic visit)

At this visit, you will be asked to do the following:

- Measurement of your height, weight, and waist circumference
- Measurement of your vital signs
- Fasting blood collection (about 1/2 tablespoon of blood will be drawn)
- Montreal Cognitive Assessment (MoCA)
- A measure of your grip strength
- A 6-minute walk test
- Questionnaires about fatigue levels
- Return activity monitor to study staff
- Review food intake and sleep diaries
- Review any changes to your health since last study contact.
- Satisfaction survey and exit interview

This visit should take approximately 2 hours.

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?

You will be in this study for approximately 4 weeks.

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

We expect to screen about 200 of participants. We are looking for 10 participants to complete this 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?

Risks associated with intermittent fasting (time restricted feeding). There have been a number of human clinical trials published to date evaluating intermittent fasting dietary interventions in young and middle-age adults. Few studies have been conducted on intermittent fasting (time restricted feeding) in older, healthy participants. Of the adverse effects reported in these and other studies, undesirable weight loss and hunger were the two most frequently reported occurrences. It is possible that hunger will persist throughout the duration of the 4 week intervention period.

As you adjust to time restricted feeding eating pattern, you may feel stomach discomfort, feelings of being more or less hungry than usual, and have more or less energy at certain times of the day than you usually have.

You may feel your blood sugar levels go up and down more rapidly than you are typically used to, which may affect your energy levels and how hungry or full you feel. Also, there is a small risk that your blood sugar levels will go too high or too low. If your blood sugar levels drop too low, you may experience dizziness, sweating, sleepiness, anxiety, hunger, or weakness.

To minimize the risks associated with intermittent fasting, phone visits will be conducted weekly to monitor any changes in your health. You are encouraged to contact the PI if you become concerned while adhering to this eating pattern.

Risks associated with the 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. To minimize these risks, study staff are trained to properly draw blood and use measures that help prevent complications.

Risks associated with blood pressure measurement. The risks of placing a blood pressure cuff on your arms include pinching or slight bruising. To minimize these risks, study staff are trained to appropriately administer blood pressure tests.

Risks associated with physical performance tests. There is a risk of losing your balance and falling associated with the physical performance-based tested (e.g., 4 meter walk and 6 minute walk tests). Falling places you at risk for a bone fracture and soreness or injury to muscles or tendon/ligaments. To lessen these risks, you will be safely escorted to chairs located along the walking course should you become unsteady. A Study Coordinator will follow at a close distance during the walking tests and will be monitoring you for safety.

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?

If you choose to consent to this study, you will participate in the study's intermittent fasting intervention (time restricted feeding) which may or may not result in various health benefits, such as reduced levels of inflammation and/or improvement in your physical function.

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

The results from this study could be used to establish guidelines for future, larger studies on the effects of intermittent fasting in older adults. Therefore, even if this study may not affect you directly, it could impact the well-being of many future generations.

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?

The other option that you have if you do not want to participate in this study is to do nothing. If you do not want to take part in this study, tell the Principal Investigator or study team member and do not sign this Consent 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 from this study, no further information will be collected. However, information that has already been collected will have become a part of the study and is required to retain the study integrity.

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

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

- If the Principal Investigator or study physician decide that your participation in the study could be harmful to you
- If you develop a medical condition or need treatment not allowed in the study
- If you do not follow study instructions
- If the study is cancelled
- Other various administrative reasons

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

No. There will be no extra cost to you for participating in this Research Study.

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

You will receive $25 at the Screening/Baseline visit and an additional $25 at the Week 4 visit. No compensation is available for the phone visits.

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 the 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.

If you have any problems regarding your payment, contact the study coordinator.

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:

- Name
- Contact information
- Date of birth
- Information about your past and current medical history
- Vital signs
- Physical measurements (e.g. height, weight, and waist circumference)
- Medications you are taking
- Results of the physical function tests (e.g. 4 meter and 6 minute walks, as well as grip strength)
- Information about your current mental status
- Information from the questionnaires about your fatigue and energy levels
- Information from the Food Intake Time diary
- Information from the provided activity monitor
- Information from the satisfaction survey and exit interview
- Results from the laboratory tests done with your blood samples

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 test the risks and benefits of intermittent fasting of 16 hours per day in older adults
- To test whether intermittent fasting in older adults can have a beneficial effect on reducing inflammation
- To test the effects of intermittent fasting on physical function

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 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.

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