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:_____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the title of this research study (this "Research Study")?

Assessment of Fuel Utilization and Circadian Rhythms in Overweight, Older Adults Following Time Restricted Eating – Phase 2 (FAR Phase 2)

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

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

Study Physician: Bhanuprasad Sandesara, MD: 352-294-5804

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

4. Who is paying for this Research Study?

The sponsor of this study is the National Institute of Health.

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 way our body uses energy and the body's internal 24-hour clock have emerged as important targets to improve the health of living cells in our body. This could ultimately affect how well we function as we age. The purpose of this study is to develop a minimally invasive way to measure, assess, and detect changes in the body's energy expenditure and the body's internal clock, specifically in older adults following a Time Restricted Eating intervention. Your participation period in this study will be a minimum of 8 weeks and a maximum of 18 weeks. Each assessment visit will last 2-3 hours.

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

There will be an initial screening and two in-person assessment visits. You will be asked to participate in a Time Restricted Eating Intervention described later in this consent form. The visits will vary in length and will include monitoring of overall vital signs, walking tests, fasting blood draws, urine collections, blood sugar fingerstick test (only at screening visit), questionnaires, collection of medical history/medication inventory, your self-reported outcomes physical difficulty with daily activities, receive a blood sugar control handout, complete the Fasting & Sleeping diary daily, and Dual X-ray Absorptiometry to measure your body fat, muscle mass and bone density. You will also be wearing the iButton, Continuous Glucose Monitor, 24-hour ambulatory blood pressure monitor, and an Actiwatch that will serve as activity monitors and collect other data.

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

The risks associated with the study are greater than minimal risks. Potential risks are those associated with venipuncture such as bruising or discomfort, risk of falling and/or injuries (for example, spraining an ankle) during walking assessments, risk of skin irritation from wearing the iButton, Continuous Glucose Monitor, Actiwatch, 24-hour ambulatory blood pressure monitor and a risk of slight pain from the fingerstick. There is a potential radiation risk associated with the Dual X-ray Absorptiometry scan and potential loss of your confidentiality when you participate in the in-person/Zoom intervention meeting. Additionally, you might feel uncomfortable answering health-related questions. There is also a small risk that you may

experience symptoms of low blood sugar while following the Time Restricted Eating intervention. Some symptoms include dizziness, excessive hunger, headache, and weakness.

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

There are potential benefits to you from Time Restricted Eating intervention such as weight loss, reduced fat mass, and improved blood sugar control. Others may benefit if the study findings eventually lead to the development of new methods to measure how your body uses energy.

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

If you do not wish to be in this study, please tell a study team member and do not sign this form.

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.

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 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 the current or future health care you receive.

7. What will be done only because you are in this Research Study?

For this study, you will be asked to attend a screening visit (V1), 2 assessment visits (V2 & V3) and additional Time Restricted Eating intervention visits.

Table 1. Schedule of visits.

Visits	**Screening (V1)**	**Baseline (V2)**	**Intervention visits**	**Post Intervention visit (V3)**
Timeline	*0 week*	*First week*	*First 4 weeks: meeting weekly* *Following 4 weeks: meeting bi-weekly*	*90 days from the start of the intervention period (Approximately 8-18 weeks)*
Consent	**X**			
Questionnaires	**X**	**X**		**X**
Physical function test and measurement	**X**	**X**		**X**
Dual Energy X-ray Absorptiometry scan		**X**		**X**
Time Restricted Eating intervention			**X**	
Wearing/data collection on wearable technology and health updates.	**X**	**X**	**X** (last 2 weeks only)	**X**
Fasting blood draw	**X**	**X**		**X**
Urine collection		**X**		**X**

Screening Visit (clinic visit): At this visit, you will be asked to do the following:

- Informed Consent review and discussion
- Provide contact and demographic information
- Review of your medical history, and medication inventory
- Measurement of your height, weight, and waist circumference
- A 4-meter walk test (about 13 feet)
- Measurement of your resting blood pressure and heart rate
- Fasting blood draw/collection
- Finger stick test for blood sugar level
- Wear FreeStyle Libre Pro Continuous Glucose Monitor (see details below)

If you qualify to participate in this study after the above screening, you will be invited to attend a second study visit within 45 days. If more than 45 days pass from the screening visit, then you will be re-screened to ensure you still meet the eligibility criteria. If you still qualify, then you will have your Baseline Visit (V2) on the same day for your convenience. You will be compensated an additional $20 for rescreening for your time.

Rescreening Procedures: During this part of the visit, you will be asked to do the following:

- Review of your medical history, and medication inventory
- Measurement of your height, weight, and waist circumference
- Measurement of your resting blood pressure and heart rate
- Finger stick test for blood sugar level

Assessment Visits (Visit 2 and Visit 3): At the clinic visit, you will be asked to do the following:

- Measurement of your weight, and waist circumference
- Receive blood sugar control handout
- Measurement of your resting blood pressure and heart rate
- Fasting blood draw/collection (see details below)
- Urine collection
- Wear/remove the FreeStyle Libre Pro Continuous Glucose Monitor (see details below)
- Wear Actiwatch and iButton (see details below)
- Wear an ambulatory blood pressure monitor for 24 hours (see details below)
- A 6 Minute Walk test – we will ask you to walk as fast and as far as you can for 6 minutes
- Perform short tests of mobility function, such as a test of your preferred walking speed, balance ability, and ability to rise from or sit down in a chair

- A test to assess your mental abilities including memory, processing speed, attention and your ability to inhibit your impulses
- Assessment of your body composition using Dual X-ray absorptiometry (DXA).
- Grip strength measurement – we will ask you to squeeze a handgrip device as hard as you can for a few seconds.
- Your self-reported physical difficulty with daily activities
- Questionnaires about mood, quality of life, and sleep
- Ask you about changes in your health status and update medication changes

If the blood draw is not completed at V2, then we will schedule an additional appointment before the intervention so our study physician can check for any abnormalities. Additional compensation will be provided for time and travel, as outlined in Section 17 below.

Time Restricted Eating Intervention visit: Occurs weekly during the first month and bi-weekly during the second month. You will be asked to bring the Fasting and Sleeping dairy at this visit. We will do the following approximately every 2 weeks:

- Review your Fasting and Sleeping diary and provide feedback (occurs at every Time Restricted Eating intervention visit)
- Collection of the Continuous Glucose Monitoring data
- Review Continuous Glucose Monitoring data and Fasting and Sleeping diary to check for high and/or low blood glucose level events.
- Replace the Continuous Glucose Monitoring
- Update medication changes
- Ask you about changes in your health status

Time Restricted Eating intervention: You will be asked to stop eating by 7 PM every day and fast for a target of 16 hours per day for 8 weeks. During the first two weeks of the intervention, you will gradually ramp up to a full 16-hour fasting period (Week 1 - fast for 12-14 hours per day, Week 2 - fast for 14-16 hours per day, Week 3 – 8 - fast for 16 hours per day). You are allowed to consume calorie-free beverages, tea, black coffee, sugar-free gum, and will be encouraged to drink plenty of water throughout the entire intervention period. You will be asked to record the time of your first and final food/drink consumption, the time of sleep and wake each day, and report low/high blood sugar symptoms in a Fasting and Sleeping diary. You will bring the diary with you to the intervention sessions. The intervention will be in a group format face-to-face or via Zoom. The group session will be held on a weekly basis for the first month and then bi-weekly during the second month. If you are unable to make a session, then make up sessions will be offered. They can be completed in person or via Zoom. The group intervention will begin once three to five participants have been enrolled.

Blood Draw: You will be asked to fast for 12 hours before the screening and assessment visits (Visit 2 and Visit 3) because blood will be collected during these visits. We will collect blood from a vein in your arm or hand.

Urine Collection: You will be asked to complete a urine collection during the assessment visits (Visit 2 and Visit 3), which will be analyzed after data collection is complete.

Blood sugar level fingerstick test: We will prick your fingertip with a small, pointed lancet to collect approximately 1 tiny drop of your blood. The collected blood will be used to test for your blood sugar level. After we draw your blood and complete the fingerstick test, we will provide a snack for you before you continue with your visit procedures.

Dual X-ray Absorptiometry: For this scan, we will ask you to lie on the machine for about 10 minutes while the scanning arm passes slowly over your body. This medical imaging device uses very low levels of X-rays to measure your body fat, muscle mass, and bone density. The scan will be conducted at the University of Florida's Clinical and Translational Research Building.

Actiwatch and iButton: We will fit the Actiwatch and the iButton around your wrist at the end of Visit 2 for 2 weeks prior to the intervention start. If any devices are given at Visit 1 and Visit 2 is not scheduled within 14 days of Visit 1, then we will give you a pre-paid envelope to mail back the devices so we can timely collect the data. We will also ask you to wear it for the last 2 weeks of the intervention period through Visit 3. The Actiwatch, made by Philips Respironics, measures activity and the iButton measures body temperature. We will not collect or store any identifiable information about you, such as your name or date of birth, on either the iButton or the Actiwatch. The data from both devices will be saved internally on our secure departmental drive.

Ambulatory Blood Pressure Monitor: At the end of the assessment visits (Visit 2 and Visit 3), you will receive a blood pressure monitor to wear on your arm for 24 hours. This monitor will measure your blood pressure every 20 minutes during the day (approximately from 7:00 AM until 10:00 PM) and every 60 minutes overnight (approximately 10:00 PM until 7:00 AM). We will ask you to bring the monitor back or give you a pre-paid envelope to return this monitor to us after the 24-hour collection has been completed. The data from the blood pressure monitor will be saved internally on our secure departmental drive.

Continuous Glucose Monitor: Prior to the start of the intervention, a study team member will also insert a Continuous Glucose Monitoring device on the back of your upper arm. The Continuous Glucose Monitoring is a 14-day system that uses a sensor that adheres to the back of your upper arm to measure your glucose (sugar levels) every 15 minutes. The sensor is small (about the size of two US quarters) and uses a thin, flexible filament inserted just under the skin to take the measurements. We will clean an area on the back of your upper arm with an alcohol pad prior to inserting the sensor. We will use a sensor applicator to place the sensor on the back of your arm by pressing the applicator firmly over the area we clean with the alcohol pad. Inserting the filament just under your skin should cause minimal discomfort. If your Continuous Glucose Monitor (CGM) falls off some time before next visit, then please give us a call so we can schedule a time for you to come in to get a new device and collect the data from the old one.

We will then ask you return to the Research Center during weeks 2, 4, and 6 of the intervention so that we can collect Continuous Glucose Monitoring data and replace the Continuous Glucose Monitor. During these visits, we will also update any medication changes, and inquire about any adverse events during weeks 2, 4, and 6 of the intervention. We will also review your Fasting & Sleeping dairy and your collected blood glucose data from the Continuous Glucose Monitor to ensure your safety in participating in the Time Restricted Eating intervention.

The Continuous Glucose Monitor is water-resistant and can be worn while bathing, showering, or swimming as long as it is not taken deeper than 1m (3ft) and is not kept under water for longer than 30 minutes at a time. The study coordinator will review your Continuous Glucose Monitoring data and the Fasting and Sleeping diary to check for high and/or low blood glucose levels. If your reported symptoms and the Continuous Glucose Monitoring data value is aligned, you will be asked to meet with our Study Physician – Dr. Bhanu Sandesara to review your symptoms and determine the best course of action.

If any identifiable information or identifiable biospecimens were collected as part of this research, it is possible that your research information or specimens, with all personally identifiable information removed, 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 this Research Study, please contact one of the Research Team members listed in question 3 of this form.

Throughout the study, the research investigators will contact you by email, text, telephone and/or video conferencing for all study-related communication. Some of the reasons we may contact you may be to schedule your next visit, to ask you questions about your health, and/or to conduct an intervention session. We will take into account

your preference in the type of communication (shared at the start of your participation in the study) when reaching out to you.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect:

- Name
- Contact information
- Date of Birth
- Laboratory results
- Information about your health and medical history
- Information about medications you are taking
- Information about your vital signs and body measurements
- Information about your physical abilities
- Information about your blood sugar level
- Information about your cognitive abilities
- Information about your body composition
- Information about the total number of calories burned when your body is at rest

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals, or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- The study sponsor (listed in Question 4 of this form);
- United States governmental agencies which 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 which are responsible for overseeing public health concerns, such as the Centers for Disease Control and federal, state, and local health departments,
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

You will actively participate in the study for a minimum of 8 weeks and a maximum of 18 weeks, depending on the length of time between the screening visit (visit 1) and visit 2. Visit 2 will be completed any time between 1 day after the screening visit and no more than 45 days after the screening visit. Assessment visit 3 will be approximately 8 to 12 weeks after the start of the intervention period. You will receive a weekly group-based face-to-face intervention for the first month and then a bi-weekly group session during the second month. The group intervention will begin once three to five participants have been enrolled. This Authorization to use and share your health information expires at the end of the study unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

We expect to screen up to 150 participants to enroll 20 participants in this study that meet all eligibility criteria. Participants will be initially screened by phone and if eligible, we will then invite participants to come in for an in-person screening visit.

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

12. What are the possible discomforts and risks from taking part in this Research Study?

- Risks associated with blood draw. Risks include discomfort with the puncture and the possibility of a small bruise at the puncture site, rarely an infection; and, uncommonly, faintness from the procedure. To avoid these risks, research staff are trained in proper phlebotomy techniques.
- Risks associated with urine collection. There is a risk your hands may get contaminated with some of your urine during the collection. If this does occur, we recommend that you wash your hands thoroughly with soap and warm water.
- Risks associated with blood pressure measurement. The risks of placing a blood pressure cuff on your arms are that it may cause pinching or slight bruising. To avoid this risk, research staff are trained in procedures for measuring blood pressure.

- Risks associated with the 6 Minute Walk. The 6 Minute Walk test may be associated with the risk of falling or development of chest discomfort due to coronary ischemia or dyspnea due to heart failure or lung disease. Rarely, falling during the 6 Minute Walk test may result in a fracture. Research staff members who collect data have been trained and certified in 6 Minute Walk testing before they work with you. Re-certification is performed annually. Contraindications to performing the 6 min walk test according to the American Thoracic Society guidelines include recent angina or myocardial infarction during previous month, resting heart rate > 120, systolic blood pressure > 180 mm Hg or diastolic blood pressure > 100 mm Hg.

  To minimize these risks, study staff members are trained not to administer the 6 Minute Walk test if they feel or you feel that testing is unsafe. Safety precautions will be taken during the 6 Minute Walk test by applying standardized stopping criteria. If you report or experience any of the following: chest pain, intolerable dyspnea, leg cramps, staggering, diaphoresis, or pale or ashen appearance, the test will be stopped. In addition, you are asked whether you feel the test is safe. Those who state it may be unsafe are not allowed to complete the test. Staff members are trained to protect against falling and are trained in CPR. They are trained in activating the emergency response system. During the test, a study coordinator will present side by side with the participant to prevent falling.

- Risks associated with the Short Physical Performance Battery test. Similar to the 6 Minute Walk test, completion of the SPPB may be associated with the risk of falling or development of chest discomfort due to coronary ischemia or dyspnea due to heart failure or lung disease. Rarely, falling during the SPPB test may result in a fracture. Research staff members who collect data will be trained in proper administration of the SPPB prior to administering the SPPB test to you.

  To minimize these risks, research staff are trained in the conduct of all physical performance tests and certified by Dr. Anton or his designee before they work with you. Study staff are instructed not to perform these tests if they feel that testing is unsafe for you or if you are concerned about safety. If safety concerns are identified by either the study staff or you during the testing procedures, testing is halted, and you are not allowed to complete the test. In either case, you are assessed to determine the need for medical intervention and the cause for concern is evaluated. All study staff are trained in activating the emergency response system at The University of Florida facility. During the test, a study coordinator will present side by side with the participant to prevent falling.

- Risks associated with the iButton and Actiwatch. The Philips Respironics Actiwatch is FDA approved to conduct research, and we will use it for research purposes only to track movement and sleep patterns. Skin irritation may be a risk associated with wearing the device. To help prevent skin irritation, use a soft cloth with mild soap and water to clean the wrist and band, always

remembering to dry off after washing your hands. (If you experience skin irritation/redness on your wrist remove the product immediately. If symptoms persist longer than 2-3 days, while not using your product, please contact a dermatologist/medical professional).

- Risks associated with ambulatory blood pressure monitor include pinching, slight bruising, discomfort, or skin irritation from the cuff. To avoid this risk, research staff are trained in procedures for helping participants to wear the blood pressure cuff.

- Risks associated with the use of the Continuous Glucose Monitor include:
  - Local infections
  - Skin irritation or redness
  - Skin inflammation
  - Pain or discomfort
  - Bleeding
  - Bruising
  - Skin edema
  - Skin rash
  - Itching
  - Scarring or skin discoloration
  - Allergic reactions to the sensor needle or adhesives
  - Sensor or needle fracture during insertion, wear, or removal

  To minimize these risks, the continuous glucose monitor will be administered by or under the guidance of a study physician. You will be asked if they have any known allergies to needs or adhesives before this monitor is applied. If you experience any of the symptoms listed above, you should contact the study coordinator who will then consult with the study physician who will determine the appropriate course of action.

- Risks associated with questionnaire administration. You may feel uncomfortable with the number or detail of questions we ask about your health, lifestyle, and mood. Participation also includes a risk of loss of confidentiality of personal health information.

  You are not required to answer any question you feel uncomfortable answering. There are no right or wrong answers on the mood questions, and the test scores are used for research purposes only. Participants with high GDS scores will be provided with relevant resources after the PI is notified.

  To minimize these risks to confidentiality, a number of methods are employed to maintain your confidentiality. First, questionnaire data are collected in secure spaces where the interview cannot be overheard. Second, only study investigators and key research staff have access to the study database. Third, you are assigned a unique study identifier. Individual names will ultimately be removed from the study database and only the unique study identifier is used to distinguish participants in the database. Fourth, collected data are

maintained in locked computer files and file cabinets to which only study investigators have access. Collected data will be used only for research purposes. Published data will not contain any individual identifiers. Finally, all research staff members have to complete annual HIPAA (Health Insurance Portability and Accountability) training that is required by UF.

- Risks associated with Dual Energy X-ray Absorptiometry. This research study involves exposure to radiation from x-rays. You will receive 2 DEXA scans during this study. The radiation exposure from the DEXA scans is equal to about 5 millirems, which is comparable to about 5 to 6 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. The radiation exposure in this study is thought to be minor. However, the effects of radiation add up over your lifetime. Repeated exposures may increase your risk of injury or disease. When deciding to enter this study you should consider previous and future potential exposures. Examples would include x-rays taken for a broken bone or radiation therapy treatments for cancer.

- Risks associated with Time Restricted Eating intervention. Only a limited number of human clinical trials have been published to date evaluating intermittent fasting dietary interventions. Of the adverse effects reported in these and other studies, undesirable weight loss and hunger were the two most prominent. It will likely take you several days to start adjusting to a Time Restricted Eating pattern. During these times, you may experience gastrointestinal 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.

  While adhering to Time Restricted Eating, your blood sugar levels may fluctuate more than you are typically used to, which may affect your energy levels and how hungry or full you feel. If your blood sugar levels drop too low, you may experience anxiety, dizziness, excessive hunger, headache, lightheadedness, sweating, sleepiness, or weakness. In these instances, you will be instructed to immediately break your Time Restricted Eating intervention and/or to consume food or caloric beverages (hypoglycemia guidance will be provided to you at the baseline visit). We will also ask you to wear a Continuous Glucose Monitor and will review your blood glucose readings every two weeks.
  If the blood glucose values fall outside the normal range, we will ask our study endocrinologist or physician to review the readings and meet with you to determine the best course of action.

  To minimize these risks, you will be encouraged to increase your fasting time progressively during an initial “adoption” period. Additionally, you will be provided dietary guidance consistent with your intervention allocation, to ensure adequate intakes of all essential nutrients and amounts of core food groups, defined as foods that have a high nutrient content, and are readily

identifiable, fresh, and less processed, consistent with long-term good health. A trained interventionist will monitor safety and occurrence of adverse effects at weekly and/or bi-weekly intervention visits.

- Risks associated when participating in the intervention groups of the Time Restricted Eating intervention. Participation includes a potential risk of loss of confidentiality of your name and information you disclosed during the meeting.

  To minimize these risks, we will ask all group members to not disclose information discussed during intervention sessions or to share information about the identity of participants in the meetings.

- Risks associated with Cognitive Tests. There is a risk that you will find memory and concentration tests stressful and might feel tired or sad because it may be difficult to remember things that you are asked to remember. You may skip any question you do not wish to answer. Research staff will explain what to do and answer questions that you might have during cognitive testing.

  To minimize this risk, questionnaire data are collected in secure spaces where the interview cannot be overheard. You can decline to answer questions that are uncomfortable or concerning. All research staff members complete annual HIPAA for Researchers training as required by UF.

  Collected data are maintained in locked computer files and file cabinets to which only study investigators have access. Only study investigators and key research staff (i.e. data managers and study programmers) have access to the study forms or database. You will be assigned a unique study identifier; individual names will be removed from the study database and only the unique study identifier used to distinguish participants in the database. Collected data will be used only for research purposes, and publications will not contain any individual identifiers.

- Risk associated with the HbA1c fingerstick test. Risks include slight pain from being pricked by the fingerstick, temporary discomfort with the squeezing of the fingertip, and rarely an infection at the puncture site.

  To minimize these risks, research staff are trained in proper administering of the fingerstick technique. To avoid infection, the puncture site will be clean and air dry with 70% isopropyl alcohol prior to administering the test.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a 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.

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

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

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.

13a. What are the potential benefits to you for taking part in this Research Study?

Completing the intermittent fasting (Time Restricted Eating) intervention may help you lose body weight, reduce fat mass, and improve your blood sugar control.

13b. How could others possibly benefit from this Research Study?

Others may benefit if the study findings eventually lead to the development of new methods to measure how the human body uses energy.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

13d. Will you be allowed to see the research information collected about you for this Research Study?

You may not be allowed to see the research information collected about you for this Research Study, including the research information in your medical record, until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected and placed in your medical record. You will also receive the results from your baseline and final DEXA scans once the study has concluded. If there are abnormal lab values that need to be determined by a physician, we will notify you as soon as we can.

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

If you do not want to be in this study, do not sign this form. If you have already signed this form, please notify the Principal Investigator listed in question 3 above. If you do not want to be in this study, the alternative choice is simply to not participate.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

Your participation is valuable to us, and we want to make sure you're comfortable throughout the study. Over the course of your participation in the study, we will communicate with you via email, text, and/or call and will take your preferred means of communication into account when reaching out.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- If the Principal Investigator or study physician decides 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
- Unexpected circumstances

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No, there will be no additional costs to you or your health plan as a result of your participation in this study. There are no expected protocol-required items, services or procedures that will generate any charges at UF Health. However, if you feel you have received a bill related to this study, please contact the Principal Investigator. There may be incidental costs associated with travelling to the study site (e.g., cost of gas) or purchasing food before or after your visit.

If you receive any healthcare at UF Health that is not related to this study, this care will be billed as usual.

17. Will you be paid for taking part in this Research Study?

Yes, you will be compensated up to $180 in the form of gift cards. A gift card of $50 will be given at the completion of Visit 2 and Visit 3. You will receive your compensation for Visit 2 and Visit 3 once you return iButton and Actiwatch. Additionally, you will be compensated $10 for travel for each Time-Restricted Eating intervention session ($60 total). Moreover, you will be given $20 to cover travel costs related to any additional visits. You will not be compensated for the Screening Visit.

If you are paid more than $199 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. Payments to nonresident aliens must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, 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 Research Participant Payment (RPP) 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 (RPP) 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.

18. What if you are injured while in this Research 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 Research Study.

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 above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Participant Date