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")?

Effects of a Very Low Carbohydrate Ketogenic Diet versus Mediterranean Diet on Markers of Bone Health and Muscle Function in Older Adults: A Pilot Study

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

Principal Investigator
Dr. Cora Best, Ph.D., R.D.N, Food Science and Human Nutrition Department
(352) 294-3751
bestlab@ufl.edu

Other research staff:
Study Coordinators
(352)-273-9212
recruit@aging.ufl.edu

4. Who is paying for this Research Study?

The study sponsor is the University of Florida Claude D. Pepper Older Americans Independence Center (funded by the National Institutes of Health, National Institute on Aging).

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 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.

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

The purpose of this research is to determine the effects of popular dietary patterns on the musculoskeletal system of older adults. The dietary patterns that we will test include a very low carbohydrate ketogenic diet and a Mediterranean diet. These diets may help prevent and treat age-related diseases, so we want to know how the bones and muscles of older adults respond to these diets.

As a first step, we are conducting a pilot study to find out how long it will take us to identify older adults who want to participate in the study. We would also like to learn from study participants about their experiences in the study. You will be involved in the study for a little over 9 weeks. You will be following the diet for 6 weeks.

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

First, you will complete the screening process so that we can determine whether you are eligible to enroll in the study. You will attend two screening visits over a 2 week period. If you remain eligible after the second screening visit, we will enroll you in the dietary intervention study. You will be assigned to either a very low carbohydrate ketogenic diet or a Mediterranean diet. Given the study design, you will have a higher likelihood of being assigned to the ketogenic diet, with approximately 75% of participants receiving this diet and 25% receiving the Mediterranean diet. The study team will have no control over which diet you are assigned to.

We will provide most of the food you will need each day in the form of a nutrition shake (breakfast) and two prepared meals (lunch and dinner). The meals will be delivered to your home on Monday and Wednesday afternoons and Saturday mornings each week by a professional courier. You will be expected to self-provide any additional food you desire, including any snacks you eat between meals. To help you stick with your assigned dietary pattern, we will give you snack recipes and diet education. In addition, a study dietitian will be available to provide continuous support through a secure messaging app. While you are in the dietary intervention phase of the study, you will come to the UF Clinical and Translational Science Building once a week for 6 weeks to check in with the study personnel and complete some assessments, which are described in detail in section 7 of this form. .

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

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.

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

Likely benefits to you:

- New nutrition knowledge
- Beneficial changes in select metabolic risk factors, for example, your blood sugar level

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

This is not applicable because this research study is not related to your clinical care. The Research Study is designed to learn more about normal response to diet, and you will not receive treatment for a condition.

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.

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.

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 aspect of this study is part of your clinical care. If you do not participate in this study, then you will not complete any study procedures or receive the dietary intervention.

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

First, you will complete the screening process so that we can determine whether you are eligible to enroll in the study. At the first screening visit, we will measure your blood pressure, height, and weight. You will complete questionnaires that collect information about your health history, dietary intake, and physical activity habits. We will collect no more than 50 mL of blood to run routine clinical lab tests to evaluate your health status.

If you remain eligible after the first screening visit, we will schedule your second screening visit, and you will complete a 24-hour urine collection at home sometime in the next week. At the second screening visit, a physician will conduct a physical exam and assess your body composition (muscle mass and fat mass) with an x-ray technology called dual-energy x-ray absorptiometry (DEXA or DXA).

If you are found to be ineligible for the dietary intervention study, then we will keep some data that we collected during the screening period including your age, sex, race and ethnicity, and the reason that

you were not eligible. The data will be de-identified meaning we will destroy any information that could connect the data to your identity, such as your name, phone number, date of birth, and any other identifying information.

If you remain eligible after the second screening visit, we will enroll you in the dietary intervention study. You will be assigned to either a very low carbohydrate ketogenic diet or a Mediterranean diet. Like with a coin flip, you will have a 50% chance of being assigned to either diet. The study team will have no control over which diet you are assigned to. If another individual(s) living in your household is also participating in the study, you will be assigned to the same diet.

We will provide most of the food you will need each day in the form of a nutrition shake (breakfast) and two prepared meals (lunch and dinner). The meals will be delivered to your home on Monday and Wednesday afternoons and Saturday mornings each week by a professional courier. For this reason, you will not be able to participate in the study unless you agree to refrain from elective travel during the study. Please check the box below if you agree.

☐ Yes. I understand that I should avoid traveling during the study because I will be receiving meal deliveries 3 times per week. I have no travel plans and will only travel for urgent or emergency reasons.

You will be expected to self-provide any additional food you desire, including any snacks you eat between meals. To help you stick with your assigned dietary pattern, we will give you snack recipes and diet education. In addition, a study dietitian will be available to provide continuous support through a secure messaging app called Nourishly. You will need to download Nourishly to your smartphone to participate in this study. The study team will communicate with you through this app as well as by text, phone, or email. You will be able to use any of these modes to contact the study team.

This study is not a weight loss study, and you are not expected to try to lose weight. You will eat the food that we provide. You do not have to finish your meals if you are no longer hungry. You will document what you eat and drink by taking photos of your meals and snacks and making brief notes in a daily food record. The record will be kept within the same Nourishly smartphone app that you will use to communicate with the dietitian.

For the scientific success of this study, it is very important that you eat the food we give you and that you stick with the dietary pattern you are assigned to. I will now show you the menus that will be available in each diet group.

After reviewing the menus, please check one:
☐ Yes, I am willing to eat the meals presented in the menus, and I understand that I will be randomly assigned to one of the diet groups.
☐ No, I am unwilling to eat these meals or be randomly assigned to one of the diet groups

While you are in the dietary intervention phase of the study, you will come to the UF Clinical and Translational Science Building once a week for 6 weeks. At the weekly study visit, you will check in with the study team and pick up your weekly supply of oral nutrition shakes and daily multivitamins. We will measure your blood pressure and weight at each visit. At the first, middle, and final visits, we will collect blood and urine for lab testing, and you will complete a short series of tests that measure physical performance. For example, we will test your balance by asking you to stand on one foot. You will also

complete two questionnaires at the middle and final visit. At the final visit, the physician will assess your body composition again by DEXA.

We would like to collect ribonucleic acid (RNA) from your blood collected at visits 1 and 7 so that we can measure how diet impacts the expression of genes involved in metabolism. You can decide if you want your blood sample to be used for RNA testing for this study. Your decision about your blood sample for RNA testing will not affect your participation in the rest of this study. In other words, you can still be in the study and opt out of the RNA testing. Please note, we will not be collecting DNA or assessing your risk for genetic diseases.

Please check one:
☐ Yes, you may use my blood samples for the RNA testing described above.
☐ No, you may not use my blood samples for the RNA testing described above.

You will wear an activity monitor for 1 week during the screening period and again during the final week of the study. The activity monitor is a small device that you wear on your hip. It will tell us how physically active you are.

You will complete two 24-hour urine collections at home, one before you start the diet and one during the final week of the study. We will provide a kit that includes all supplies and instructions for the collection. You will collect all the urine you make over a 24-hour period using the supplies we give you. Then you will mail a small sample of the urine to a lab called Labcorp in the tube provided. You will not need to pay for shipping because a shipping label will be provided.

All study procedures are for research purposes only. Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. This/these test(s) may need to be repeated if required for your medical care in the future.

It is possible that your research information or blood samples, with all personally identifiable information removed, could be used for future research. It may be distributed to another investigator for future research without additional informed consent from you. There will be no link between your identity and your research information or blood samples.

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.

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

The Research Team will collect demographic information and results of physical exams, blood tests, x-rays, and other diagnostic and medical procedures, as well as medical history.

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 government 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
- United States government agencies that 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 that 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?

9 to 10 weeks including the screening period. You will be following the diet for 6 weeks.

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 about 200 people. Many of the participants will not meet all of the criteria and will not be eligible to participate in the study. Ultimately, we plan to enroll 19 participants in the dietary intervention.

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?

- 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.
- This research study involves exposure to radiation from x-rays. You will receive two DEXA scans during this study. The radiation exposure from the DEXA scan is equal to about 6 millirem, which is comparable to about one week of natural background radiation to which people in the United States are exposed to during their lives. The risk from this radiation exposure is low when compared to other everyday risks.

- You may have gastrointestinal discomfort like bloating, gas, or constipation because you are trying a new diet. If you experience any discomfort, then we (the study team) expect it to be short-term.
- There may be a change in your bone turnover (bone formation and bone breakdown) that we expect to be short-term and thus not influence long-term bone health.
- Negative effects on mood or feelings of fatigue. If these effects occur, then we expect that they will disappear after the study ends.
- Small increase in circulating low density lipoprotein cholesterol concentration. If this occurs, then we expect that it will resolve after the study ends.

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?

This study is not designed or intended to benefit you directly. The reason for doing this study is to discover how the very low carbohydrate ketogenic diet and Mediterranean diet impact bone and muscle in older adults. However, direct benefits to you are possible including:

- New nutrition knowledge
- Improved skeletal muscle function (short-term change likely to disappear after study ends)
- Beneficial changes in several metabolic risk factors (will likely disappear after study ends)
- Positive effects on mood and feelings of fatigue (will likely disappear after study ends)

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

The Research Study is expected to lead to new knowledge about the effects of two dietary patterns on the musculoskeletal system of older adults. We expect the new knowledge to inform healthcare decision-making. In other words, we expect the new knowledge to be used by physicians and dietitians when they are considering what diet will be effective and safe for a particular older patient.

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 until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected and any that is placed in your medical record.

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

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 diagnostic or intervention 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.

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:

- Missing study visits
- Low level of participation, for example, you are not eating the supplied food
- If you experience an adverse event, the study physician may withdraw you from the study for safety reasons.

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. The sponsor will pay for all health care costs related to your participation, including all required study items, services and procedures described in this consent form. However, if you feel you have received a bill related to this study, please contact the Principal Investigator.

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 paid immediately at the end of every visit, including the screening visits. The size of the payment will increase with each phase of the study, with the largest payment occurring at the final study visit. If you complete the entire study, you will receive a total of $415.

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.

If you have any problems regarding your payment, contact the study coordinator (*see* item 3).

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

Since this is a study of popular diets, there is a very low risk of study-related injury. However, 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.

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 Person Consenting and Authorizing Date