TEXAS A&M UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM

INFORMED CONSENT DOCUMENT

Title of Research Study: Comparing intracellular anabolic capacity and food-derived amino acid bioavailability of peanut and dairy protein in healthy non-frail older adults at risk for (pre)frailty

Investigator: Marielle Engelen, PhD

Key Information:
The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research. More detailed information is listed later on in this form.

Why you are invited to take part in this study:	You previously participated in the Prandial Metabolic Phenotyping in Sarcopenic Older Adults Comparing Plant Based and Whey Based Protein. Your participation in this study will assist us in understanding how your body can use a variety of plant based proteins.
Purpose of this study:	Assess the bioavailability of amino acids coming from peanut-based protein as compared to animal-based protein
Voluntary Participation:	Your decision to be in this study is voluntary.
Right to Withdraw from Study:	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Study Participation:	This study will include 1 screening visit (~1.5 hours) and 1 study visit (~6 hours). All visits will be scheduled at your convenience. You are anticipated to finish all study visits within a 4-week timeframe.
Study Procedures:	The main procedures in the study include: Screening visit: Review the Informed Consent Form, conduct medical screening and body composition measurements Study visit: Arrive fasted in the morning, placement of an intravenous catheter (IV) in the hand that will be used for frequent blood draws. This IV will also be used for the administration of a solution of amino acid tracers. You will consume sips of an oral nutrition supplement containing peanuts.

Risks of Study Participation:	The most common risks are from the following procedures. - Body composition scanning that includes X-ray - Placement of IV may cause bruise, infection, allergic reaction, lightheadedness, nausea and possibly vomiting - The temperature controlled hot box may cause minor irritation to your hand Additional details are provided in the section “Are there any risks to me?”
Benefit of Study Participation:	There is no direct benefit to you for participating, but your participation may help researchers learn more about metabolism.
Costs of Participation:	Aside from your time, there are no costs for taking part in the study.
Confidentiality of your information:	Information about you will be kept confidential to the extent permitted or required by law.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator, Marielle Engelen, PhD, at 979-220-2282 or Research Staff at 979-422-1789 or email research@ctral.org.

This research has been reviewed and approved by the Texas A&M Institutional Review Board (IRB). You may talk to them at 1-979-458-4067, toll free at 1-855-795-8636, or by email at irb@tamu.edu., if

- You cannot reach the research team.
- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in the research?
We expect about 15 people to participate in this research at our site.

What happens if I say yes, I want to be in this research?
- Includes 1 screening visit and 1 study visit, scheduled at your convenience
- Expect to finish all study visits within 4 weeks
- Procedures performed are for research purposes only

- All personnel have received training for performing research procedures, but may not have a medical license.

The procedures you will be asked to perform are described below.

The screening visit

a. This visit will last about 1.5 hours and takes place before the first study visit. Before any study-related procedures are performed, researchers will discuss the study, its risks, benefits, and compensation with you. If you agree to participate, you will need to sign this consent form.
b. During the screening visit, you will be asked questions about your health history and use of medication to determine eligibility.
c. Furthermore, we will assess body weight, height, and vital signs.
d. Body composition and bone density will be assessed by Dual energy X-ray Absorptiometry (DXA) and bioelectrical impedance analysis (BIA).

Once the screening test results have been reviewed by the study personnel, we will contact you about participating in the study.

On the evenings before all study visits, from 10pm on, you will refrain from any food and drink intake. Drinking water is allowed. You can take medications as prescribed with water in the morning. At the end of the study visits, you are allowed to eat and drink again. During the visits there will be the opportunity to watch television, and listen to music etc., as long as you remain in a lying or elevated position on the bed. We will also provide you a meal at the end of the visit.

The study visit:

a. Please arrive fasted. This means no food or drink intake after 10pm the night before the visit. You will be allowed to have only water after 10pm. This visit will last approximately 6 hours.
b. The research nurse will place a catheter (small, flexible, plastic tube) in a vein of the arm or hand. We will use this catheter to provide you with a small dose of stable (NOT radioactive) tracers. Amino acids are present in food, and our body has some of these tracers inside; we provide a dose a little heavier than normal for our lab machines to count them.
c. The hand will be placed in a warmed box to increase blood flow. If the hand feels too warm, remove your hand from the box and notify study personnel. They will be able to make some adjustments for your comfort. The hand may be removed from the box between blood draws, but must be kept in the box for 10 minutes prior to the next blood draw. The total volume of blood drawn during the visit will be approximately 4 tablespoons, or 65 ml.
d. On the visit, you will consume the pre-defined liquid supplement meals as sips every 20 minutes for 5 hours. This meal will be made from commercially available peanut protein powder. We will mix the protein powder with water.

All of the above mentioned procedures are experimental. Results of testing are available upon your request.

What are my responsibilities if I take part in this research?

If you take part in the research, it is important for your safety that you:

- Follow the directions of the research staff.

- Tell research staff about all medications you are taking (prescription and over the counter) and all of your health issues.
- Call the research staff at 979-422-1789 if you have any questions.

What happens if I say yes, but I change my mind later?
You are free to leave the study at any time with no penalties or lose of benefits. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research.

Can I be removed from the research without my OK?
You may be removed from the study by the nurse or investigator when, in their opinion, any of the following situations is applicable:

- Determination that a condition developed that would interfere with the research methods, and which was not applicable at screening (e.g., illness, drugs).
- Signs and symptoms not seen at baseline or that worsen in severity during/ after intervention
- Catheters needed for research methods are removed before completion of the study day.
- You are not willing or unable to comply with the guidelines and procedures explained to you and mentioned in this Informed Consent form.

Early termination of your participation in the study, as decided by the Principal Investigator, can occur without your consent.

What are the risks of being in this study? (Detailed Risks)
The things that you will be doing or undergoing have significant more risk than you would come across in everyday life. The discomforts and risks include the following:

a. Amino acid tracers: The amino acid tracers are mixed under supervision of a licensed pharmacist in a certified clean room in the Human Clinical Research Building. On the study days, the tracers are filtered as they go directly into the bloodstream. The risks associated administration include allergic reaction and infection, such as a change in body temperature, blood pressure and/or heart rate, flushing, itching, nausea, vomiting, fatigue, body ache, headache, sweating and chills. We will monitor for these side effects during the infusion and stop the study if needed.

b. Blood draws / catheterization: Blood will be drawn multiple times during the studyvisit,and you will receive saline after each blood sample is taken. You should experience no noticeable effects of the blood draws. A risk associated with having blood drawn is a low concentration of red blood cells, which might increase the need for blood transfusions. This is unlikely for you due to the low volume of blood samples needed for this study. Furthermore, there is a risk of infection due to having blood drawn. This risk will be small as well, because it will be done using strict procedures to prevent infections. You may get a skin rash. This is associated with an allergic reaction to tape or other medical disposables used for the study. There may also be bleeding when the needles are inserted and when the catheters areis removed.

In some instances, there might be a hematoma or bruise at the site of the catheter, or you might experience some pain as the vessel wall is pierced. Some individuals have a sudden drop in blood pressure in response to the placement of catheters in their arms. Symptoms may include lightheadedness, nausea, vomiting, and fainting. There are no long-term problems associated with this response. If you should have this response, you will be examined by the study nurse or physician and given the option of discontinuing the experiment. If they find no reason to stop the study and you want to continue, you will be able to finish the study.

c. Use of temperature controlled box: The warmed box is used to allow collection of blood, which is made "arterialized" by heating the air inside the box and around your hand to 50-55°C. In the event that you experience sensitivity to the heat, a wash cloth or gauze will be placed over the back of your hand and knuckles to minimize heating of the thin skin over the knuckles. Additionally, your hand may be removed from the hotbox between blood collections to improve comfort, but must be placed inside the hotbox 10 minutes prior to each blood collection.

d. Assessment of body composition and bone mineral density by dual energy X-ray absorptiometry (DXA): This procedure is used to estimate the amount of fat and lean mass in your whole body,arms, and legs. Also, DXA will measure bone mineral density in your spine and hip. The DXA-scans expose you to minimal radiation (2.5 mRem), equal to the natural radiation during 2 days in College Station. It is not harmful to you. All radiation doses carry a finite risk of inducing cancer or genetic disorders in a fetus. The DXA doses are such that these risks are small by comparison with the natural incidence of these conditions.

e. Demographic and Socioeconomic Questions: Responding to questions could cause you to feel uncomfortable or upset. Please tell the study staff if you feel uncomfortable or upset while answering to the questions.

Although the researchers have tried to avoid risks, you may feel that some questions/procedures that are asked of you will be stressful or upsetting. You do not have to answer anything or undergo any procedures you do not want to.

What are the costs of being in the research?
Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the TAMU HRPP/IRB and other representatives of this organization.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples

could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

This would include blood specimens and other data obtained during this study and the previous study visits completed as part of "Prandial Metabolic Phenotyping in Sarcopenic Older Adults Comparing Plant Based and Whey Based Protein" that will be stored for a minimum 7 years in laboratories, and may be used in future research upon approval of the Texas A&M University Human Research Protection Program office. These samples will be labeled with a code number and not with a name. These samples may be used to study other markers of protein metabolism and gut function. However, *no genetic* testing will occur on these samples. Please indicate whether you permit these specimens to be used in future research by selecting one of the following statements in the REDCap system:

- I **agree** to allow my specimens to be stored for future research.
- I **do not agree** to allow my specimens to be stored for future research.

If, in the future, you decide that you do not want the specimens used for research, please notify the Principal Investigator.

Funded/Supported By: The Peanut Institute Foundation

What else do I need to know?
If you become ill or get injured as a result of this study (devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.
Texas A&M University has no program to pay for medical care for research-related injury. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research, we will pay you for each visit you complete:

- $20 for the screening visit
- $100 for the study visit.

If all visits are completed, you will be compensated up to a total of $120 for your time and effort.

The financial office at Texas A&M University may be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.		
_____		_____
Signature of subject		Date
_____		
Printed name of subject		
_____		IRB NUMBER: STUDY2024-0862 IRB APPROVAL DATE: 10/2/2024

Signature of person obtaining consent		Date
_____		
Printed name of person obtaining consent		