**Document Type:** Informed Consent Form

**Official Title:** Protein Eating Patterns and Weight Loss

**NCT Number:** NCT03202069

**IRB Approval Date:** 01/27/2023

# CONSENT TO PARTICIPATE IN RESEARCH

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| **TITLE:** | *PROTEIN EATING PATTERNS AND WEIGHT LOSS* |
| **PROJECT DIRECTOR:** | *Shanon Casperson, PhD* |
| **PHONE #** | *701-795-8497* |
| **DEPARTMENT:** | *ARS-USDA Human Nutrition Research Center* |

## STATEMENT OF RESEARCH

A person who is to participate in research must give his or her informed consent. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Only people who want to take part in a research study may do so. Please take your time in making your decision about joining this study. If you have questions at any time, please ask.

## WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to be a part of this research study because you are a woman of reproductive age (20 – 44 or older if still having regular periods) and your Body Mass Index (BMI) is between 28 and 45.

The purpose of this study is to determine the effects of daily protein intake patterns on body composition and eating behaviors during weight loss. You will be assigned to 1 of 2 groups. You will not have a choice on which group you will be assigned. Everybody will eat the same amount of protein but when the protein is eaten will be different. One group will eat most of their protein with supper – this is the same protein intake pattern that we normally eat. The other group will eat the same amount of protein with each meal.

## HOW MANY PEOPLE WILL PARTICIPATE?

A total of 50 people will take part in this study at the USDA Grand Forks Human Nutrition Research Center (GFHNRC).

## HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for 16 weeks. In addition to this meeting, you will come back for testing to see if you meet the requirements to be in the study. If you do, you will come to the Center each day during the work week to pick up all the food you will be required to eat for the 1st 8 weeks. After this you will come to the Center once a week to pick up your weekly portion of beef.



Date: _____
Subject Initials: _____

There will be 8 classes that you will have to attend throughout the 16week study. There will also be 3 times during the study that you will have to stay overnight at the Center.

## WHAT WILL HAPPEN DURING THIS STUDY?

### A. Screening Visit

This visit will take about 1½ to 2 hours to do all the testing.

You must arrive for this visit *without eating or drinking anything but water for 12 hours*.

During this visit a nurse and/or trained staff will obtain your health history, height, weight, blood pressure, and fasting glucose. Your glucose will be checked by poking your finger to get a drop a blood. We will also measure your resting energy expenditure to calculate your calorie needs. To do this you will lie in a quiet room for 30 minutes. A clear plastic hood will then be placed over your head to collect your breath. You will be asked to breathe normally while you lay awake in bed for about 30 minutes. When this test is done, you will taste some snack foods (such as candy, cookies, chips) and pick the one you like most. You will then fill out a food frequency survey so we can understand your usual food intake.

If your screening results are abnormal, you may not be permitted to take part in this study. If the results are normal, you will be scheduled to start the study.

### B. Study Overview

This is a 2-part weight loss intervention study. Each part will last for 8 weeks. We will meet with you at least once per week to monitor your progress and to address any concerns. These visits should take no more than 15 minutes.

For the 1st 8 weeks of the study, we will give you all of your food - equal to 80% of your calorie needs. You *will not* be able to eat anything except the foods we give you during this time. You will have a chance to look over a sample menu before deciding to join the study to make sure you can eat all the foods. We will make all your meals at the Center and pack them for you to pick up. We will ask you to pick up your food each day Monday – Friday. You will also pick up all your weekend meals on Friday. You can only eat the foods we give you during this part of the diet. You may drink as much water, black coffee, unsweetened tea as you would like. Every day, about 1½ hours after dinner, you will fill out a survey about your hunger and food cravings.

For the 2nd 8 weeks of the study, you will be responsible for choosing and making your own meals. We ask that you try to keep the same eating pattern as we gave you for the first part of the study. We will give you an allotment of beef each week to include in your diet. This will be the same amount of beef that you ate during the first part of the study. Each week you will fill out several questionnaires about your happiness with the diet and eating behaviors. You will bring these questionnaires with you when you pick up your beef for the next week. You will also get an email

asking you to log onto a secure website and complete a diet recall for the day before. This email will come randomly on different days of the week. You will receive training on how to do the diet recalls during your 1st testing visit. Each recall will take about 30 minutes.

During the 16 weeks you will attend classes focused on reinforcing positive dietary changes and addressing barriers to weight loss. Classes will be held at the Center. Topics to be covered in the program will include diet, physical activity, behavior modification and self-monitoring. Classes will include discussions, activities, and assignments that you will do at home. There will be 8 classes that you will have to attend. These classes will be held during weeks 5, 6, 7, 8, 9, 10, 12 and 14 of the study.

There will be 3 times that you will report to the Center for an overnight study visit. The 1st study visit will be right before you start the diet. The 2nd study visit will be when you are changing from eating only the foods we give you to trying to maintain the same diet on your own (week 8). The 3rd study visit will be at the end of study (week 16). Details about these visits are outlined below.

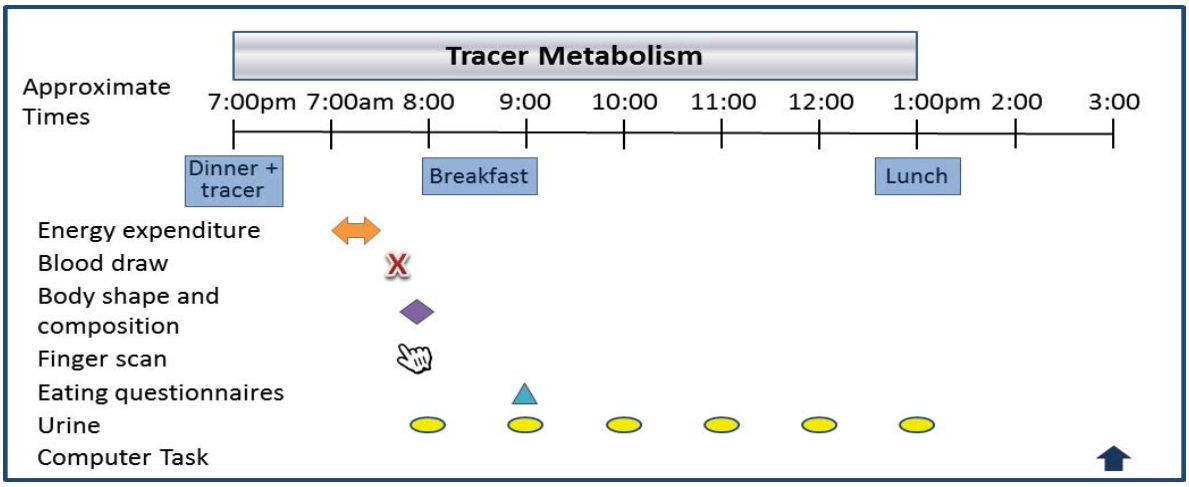
### C. Testing Visits

Testing will take about 24 hours. You will need to refrain from exercise for 2 days before each visit. You will not be allowed to have any caffeine during the testing visits.

You will check into the Center no later than 5pm. With your evening meal you will ingest a small amount of a stable isotope. Stable isotopes are naturally occurring compounds, also called "tracers", that allow us to determine how certain nutrients are used in your body. Tracers do not give off radiation and are already present in small amounts in your body. The tracer used in this study is called 3-methylhistidine, which is an amino acid, and will be mixed with a small amount of liquid that you will drink with your dinner. The next day we will collect your urine every hour for 6 hours. This procedure will allow us to calculate the rate at which your muscles are breaking down protein.

Twelve hours after you drink the tracer is when all the testing will begin. We will wake you up and ask you to empty your bladder. Next, we will measure your resting energy expenditure. This will be the same procedure as during your screening visit. When this test is done, we will take about 2 tablespoons of your blood. After this, we will measure your body shape and composition. We will then measure an index of your vegetable and fruit intake by scanning the tip of finger. After all this testing is done you will eat a breakfast that contains no animal products and fill out questionnaires about your diet and eating behaviors. After we have collected your last urine sample you will eat lunch. About two hours after lunch, you will do a computer task to gain access to your most liked snack food and/or activity.

This picture will give you an idea of how these study visits will go. These are approximate times.




## D. Tests

The following describes all testing procedures for each visit:

1) *Resting Energy Expenditure:* As soon as we wake you up, we will ask you to empty your bladder. You will then be asked to lie quietly in bed without falling asleep with a clear plastic dome over your head. You will need to remain still and breathe normally during this test. We will measure your breath for about 30 minutes.

2) *Body Shape:* We will use a 3D body scanner to measure the shape of your body. The scan will take 15 seconds and does not involve any injections or blood draws. The scanner cannot see through your clothes, so you will be asked to take off your clothing to get the most accurate scan results. If you are uncomfortable being scanned without clothes you will be allowed to wear your undergarments. A curtain is in place for privacy during the measurement. Results will be made available to you upon request.

3) *Body Composition:* A special x-ray scan (DXA) will be done to measure the changes in your muscle and fat mass The scan will take about 10 - 15 minutes and does not involve any injections or blood draws. A pregnancy test will be done prior to the scan. Results will be made available to you upon request.

4) *Finger Scan:* You will place your finger in a device, similar in size and shape of an electric pencil sharpener, for 20 seconds while a light is shined on the skin. The light interacts with carotenoids in the skin. Carotenoids are what give fruits and vegetables their bright colors. The amount of carotenoids in your skin tells us about your fruit and vegetable intake. There are no known risks associated with this test.

5) *Eating Questionnaires:* You will fill out several questionnaires. The questions will ask you about how happy you are with your diet, why you eat, and what motivates you.

6) *Urine Samples:* You will be asked to collect all of your urine. We will also ask you to collect your urine every hour for 6 hours after you wake up. During this time, we ask that you urinate only at the collection times. There are no known risks associated with this test.

7) *Computer Task:* This task will be done about 2 hours after you finish eating lunch. It is like playing a slot machine game. There are 2 computers. At one computer you will play to get a small serving of your favorite snack food. At the other computer you will play to earn time to do your favorite activity. You will press the mouse button until the color and shape of the objects match. You win points each time all the objects match. For every 5 points you win you will get a serving of snack food or 5 minutes of activity. When you finish playing you will be able to eat the snacks and do your chosen activity for the amount of time that you earned. There are no known risks associated with this test.

**E. Experimental Tests Not Related to This Research**

Some of your urine and blood taken during this study will be stored indefinitely in the scientist's laboratory and may be used in future research. These samples are left over after the research study tests are done and do not involve extra samples being taken. These leftover samples will be labeled only with the code number that will be assigned to you for this study. There will be no human genetic tests performed on these leftover samples.

Please indicate whether you will allow your samples to be used in future research by initialing one of the following statements:

_____ I agree to allow my samples to be preserved for future research.

_____ I do not agree to allow my samples to be preserved for future use.

Your decision will not affect any benefits to which you are otherwise entitled or your current or future relations with the GFHNRC or the University of North Dakota. If in the future you decide that you do not want your samples used for research, please notify Dr. Casperson at 701-795-8497 and your samples will be destroyed.

## WHAT ARE THE RISKS OF THE STUDY?

The risk involved with doing the tests that were just explained are thought to be limited, yet, you need to know what those risks might be. The risks may vary from person to person and there may be other side effects that cannot be predicted.

Approval Date: 1/27/2023

Expiration Date: 1/26/2024

**University of North Dakota IRB**

1) *Risks from the diet*

The study diet will consist of foods purchased through local grocery stores and food vendors. There is no known risk of eating these foods. However, these foods are being provided on a 5-day rotation. You may get bored eating the same foods for 8 weeks. In addition, you will be eating fewer calories than your body needs to maintain your current weight which may cause you to feel hungry or have strong cravings. We will be monitoring your progress at all times and will address any concerns you have as they appear.

2) *Risks from taking your blood*

The risks of taking blood include possible pain, bruising, or infection. The use of sterile methods will minimize these risks but will not remove them completely. We will take a total of about 6 tablespoons (2 at each study visit) of blood for the entire study. Some individuals experience lightheadedness and/or nausea and vomiting during or right after their blood is taken. Some people have fainted. There are no long-term problems related to these responses. In our experience, this occurs in about 3.3% of people.

3) *Risks from testing your resting energy expenditure*

We will be placing a clear plastic dome over your head and you may experience claustrophobia. Claustrophobia is a fear of enclosed spaces. Most people know if they experience this type of fear. The dome is completely see-through, to help avoid any fears. Should you not be able to do this test you may still be able to take part in the study.

4) *Risks from determining your body shape*

The test to determine your body shape requires you to be scanned without your clothing. This may make you feel uncomfortable. You may be scanned in your undergarments. A thick curtain is in place for privacy during the measurement. No x-rays or radiation is involved and no detailed body images will be obtained.

5) *Risks from the DXA scan*

The test to determine how much muscle and fat you have involves minor x-ray exposure. Your total radiation exposure from all DXA scans in this study is similar to the amount of radiation exposure you would experience from being outside for roughly 1½ days.

6) *Risks from filling out questionnaires*

Some of the forms we are asking you to fill out may cause you to feel stress, anxious, or upset. You may feel uncomfortable answering some of the questions. We will only ask questions that are important to the study. If there is a question(s) you do not want to answer, please inform the staff to see if you can still take part in the study.



Date: _____
Subject Initials: _____

## WHAT ARE THE BENEFITS OF THIS STUDY?

You may not benefit personally from being in this study. You may lose weight and view this as a benefit. In addition, the knowledge you may gain while participating in this study may help you with your weight loss efforts. We hope that, in the future, other people might benefit from this study because the knowledge we will gain from your participation will help us better understand how to help people stick to their weight loss goals.

## WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

There will be no charge to you for any tests done during the study. You will be expected to provide your transportation to and from the Center. In addition, we do not withhold taxes from any monies you will receive. Any questions you have related to taxes will need to be directed to your personal accountant or the Internal Revenue Service.

## WILL I BE PAID FOR PARTICIPATING?

You will be compensated for being in this research study. A total of $1455.00 will be paid upon completion of all study visits. You also have the option to receive a 35-month individual membership or a 25-month family membership to Choice Health and Fitness.

If you are unable to complete the study, you will receive a pro-rated amount based upon the parts of the study you finished. Membership to Choice Health and Fitness will not be offered to those who do not complete the study.

a) Meal pick-up - $5.00/day

b) Overnight testing visits - $150.00/visit

## WHO IS FUNDING THE STUDY?

The GFHNRC and the North Dakota Beef Commission are funding this research study. This means that the GFHNRC is receiving payments from the North Dakota Beef Commission to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or an increase in salary from the North Dakota Beef Commission for conducting this study.

## CONFIDENTIALITY

Study records that identify you will be kept confidential as required by law. Federal privacy regulations provided under the Health Insurance Portability and Accountability Act (HIPAA) provides safeguards for privacy, security, and authorized access of your records. Except when

required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the US Department of Agriculture as specified in the USDA/ARS Privacy Act System of Records, the UND Research Development and Compliance office, and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of assigning you a unique identification (ID) number that will not contain any personal identifiers. This ID number will be used on all data collection instruments, including questionnaires and computer records, so that no data can be connected to you. A master list linking your name to your ID number will be kept in a separate locked file or in a computer file with password protected access that is restricted to study personnel.

## USE AND DISCLOSURE OF YOUR RESEARCH STUDY INFORMATION

All tests will be done only because you are in this study. The results of this study may be published in scientific journals. Any reports or articles about this study will only describe the study results in a summarized manner so that you cannot be identified. You may see or receive a copy of some, but not all, research information that is collected about you. If you would like a copy of your study results, please contact the scientist listed below.

## COMPENSATION FOR STUDY RELATED INJURY

In the event that any research test results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.). No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you.

## THIS STUDY IS VOLUNTARY

Your participation is voluntary. You may choose not to join or you may stop your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect your current or future relations with the GFHNRC or the University of North Dakota. We will let you know about any new information that might cause you to change your mind about being in this study. We ask that you tell us if at any time you no longer wish to be in the study.

Approval Date: 1/27/2023

Expiration Date: 1/26/2024

**University of North Dakota IRB**

Date: _____
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## REASONS FOR THE SCIENTIST TO STOP YOUR PARTICIPATION

We reserve the right to stop your involvement in the study if we feel you are not complying with the study protocol or if we feel your safety and well-being, or that of other study participants, is being affected.

## CONTACTS AND QUESTIONS

The scientist conducting this study is Shanon Casperson, PhD. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Dr. Casperson at shanon.casperson@ars.usda.gov or by phone at 701-795-8497.

If you have questions regarding your rights as a research subject, you may contact The University of North Dakota Institutional Review Board at **(701) 777-4279**.

- You may also call this number about any problems, complaints, or concerns you have about this research study.
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.
- General information about being a research subject can be found by clicking the "Information for Research Participants" button on the following web site: http://und.edu/research/resources/human-subjects/research-participants.cfm

## CONSENT

Informed consent is required of all persons who participant in research studies. Your signature indicates that the study you have volunteered for has been explained to you, that your questions have been answered, and that you agree to take part in this study. By signing this consent form, you are authorizing the use and disclosure of your health information for the purpose of completing the research study. You will receive a copy of this form.

Subject's Name: _____

_____ _____
Signature of Subject Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

_____ _____
Signature of Person Who Obtained Consent Date

Approval Date: 1/27/2023

Expiration Date: 1/26/2024

**University of North Dakota IRB**

Date: _____
Subject Initials: _____