Document Type: Informed Consent Form – Main Study

Official Title: Food, Activity and Behavior Study (FAB)

NCT Number: NCT04577547

IRB Approval Date: 03/22/2022

GRAND FORKS HUMAN NUTRITION RESEARCH CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Project Title:	Food, Activity, and Behavior (FAB) Study
Principal Investigator:	Drs. Shanon Casperson, Julie Hess, and James Roemmich
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Department:	USDA Grand Forks Human Nutrition Research Center (the Center)

The purpose of this research is to test the effects of the Dietary Guidelines for Americans (DGA) and the Physical Activity Guidelines for Americans (PAGA) on health and on eating and exercise behaviors. The study takes about 13 weeks to complete. You will come to the Center each month while you are in the study for testing. You will have to eat all the food we give you, and only the food we give you, for 12 weeks.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you do not take part, it will not be held against you.
- You can take part now and later drop out, and it will not be held against you.
- If you do not understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

The study last about 3 months and includes this consenting/screening visit, four (4) 2-day testing visits, and coming to the Center each weekday to pick up your food.

Why is this research being done?

We are testing the effects of the federal guidelines for eating (DGA) and exercise (PAGA) to better understand the impact following these guidelines has on health.

What happens to me if I agree to take part in this research?

If you decide to take part in this study, you will fill out some questionnaires about your health and your liking of different types of exercise (such as walking on a treadmill) and non-exercise

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activities (such as watching TV) and snack foods (candy and chips). We will measure your height and weight and blood pressure. We will also record your heart rhythm so a doctor can determine if you are healthy enough to exercise. We will give you an activity monitor to wear for 7 days to measure your daily activity and schedule you for your first testing visits. You will then be randomly assigned to a group. You cannot choose which group you will be in.

Testing Visits: Each testing visit (baseline, week 4, week 8 and week 12) involves coming to the Center on 2 different days. The main testing day will take about 9 hours to complete, so you will need to take a day off of work or arrange to do your schoolwork at the Center. The other testing day will take about 2 hours to test your aerobic fitness and muscle strength. Here is what to expect at each testing visit:

Testing Day 1: You will need to come to the Center in the morning after having fasted for at least 10 hours. You must not exercise for at least 2 days before your visit. Breakfast and lunch will be provided. During this testing visit we will measure the following:

1. *Resting Energy Expenditure:* You will lie in a quiet room for about 30 minutes. We will then place a clear hood over your head to collect your breath. You will be asked to breathe normally while you lay awake for the next 30 minutes. If the results are found to be questionable for accuracy, we may ask you to repeat the test.
2. *Blood Draw:* A nurse and/or trained staff will draw blood from the vein in your arm.
3. *Body Composition and Shape:* To measure your body composition, you will lay face-up on a table and an x-ray of your entire body will be taken. You cannot wear any metal for this test so we may ask you to change into scrubs. You must lie still for the 15-minute scan. If the results are found to be inadequate, we may ask you to repeat the scan. If you are a woman of child-bearing age, a urine pregnancy test will be done prior to the scan. We will also use a 3D body scanner to measure the shape of your body. The scan takes 15 seconds. The scanner cannot see through your clothes, so you will need 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.
4. *Computer Task:* This task will be done once in the morning to see how much you like and value your chosen exercise and once in the afternoon to see how much you like and value your chosen snack food. You will play a game that mimics a slot machine

to earn points to have access to your chosen activities and snack food. You can earn as few, or as many points as you wish.

5. *Questionnaires:* We will ask you questions about your eating, activity, and health behaviors. Most of the questionnaires will be on a computer, some will be paper.

Testing Day 2: This testing day is scheduled up to 3 days before or after the Testing Day 1. You will arrive at the center about 2 hours after you have eaten a meal. You must not exercise for at least 2 days before your visit. To test your muscle strength, we will measure how hard you can press and pull with your legs – you will not be lifting any weights. To test your aerobic fitness, you will walk on a treadmill as we adjust the speed and the incline after 3 minutes. You will wear a specialized face mask to collect and measure your breath and a chest strap to measure your heart rate. We will also ask you questions about how you are felling. The test will stop when you tell us that you cannot do any more or if we feel that it is not safe for you to continue.

At-home testing: You will take you blood pressure every day. We will give you a blood pressure monitoring device and a cuff and detailed instruction about taking your blood pressure at home. You will also wear a continuous glucose monitoring device. We will place the monitor while you are at the center, but the monitor will need to be replaced every 10 days. We will give you detailed instructions and everything you need to do this. If you do not feel comfortable doing this, you can come to the Center and we will replace the monitor for you.

Daily Questionnaire: You will complete a questionnaire each day asking about your gastrointestinal (GI) health. This includes keeping a diary about your bowel movements.

Intervention: You will be randomized to receive either a typical American diet or a diet that follows DGA recommendations. You will not be able to choose which diet you will receive. We will give you a copy of the menus so that you can decide if you can eat all the foods. You must eat everything we give you and nothing else. You will be free to drink whatever you want as long as it does not have any calories (water, non-sweetened or artificially sweetened tea and coffee, diet pop). You will come to the Center every weekday to pick up food.

If you are healthy enough to exercise, we may ask you to follow an exercise plan that is designed for you. You must follow your exercise plan if you are put in this group. If you do not already have a gym membership, we will give you access to the Choice Health and Fitness Center or the YMCA so you can do your exercise plan.

Could being in this research hurt me?

The risk involved with being in this study are thought to be limited, yet, you need to know what those risks might be. Most of them are listed below and may vary from person to person. There may be other side effects that cannot be predicted.

DXA Scan: The DXA scan is an x-ray and is considered to be a no greater than minimal risk procedure. 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 2 days. A quality assurance check will be completed on the DXA each day prior to its use; the software will not allow the use of the DXA if the quality assurance check fails. The effects of small doses of radiation on a developing fetus are not known; therefore, we will not knowingly allow a pregnant woman to have a DXA. Pregnancy tests will be done before each scan if you are a woman of child-bearing age.

Blood draws: The needle stick may hurt. There is a small risk of bruising. You may feel lightheaded or faint during or right after a blood draw. This is more likely to happen if you have had problems with fainting during blood draws in the past. Let us know. Trained staff use sterile techniques when drawing blood, but there is a chance that the site may become infected. We will collect 50 milliliters (about 3.5 tablespoons) at the testing visits for a maximum of 200 milliliters (about 14 tablespoons) taken for the entire study. This is much less than the pint or 475 milliliters that blood banks draw every 8 weeks.

Questionnaires: You may have some uncomfortable feelings when answering questions. Only questions required to determine eligibility and assess factors related to the study will be asked.

Resting metabolic rate: The clear hood placed over your head during the test allows you to freely breathe room air. However, some people find the hood uncomfortable or emotionally trying (e.g., claustrophobia and/or boredom). A trained researcher will be available at all times in case you experience any problems.

Exercise: If you are assigned to the exercise group you may not like doing the exercise required for this study. There is a small risk of sprains, strains, and broken bones as a result of do the exercise. To reduce this risk, you will be supervised by experienced staff until you and the staff feel comfortable with you doing the exercises on your own. You may be sore after exercise, but it will go away with time. Nausea, dizziness, and lightheadedness are also common side effects of exercising. These can be minimized

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with meal timing and hydration. Exercise can uncover or worsen hidden heart problems, such as not enough blood flow to the heart muscle and irregular beats, but this rare. Should you develop symptoms of any medical problems, the study will be stopped immediately.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research. We hope that in the future, others might benefit from our findings. Results of this study will yield knowledge of how diet and exercise affect health and behavior. This may provide valuable information that may guide federal dietary and physical activity recommendations. Possible benefits to others include improving the health of all Americans.

How many people will participate in this research?
At least 117 people will be asked to take part in this study.

Will it cost me money to take part in this research?
You will not have any costs for being in this study. You will be expected to provide your transportation to and from the Center. We do not withhold income, social security, unemployment taxes, or any other taxes. You may have to pay income taxes on the money you receive. All tax questions should be directed to your personal tax accountant or to your local Internal Revenue Service Office. If you are not a United States citizen, check your documentation to make sure you can receive money from a non-University source without risking your status in the United States.

Will I be paid for taking part in this research?
You will receive $2,050 for completing this study. Instead of the money you can choose to get a 4-year individual membership OR a 3-year 3-month family membership to the Choice Health and Fitness Center. If you are not able to complete the study, you will receive $100 for each testing visit completed, this includes both testing days, and $15 for each weekly dietary assessment completed.

Who is funding this research?
The United States Department of Agriculture (USDA) is funding this study. This means that the Center is receiving payments from the USDA 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 USDA for conducting this study.

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What happens to information collected for this research?

Your private information may be shared with individuals and organizations that conduct or watch over research, including:

- The Center
- The USDA, as specified in the USDA/ARS Privacy Act System of Records
- The University of North Dakota (UND) Research Compliance & Ethics Office
- The Institutional Review Board (IRB) that reviewed this research.
- and as required by law or court order.

We may publish the results of this study. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. Clinical trial information will be submitted to the National Institutes of Health/National Library of Medicine to be included in the clinical trial registry data bank (www.clinicaltrials.gov).

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

Could being in this research hurt me?

In the event that being in this study causes 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. If you are injured while taking part in this study as a result of the negligence of a United States Government employee who is involved with this study, you may be compensated for your injury in accordance with the requirements of the Federal Tort Claims Act. Compensation from individuals or organizations other than the United States might also be available to you.

What if I agree to be in the research and then change my mind?

If you decide to leave the study early, we ask that you inform us. Your decision will not affect your current or future relations with the Center or UND.

Why would the scientist stop my study participation?

We reserve the right to stop your involvement if we feel your safety and well-being, or that of other study participants, is being affected. We also reserve the right to stop your involvement

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in the study if we feel you are not complying with the study protocol or there are any changes in your medications during the treatment period that will interfere with study outcomes.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 701.777.4279 or UND.irb@UND.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.
- You may also visit the UND IRB website for more information about being a research subject: http://und.edu/research/resources/human-subjects/research-participants.html

Supplemental information about samples for genetic research: Your samples may be used for genetic research. No individual information about genotypes will be made available to you or to a third party. Genotyping carries no medical or therapeutic value. There is no medical significance linked with the DNA test results. Your samples will not be sold in the future. Your samples will become the property of the Center, and you do not have rights to them.

Please indicate below if you consent that your samples may be used in future genetic research. You will not be paid an additional amount for these samples. If you choose not to allow the use of your samples for future research, they will be destroyed at the end of the study.

(Please circle one) YES NO

Initials _____

Supplemental study about how diet and exercise affect metabolism: In addition to the study procedures outlined above, we are asking people if they are willing to spend about 36 hours in

our metabolic room. This will happen before you start the intervention and then again at the end of the intervention. If you elect to take part in this extra study, we will meet with you to explain the details of this study.

If eligible, would you be willing to take part in this extra study? Please indicate your choice below. You will be paid an additional $500 if you compete these extra study visits.

(Please circle one) YES NO

Initials _____

Request to contact for future studies:
We would like to alert you about studies you may qualify for in the future. Please indicate below if you consent to be contacted.

(Please circle one) YES NO

Initials ___

Consent: Your signature documents your consent to take part in this study. You will receive a copy of this form.

Name: _____

_____ _____
Signature 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: 3/22/2022

Expiration Date: 3/21/2023

University of North Dakota IRB

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Initials: _____

Document Type: Informed Consent Form – Sub Study

Official Title: Food, Activity and Behavior Study (FAB)

NCT Number: NCT04577547

IRB Approval Date: 03/22/2022

GRAND FORKS HUMAN NUTRITION RESEARCH CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Project Title: Food, Activity, and Behavior (FAB) Study

Principal Investigator: Dr. Shanon Casperson

Phone/Email Address: 701-795-8497, Shanon.Caperson@usda.gov

Department: USDA Grand Forks Human Nutrition Research Center (GFHNRC)

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last about 3 months.

Why is this research being done?

The purpose of this research is to test the effects of the Dietary and Physical Activity Guidelines for Americans on how easily your body switches between using carbohydrates and fats for energy after a meal and exercise.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, you spend about 1½ days in the metabolic room. Females will be scheduled based on their menstrual cycle. You will do this once before you start feeding phase and again in 3 months, after you finish the feeding phase of the big study.

Study Overview

You will enter the metabolic room at around 4PM on day 1 and stay until about 8AM on day 3. You may watch TV, read, play on your computer, or bring your game system from home. While you are in the metabolic room you will be asked to collect all your urine and we will monitor your sleep quality. On day 2 breakfast and lunch will be either a high carbohydrate meal or high fat meal in the form of a milk shake. In the afternoon you will be asked to walk on a treadmill at an easy pace, 50% of your heart rate reserve based on your age, for 1 hour. The figure below will give you an idea of how the study will go.

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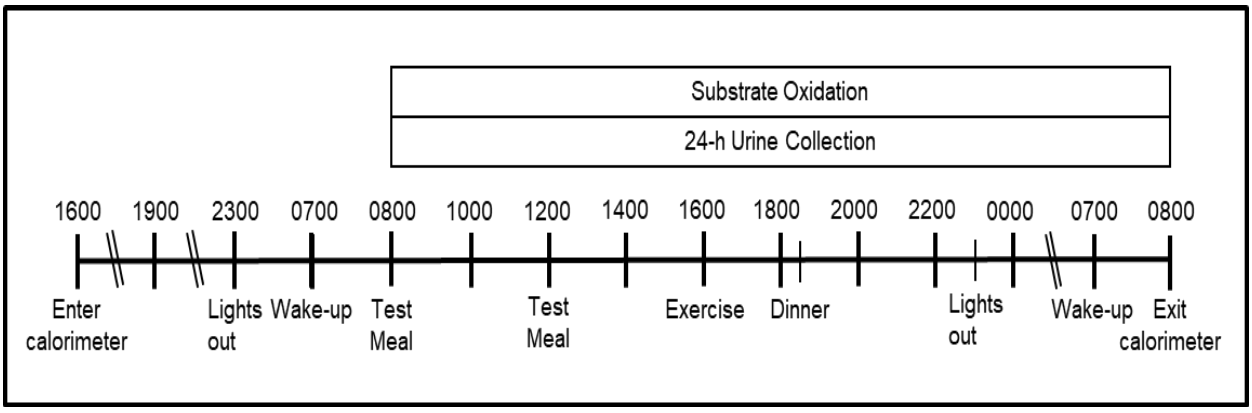

Tests

The following describes all testing procedures:

1) *Metabolic Room:* The metabolic room will provide us with an estimate about how your body is using food for energy. You will be able to choose how you spend your time (watching TV, reading, etc.). You *will not* be allowed to sleep during the day. You will be monitored by a closed-circuit video system at all times. The temperature is kept at about 72°, extra blankets can be provided if needed. You will stay in the metabolic room for about 1½ days.
2) *Urine Samples:* You will be asked to collect your urine while you are in the metabolic room. You will be asked to void your bladder when you wake up, before lunch, exercising and dinner, and before going to bed. In addition to these times, you will need to collect all other urine you produce during the day.
3) *Test Meals:* You will be given two test meals. These meals will in the form of a milk shake and will be either high in sugar or fat. You will be asked to drink the shake in 15 minutes. No other foods will be offered until dinner, but you may ask for water as desired.
4) *Exercise:* You will be asked to walk on a treadmill for 1 hour at a target heart rate. During the exercise you will be asked to wear a chest strap so that we can monitor your heart rate while you are exercising.
5) *Sleep Monitoring:* At least 30 minutes before lights out you will be asked to apply small sensor pads behind your ears and on the back of the neck. When ready for bed you will snap cables to the sensor pads and connect the cable to a Zmachine that is about the size of an iPhone 4. You will put the Zmachine under your pillow or hang it from the hook located on the wall next to your pillow. We will give you instructions on how to apply the sensor pads and how to use the Zmachine to monitor your sleep quality.

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Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research is claustrophobia and/or boredom from having to stay in the metabolic room for 1½ days. You will be shown the room prior to your participation so that you can be familiar with it. There are 2 windows, and the glass door does not lock. If you find that you feel overwhelmed you can open the door, but this will stop your study. Staff will be here for you at all times in case you experience any difficulties. In addition, you may feel uncomfortable being monitored by closed-circuit video. No video recording will take place. There are curtains for privacy.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research. We hope that in the future, others might benefit from our findings. Results of this research will yield knowledge of how diet and activity affect your body's ability to respond or adapt to changes in metabolic demand.

How many people will participate in this research?
Approximately 36 people will take part in this study at the GFHNRC.

Will it cost me money to take part in this research?
You will not have any costs for being in this research study. You will be expected to provide your transportation to and from the GFHNRC. We do not withhold income, social security, unemployment taxes, or any other taxes because you are not an employee of the GFHNRC. You may have to pay income taxes on the money you receive. All tax questions relating to the taxability of the payment should be directed to your personal tax accountant or to your local Internal Revenue Service Office. If you are not a United States citizen, check your documentation to make sure you can receive money from a non-University source without risking your status in the United States.

Will I be paid for taking part in this research?
You will be paid for being in this research study. Reimbursement for completing the study is $500; **OR** you may choose to receive your choice of a 12-month individual membership or 9-month family membership to the Choice Health and Fitness Center. You will be paid when you finish both study visits. This is in addition to the payment you will receive for being in the bigger study. If you decide to no longer continue in the study or are found to no longer qualify, you will be paid a prorated amount for the procedures completed.

Who is funding this research?
The United States Department of Agriculture (USDA) is funding this research study. This means that the GFHNRC is receiving payments from the USDA 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 USDA for conducting this study.

Date: _____
Subject Initials: _____

What happens to information collected for this research?
Your private information may be shared with individuals and organizations that conduct or watch over this research, including:

- The GFHNRC
- The USDA, as specified in the USDA/ARS Privacy Act System of Records
- The University of North Dakota (UND) Research Compliance & Ethics Office
- The Institutional Review Board (IRB) that reviewed this research
- and as required by law or court order.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. Clinical trial information will be submitted to the National Institutes of Health/National Library of Medicine to be included in the clinical trial registry data bank (www.clinicaltrials.gov).

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

Could being in this research hurt me?
In the event that this research activity 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. If you are injured while taking part in this research project as a result of the negligence of a United States Government employee who is involved in this research project, you may be able to be compensated for your injury in accordance with the requirements of the Federal Tort Claims Act. Compensation from individuals or organizations other than the United States might also be available to you.

What if I agree to be in the research and then change my mind?
If you decide to leave the study early, we ask that you inform the study staff. Your decision will not affect your current or future relations with the GFHNRC or UND. If you begin taking medications during the treatment period, please notify the study staff. Some medications may interfere with the outcomes of the study. If your medications interfere with the study outcomes, your participation will be ended, and you will be compensated for the portions of the research completed.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

Approval Date: 3/22/2022

Expiration Date: 3/21/2023

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- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.
- You may also visit the UND IRB website for more information about being a research subject: http://und.edu/research/resources/human-subjects/research-participants.html

Your signature documents your consent to take part in this 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: 3/22/2022

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Date: _____

Subject Initials: _____