Document Type: Informed Consent Form

Official Title: Exercise is Medicine. How Exercise Signals Health Responses

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GRAND FORKS HUMAN NUTRITION RESEARCH CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Project Title:	**Exercise is medicine: How exercise signals for health**
Principal Investigators:	Dr. James Roemmich
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Department:	Grand Forks Human Nutrition Research Center

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 3 to 4 weeks but could take longer depending on being able to schedule your participation.

Why is this research being done?
The purpose of this research is to determine the blood signals that promote health and wellbeing in response to exercise at different intensities.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, you will be asked to provide written informed consent. You will be briefed on the study and given an opportunity to ask any questions you may have. After signing this consent, you will be given a small activity monitor to wear on your hip for 7 days that measures your physical activity. After this 7-day period, 5 days of assessments will occur as outlined here:
- Body Composition Visit: Your height, and weight, and resting heart rate will be recorded, and body composition determined (using an x-ray machine that gives off a very small amount of ionizing radiation).
- Computer Task Visit: You will complete some computer-based questionnaires and tasks, which will determine your liking and reinforcing value of exercise. You are free to skip any questions that you prefer not to answer. For the reinforcing value assessment, you will be asked to play a game that mimics a slot machine. You will be asked to earn as few, or as many points as you wish, which can then be exchanged for access to exercise or sedentary options. The time

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you earn will be used immediately afterward toward exercise (biking, walking, etc.) or sedentary activities (reading, word puzzles, etc.).

The order of Visits 1, 2, and Control will be randomly assigned.

- Exercise Visit 1: For the three days before exercise visits we will provide all of your meals for you. Please avoid taking any additional supplements and avoid eating food other than what we have provided. Please also do not engage in exercise for 24 hours prior to this visit. At your exercise visit, you will arrive a couple hours after eating and a small sample of blood will be taken. Next, you will wear a chest strap to monitor heart rate and perform approximately 30 minutes of moderate or high intensity exercise on an exercise bicycle. A coach will be with you throughout the exercise session to help you avoid over-exertion. After completing exercise, we will collect 4 more blood samples. These samples will be taken immediately after exercise, then at 30, 60, and 90 minutes after exercise.
- Exercise Visit 2: For the three days before exercise visits we will provide all of your meals for you. Please refrain from taking any additional supplements and avoid eating food other than what we have provided. Please also do not engage in exercise for 24 hours prior to this visit. At your exercise visit, you will arrive a couple hours after eating and a small sample of blood will be taken. Next, you will wear a chest strap to monitor heart rate and perform approximately 30 minutes of moderate or high intensity exercise on an exercise bicycle. A coach will be with you throughout the exercise session to help you avoid over-exertion. After completing exercise, we will collect 4 more blood samples. These samples will be taken immediately after exercise, then at 30, 60, and 90 minutes after exercise.
- Control visit: This visit will be very similar to your exercise visits. We will provide all your meals for three days prior to this visit. please refrain from taking any additional supplements and avoid eating food other than what we have provided. Please also do not engage in exercise for 24 hours prior to this visit. During this visit, you will arrive a couple hours after eating and a small sample of blood will be taken. You will wear a chest strap to monitor heart rate and sit near the exercise bike for approximately 30 minutes. After this rest period, we will collect 4 more blood samples. These samples will be taken immediately after the rest period, then at 30, 60, and 90 minutes afterwards.

Study Blood Draws: Blood volume totals for analysis are 3 ml whole blood and 5.5 ml serum for first visit and 5.2 ml serum each for second and third visits. With 0.4 ml serum per 1 ml whole blood, the whole blood draw volume totals are 17 ml (just over a tablespoon, 14.7 ml) for the first visit and 13 ml (just under a tablespoon) each for visits 2 and 3. Total whole blood draw volume for study participant is 43 ml (less than 3 tablespoons).

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include psychological and physical risks as outlined below:

- **Questionnaires:** You may get frustrated when doing the surveys. Some questions may be sensitive, and you may become upset. If you become upset by the questions you may stop at any time or choose not to answer a question.
- **Blood Sampling:** There is a small risk of local bruising, swelling, or irritation from blood sampling. There may be pain as the needle passes through the skin. To minimize these problems, trained and experienced personnel will ask you about your blood draw history and draw your blood. They will follow standard medical precautions to reduce risk. Please tell them if you have, or have ever had, problems with blood sampling. Since more than one blood draw is needed for this study, you will have the option to have a catheter placed to avoid multiple sticks.
- **Exercise Assessments:** You may not like participating in the exercise required for this study. There is a small risk of sprains, strains, and broken bones as a result of exercise. To reduce this risk, you will be supervised by experienced staff. Soreness may occur 24-48 hours after exercise but will go away with time. Exercise can uncover or worsen hidden heart problems such as not enough blood flow to the heart muscle and irregular beats. It is unlikely you will have problems with your heart or circulatory system. Nausea, dizziness, and lightheadedness are common side effects of high intensity exercise. These can be minimized with proper nutrition and hydration. Should you develop symptoms of any medical problems, testing will be stopped immediately.
- **Body Composition:** The DEXA scan is an x-ray and is considered to be a no greater than minimal risk procedure. The radiation dose of the whole-body scan is no more than 1.0 millirem. This dose is equivalent to approximately 1/620 of normal annual background radiation, ¼ the radiation received in a long flight, or 1/10 of the radiation received in a chest x-ray. A quality assurance check will be completed on the DEXA each day prior to its use; the software will not allow the use of the DEXA if the quality assurance check fails. The effects of small doses of radiation on a fetus are not known; therefore, we will not knowingly allow a pregnant woman to have a DEXA scan. Pregnancy tests will be done before the DEXA if you are a woman of child-bearing potential.
- **Chest straps:** There is a slight chance of skin irritation from the chest strap. These devices will be cleaned between uses, and staff will instruct you on properly wearing the devices. If any discomfort occurs, please remove the device or adjust its position, and report the discomfort to the staff.

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.

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Will being in this research benefit me?
It is not expected that you will personally benefit from this research.

Possible benefits to you and others include future understanding of the molecular signaling mechanisms that are responsible for causing the benefits observed with exercise. This knowledge could improve the health and wellbeing of the population in the future.

How many people will participate in this research?
Approximately 40 people will take part in this study at the Grand Forks Human Nutrition Research Center (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. You will receive reimbursement in the amount of $600 for completion of the study. Instead of the reimbursement money, you may choose to receive your choice of a 9-month family membership or an 11-month individual membership, at Choice Health and Fitness, to be paid at the end of the study. There is no reimbursement for screening procedures. If you complete the entire study, payment will be made at the end of the trials. In the event you drop out of the project, you will be paid for partial participation based on the procedures that were completed. You will receive compensation for wearing the physical activity monitor for those days that you wear the monitor for at least 10 waking hours. If you wear the activity monitor for at least 10 hours for 7 days and adhere to all other testing through visit 2, you will receive $220. You will be required to provide your SSN and address to receive your payment (W9 form).

Who is funding this research?
There is no independent funding for this research study. The USDA ARS-GFHNRC will provide funds 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 for conducting this study.

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:

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- The USDA ARS-GFHNRC research staff
- The Institutional Review Board (IRB) that reviewed this research

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.

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 study volunteers unique subject identification (ID) numbers that will not contain any personal identifiers. This subject ID number will be used on all data collection instruments, including questionnaires and computer records, so that no data can be connected to an individual subject. A master list linking the volunteers' names to the ID numbers will be kept in a separate locked file in the principle investigators office, or in a computer file with a password protected access restricted to study personnel. Confidential information may be made available to the USDA as specified in the USDA/ARS Privacy Act System of Records, to UND, and as required by law or court order. 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).

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 call Dr. Roemmich (701-795-8272) or Bill Siders (701-795-8460) to inform them of your withdrawal.

You will be informed by the research investigator[s] of this study of any significant new findings that develop during the study which may influence your willingness to continue to participate in the study.

There may be special circumstances that will result in your early withdrawal from the study without your approval. Such situations may include realization that exercise is not healthy for you or that other conditions might make continued participation harmful to you. You will also be withdrawn from the study if you are not willing or not able to follow the study directions.

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:

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Expiration Date: 3/9/2024

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- 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

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. This information will be kept in a separate file from the signed study consent form.
(Please circle one) YES NO

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

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