United States Army Research Institute of Environmental Medicine (USARIEM)

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Effect of short-chain fatty acids on aerobic endurance

Principal Investigator: J. Philip Karl, PhD, RD

Introduction: You are being asked to participate in this research study because you are a healthy and physically active man or woman between 18-39 years old (or between 17-39 years old for active-duty personnel). You do not have to take part in this research. It is your choice.

The table below summarizes some **key** points to think about. After reading this summary, if you think you might be interested in participating, read the rest of the consent form for more details about the study.

RESEARCH SUMMARY	
Informed Consent	It is important that you understand this research study so that you can make an informed decision. This process is called informed consent. • Please ask questions about anything you do not understand. • Feel free to talk with your family, friends, or others before you decide. • After your questions have been answered, you will be asked if you want to participate. If you agree, you will sign this consent form. • You will be given a copy of this form to keep.
Voluntary Participation	You do not have to take part in this research. It is your choice. You can also choose to stop participating at any time during the study.
Purpose	This study will help us determine whether a daily diet supplement that feeds bacteria in your gut improves your exercise performance. Results from this study will be used to develop strategies for increasing physical endurance to improve military readiness, health, and performance.
Duration	You will be in this study for about **6** weeks, but this may be longer based on your schedule. During that time, you will participate in about **50** total hours of study-related activities.
Restrictions	During the two study phases described in the "Procedures" section below, you will: • **Not be allowed** to consume any foods or beverages other than what is provided to you (except water). • **Not be allowed** to participate in any exercise not prescribed by study staff. • **Not be allowed** to drink alcohol or use nicotine- or caffeine-containing products. • **Not be allowed** to take dietary supplements, probiotics, or prebiotics (also for 2 weeks before and throughout the study).

Procedures	While you are in the study, you will complete baseline testing that includes familiarization with study activities and a fitness test on a treadmill, and then ***two*** non-consecutive weeks of study activities. During each of those weeks or "study phases" you will: • **Consume a diet supplement 3 times daily**. • Exercise 30 mins daily for five days in a row • Follow a strict, **provided diet**. • **Collect your own poop** 2 separate times using a provided kit (total 4 samples for the study). At the end of each week, you will participate in a day of testing where you will: • **Provide blood** (8 times [total 16 samples and about 1.25 cups for the study]), **urine** (1 spot collection and a 7.5 hour collection), **and breath** (3 times, total 6 samples for the study) samples. • Participate in an **intravenous infusion** study of your metabolism**.** • Complete **2 biopsies of your thigh muscle** (total 4 samples for the study), midway between your knee and hip, while under a local anesthetic (numbing medication). • **Ride a stationary bike** at a moderate pace **for 90 minutes**. • **Run 3.1 miles** on a treadmill test as fast as you can.
Risks	The **main** risks from being in this study are: • Muscle fatigue and soreness from exercise. • Bruising, swelling, local discomfort and low risk of infection from blood collection, intravenous infusion, and muscle biopsy. • Gastrointestinal discomfort (bloating, gas, cramping) from the dietary supplements or provided diet. *Additional risks and steps taken to minimize these risks are described later in this form.*
Benefits	There is no direct benefit to you, but we hope that results from this study will help determine new ways to improve physical performance.
Payment	You will be paid for your participation in this study.

WHY IS THIS RESEARCH BEING DONE?

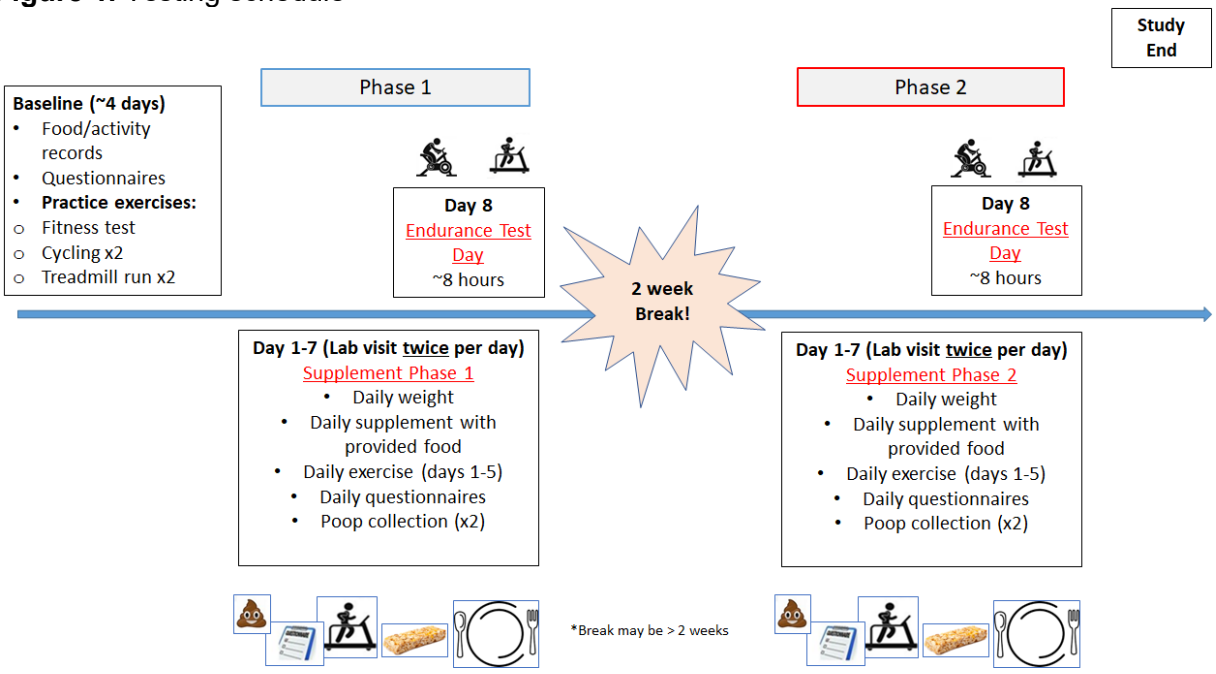
Healthy bacteria living in our intestines transform certain carbohydrates we eat in our diets called fiber into nutrients that our body can use as energy and in other beneficial ways. One benefit may be to alter metabolism in ways that increases endurance during moderate-intensity exercise. In this study, we will determine if eating a high fiber diet supplement alters metabolism and increases exercise endurance. If successful, these supplements, or similar supplements, could be provided to military personnel or others to improve physical performance.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will first be screened for eligibility. This will include completing a questionnaire which will ask about you (for example, age, race, physical activity) and about the eligibility criteria for participating in the study. After completing the questionnaire, we will also ask you to complete a medical screening with USARIEM medical staff where you will have blood drawn and complete a physical. Your height and weight will also be measured. If the combination of your weight and height exceeds standards set by the Army, you will also have body circumferences measured using a tape measure to estimate your body fat. For men, the neck and abdomen will be measured. For women, the neck, waist, and hip will be measured. To participate in the study, you must meet the height, weight and, if needed, circumference standards set by the Army. Screening will take place over 1 or 2 visits to USARIEM and will take about 2 hours total. If you pass screening, we will ask you to continue in the study.

During the study you will be asked to do the activities shown in Figures 1 and 2 and described in Table 1. There will be an approximately 2-week break period in the middle of the study where you will not participate in any study activities. The break period may be longer than 2 weeks if needed.

Figure 1. Testing schedule



Baseline

Orientation: During this visit we will provide you with general instructions for the study and with instructions for completing a 3-day food and activity record. We will also measure your height and weight. This visit will take about 60 minutes.

Menstrual Cycle Interview (females only): Female participants will be asked to complete a menstrual cycle interview, which will be administered by a female research staff member. The purpose of the menstrual cycle interview is to determine when your hormones are at their lowest level (follicular phase) if you are not using certain oral/hormonal contraceptive. It is during this

phase of your menstrual cycle that you will participate in the Endurance Test Day as described below. This interview takes about 10 minutes to complete.

Familiarization testing (up to 2 weeks): During baseline testing, you will complete several tasks to help you become familiar with the tests that will be performed later during the study. These tasks will include completing questionnaires, a fitness test on a treadmill and two practice endurance tests: one on a stationary bicycle and one on a treadmill (see Table 1 for details about each task). These tasks will be completed over 2 to 4 lab visits that are about 30-180 minutes each. If needed, we may repeat practice tests to make sure you are comfortable with the testing.

Supplement phases 1 and 2 (days 1-7)

***Supplement*:** You will receive two dietary supplements during this study, but only one during each phase: fiber or placebo. You will consume 3 doses of assigned supplement per day during each phase. The order in which you receive each supplement will be random and based purely on chance, like flipping a coin. You will have a 50% chance of being assigned to the fiber or placebo group first.

During your fiber phase, you will take the fiber supplement. The fiber supplement is made from a type of carbohydrate derived from corn known as resistant starch. The fiber supplement has also been enriched with the healthy bacteria-derived nutrient called short-chain fatty acids. During your placebo phase, you will take a supplement that looks and tastes like the fiber supplement but contains corn starch. Both the fiber and placebo will be hidden inside a snack bar, a pudding and a drink. Neither you nor the study staff will know which supplement you are receiving at any time.

We will ask you to collect a poop sample in a provided container 1-2 days before starting each supplementation phase. Then, during the 7 days of each supplementation phase, you will be asked to avoid participating in any strenuous activity outside of the lab and to visit the lab twice daily:

Morning visit (approximately 75 minutes): You will consume your assigned supplement (1st dose of the day), eat a provided breakfast, have your body weight measured, answer daily questionnaires regarding your appetite and gastrointestinal symptoms, and complete any prescribed exercise (30 mins daily for the first five days).

Afternoon visit (approximately 30 minutes): You will consume your assigned supplement (2nd dose of the day), eat a provided lunch, and pick up your 3rd supplement dose to consume on your own, along with your remaining meals (dinner) and snacks for the day. We will also ask you to complete any prescribed exercise if you were unable to do so in the morning.

On day 7 of each phase, you will be asked to provide a poop sample (collection will extend to day 8 if no sample is produced), drink three liters (about 13 cups) of water between 1100 and 2100 and fast overnight (8 hours). A staff member will video call you (via Facetime or similar) about 9 hours prior to when you are scheduled to return to the lab the next morning and watch you consume the assigned supplement (3rd dose of the day) during the video call which will take <10 minutes.

Diet: During days 1-7 of each phase, you will be asked not to consume any food or beverages other than what we give you, except for water. Provided foods and beverages will consist of commercially available items and/or the US Armed Services Meal, Ready-to-Eat ration. The amount of food provided will be individualized by study dietitians to maintain your body weight. You will also be asked to return all empty food packaging and not to consume alcohol, caffeine, or nicotine during this time.

Post-supplementation testing: Endurance Test Day

On day 8 of each supplementation phase, you will participate in an "Endurance Testing Protocol". This will take ~8 hours and include the exercises you were familiarized with during familiarization testing (see Figure 2 and Table 1). Upon arrival you will eat breakfast and one supplement dose.. Additionally, you will complete questionnaires, participate in a carbohydrate tracer study using an intravenous infusion, complete a sugar substitute absorption test and provide blood, urine, breath, and muscle samples. You will also collect a urine sample at home in the morning and bring it with you. If you are female, you will complete a urine pregnancy test. Study procedures are described in detail in Table 1.

If you are unable to complete Day 8 due to unforeseen circumstances such as illness, injury, you will be asked to continue following all restrictions and supplementation period procedures (prescribed exercise and consuming the supplements and provided diet) until Day 8 testing can be completed.

Figure 2. Testing schedule for Endurance Testing Protocol.

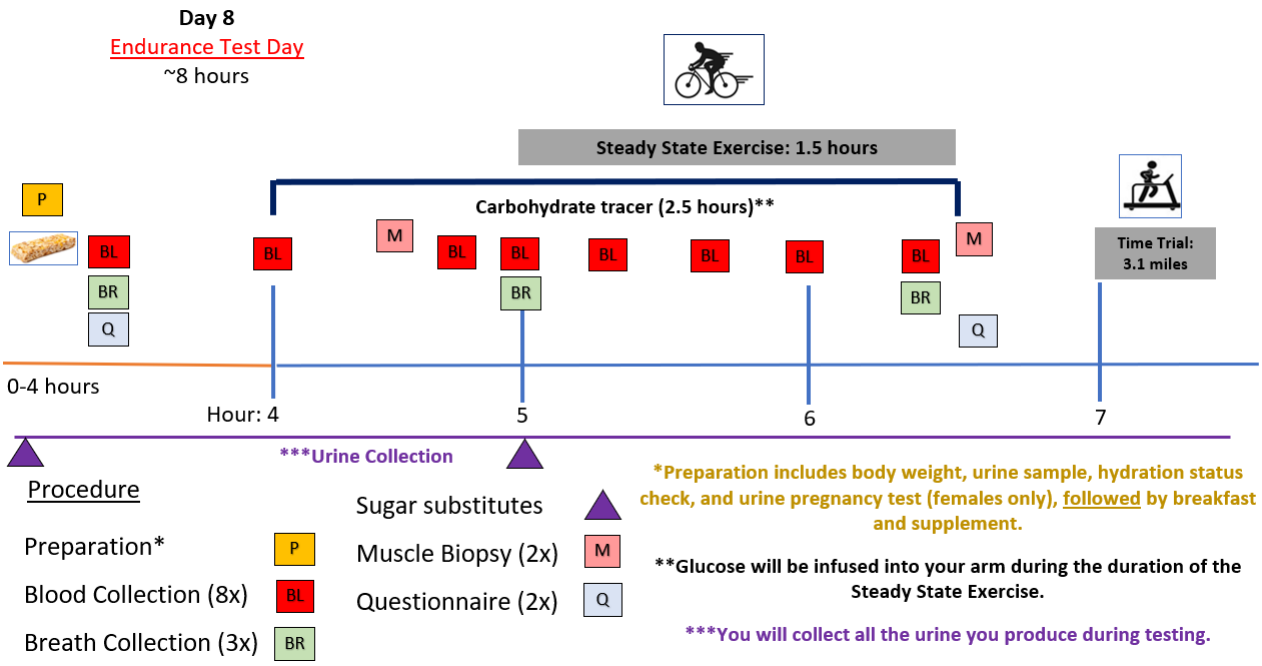


Table 1. Detailed description of study procedures.

Procedure	Description	Day
Menstrual cycle interview (Females only)	A female staff member will interview you regarding the timing of your menstrual cycle. Some study activities will only occur during certain times of your cycle.	Baseline
Pregnancy test (Females only)	You will collect a urine sample for pregnancy testing. Results will be reviewed with you privately by a staff member. If the result is positive, we will not have you participate in the study.	Phase 1 and 2 day 8

Food and activity records	You will record everything you eat and drink, and your physical activity for 3 days in a row. This will help us determine how much to feed you during the study.	Baseline
Fitness test	Your fitness level will be determined on a stationary bicycle, while wearing a heart rate monitor and breathing through a rubber face mask or mouthpiece connected to a machine that measures your breathing. The heart rate monitor is held in place using an elastic band that fits around your chest. You will be asked to cycle at a certain pace while the resistance increases until you can't maintain the pace anymore. This test takes about 10-20 minutes.	Baseline
Body weight	We will measure your body weight using a digital scale.	Baseline, Phase 1 and 2 days 1-8
Daily exercise	You will be asked to exercise for 30 minutes at moderate intensity on a treadmill (jogging) or stationary bicycle.	Phase 1 and 2 days 1-5
Steady-state cycle exercise	You will complete 1.5 hours of moderate intensity exercise using a stationary bicycle. During the exercise you will wear a heart rate monitor and periodically breathe through a rubber face mask or mouthpiece connected to a machine that measures your breathing.	Baseline (x2**), Phase 1 and 2 day 8
Time trial	You will complete a 5-kilometer (3.1 mile) time trial on a treadmill. The treadmill will be set at a constant 1% grade for the entire test. You will blindly (you will not be able to see the display) set the speed of the treadmill to complete the distance as quickly as possible. The only feedback you will receive is the distance covered at half mile increments. You will be able to change the speed as needed throughout the test. You will wear a heart rate monitor during the test.	Baseline (x2**), Phase 1 and 2 day 8
Carbohydrate tracer study (intravenous infusion)	We will inject a carbohydrate tracer into your bloodstream by an intravenous (IV) catheter placed in your arm by a trained staff member to measure how your body uses carbohydrate. The tracer is a carbohydrate that is labeled with a stable non-radioactive isotope. These isotopes are naturally occurring in your body and are considered safe.	Phase 1 and 2 day 8 (before and during exercise)
Blood samples	Blood samples will be collected to measure markers of gut health, inflammation, and metabolism. To collect samples a thin, flexible tube will be inserted into a vein in your arm by a trained study staff member (this tube will be inserted in the arm opposite to the arm used for the carbohydrate tracer study). A blood sample will be collected from this tube 8 times during each Endurance Testing Protocol (or 16 times total during the duration of the study). We will collect a total of about 300 mL (approximately 1.25 cups) of blood from you during the entire study.	Phase 1 and 2 day 8 (before and during exercise)

Muscle biopsy	A muscle sample will be collected from your thigh by performing a muscle biopsy. You will be awake during the muscle biopsies and the procedure will take about 10 minutes to complete. A trained researcher will clean the skin with a medical cleaning solution and numb a small area of your thigh with a shot of a local anesthetic, such as lidocaine (the same shots used when removing wisdom teeth). The researcher will make a small cut (less than ½ inch) in the skin and use a needle to remove a small piece of muscle about the size of an un-popped popcorn kernel. The researcher may need to use more than one needle to get a full sample. You may feel minor discomfort during a muscle biopsy, including some pressure (like a muscle cramp) or tugging. It should not be painful. You may feel a burn or sting where you get the shot of anesthetic (such as lidocaine). After the local anesthetic wears off, your leg may feel sore for about a week. The cuts will be covered with sterile strips (a type of sticky Band-Aid), sterile gauze pad, clear sterile dressing, and an elastic bandage. The elastic bandage should be kept in place for 5 hours after the biopsy and then removed. A study team member or USARIEM medical personnel will remove the sterile dressing and gauze pad the following morning. You will be provided instructions on how to care for the biopsy wounds. To ensure proper healing, USARIEM medical personnel will follow-up with you within 72 hours after finishing the muscle biopsies. Muscle samples will be used to measure metabolism in your muscle.	Phase 1 and 2 day 8 (before and after exercise)
Urine collection (sugar substitute absorption test)	You will drink water mixed with two types of sugar substitutes commonly used in foods and beverages (sucralose and erythritol). You will also consume a drink mixed with a sugar substitute (mannitol) that is labeled with a stable non-radioactive isotope. We will ask you to use a provided jug to collect all the urine you produce starting from the time you drink the first beverage to the time you finish the Endurance Testing Protocol. The amount of sugar substitutes in your urine will be used as a measure of gut leakiness.	Phase 1 and 2 day 8
Breath collection	You will be asked to exhale into a bag until inflated or small tube. The amount of hydrogen and methane in your breath will provide a measure fermentation activity by bacteria in your intestines.	Phase 1 and 2 day 8 (before and during exercise)
Poop collection	We will collect 4 total poop samples from you to identify the types and activities of bacteria that are present in your intestines. You will be given detailed instructions on how to collect a sample and the supplies needed to do it. This may require transporting samples from your home to the laboratory. We will provide supplies for transporting samples.	1-2 days before and end of each phase

Questionnaires	You will complete questionnaires asking about your background and perceived effort during exercise and assessing gastrointestinal symptoms and your appetite.	Baseline, Phase 1 and 2 days 1-8
**These activities may be repeated if needed.		

HOW LONG WILL I BE IN THE STUDY?

The study will last about 6 weeks and require about 50 hours of your time. However, if the study is interrupted for any reason (e.g., illness, unexpected travel), we may ask you to extend your participation and repeat some study activities. If you decline to extend your participation or to repeat testing, you may be removed from study participation.

Additionally, if you are a female who is not taking a continuous hormonal contraception (e.g., your oral contraception includes a placebo pill or you are not taking oral contraception), the duration of the study will depend on your menstrual cycle length and timing in order to minimize the effects of hormone changes on the study results.

WHAT PRECAUTIONS DO I NEED TO TAKE?

There are several precautions and instructions that need to be followed in order to participate in the study. These are listed below.

You should not participate in this study, if you:

- Are pregnant or expecting to become pregnant during the study period.
- Do not meet Army weight for height and body composition standards as defined in Army Regulation 600-9.
- Have Anemia and/or Sickle Cell Anemia Trait.
- Have medical issues affecting your ability to exercise (e.g., broken leg).
- Follow a vegetarian/vegan diet or other highly restrictive diet (e.g., ketogenic diet, very high protein diet, Paleo diet, etc.).
- Have had a colonoscopy or used antibiotics or antifungal medications (except topical usage) within 3 months of study participation.
- Have an allergy to skin adhesives or certain local anesthetics, such as Lidocaine.
- Do not poop every other day or more frequently.
- Are not willing to participate in all study procedures.

You will be asked to adhere to the instructions below and take following precautions:

- **No** dietary supplements starting 2 weeks before and throughout the study.
- **No** foods containing added live microorganisms (e.g., yogurt, kefir, kombucha) or added prebiotics (e.g., Fiber One products) beginning 2 weeks before and throughout the study.
- **No** caffeine, alcohol, or nicotine during the provided supplement phases of the study and until day 8 testing is completed.
- **No** strenuous exercise (other than the exercise prescribed) during the provided supplement phases of the study and until day 8 testing is completed.
- Eat **all** of the foods, beverages and supplements provided to you and participate in **all** study activities.
- **Do not** donate blood within 8 weeks of starting the study or during the study.

HOW MANY PEOPLE WILL BE IN THE STUDY?

A total of 12 participants are needed to complete this study. We may screen up to 100 people to achieve that goal.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source of Risk	Risk(s)	How We Will Minimize
Muscle Biopsy	Rare risks include: feeling faint or fainting, pain, reddening of the skin, and bruising. Very rare risks include: infection, panic episode, bleeding, swelling, or long-term numbness. You may feel moderate stiffness and swelling around the cut after the biopsy. There might be minimal scarring as the cut heals and in rare cases permanent scars are possible.	• A qualified researcher will perform the biopsy under sterile conditions to prevent infection or pain and close the cut quickly to prevent scarring. • You will receive biopsy care instructions and a qualified researcher will watch for any sign of infection, bleeding, or bruising. • Any stiffness and/or swelling usually stops within days and does not interfere with walking and exercise.
Shot of local anesthetics, such as lidocaine	You might feel a slight, brief pain when you get the shot of local anesthetic. Rare, but possible side effects include: dizziness, confusion, shakiness, visual changes, nausea, unusually slow heartbeat and convulsions. Rare, but possible allergic reactions, include: swelling, itching, rash, and hives.	• You will be excluded if you have a known allergy to the local anesthetic being used. • Trained staff will watch closely for any signs of side effects or allergic reactions during the procedure. • If you have a bad reaction to the local anesthetic, medical staff will be called immediately. • Epi-pens are onsite for emergency use
Carbohydrate tracer study	No risk or side effects with administration of stable isotopes to humans Small risk with intravenous infusion: volume overload, infection, and allergic reaction	• Qualified pharmacists will prepare the injected tracers • Only qualified, credentialed study staff will administer the infusion • Infusions will be provided in small amounts.
Blood Sample collection	Small risks include: feeling faint, irritation, bruising, swelling, infection, or allergic reaction	• You will tell study staff if you have ever fainted during a blood draw • Trained staff will wash their hands, wear gloves, apply rubbing alcohol to the area and use a sterilized needle to place your IV.

		• Trained staff will watch closely for any signs of infection (i.e. prolonged swelling, redness, etc.).
Exercise	Lightheadedness; muscle discomfort, fatigue, or skeletal strain, sprains; accidental injury Cardiovascular event (such as heart attack) May experience claustrophobia from wearing the face mask	• You will be monitored by study staff during exercise. • Stop exercising if lightheaded. • You will be screened by medical staff to ensure you are healthy and fit. • May use mouthpiece instead of mask if symptoms of claustrophobia occur.
Diet supplementation and sudden changes in diet	The fiber supplements used in the study, and sudden changes to your diet, can cause gas, cramping, bloating, constipation, or other gastrointestinal discomfort	• You will be asked about any symptoms. • If symptoms are severe, we may try to modify your diet or may withdraw you from the study.
Sugar substitutes	Gas, cramping, diarrhea, bloating, nausea or other gastrointestinal discomfort from the sugar substitutes No risk or side effects with administration of stable isotopes to humans	• Doses used in this study are not likely to have side effects. • You will be asked to report any side effects and may be removed from study participation if severe.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There are no direct benefits to you for participating in this study. However, results from this study are expected to benefit military personnel and other individuals in the future.

WHAT IF UNEXPECTED INFORMATION IS LEARNED ABOUT MY HEALTH?

Any health problems identified during the screening process will be documented and a copy provided to you. You will be encouraged to make an appointment with your primary care provider (or the USARIEM Office of Medical Safety and Oversight for military individuals) for a full evaluation. If you have evidence of any physical, mental, and/or medical conditions that would make participating in this study relatively more hazardous, you will not be allowed to participate.

No diagnoses will be made by study staff; therefore, no findings will be reported to your primary care provider or authorities.

WILL RESEARCH RESULTS BE SHARED WITH ME?

Once you have completed the study, we will be able to share the results of your fitness test measurements if you are interested. No other research results will be available to share.

WHAT ARE MY OTHER OPTIONS IF I DO NOT PARTICIPATE IN THIS STUDY?

The only alternative to participating in this research is to not to participate.

WILL I HAVE TO PAY FOR ANYTHING IF I TAKE PART IN THIS RESEARCH?

If you do not live on the Natick Soldier System Center, you will be responsible for paying for your transportation to and from the center. You will not be reimbursed for any travel costs or other costs related to participation in this research

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

Yes. You will receive $50 for each successful blood draw, for a total of up to $800 if you complete the study (16 total blood draws). If you are not Active Duty military and you are not a Federal Civilian employee who participates while on duty, you will also be compensated $200 for each phase of the study completed ($20 per day for days 1-7 and $60 for day 8) for a total compensation of up to $1200. If you do not complete the study, you will be compensated for the study activities you successfully completed up to the time of withdrawal.

You will receive payment by direct deposit within approximately ten weeks of study completion. Your social security number (SSN) will be needed to process your payment, as required by law. This information will be carefully protected. Total payments of $600 or more within one calendar year will be reported by the Defense Finance and Accounting Service to the Internal Revenue Service (IRS). This may require you to claim the compensation that you receive for participation in this study as taxable income.

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH?

If at any time you believe you have suffered an injury or illness as a result of participating in this research, please contact J. Philip Karl (the principal investigator) at 508-206-2318 (office) or 617-823-8074 (cell).

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active-duty military, dependent of active-duty military, retiree), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are entitled to care for your injury at DoD hospitals or clinics, but care for your injury may be limited to a given time period, and your insurance may be billed. It cannot be determined in advance which DoD hospital or clinic will provide care. If you obtain care for research-related injuries outside of a DoD hospital or clinic, you or your insurance will be responsible for medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided. No reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights. If you believe you have sustained a research-related injury, please contact the principal investigator (PI). If you have any questions, please contact the PI by phone or email (james.p.karl.civ@health.mil).

HOW WILL YOU PROTECT MY PRIVACY AND THE CONFIDENTIALITY OF RECORDS ABOUT ME?

All data and medical information obtained from you will be considered privileged and held in confidence. To protect your privacy, any of your research-related records, including biological samples (blood, urine, breath, poop), and answers to questionnaires will be "coded" with an assigned research participant ID number that will not include your name or any other identifying information such as your social security number, address, date of birth, zip code, etc. This participant ID number will be used on all data collection sheets, computer records and biological samples. The principal investigator and the project coordinator will keep the link between your participant number and your research records in a locked cabinet or in a password-protected computer file. The principal investigator, their designee and project coordinator are the only people who will be able to match your research participant number with any of your personal identifying information. The master key linking your ID number to your name will be destroyed when the study is closed. Any collected data and samples will be stored indefinitely using your participant identification number.

Your biological samples (urine, blood, breath, poop) will be shared with researchers at the Pennington Biomedical Research Center, University of Leuven, Metabolon, EzBiome, and Metabolic Solutions for analyses needed to generate and interpret results from the study. Any shared data will be transferred using secure methods. Any remaining samples will be returned to USARIEM or destroyed.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others without your permission. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised if you so choose. If you do not sign a photo release form, we will not take your photograph and any photographs accidentally taken of you will be destroyed.

Authorized representatives of the following groups may need to review your research and/or medical records as part of their responsibilities to protect research participants:

- U.S. Army Medical Research & Development Command Institutional Review Board responsible for review and oversight of human research
- DoD and other Federal offices charged with regulatory oversight of human research
- US Army Research Institute of Environmental Medicine, Office of Medical Support and Oversight (OMSO)
- US Army Research Institute of Environmental Medicine, Office of Research Quality and Compliance

Once information that personally identifies you is removed from your data or specimens, then your data or specimens may be used for future research studies or given to other researchers for future research studies without your permission to do so. This includes data related to the types of bacteria and other microbes living in your intestines, which may be posted in a publicly available data repository without any data that identifies you.

Complete confidentiality cannot be promised to military participants because certain health information may be required to be reported to appropriate medical or command authorities.

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 results. You can search this Web site at any time.

WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS RESEARCH?

It is your choice whether you want to participate in this research. You can choose not to be in the study now without any penalty or loss of benefits to which you are entitled.

If you decide to participate, you can stop taking part in this research at any time without any penalty or loss of benefits to which you are entitled. Deciding not to participate now or withdrawing at a later time does not harm, or in any way affect, your medical care future relationships with USARIEM.

If you decide to withdraw, you will be compensated for the portion of the study you completed. The data and samples collected from you will be retained by study investigators and may be used when analyzing the results of this research. If you decide to withdraw from participation, please tell the principal investigator or study coordinator verbally or in writing. You will be asked to disclose your reason(s) for choosing to withdrawal so that the reason(s) can be documented. It is your choice whether to disclose the reason(s).

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

The principal investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. This includes if you are unwilling or unable to comply with study procedures (including diets/exercise prescriptions), if you become ill or injured, or if it would not be in your best interest to continue the study.

The principal investigator will make the decision and let you know if it is not possible for you to continue. Your taking part in the study may be stopped without your consent if it is determined by the principal investigator that remaining in the study might be dangerous or harmful to you.

WHAT IF ANY NEW INFORMATION IS FOUND OUT?

During the course of the research, the investigators will tell you of any new findings that might cause you to change your mind about continuing in the study. If you receive any new information, the investigators will obtain your consent to continue participating in this study.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH?

If you have questions about the research at any time, you should contact J. Philip Karl (the principal investigator); Office phone: 508-206-2318; Cell phone: 617-823-8074; email: james.p.karl.civ@health.mil.

If you have questions regarding your rights as a research participant, you may contact the HQ USAMRDC IRB Office at 301-619-6240 or by email to usarmy.detrick.medcom-usamrmc.other.irb-office@health.mil. The USARIEM Office of Research Quality and Compliance at (508) 206-2371 or by email to usarmy.natick.medcom-usariem.mbx.usariem-rqc-protocol@health.mil.

By signing below, I agree that I have been provided time to read the information describing the research study in this consent form. The content and meaning of this information has been

explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

SIGNATURE OF RESEARCH PARTICIPANT

Printed Name of Participant

Signature of Participant | Date

CONSENT DISCUSSION CONDUCTED BY:

Printed Name | Date Received