The U.S. Army Research Institute of Environmental Medicine (USARIEM)

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: The effects of varying essential amino acid intakes on resting and post-exercise skeletal muscle and whole-body protein kinetics during negative energy balance

Principal Investigator: Stefan M. Pasiakos, PhD

Funding Source: Military Operational Medicine Research Program

INTRODUCTION

You are asked to participate in a research study conducted at the United States Army Research Institute of Environmental Medicine (USARIEM) Natick, MA by Dr. Stefan M. Pasiakos, Nutritional Physiologist, at the Military Nutrition Division, USARIEM. You are asked to participate in this research because you are representative of active duty male and female Soldiers, are healthy and routinely participate in resistance exercise (such as weightlifting) at least two times a week for the past six months.

You may choose whether or not to participate in this research. It is important that you read what is written below and ask questions about anything you do not understand. You may take up to an hour to decide if you want to be part of this study. When you feel that your questions have been answered, you will be asked if you agree to be part of the research or not. If you agree, you will be asked to sign this consent form. You will be given a copy of this form to keep.

WHY IS THIS RESEARCH BEING DONE?

When a person does not eat enough calories to stay the same body weight, this can affect the body's ability to build muscle. The purpose of this study is to see if, after resistance exercise during a time when the body is not getting enough food, drinking beverages with different amounts of essential amino acids [EAA, (the part of dietary protein that helps build muscles)], could help solve this problem. Results from this study will be used to help researchers develop a new combat ration food product for Soldiers recovering during tough military operations.

Up to 70 volunteers may be enrolled in this study, but the researchers only need complete data from 20 people to finish the study. All screening will stop once complete data has been collected from 20 volunteers. Although you may consent and desire to participate in this study, if the investigators are able to get enough data from past subjects, then you may not be tested and your participation will end.

You can participate in this study if you:

- Are a man or woman who is 18-35 years old
- Have a body mass index (BMI) of less than 30.
- Have no signs of chronic illnesses or muscle or bone injuries as determined by OMSO
- Perform resistance exercise at least twice per week for the past six months
- Don't take any nonsteroidal anti-inflammatory medications (e.g., aspirin, Advil®, Aleve®, Naprosyn®), or any other aspirin-containing product for 10 days before starting and at least 5 days after completing the study.

- Don't drink alcohol, smoke (including e-cigarettes), vape, chew tobacco, take caffeine or take dietary supplements during the entire study
- Have supervisor approval if you are a federal civilian employee or non-Human Research Volunteer (HRV) Active Duty military person working within the U.S. Army Natick Soldier Systems Center

You cannot participate in this study if you:

- Show signs of muscle or bone injuries or chronic illnesses as determined by OMSO
- Have abnormal blood clotting as determined by OMSO
- Have bad reactions to lidocaine (i.e., a shot used to numb a body part to reduce pain or discomfort)
- Engage in heavy drinking or have any substance abuse issues, or use of anabolic steroids
- Donated blood within the last 8 weeks
- Are pregnant
- Are unwilling or unable to eat study diets and foods provided

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be a study volunteer for about four to five weeks (maybe more depending on scheduling). You will be asked to do the following:

Study Timeline:

The table below shows the study activities you will complete during each phase of the study and how much time it should take to complete each activity.

Study Phase	Day(s) / Activities
Pre-Study Procedures	**Pre-Study**
	• Medical Screening *(1 hour)* • Background/Diet/Activity Records *(3 days only)* • Body Composition • Record Height and Weight • 1 Repetition Maximum Study (exercise test)
Testing Period I (9 days long)	**Day 1-3**
	• 3-Day Run-In Diet • Non-Study Exercise Prohibited *(all 3 days)* • Weight Recorded each day
	Day 4-8
	• 5-day Reduced Calorie Diet • Non-Study Exercise Prohibited *(all 5 days)* • Weight Recorded each day
	Day 9
	• Metabolism/Feeding/Exercise Study • Muscle biopsies (3 on rested leg, 2 on exercised leg) • Non-Study Exercise Prohibited

	• Weight Recorded
Washout Period (14 days between study periods)	**Day 10-23**
	• Body Composition *(Day 10 only)* • Resume normal diet and exercise *(all 14 days)* • Review 24-Hour Diet/Physical Activity *(every 3rd day)* • Weight recorded *(every 3rd day)*
Testing Period II (9 days long)	**Day 24-26**
	• 3-Day Run-In Diet • Non-Study Exercise Prohibited *(all 3 days)* • Weight Recorded each day
	Day 27-31
	• 5-day Reduced Calorie Diet • Non-Study Exercise Prohibited *(all 5 days)* • Weight Recorded each day
	Day 32
	• Metabolism/Feeding/Exercise Study • Muscle biopsies (2 on each leg) • Non-Study Exercise Prohibited • Weight Recorded

Study Design:

The study is divided into three parts: a first testing period, a 14-day washout period and a second testing period. Each testing period will last for nine days.

The research staff will give you all of your meals during both testing periods. In each testing period, your meals for the first three days will have enough calories to help you stay the same weight. This diet will help you get used to eating the same food Soldiers eat. For the next five days during each testing period, the calories you eat per day will be reduced by 30%. This will mimic the energy deficit Soldiers can experience during missions. During both testing periods, you will not be allowed to eat any food or perform any exercise that is not already part of the study because this could interfere with study results.

On the last morning of each testing period, you will go through a Metabolism/Feeding/Exercise study. During each of these studies, you will do leg presses and leg extensions on one leg while the other leg remains still. After completing these exercises, you will drink an artificially flavored beverage with either a smaller or larger amount of EAA. A research assistant who will not analyze the data will make the drinks in unmarked water bottles and hand them out. You will receive both amounts during the study (one on each of the two study testing days), but the order of the test days that you receive either the smaller or larger amount is completely random. You have an equal chance of getting either of the drinks with the smaller or larger amount of EAA first. The study is also double-blind, which means that neither you nor the primary researchers will know how much EAA is in your drinks at any time.

On that same day, we will take small muscle samples (biopsies) from both of your outer thighs. We will get 3 muscle samples on your rested leg (75 min before you exercise, immediately after exercise, 3 hrs after drinking the beverage). We will get 2 muscle samples on your exercised leg (immediately after exercise, 3 hrs after drinking the beverage). This will allow us to measure how well your muscles and

body respond to different amounts of EAA and recover from exercise, especially when the body is not getting enough calories.

There will be a 14-day washout period between the testing periods, when you can return to your normal eating and exercising routine. On every third day of the washout period, you will come in to be weighed by study staff, and the staff will review what you have eaten and drunk within the past 24 hours, along with your exercise (you will have forms to record this information on).

More details about study procedures are listed below.

Screening Procedures:

Screening tests will determine if you are able to join this study. After signing the consent form, if you still wish to be in the study, you will be asked to answer questions about your medical history, exercise and eating habits, and make an appointment for a medical screening visit.

Medical Screening: You will meet with the staff of the Office of Medical Support and Oversight (OMSO) to undergo a general medical clearance. This will include drawing less than a tablespoon of blood from your arm to see how quickly your blood clots. The one-hour medical screening visit will be done at USARIEM or at your respective unit's medical oversite location. You will be told about any possible medical concerns found from the screening.

Health problems found during the screening process will be documented, and you will be provided a copy. You are encouraged to make an appointment with your doctor to follow up with a full evaluation of the identified health concerns. If you have any evidence of existing physical, mental and/or medical conditions that would make the proposed study more hazardous, you will be excluded.

Study Procedures:

Body Composition: We will use a dual energy x-ray absorptiometry (DEXA) scan to measure your total body, muscle and fat masses at the beginning of the study and on the last day of the washout period. During the DEXA scan, you will lie on your back and remain still for about 5-10 minutes while the x-ray scanner moves over your body. DEXA scans do not hurt. If you are female, you will give a urine sample to test if you are pregnant before getting the scan. A female staff member will oversee the urine pregnancy test. A researcher will measure your height and weight at the beginning of the study. During the two testing periods, your body weight will be measured every day and every third day during the washout period.

Maximal Strength Assessment: One week before the study, you will perform a one-repetition maximum (1-RM) test. The 1-RM is a test of your maximum muscle strength for the leg press and leg extension exercises. Your 1-RM result will help us decide the weight you will lift during the Metabolic/Feeding/Exercise studies. For the 1-RM, you will complete several sets of leg-presses and leg-extensions with the leg you use most often (your dominant leg, or the leg you normally kick a ball with). You will warm up with a set of 5-10 leg exercises with light resistance (weight) on the machine. You will then have one minute to rest, followed by another set of 3-5 warm up leg exercises with a slightly heavier resistance on the machine (10 – 20% heavier than the first set). You will then have two minutes to rest, followed by 2-3 leg exercises with 10 – 20% more resistance on the machine than the previous set. If you can lift the weight after these sets, we'll ask you to do a single leg exercise with a 10-20% heavier resistance. If you can lift that weight, you will rest for 2-4 minutes and try another single exercise with a 10-20% heavier resistance. If you cannot lift the weight we gave you, you will rest for 2-4 minutes. We

will make the weight 5-10% lighter than the weight you could not complete to see if you can lift that amount. You will take the test three to five times to find your true 1-RM.

Diet and Physical Activity Records: Before the study, you will write down everything you eat and drink and how much exercise you perform for three days. Study dietitians will provide you with forms you will use to write down your eating and exercising habits. They will show you how to fill out and review the forms. It should take one hour, at most, to complete them. The information in these forms will help the researchers see your normal eating habits and how many calories you eat per day. They will use that information to decide how many calories you need to eat at the beginning of the study to stay the same weight. You will also use these forms during the washout period to record 24 hour diet and exercise habits, and they will be reviewed every third day to show how much you eat and exercise during the washout period.

Study Diets: During the study, you will mostly eat military combat ration items from Meals, Ready-to-Eat (MREs), along with some store bought food items. The different amounts of nutrients in this diet are similar to amounts military personnel within your age range normally eat. This means that more than half (50-65%) of the calories you eat per day will come from carbohydrates. The amount of protein you eat will be measured depending on your body weight (0.73 grams protein for every pound you weigh; if you weighed 180 lbs, you would eat 131.4 grams of protein). The rest of your calories will come from fat. During the first three days of each testing period, researchers will provide you with enough food to stay the same body weight. During the next five days of each testing period, you will receive meals, but the amount of calories you eat per day will be 20% lower. You will eat less carbohydrates and fat than your normal diet. You can expect to lose about one pound during those five days. All food and drinks (except water) will be given to you. You will be asked to return all combat ration and extra food wrappers to study dietitians. During both testing periods, you cannot have food or drinks (except water) or perform any exercise outside of the study. During the 14-day washout period, you are free to continue your normal diet and activity habits, which we will keep track of with 24-hour eating and exercise records (described above).

Metabolic/Feeding/Exercise Studies: These studies will occur twice during the study on the final morning of each testing period and will last for seven hours. These studies, which involve collecting blood and muscle samples, will tell us how well your body and muscles respond to EAA while resting and recovering from resistance exercise, especially while you're not eating enough calories.

To actually track how your body is using the EAA, we will inject an infused substance called a protein tracer into your bloodstream. While some tracers used in medical research are radioactive, the tracers we use in this study contain molecules that your body already naturally makes. We will give you a larger amount of these molecules than what your body naturally makes so we can track how your body uses the EAA that is contained in the beverage you will drink. To inject the protein tracers into your veins, you will first lie in a bed or sit in a recliner wearing a t-shirt, athletic shorts and socks. Two intravenous (IV) catheters will be placed, one in each of your arms. The IVs will be covered with heating pads to help keep your blood flowing. One IV will constantly, slowly inject protein tracers dissolved in a salt water solution into your veins. The other IV will take blood draws. There will be 16 blood draws (enough for slightly more than a ½ cup of blood) during the seven-hour study. The blood is taken from the IV so you are not stuck with a needle each time. Since the *Metabolic/Feeding/Exercise Studies* will be done twice, this means that we will draw a total 1 ¼ -cup of blood during the entire study.

About two hours after starting the protein tracer injections, a researcher will do a muscle biopsy on the thigh of your resting leg. During a muscle biopsy, the researcher makes a small cut in your skin to remove

and study a small piece of muscle tissue. This is not a practice you would typically see in a doctor's office or hospital setting. Muscle biopsies have been done thousands of times in human studies. About three hours and 15 minutes after starting the protein tracer injections, you will perform eight sets of 10 leg-presses and leg-extensions at 80% of the weight that you were able to lift during the 1-RM test. The researcher will lighten the weight if you cannot complete the sets.

After completing the leg exercises and resting for five minutes, a researcher will do muscle biopsies on your resting and exercised thighs. You will then have five minutes to drink a beverage with either a larger or smaller amount of EAA. You will drink both EAA beverages during the entire study but it will be in random order (one on each test day). You will then rest in a bed or recliner until the researcher collects muscle samples (one in each leg) three hours later.

We will do ten muscle biopsies throughout the entire study. We will get five separate muscle samples on each of the two testing days (three from the resting leg from the same cut, two from the exercised leg from the same cut). The two biopsies that are taken from the exercised leg on a test day will be spread out by 3 hours. The 1st and 2nd biopsies of the rested leg will be spread out by 2 hours, the 2nd and 3rd biopsies will be spread out by 3 hours. The resting and exercised legs will be the same for each testing day.

The muscle biopsy will be done while you are awake, but a trained researcher will clean the skin with iodine and numb the thigh with a lidocaine shot (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 tissue (about the size of an un-popped popcorn kernel). The researcher may need to use more than one needle to get a large enough 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 lidocaine shot. After the lidocaine wears off, your leg may feel sore for about a week. The resting and exercised leg will only be cut once during each *Metabolic/Feeding/Exercise Study*. The researchers will not use the same cuts from the first study on the second study because that could cause an infection, so the researchers will make two new cuts for the second *Metabolic/Feeding/Exercise Study*. Each cut will be covered with a gauze pad, transparent sterile dressing, and an elastic bandage. The elastic bandage should be kept in place for 5 hours after the biopsy and can then be removed. The principal investigator will remove the sterile dressing and gauze pad the following morning. You will be provided specific instructions on how to care for the biopsy wounds. To ensure proper healing, OMSO will follow-up with you within 72 hours after finishing the muscle biopsies.

WHAT ARE THE POTENTIAL RISKS AND DISCOMFORTS FROM BEING IN THIS RESEARCH?

Dietary Intervention: The foods that you will be given to eat in this study pose no known risk. Sudden changes to your diet can cause gas, cramping, bloating, constipation or other abdominal discomfort in some people. You may still feel hungry when eating a low-calorie diet. In addition, low-calorie diets may be low in specific vitamins and minerals. You will be shown the study menus before the study begins.

Body Composition: You could be exposed to a small amount of radiation during the DEXA scan. The amount of radiation you will receive from both tests will be equal to about 1/15 of a chest x-ray. The health risks of very low levels of x-ray exposure are unknown but are probably very small. All females will be required to take a pregnancy test the day before or the day of testing, which will be administered and checked by a female staff member. If you are pregnant you will not be scanned, nor will you be able to continue the study.

Blood Draws: Providing blood samples has few risks. You may experience bruising or swelling where the needle entered. A person may sometimes feel faint or actually faint during or right after the blood draw. If you have fainted during past blood draws, it is more likely to happen again. So, you should advise us of that. Trained staff will wash their hands, wear rubber gloves, apply rubbing alcohol to the area and use a sterilized needle before drawing your blood. However, in spite of being careful there is a chance of infection. You should not give blood for 8 weeks before or after this study.

Intravenous (IV) Catheter Placement: The risks related to inserting an IV are small. A needle will be inserted in your arm or hand (same as *Blood Draws*) and, once the needle is removed, a small tube will remain for blood sampling throughout the day. A person may sometimes feel faint or actually faint during or right after the IV is placed. If you had problems with fainting during catheter placement in the past, it is more likely to happen again, and you should advise us of that. In addition, the catheter can cause irritation, bruising, swelling, infection or an allergic reaction. Trained staff will use hygienic practices to place your catheter and will watch closely for any signs of infection. If the catheter becomes clogged, we will have to replace it to continue blood sampling. This will require inserting another needle. Despite being careful, there is a chance that the site may become infected.

Muscle Biopsies: A muscle biopsy is a safe research procedure that involves making a small cut in the skin to get a small muscle sample. Like blood draws, there is a risk that volunteers will feel faint or may actually faint during or right after a muscle biopsy. If you have had problems with fainting during past blood draws or muscle biopsies, it is more likely to happen again. The most common risks in muscle biopsies are pain (1-2%), reddening of the skin (1-2%) and bruising (1-2%). Panic episode (less than 1%), bleeding (less than 1%) and swelling (less than 1%) have also been reported. These problems do not normally interfere with normal walking and heavy exercise. Permanent or long-term numbness may be possible but has not been reported. You may feel moderate stiffness and swelling around the cut after the biopsy, but this usually stops within several days. There might be minimal scarring as the cut heals. Permanent scars are possible, but the chance of this happening is 5-10% for dark-skinned people and is even rarer for fair-skinned people. The cut will be closed as soon as possible to prevent scarring. A qualified researcher will perform the biopsy under sterile conditions to prevent infection or pain. If you bleed during the biopsy, the researcher can quickly act by applying direct pressure to the cut. You cannot take aspirin or other medications that interfere with blood clotting for 10 days before or 5 days after the muscle biopsy. You will receive careful instructions on preventing bruising and infections. We will also watch you for any sign of infection, bleeding or bruising.

Lidocaine Shot: You might feel a slight, brief pain when you get the lidocaine shot. Rare, but possible side effects could include: dizziness, confusion, shakiness, visual changes, nausea, unusually slow heartbeat and convulsions. Allergic reactions, including swelling, itching, rash, hives, difficulty swallowing or difficulty breathing, are also possible. Trained researchers will watch closely for any of these signs throughout the entire procedure. If you have a bad reaction to lidocaine, medical staff will be called immediately.

Protein Tracer Studies: During the final day of each testing period, protein tracers will be injected into your bloodstream. While some protein tracers use radioactive molecules, the tracers used in this study contain molecules that your body already naturally makes. There are no known risks or reported side effects related to using these natural protein tracers on people. However, possible side effects could include volume overload (when your blood volume is too large for your heart to work properly), infection or an allergic reaction. To reduce these risks, qualified researchers will prepare the protein tracers. The tracers will slowly be injected into your blood for seven hours while qualified researchers supervise.

Resistance Exercise: Resistance exercise is generally considered safe and healthy for people without muscle or bone injuries and heart disease. You may feel discomfort and fatigue in the muscles you use during and shortly after the exercise. Mild to severe muscle soreness may continue for one to seven days. For safety, there will be at least one spotter during all resistance exercise sessions. In addition, exercise monitors and test administrators will be CPR-certified.

Some of the study procedures may involve risks to you that are currently unforeseeable. These risks could also cause harm to an embryo or fetus if you are female and were to become pregnant during the study.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There is no direct health or other benefits related to participating in this study. Information gathered from this research may benefit other people in the future.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

You will receive $33.75 for each successful study blood draw. There are 32 blood draws during the entire study (16 per Metabolism/Feeding/Exercise study). This does not include the blood sample taken during your medical clearance, which you will not be compensated for. If you complete all 32 study draws, you will receive $1,080.00. If you do not complete the entire study, you will receive money for every successful blood draw you do complete. You will not be eligible for any other form of compensation during this study.

Your Social Security Number (SSN) will be needed to process your payment, as required by law. This information will be carefully protected. The Defense Finance and Accounting Service will report total payments of $600 or more within 12 months to the Internal Revenue Service (IRS). This may require you to claim the compensation that you receive for participating 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 from participating in this research, please contact:

Stefan M. Pasiakos, PhD
U.S. Army Research Institute of Environmental Medicine
Building 42, Room 219
10 General Greene Ave
Natick, MA 01760
Phone: 508-233-6474
Email: stefan.m.pasiakos.ctr@mail.mil

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 medical care for your injury at an Army hospital or clinic; medical care charges for care at an Army hospital or clinic will be waived for your research-related injury. You are also entitled to care for your injury at other DoD (non-Army) 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 Army or DoD hospital or clinic will provide care. If you obtain care for research-related injuries outside of an Army or 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 Pl (name and telephone number of principal investigator).

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

The principal investigator will keep records of your participation in the research. To protect your privacy, any of your research-related records will be labeled with an assigned research participant number that will not include your name or Social Security Number. Dr. Stefan M. Pasiakos and a designated research assistant will keep the link between your participant number and your research records in a locked cabinet. The principal investigator and the designated research assistant are the only people who will be able to match your research participant number with any of your personal identifying information.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others. If photographs, videos or audiotape recordings of you will be used for educational purposes, your identity will be protected or disguised. Names and faces will be covered in any photographs unless volunteers agree to sign a photo release form. If you do not sign the photo release form, any photographs 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 & Materiel Command Institutional Review Board
- U.S. Army Human Research Protections Office and other DOD offices charged with oversight of human research
- USARIEM Office of Research Quality and Compliance

Complete confidentiality cannot be promised for military personnel because required health information may need to be reported to appropriate medical or command authorities.

It is the policy of the U.S. Army Medical Research and Materiel Command that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information entered into this confidential data base includes your name, address, Social Security Number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research conducted within the USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are

adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

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

WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS RESEARCH?

Your participation in this research is voluntary. You may decline to participate now or 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 benefits to which you would otherwise be entitled to regarding future relationships with USARIEM. If you do not complete the entire study, you will be compensated for the number of successful blood draws you did complete.

WHAT COULD END MY INVOLVEMENT IN THE RESEARCH?

The investigator or study sponsor may withdraw you from participating in this research if:

- You are not willing to follow study diets and exercise prescriptions
- You become ill or injured, or to protect your health and safety

The 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 investigator that remaining in the study might be dangerous or harmful to you.

If you are withdrawn or decide to withdraw during the study, no further data will be collected from you. You will be asked to return any study food and/or wrappers that you had been provided, in addition to any diet and exercise logs that you had started to complete. The data that has been collected from you up to that point may still be used for analysis.

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 new information is provided to you, the investigators will obtain your consent to continue participating in this study. Your blood and/or muscle tissue may be used in future research if extra sample remains after analysis for the study is complete.

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:
Stefan M. Pasiakos, PhD
U.S. Army Research Institute of Environmental Medicine
Building 42, Room 219
10 General Greene Ave
Natick, MA 01760
Phone: 508-233-6474

If you have questions regarding your rights as a research participant, you may contact the HQ USAMRMC IRB Office at 301-619-6240 or by email to usarmy.detrick.medcom-usamrmc.other.irb-

office@mail.mil or USARIEM ORQC at phone (508-233-6306/4811) or by email at usarmy.natick.medcom-usariem.mbx.usariem-rqc@mail.mil

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SIGNATURE OF RESEARCH PARTICIPANT

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date