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

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: **Skeletal muscle recovery from aerobic exercise during acute high altitude exposure when consuming carbohydrate compared to carbohydrate plus protein**

Principle Investigator: Lee M. Margolis, PhD

Introduction: You are being asked to participate in this research study because you are between the ages of 18-39 years old, healthy, physically active 2-4 days per week, were born at altitudes less than 2,100 meters, and are representative of active duty male or female Soldiers. You do not have to take part in this research. It is your choice.

The table below summarizes some **key** points of this study. After reading this summary, if you might be interested in participating in the study, 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 participate in this research. It is your choice. You can also choose to stop participating at any time during the study.
Purpose	The purpose of this study is to compare muscle recovery at high altitude (HA) when participants consume a drink containing only carbohydrate (sugar) (CHO) versus a drink that contains both carbohydrate and protein (CHO+PRO).
Duration	The study consists of a 2 day baseline period followed by two, 3 day trial periods. On the third day of each trial period will be a testing day. The two testing days will be separated by a minimum of 4 days. The total duration for the study will be a minimum of 13 days depending on your schedule.

Procedures	While you are in the study, you will be asked to do the following:
	• Ascend to HA (**4300** m, ~14,000 feet) in a simulated HA environment (altitude chamber) (**~7** hours each trial period)
	• Complete **6** exercise sessions:
	  ○ 1 aerobic fitness assessment during the baseline phase at sea level (SL)
	  ○ 1 practice stationary bike session during the baseline phase at SL
	  ○ **2** exercise sessions on a stationary bike (1 per each trial period) at SL and **2** exercise sessions on a stationary bike (1 per each trial period) at **HA**
	• Consume either CHO or CHO+PRO drink on testing day. Drinks will be consumed in random order, 1 drink per each trial period.
	• Complete **8** total muscle biopsies (4 per trial period)
	• Complete **16** blood draws (~1 cup total) from IV catheter (8 per trial period)
	• Eat **only** food and drinks (except water) that we give you during controlled feeding phase of each trial period (**4** days total)

Study Restrictions	• During the study:
	  • You **will not** be allowed to use nicotine-containing products or to drink alcohol
	  • You **will not** be allowed to use dietary supplements during the study period
	  • You **will not** be allowed to consume any non-study foods or beverages other than water during 2 trial periods (**4** days total)
	  ▪ Caffeine will be restricted to one calorie-free caffeinated beverage per day (must be provided by study staff) and may not be consumed prior to participating in bike exercise sessions and/or during any fasting requirements
	  • You **will not** be allowed to participate in non-study exercise or physical activities (i.e., rec sports, personal workouts, army PT work outs) during **2** trial periods (6 days total)
	  • You **will not** be allowed to donate blood within 8wks of the study.

Risks	The **main** risks from being in this study are:
	• Minor discomfort and/or fainting associated with:
	  • Intravenous (IV) catheter placement & blood draws
	  • Muscle biopsies
	  • Exercise
	• Chance of infection associated with:
	  • IV catheter placement & blood draws
	  • Muscle biopsies
	• Potential side effects from HA exposure
	  • Low blood-oxygen level
	  • Lightheadedness
	  • Acute Mountain Sickness (AMS) which can present as one or more of the following symptoms:

	▪ Headache, nausea, loss of appetite, lethargy, dizziness, tiredness, weakness, insomnia, vomiting • Ear pain/discomfort • Swelling of the legs, hands, and/or face • High altitude cerebral edema (HACE) – swelling of the brain • High altitude pulmonary edema (HAPE) – swelling of the lungs Steps to lessen the risks are described later in this consent form.
Benefits	There is no direct health or other benefits related to participating in this study. Information gathered from this research may benefit the development of next generation of nutrition products for HA military operations.
Alternatives	The only alternative is to not participate.
Payment	You will be paid for your participation in this study.
Exclusion Criteria	• Females **Not** on continuous hormonal contraception, pregnant, trying to become pregnant, or have a menstrual cyclenot between 26-32 days in duration, did not have 5 menstrual cycles within the past 6 months, and/or are breastfeeding • Born at an altitude above 7,000 ft • Spent more than 5 days at an altitude above 4,000 ft in the past 2 months • Smoking or vaping • Metabolic or cardiovascular abnormalities, or gastrointestinal disorders • Previous diagnosis of HACE or HAPE • Anemia and Sickle Cell Anemia/Trait, asthma • Taking medication that affects macronutrient metabolism and/or the ability to participate in strenuous exercise (e.g. thyroxine, beta blockers, insulin etc.) • Taking medications that interfere with oxygen delivery and transport (e.g. albuterol, EPO, etc.) • Musculoskeletal injuries that compromise exercise capability • Blood donation within 8 weeks of the study *Other exclusion criteria will be discussed during briefing and medical clearance*

WHY IS THIS RESEARCH BEING DONE?

Service members who are rapidly deployed to high altitude environments experience impaired muscle recovery after physically demanding military operations. This is due, in part, to a difference in the way the body uses and stores energy at high altitude compared to at sea level. Impaired muscle recovery can cause a decrease in physical performance and/or injury. Proper

post-exercise nutrition designed for high altitude operations may help with muscle recovery and physical performance.

The purpose of this study is to compare the impact of two different post-exercise drinks (CHO vs. CHO+PRO) on muscle recovery while at high altitude. The results from this study will help develop future nutrition products for HA military operations.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be a study volunteer for about 13 days (depending on your schedule). You will be asked to do the activities in the table below. This is an example schedule and the order you complete each task may vary.

Throughout the study, you will wear PT attire or appropriate athletic attire (t-shirt, athletic shorts, socks, and running shoes) and a heart rate monitor during exercises.

Study Phase	Duration/Activities
Pre-Testing & Baseline Procedures	~ 3 Days
	• Medical Screening (*~ 1 hour*) • Height measurement (*1 time, 1 min*) • Body weight measurement (*fasted, ~1 min*) • Body Composition: DEXA Scan (*fasted, ~10 min*) • Menstrual Cycle Interview (*females only, ~10 min*) • VO_{2peak} Aerobic Fitness Test (*fasted, 1 time, ~45 min*) • 1 practice exercise testing sessions (*fasted, stationary bike, ~1-2 hour session*)
Trial 1 (Controlled Feeding)	3 Days

	• Follow all study restrictions
	• Consume study diet for 2 days
	• Body weight measurement (*fasted, ~1min)*
	• Stationary bike exercise at sea level (*fasted, ~60 min*)
	• HA exposure in chamber on testing day *(~7 hours)*:
	  • Stationary bike exercise *(~60 min)*
	  • Muscle Biopsy *(4 total (1 at SL and 3 at HA), ~10 min each)*
	  • Blood sampling *(8 total, ~ 1min each)*
	  • Recover in HA chamber *(~6 hours)*
	  • Consume carbohydrate (sugar) OR carbohydrate and protein beverage during recovery time

Washout Period	4 Days
	Restrictions: • **No** using nicotine-containing products • **No** use dietary supplements • **No** alcohol consumption • **No** blood donation
	3 Days

Trial 2
(Controlled Feeding)
	• Follow all study restrictions
	• Consume study diet for 2 days
	• Body weight measurement (*fasted, ~1min)*
	• Stationary bike exercise at sea level (*fasted, ~60 min*)
	• HA exposure in chamber on testing day *(~7 hours)*:
	  • Stationary bike exercise *(~60 min)*
	  • Muscle Biopsy *(4 total, (1 at SL and 3 at HA) ~10 min each)*
	  • Blood sampling *(8 total, ~ 1min each)*
	  • Recover in HA chamber *(~6 hours)*
	  • Consume carbohydrate (sugar) OR carbohydrate and protein beverage during recovery time

Note: The order in which you receive the beverages will be random and both you and the study team will not be told which beverage you are receiving each time.

Study Timeline

Table 1: Study Timeline

Timeline may shift based on participant availability, weekend, and holiday schedules.

		Baseline			Trial 1							Trial 2		
Study Day	**SV**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
Medical Screening	X													
Menstrual Cycle Interview (Female only)		X												
Body Composition		X												
Height		X												
Weight		X					X							X
VO_2peak		X												
High Altitude Exposure							X							X
Glycogen Depletion			X		X		X					X		X
Study Diet					X	X						X	X	
CHO/CHO+PRO							X							X
Muscle Biopsy							X							X
Blood Sampling							X							X

Screening Procedures:

After signing the consent form, you will be asked to 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 health screening (~ 1 hour, ~ 2 visits), during which OMSO will have you provide a blood sample and complete a physical to make sure you are in good health. The medical screening will be done at USARIEM or, if you have been recruited through NSSC SS&PIT, you may undergo medical screening at your home duty station prior to your arrival at USARIEM.

Study Procedures:

Body Composition: We will use dual energy x-ray absorptiometry (DEXA) scan to measure your total body, muscle, and fat mass once during the study. For this, you will lie on your back and remain still for about 8-10 min while the x-ray scanner moves over your body. The DEXA will not cause pain or discomfort. If you are female, you will give a urine sample to test if you are pregnant within 24 hours prior of the DEXA scan. A female staff member will oversee the urine pregnancy tests. After the test, the female staff member will document the pregnancy test on a Pregnancy Screening Documentation form. You will be asked to review and sign this form if the pregnancy test is positive, you will be excluded from further participation in this study.

Menstrual Cycle Interview: If you are a female, a female staff member will ask you questions about your menstrual cycle to schedule your study timing. If you are on continuous hormonal contraceptives (e.g., IUD or pills without the placebo week), we will ask you to provide documentation (e.g., doctor's note, paperwork accompanying medication, etc.).

Height & Weight: A researcher will measure your height and weight at baseline. Additional weight measurements will be taken on the study testing days. All weight measurements will be taken following an overnight fast while wearing a t-shirt and shorts. This will take ~ 1 min each time.

VO_2peak (Fitness Assessment): This test determines the maximal amount of oxygen your body can use while you are exercising at your highest ability. You will perform this test on a stationary bike after a 10 hour overnight fast. The test will occur at Sea Level conditions.

During the fitness assessment you will wear a mask over your nose and mouth or a mouthpiece with nose clip that is connected to a machine that measures the amount of oxygen you breathe in and the amount of carbon dioxide you breathe out. You will also wear a strap around your chest to record your heart rate during the test. The test will start with easy pedaling for 5 minutes, and then the difficulty will increase every minute until you can no longer pedal and/or are too tired to continue. The procedure takes about 45 minutes.

Study Diet: During the trial phases of the study, all food and drinks (except water) will be prepared and given to you by study dietitians and will be largely from military combat ration and supplemental food items. You will be asked to eat all provided food and return wrappers to study dietitians the following study day. You will eat this diet for 4 days total (2 days per trial

period). No other food or beverage products (except water) can be consumed during this time. You will be allowed one calorie free caffeinated beverage per day if you choose, but it must be supplied by study staff and not consumed during fasting periods or prior to exercise. The different amounts of nutrients in this diet are similar to amounts military personnel within your age range normally eat and will be individualized by study dietitians to maintain body weight.

Study Beverage: On each trial day, following the completion of the study exercise, you will be asked to consume a study beverage that will contain either carbohydrates (CHO) or carbohydrates and protein (CHO+ PRO). You will consume the study beverage over the course of 3 hours, it will be provided to your every 30 minutes, and you will finish the drink within 15 minutes upon receiving). The amount of CHO or CHO+PRO you will consume each time will be calculated using your body weight (1.2g CHO/kg/hr or 0.9g CHO/kg/hr +0.3g PRO/kg/hr).

Glycogen Depletion: To make sure the only difference between testing periods is the composition of the study beverage (CHO OR CHO+PRO), we control your exercise. Specifically, following an overnight (10 hour) fast, you will complete a bout of exercise on a stationary bike to reduce the amount of carbohydrate stored in your body. To do this, you will ride the stationary bike at varying intensities based on your fitness assessment. After warming-up for 5 min, we will increase the intensity to about 80 ± 10% of your peak fitness level. You will pedal at this intensity for 2 min followed by a 2 min recovery period at about 50 ± 5% of your peak fitness. You will complete this cycle 15 total times in ~ 60 min. This will be performed once at Sea Level and once at high altitude for each trial.

Muscle Biopsies: You will be awake during the muscle biopsies. A trained researcher will clean the skin with a medical cleaning solution (includes alcohol) and numb a small area of your thigh with a lidocaine shot (or similar numbing medication, 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 lidocaine shot. After the lidocaine (or similar numbing medication) wears off, your leg may feel sore for about a week. The cuts will be covered with steri-strips (a thin, strong 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. The Principal Investigator or OMSO 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, OMSO will follow-up with you within 72 hours after finishing the muscle biopsies. Biopsies will be performed on the testing days, which occur twice in the study.

Each testing day will include 4 biopsies which will be taken from a total of 2 incisions, one on each leg samples will be taken from alternating legs. Biopsies will be taken before (at sea level) and after exercise (at HA and at hours 4 and 6 of recovery) (4 total per testing day). Therefore, a total of 8 biopsies will be taken over the entire study. Each biopsy will take ~10 minutes.

High Altitude Exposure: On testing days, immediately following your first muscle biopsy you will ascend to HA (4,300 m, ~14,000 feet) in a simulated altitude chamber where you will complete

a glycogen depletion exercise. Immediately following the glycogen depletion, a second muscle biopsy will be taken. We will then provide you with the study beverage which you will drink over a span of 3 hours while you recover. At hours 4 and 6 of recovery, we will take a third and fourth muscle biopsy. Following the fourth biopsy, we will descend to sea level and the study day will end. You will always be in the presence of study staff members when in the altitude chamber. Additional staff will be on the outside of the chamber for close monitoring and communication with those in the chamber.

Blood Sampling: Blood sampling will occur on each of the study testing days. Blood will be collected using an IV catheter that will be placed in your arm at the beginning of the study day. A catheter is a tube that is left in your arm after the needle is removed. If the catheter becomes clogged at any time during the protocol, we will have to replace it to continue blood sampling. This will require another needle to be inserted into your arm. We may need to use regular venipuncture as an alternative to catheter placement if a single timepoint is needed. Blood samples will be taken approximately every hour with the first draw being done before your glycogen depletion exercise and the final draw will be at the end of the ~7 hours in the altitude chamber. For the two testing periods of the study a total of 16 blood draws (8 per trial period) will be taken. Total amount of blood taken during the study will be roughly 300 ml or ~ 1 cup.

No genetic tests will be performed in this study on your blood or muscle samples.

HOW LONG WILL I BE IN THE STUDY?

The study will last a minimum of 13 days but may last longer based on your availability. Study procedures will last between one to seven hours per visit.

COVID-19 related events and study duration: In the event that research processes must be halted in response to a potential or confirmed COVID-19 exposure or case involving study participants or staff members, the study duration may be extended to accommodate the halt by repeating baseline measures, trial 1, or trial 2.

WHAT PRECAUTIONS DO I NEED TO TAKE?

You must not use nicotine-containing products (i.e., chew tobacco), drinking alcohol, or take dietary supplements during the controlled feeding, testing, and washout periods of the study.

You must only eat the foods and drink the beverages provided to you, except water, during the controlled feeding phases (4 days total). Caffeine will be restricted to one calorie-free caffeinated beverage per day (must be provided by study staff) and may not be consumed prior to participating in the bike exercise.

You must not donate blood within 8 weeks of the study.

You must adhere to study physical restrictions. You will be asked not to participate in outside/personal exercise or recreational activities (i.e., pick-up basketball) during the baseline period and each trial period.

HOW MANY PEOPLE WILL BE IN THE STUDY?

A total of 10 participants are needed to complete this study. We will enroll 30 individuals to account for dropouts. All screening will stop once complete data has been collected on 10 participants. Though you may be eligible and want to participate, if we are able to finish data collection on 10 participants before you are scheduled to begin testing, you may not be tested.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source of Risk or Discomfort:	Risk or Discomfort:	How We Minimize Risk or Discomfort:
Altitude exposure	Hypoxemia (low blood oxygen), lightheadedness, Acute mountain sickness (AMS) (nausea, fatigue, headache), High altitude cerebral edema (HACE), High altitude pulmonary edema (HAPE), ear discomfort, peripheral or facial edema	• Closely monitored by staff • You will be monitored if feeling lightheaded • HAPE and HACE are unexpected, also treatable with removal from hypoxic chamber • Atmospheric pressure change is relatively slow during simulated “ascent” and “descent”; will slow this even more if ear discomfort occurs • Peripheral and facial edema are harmless and disappear after removal from hypoxic chamber
Intravenous (IV) Catheter Placement and Blood Draws	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.
Muscle Biopsies	Rare risks included: 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.	• You will tell study staff if you have ever fainted during a blood draw • 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.
Lidocaine (or similar) Shot	Slight, brief pain and possible, rare side effects: You might feel a slight, brief pain when you get the lidocaine shot.	• You will be excluded if you have a known Lidocaine allergy. • Trained staff will watch closely for any signs of side effects or allergic reactions during the procedure.

	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.	• If you have a bad reaction to lidocaine, medical staff will be called immediately. • Epi-pens are onsite for emergency use
Fitness Assessment, Bike Exercise	Lightheadedness, Fatigue, Cardiovascular Risk, Musculoskeletal Strains or Soreness You may feel discomfort and fatigue in your muscles during and shortly after exercise. You may experience claustrophobia from wearing the face mask. Mild to severe muscle soreness may continue for one to seven days.	• Safety Spotters and CPR-certified Staff • You are healthy and fit and will be excluded if not. • May use mouthpiece instead of mask if symptoms of claustrophobia occur
Body Composition	Radiation, risk to fetus.	• Low dose of radiation, the DEXA scan equal 1/3 of the radiation received in a chest X-ray • Women who are pregnant or planning to become pregnant are excluded from study. • Females will be pregnancy tested before DEXA.

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.

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 physician (or OMSO for military individuals). No diagnoses will be made by study staff; therefore, no findings will be reported to PCP or authorities.

WILL RESEARCH RESULTS BE SHARED WITH ME?

Yes, we will be able to share results of your body composition and VO_2peak tests, if requested at the completion of your study involvement. No other information will be shared.

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

The only alternative is not to participate in the study.

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

If you do not live on the Natick Soldier Systems 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.

If you are an active duty Soldier coming to Natick to participate in research on temporary duty station (TDY) permissions, your transportation and lodging will be paid for by the study and compensation for meals will be provided at the local per diem rate for days you are not following the controlled study diet.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

You will receive $50 for each successful study blood draw. There are 16 blood draws during the entire study. This does not include the blood sample taken during your medical clearance, which you will not be compensated for. If you complete all 16 study draws, you will receive $800. If you do not complete the entire study, you will receive money for every successful blood draw you do complete.

Military members may be eligible for hazardous duty pay for exposure to high altitude. We will submit a request for this but cannot guarantee they will receive it.

All payments will be sent in the form of direct deposit to a bank account. It may take up to several weeks to receive payment for study participation.

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 because of participating in this research, please contact:

Lee M. Margolis, PhD
U.S. Army Research Institute of Environmental Medicine
Building 42, Room 203A
10 General Greene Ave
Natick, MA 01760
Phone Number: 508-206-2335
Email: lee.m.margolis.civ@health.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 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 (Lee Margolis and 508-206-2335).

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

To protect your privacy, all of your research-related records and biological samples will be labeled with an assigned research participant number that will not include your name or Social Security Number. The link between your participant number and your research records will be kept in a locked cabinet or on a password-protected computer file and Dr. Lee Margolis and the study coordinator are the only people who have access. The master link will be destroyed upon study closure. Your consent form, which includes your name, but does not include a research participant number, will be kept separate from the rest of your research-related records in a locked cabinet by the principal investigator or the study coordinator.

Your coded biological samples will be stored in a designated laboratory freezer and will either remain at USARIEM until analysis or will be shipped to another laboratory, Pennington Biomedical Research Center (PBRC), or Metabolon for later analysis. There will be no sample remain at PRBC and metabolon after the analysis. A portion of some or all of the biological samples you provide during this study will be frozen and retained at USARIEM indefinitely, for either re-analysis under this research effort or under approved, future research plans. If you do not wish your samples to be retained for future use by any organization that is not listed, you should not participate in this study.

When the results of the research are published, no information will be included that would reveal your identity to others. Specific permission to use photographs or video recordings of you and the manner in which they may be used will be requested and documented in an Audio/Visual Image Release form. If you do not sign the photo release form, no photos of you will be taken.

If any photographs or video recordings are taken of you inadvertently, they will be destroyed immediately. You do not have to sign a photo release to participate in this study.

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:

- US 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
- USARIEM Office of Medical Support and Oversight (OMSO)

- USARIEM Office of Research Quality and Compliance (ORQC)

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 or future consent to do so.

Complete confidentiality cannot be promised for military personnel because information bearing on your health may 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 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 future relationships with USARIEM. You can withdraw by notifying the PI verbally or by writing.

If you do not complete the entire study, you will be compensated for the number of successful blood draws you did complete. The data and samples collected from you will be retained by study investigators and may be used when analyzing the results of this research. You will be asked to return any study food and/or wrappers that you had been provided.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

The investigator 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. 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.

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 Lee M. Margolis, PhD (the Principal investigator); Office phone: 508-206-2335; Email: lee.m.margolis.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@healthl.mil or USARIEM ORQC at phone (508-206-2371) or by email at usarmy.natick.medcom-usariem.mbx.usariem-rqc@health.mil

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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