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

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: How does stress change the way your body uses protein for muscle and carbohydrates for energy?

Technical Title: Effects of varying energy deficits on protein turnover at rest and carbohydrate oxidation during steady-state exercise

Principal Investigator: Jess A Gwin, PhD

Introduction: You are being asked to participate in this research study because you are 18-35 years old with a body mass index of less than 30, are healthy, routinely participate in exercise (i.e., running, cycling, body weight workouts, resistance training) at least two times per week for the past six months, and are representative of active duty Soldiers.

You do not have to participate. **It is your choice**.

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

RESEARCH SUMMARY	
Informed Consent	It is important that you understand this research study to make an informed decision. This process is informed consent. • Please **ask questions** about anything. • Feel free to talk with family, friends, or others before deciding to participate. • 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. **It is your choice**. You can choose to stop participating at any time without penalty.
Purpose	To determine how different levels of stress caused by exercise and not eating enough food changes how your body: • uses protein to build muscle and maintain body proteins • uses carbohydrate (sugar) as fuel during exercise
Duration	This study will take **~ 18 - 24** days depending on your individual schedule.
Procedures	While you are in the study, you will: • have protein and carbohydrate tracers put into your body through an intravenous catheter (**IV**) in your arm and a **tracer drink**, **blood samples** taken from an IV in your arm, and very **small muscle samples** taken from **small incisions** in the thigh area of your leg during 4 lab study days. (2, **~9.5** hour days and 2, **~3.5** hour days) • have your body composition, diet, fitness, metabolism measured (throughout study)

	• consume **only** study foods and beverages provided to you during controlled feeding (**10 days** total, diets are continuous unless a break is required) • consume a **reduced** calorie diet for part of the controlled feeding period (**6 days**, **~20**, **40**, or **60**% reduced energy) • complete study exercise on a stationary bike (**~13** sessions)

Study Restrictions	• During the controlled feeding and testing periods (**11 days)**
	  • You **will not** be allowed to smoke, use nicotine-containing products, use caffeine, or drink alcohol
	  • You **will not** be allowed to consume any non-study foods or beverages (other than water)
	  • You **will not** be allowed to participate in non-study exercise or physical activities (i.e., rec sports, personal work outs, army PT work outs)
	•

Risks	The **main** risks from being in this study are:
	• Minor discomfort and / or fainting associated with:
	  – Reduced food intake
	  – IV catheter placement & blood draws
	  – Muscle biopsies
	  – Lidocaine (or similar local numbing medication) shot administration
	  – Bike exercise
	• Potential injuries associated with:
	  – Bike exercise
	• Chance of infection associated with:
	  – IV catheter placement & blood draws
	  – Muscle biopsies
	Steps to lessen the risks are described later in this consent form.

Benefits	There is no direct benefit to you for participating in this study. Information from this study may benefit other people in the future.
Alternatives	The only alternative is not to participate.
Payment	You will be paid based on the number of blood draws you complete while participating.
Covid-19 Risk Mitigation	If you agree to participate, you will be asked to follow all COVID-19 risk mitigation procedures in place at USARIEM during the time of data collection. You may be asked to wear facemasks and use hand sanitizer or wash your hands during data collection activities (in accord with prevailing recommendations at the time of data collection) and may be asked to wear gloves (i.e., nitrile gloves) during data collection.

WHY IS THIS RESEARCH BEING DONE?

When a person does not eat enough calories (food) to match the amount of energy their body needs to do exercise or physical work it causes stress. This type of stress is called an energy deficit and is common in military operations. Energy deficits can hurt the body's ability to build muscle and maintain body protein levels. They can also hurt the body's ability to use carbohydrate (sugar) for fuel during exercise.

The purpose of this research is to understand how different levels of stress experienced by Soldiers may change how the body uses food. We will study how stress changes the way your body uses protein to support your muscle and overall body protein levels. We will also study how stress changes the way your body uses carbohydrate to fuel exercise. Results from this study will be used to help researchers develop new combat ration food products and feeding guidelines for Soldiers during military operations.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be asked to do the activities listed in the table and explained below. **Please ask questions.**

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

Study Phase	Duration / Activities
Pre-Testing Baseline Procedures	**Approximately 4 to 10 days**
	• Medical and Background Screening *(~1 hour)* • Height Measurement *(2 min)* • Weight Measurement *(fasted, 2 min/measurement)* • Body Composition *(fasted, ~30 min)* • Resting Energy Level Measures: Resting Metabolic Rate (*fasted,~50 min*) • Fitness Level Stationary Bike Test *(fasted, ~45 min)* • Various Stationary Bike Exercise Practice Sessions *(fasted, time duration varies)* • Menstrual Cycle Interview *(females only, ~10 min)*
Run-in Period	**3 Days**
	• Diet Instructions from Staff to Maintain Weight *(all days)* • Weight Measurement *(fasted, in morning, all days)*
Energy Balance Phase	**2 Days**
	• Stationary Bike Exercises, medium to hard difficulty and individualized sessions (*fasted, time duration varies, all days)* • Weight Measurements *(fasted, in morning both days)* • Weight Maintaining Study Diet with Supervised Meals *(both days)*
Protein Feeding Study #1	**1 Day, ~9.5 hours in lab**

	• Weight Measurement *(fasted, 2 min/measurement)*
	• Body Composition *(fasted, ~30 min)*
	• Protein Metabolic Study
	  • Protein tracer IV Infusion, IV blood collections, breath collections
	  • Single-leg muscle biopsies (*4 samples from 2 incisions*)
	  • Consume protein beverage

	1 Day, ~3.5 hours in lab

Carbohydrate Feeding Study #1	• Weight Measurement *(fasted, 2 min/measurement)*
	• Carbohydrate Metabolic Study
	  • Stationary Bike Exercise, individualized session and time trial test (fasted, ~110 min)
	  • IV blood collections, breath collections
	  • Single-leg muscle biopsies *(2 samples from 1 incision)*
	  • Consume carbohydrate beverage containing a carbohydrate tracer
	• Biopsy care *(~15 min)*

Energy Deficit Phase *(level of deficit is randomly assigned)*	**5 Days** • Stationary Bike Exercise, medium to hard difficulty and individualized sessions (*fasted, time duration varies, all days)* • Weight Measurements *(fasted, in morning all days)* • Reduced Calorie (energy) Study Diet with Supervised Meals *(all days)* • Biopsy Care *(two days, ~15 min)*

Protein Feeding Study #2	**1 Day, ~9.5 hours in lab**
	• Weight Measurement *(fasted, 2 min/measurement)*
	• Body Composition *(fasted, ~30 min)*
	• Protein Metabolic Study
	  • Protein tracer IV Infusion, IV blood collections, breath collections
	  • Single-leg muscle biopsies *(4 samples from 2 incisions)*
	  • Consume protein beverage

Carbohydrate Feeding Study #2	**1 Day, ~3.5 hours in lab**
	• Weight Measurement *(fasted, 2 min/measurement)*
	• Carbohydrate Metabolic Study
	  • Stationary Bike Exercise, individualized session and time trial test (fasted, ~110 min)
	  • IV blood collections, breath collections
	  • Single-leg muscle biopsies *(2 samples from 1 incision)*
	  • Consume carbohydrate beverage containing a carbohydrate tracer
	• Biopsy care *(~15 min)*

Follow-up Visits	**2 Days, ~30 minutes** • Biopsy Care *(two days, ~15 min)*

More details about study procedures are listed below:

Screening Procedures:

Demographic and Activity Background Survey: We will ask you questions about your medical history, exercise habits, and eating habits. If you are a female, this survey will ask questions about your menstrual cycle. This survey will be used in-part to determine if you are able to safely participate in this study.

Medical Screening: You will meet with the staff of the Office of Medical Support and Oversight (OMSO) at USARIEM, or at your Unit's supporting medical facility in coordination with OMSO, for a health screening (~ 1 hour, ~2 visits) to ensure you may safely participate. The staff will draw less than a tablespoon of blood from your arm to see how quickly your blood clots and review your medical history. If you are active duty military and your unit is not located at Natick oldier Systems Center, portions of this screening may occur at your unit's medical oversite location in coordination with OMSO.

Study Procedures:

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.).

Body Composition: After an overnight fast (≥8 hrs), we will use a dual energy x-ray absorptiometry (DEXA) scanner and bio-electrical impedance device (BIA) to measure your muscle mass, fat mass, and body water. We will ask you to provide a urine sample to measure your hydration status. We will measure your body composition 3 times during the study.

During each DEXA scan, you will lie still on your back for ~10 minutes while the x-ray scanner moves over you. For each BIA measurement, you will remove your socks; clean your feet and hands using cleansing wipes, step on the machine, and hold the handlebars for ~ 1 minute.

Urine Pregnancy Test: If you are female, you will take a urine pregnancy within the 24 hours or the morning of each DEXA scan, overseen and documented by a female staff member. If the pregnancy test is positive, you will be excluded from further participation in this study.

Height and Weight: We will measure your height once at the beginning of the study. Weight measurements will be taken almost daily following an overnight fast (≥8 hrs) and in the nude behind a privacy screen or in a locked bathroom stall. If a break is required (i.e., some females or unforeseen reasons), your weight will be measured approximately every 3-5 days during the break.

Resting Energy Levels (Resting Metabolic Rate) Measures: This procedure will measure how many calories you normally burn while resting. After an overnight fast (≥8 hrs), you will lay awake in a dimly lit room on a bed for 30 minutes. We will collect the measures by placing a clear plastic hood attached to a machine over your head for ~20 minute while you lay still and awake.

Fitness Level Stationary Bike Test: After an overnight fast (≥8 hrs), you will complete one test on a stationary bike, to measure your fitness level (VO2peak). During the test, you will wear a mouth piece and a nose clip, or a mask covering your nose and mouth, so we can measure how much oxygen your body uses. 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 are too tired to continue.

Study Diets: You will receive individualized food and beverages (except water), which consist of mostly military combat ration items from Meals, Ready-to-Eat (MREs), along with some commonly eaten store bought food items.

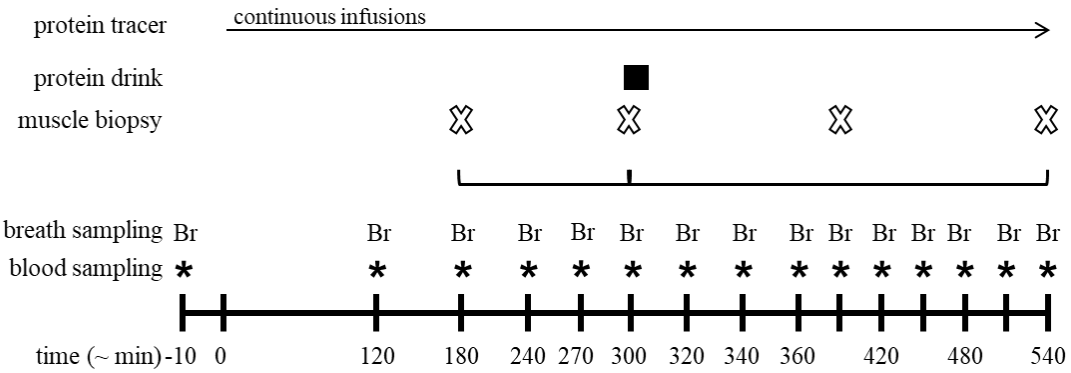
During the energy balance phase, you will eat meals that provide the amount of energy your body needs for daily living and to refuel after the daily bike exercise. During the energy deficit phase, your food will be moderately reduced to achieve an energy deficit (either ~20, 40, 60% of your total daily requirements). This is not a weight loss study or a long-term weight loss diet and you will gain any weight you lose back soon after you finish the study diet. You will be asked to return all food wrappers to study dietitians after consumption.

Medium to Hard Stationary Bike Exercise: Following an overnight fast (≥8 hrs), you will complete a hard bike ride to reduce the amount of carbohydrate store in your body. After a warm-up, you will cycle at ~80% of your maximal effort for 2 min. Cycling will then go down to ~50% maximal effort for 2 min. This will continue for ~50 min or 12 cycles. You will practice doing this exercise at least once during the baseline period. During the exercise, you can drink as much water as you like. However, if COVID-19 risk mitigation procedures are in place, you may be asked to wear a mask and will not be able to drink water until after the exercise.

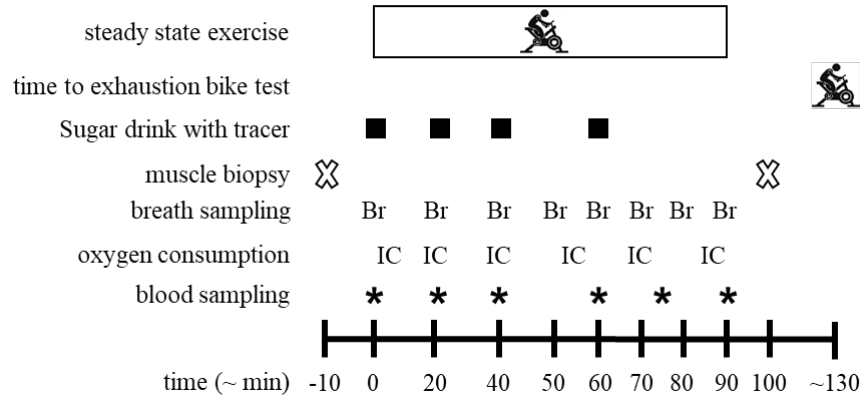
Individualized Stationary Bike Exercise during Controlled Diets: You will ride a stationary bike for individualized study exercise. The level intensity assigned to you may range from easy to more difficult depending on your exercise plan. However, you will keep same intensity for the entire exercise. We will match the intensity between the energy balance and energy deficit phases. We will measure your heart rate during the exercise.

Protein and Carbohydrate Metabolic Studies: We will use non-radioactive labeled tracers and collect your blood, muscle, breath samples to evaluate your body's ability to use protein to build muscle or maintain body proteins (Protein Metabolic Study) and your body's ability to use sugar to fuel exercises (Carbohydrate Metabolic Study).

Protein Metabolic Study



Carbohydrate Metabolic Study



Protein tracer IV Infusion: You will lay in a bed or in a reclining chair when we place an intravenous (IV) catheter in your arm or hand to inject protein tracers into your bloodstream. The

tracers are non-radioactive and are similar to substances that your body already makes naturally.

IV Blood draw: We will draw blood from an IV catheter place in your arm or hand. The IV will be covered with a heating pad to help improve blood flow. Saline (salt water) will slowly be infused while the IV catheter is in place to keep the IV open for us to draw blood. There will be 42 total blood draws (~ 2 1/4 cup) during the study.

Breath Sample: You will exhale into a special type of plastic bag with a mouthpiece assigned to you. We will collect total 46 breath samples.

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). More than one try may be needed to get a full sample.

There will be two incisions for each Protein Metabolic Study. One incision for the first and second samples and a new incision for the third and fourth samples on the same leg. New incisions will be made for the second Protein Metabolic Study on the other leg. There will be one incision for each Carbohydrate Metabolic Study. We will use the leg opposite of the one was used for the Protein Feeding Study. A new incision will be made for the second Carbohydrate Feeding Study. There will be total 6 incisions and 12 muscle samples during the study.

You may feel minor discomfort (not painful) during a muscle biopsy, including some pressure (like a muscle cramp) or tugging. You may feel a burn or sting where you get the lidocaine (or similar numbing medication) shot. Your leg may feel sore for about a week. You will receive instruction for wound care and OMSO will follow-up with you within 72 hours after each muscle biopsy.

Protein feeding: During the Protein Metabolic Studies, you will be provided a protein drink (artificially flavored; contains protein, amino acids, sugar and fat) and you should finish the drink within 5 minutes.

Carbohydrate beverage: During the Carbohydrate Metabolic Studies, we will provide you a sugar drink that contains a carbohydrate tracer. You will drink the beverage at 4 specific times, once before you start and 3 more times while you are completing the individualized stationary bike exercise (steady state bike exercise).

Time to exhaustion (TTE): During Carbohydrate Metabolic Studies, after the last muscle biopsy, you will perform a bike exercise at a fixed intensity until you are too tired to continue.

No genetic tests will be performed on any of the specimens collected in this study.

HOW LONG WILL I BE IN THE STUDY?

This study will take ~ 18 to 24 days, which includes ~45 hours of working with study staff during lab visits. The study may take longer if you are a female depending on your menstrual cycle or due to unforeseen events or individual schedule conflicts.

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, COVID-19 vaccination, or other unforeseen event, the study duration may be extended. You may be asked to repeat certain study procedures such as study diets or the bike exercise. Metabolic Studies and associated blood draws and biopsies will not be repeated. If you decline to repeat testing, you may be removed from study participation.

WHAT PRECAUTIONS DO I NEED TO TAKE?
You must not drink alcohol, smoke (including e-cigarettes), vape, chew tobacco, use caffeine-containing products, or take dietary supplements during the controlled feeding and testing periods 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 entire study.

You must only eat the foods and drink the beverages provided to you, except water, during the controlled feeding.

HOW MANY PEOPLE WILL BE IN THE STUDY?

Up to 110 volunteers may be enrolled in this study, but the researchers only need complete data from 45 volunteers to finish the study. All screening and enrollment will stop once complete data has been collected from 45 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.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source of Risk or Discomfort:	**Risk or Discomfort:**	**How We Minimize Risk or Discomfort:**
Dietary Intervention	The foods that you will eat in this study may cause: gas, cramping, bloating, constipation, or hunger.	• The diet intervention is only temporary and any discomforts are also temporary. • You will tell study staff if you have any known food allergies.
Body Composition	DEXA: Radiation, risk to fetus. There are no risks associated with BIA.	• Low dose of radiation, all 3 DXA scans together equal the same amount of 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.
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 or draw blood. • 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.
Lidocaine Shot	Slight, brief pain and possible, rare side effects: You might feel a slight, brief pain when you get the lidocaine (or similar numbing medication) shot. 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 Lidocaine allergy (or similar). • 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 numbing medication, medical staff will be called immediately. Epi-pens are onsite for emergency use.
Protein and Carbohydrate Tracers	There are no known risks or side effects directly related to infusing protein tracers or drinking carbohydrate tracers in people. Possible side effects related to infusions include: volume overload (when your blood volume is too large for your heart to work properly), infection, or an allergic reaction	• Qualified pharmacists will prepare the infused tracers. • Only qualified researchers will administer the tracers slowly, in small amounts and monitor the infusions.
Aerobic Exercise	Lightheadedness, Fatigue, Cardiovascular Risk, Musculoskeletal Strains or Soreness You may feel discomfort and fatigue in your muscles during and shortly after exercise. Mild to severe muscle soreness may continue for one to seven days.	• CPR-certified Staff. • You are healthy and fit and will be excluded if not.
Resting Metabolic Rate Measurement	Possible claustrophobia due to the plastic hood used to collect measurements.	• The plastic hood is clear and does not touch your face.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There is no direct health or other benefit 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 provider for a full evaluation of any potential problem.

WILL RESEARCH RESULTS BE SHARED WITH ME?

We will be able to share results of your body composition and maximal fitness tests after the study is complete. We will also be able to share study findings once publications are available. Any perceived clinically relevant results will not be shared with you because biological samples will not be analyzed until after you finish the study.

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, and are not participating as part of an identified and recruited Military Volunteer Group/Unit on official orders, 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 participating as part of an identified Military Volunteer Group (i.e., on official orders from another duty station as part of the study) you will be reimbursed for travel costs or other costs related to participation in this research according to Joint Travel Regulations.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

You will receive $26.00 for each completed study blood draw. There are 42 blood draws during the entire study. *This does not include the blood sample taken during your medical clearance*. If you complete all 42 study draws, you will receive $1,092.00. 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 will be needed to process 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. 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 as a result of participating in this research, please contact the Principal Investigator:

Jess A. Gwin, PhD
U.S. Army Research Institute of Environmental Medicine
Building 42, Room 245-b

10 General Greene Ave
Natick, MA 01760
Office Phone: 508-206-2300
Cell Phone: 765-401-0058
Email: jessica.a.gwin.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.

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, 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 any forms of identifiable information. Dr. Jess A. Gwin and the study coordinator will keep the link between your participant number and your research records in a locked cabinet or on a password-protected computer file. 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. The principal investigator and the study coordinator are the only people who will be able to match your research participant number with any of your personal identifying information. The link will be destroyed when study is complete.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others. No photographs, video or audiotape will be recorded without a signed photo/audio release form. In the event that it is discovered that you have been inadvertently photographed or visually recorded without your permission, the materials will be immediately destroyed. Permission through the Audio Visual Image Release form will be confirmed before any photographs or other visual recordings are used.

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

- U.S. Army Human Research Protections Office and other DOD offices charged with oversight of human research
- USARIEM Office of Research Quality and Compliance
- University of Arkansas for Medical Science Institutional Review Board

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.

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

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.

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 benefits or your future relationships with USARIEM. If you choose to withdraw from the study you will tell a study staff member verbally or in writing (electronic or paper/pencil). If you do not complete the entire study, you will be compensated for the number of 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, in addition to any diet and exercise logs that you had started to complete.

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 restrictions such as study diets and exercise and not smoking or drinking alcohol during testing periods
- You become ill or injured, or to protect your health and safety
- You are not willing to follow all COVID-19 risk mitigation procedures and policies in place at USARIEM during the time of data collection

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 should test positive or display symptoms for COVID-19, your physical fitness and eligibility to return to participation in the research processes will be determined by OMSO.

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 Jess A. Gwin, PhD (the Principal Investigator); Office phone: 508-206-2300; Cell phone: 765-401-0058.

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. You may also contact the USARIEM Human Protections Director 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