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

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Recovery protein and sleep loss

Technical Title: Recovery protein nutrition as a countermeasure for anabolic resistance following sleep loss

Principal Investigator: Jess A Gwin, PhD

Introduction: You are being asked to participate in this research study because you are 18-39 years old, are healthy, routinely participate in exercise, 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 so that you can make an informed decision. This process is called informed consent. • Please **ask questions** about anything you do not understand. • Feel free to talk with your family, friends, or others before you decide. • After your questions have been answered, you will be asked if you want to participate. If you agree, you will sign this consent form. • You will be given a copy of this form to keep.
Voluntary Participation	You do not have to take part in this research. **It is your choice**. You can also choose to stop participating at any time during the study.
Purpose	To understand if sleep loss changes the way your body builds and maintains body protein (muscle) and whether eating protein in a certain pattern can improve recovery from sleep loss.
Duration	This study will take about **18 - 27** days depending on your individual schedule.
Procedures	While you are in the study, you will: • drink protein tracer drinks (**6** times) • have blood samples taken from a **single-stick needle** (**1** time) or intravenous catheter (**IV**) in your arm (**3** times), • have very small **muscle samples** taken from small incisions in the thigh area of your leg (**3** times) • collect your saliva (spit) in a tube (**6** times) • collect your urine for about **24**hours (**3** times) and about **2**hours (**3** times) • have your body composition, diet, fitness, metabolism measured (throughout study, detailed below)

	• consume **only** study foods and beverages provided to you during controlled feeding (**11** days total, diets are **continuous** unless a break is required) • complete study exercise on a treadmill or stationary bike (**14** sessions)
Study Restrictions	During the controlled feeding and testing periods **you will not be allowed to**: • smoke, use nicotine-containing products, use caffeine, or drink alcohol • consume any non-study foods or beverages (other than water) • participate in non-study exercise or physical activities (i.e., rec sports, personal workouts, army physical training (PT) workouts)
Risks	The **main** risks from being in this study are: • Minor discomfort and / or fainting associated with: – IV catheter placement & blood draws – Muscle biopsies – Lidocaine shot (or similar local numbing medication) – Exercise • Potential injuries associated with: – 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 compensated for blood draws.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to understand how losing sleep, commonly experienced by Soldiers, may change how the body builds new muscle and body proteins. We will also study how the pattern of protein in your diet may change how your body uses protein to support your muscle and recovery. We will also study how losing sleep 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), wear a sleep watch continuously, and wear a heart rate monitor during exercise.

Study Phase	Duration / Activities
Baseline Procedures	**Approximately 3 to 10 days**
	• medical and background screening (about 1 hour) • height measurement (2 minutes) • weight measurement (fasted, 2 min/measurement) • body composition (fasted, about 30 minutes) • resting energy level measures (fasted, about 50 minutes) • fitness level treadmill test (fasted, about 45 minutes) • treadmill ruck march practice sessions (2, fasted, about 90 minutes) • menstrual cycle interview (females only, about 10 minutes)
Sleep Satiation Phase (7 days full sleep)	**Days 1-7**
	• weight measurements (fasted, about 2 minutes, all days) • weight maintaining diet instructions (about 10 minutes, days 1 to 3) • weight maintaining study diet with some supervised meals (about 40 minutes, days 4 to 7) • treadmill running or stationary biking, easy to medium difficulty and individualized sessions (fasted, time duration varies, all days) • sleep about 7-9 h/night • protein stable isotope tracer drink (about 1 minutes, days 4 and 7) • blood draw (about 5 minutes, day 4) and saliva collection (about 1 minutes, days 5 and 6) • 24 hour urine collection (from day 7 to 8)
End of Phase Metabolic Testing (about 3.5 hours)	**Morning of Day 8**
	• single-leg muscle biopsy (1 sample from 1 incision) • IV blood collections, breath collections • consume carbohydrate beverage • 90-minutes treadmill ruck marching • Urine collection
Sleep Restriction Phase (4 days short sleep)	**Days 8-11**
	• weight measurements (fasted, about 2 minutes, all days) • weight maintaining study diet with some supervised meals (about 40 minutes, days 8 to 11) • biopsy care (about 15minutes, day 9) • treadmill running or stationary biking, easy to medium difficulty and individualized sessions (fasted, time duration varies, all days) • sleep about 4 h/night • protein stable isotope tracer drink (about 1 minute, days 8 and 11) • saliva collection (about 1 minutes, days 9 and 10) • 24 hour urine collection (from day 11 to 12)
End of Phase Metabolic Testing (about 3.5 hours)	**Morning of Day 12**
	• single-leg muscle biopsy (1 sample from 1 incision) • IV blood collections, breath collections • consume carbohydrate beverage • 90-minutes treadmill ruck marching • Urine collection

Recovery Phase (3 days full sleep)	**Days 12-14**
	• weight measurements (fasted, about 2 minutes, all days) • weight maintaining study diet with some supervised meals (about 40 minutes, days 12 to 14) • biopsy care (about 15 minutes, day 13) • treadmill running or stationary biking, easy to medium difficulty and individualized sessions (fasted, time duration varies, all days) • sleep about 7-9 h/night • protein stable isotope tracer drink (about 1 minutes, days 12 and 14) • saliva collection (about 1 minutes, days 13 and 14) • 24 hour urine collection (from day 14 to 15)
End of Phase Metabolic Testing (about 3.5 hours)	**Morning of Day 15**
	• single-leg muscle biopsy (1 sample from 1 incision) • IV blood collections, breath collections • consume carbohydrate beverage • 90-minutes treadmill ruck marching • Urine collection
Follow-up Visit (1 day, about 15 minutes)	**Days 16 or 17**
	• biopsy care *(about 15 minutes)*

No genetic tests will be performed on any of the biospecimens (blood, urine, saliva, muscle tissue) collected in this study.

Screening Procedures:

Background Questionnaire & Menstrual Cycle Interview: You will be asked questions about your medical history, exercise habits, and eating habits. If you are a biological female, a female staff member will ask you questions about your menstrual cycle and any continuous hormonal contraceptives you may be using (e.g., IUD or pills without the placebo week).

Sleep Habits Surveys: We will ask you questions about your sleep habits.

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 (about 1 hour, about 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 Soldier Systems Center, portions of this screening may occur at your unit's medical oversite location in coordination with OMSO.

Information from the screening procedures will be used to determine if you are able to safely participate in this study.

Study Procedures:
Body Composition: At the beginning of the study and after an overnight fast (≥8 hours), we will use a dual energy x-ray absorptiometry (DEXA) scanner to measure your muscle, fat, and bone. You will lie still on your back for about 10 minutes while the scanner moves over you.

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

Height and Weight: We will measure your height at the beginning of the study. Weight measurements will be taken daily during days 1-14 after an overnight fast (≥8 hours).

Resting Energy Levels Measures: This procedure will measure how many calories you normally use while resting. After an overnight fast (≥8 hours), you will lay awake in a dimly lit room on a bed for about 30 minutes. We will collect the measures by placing a clear plastic hood over your head, or a mask covering your nose and mouth, attached to a machine for approximately 20 minutes while you lay still and awake.

Fitness Level Treadmill Test: After an overnight fast (≥8 hours), you will complete a treadmill test to measure your fitness level (VO2peak). During the test, you will wear a mouthpiece and a nose clip, or a mask covering your nose and mouth, so we can measure how much oxygen your body uses when you exercise at your max. This test will start with you walking and will progress to a run on a treadmill. The speed and incline on the treadmill will increase in stages until you stop because you've reached your maximal oxygen consumption or if you become too tired to continue to run. During the VO2peak test, you will wear a heart rate monitor strap on your chest so we can measure your heart rate.

Sleep Monitoring: We will ask you to wear an activity monitor on your wrist for the days 1-14 at all times. This monitor measures how much you sleep and is similar in size to a watch. This will give us a record of your sleep patterns. We will also ask you to write down the time that you go to bed (for the purpose of sleeping), the time you wake up, and answer a few questions about how 'well' you slept.

Sleep Restriction: On 4 nights, days 8-11, you will be asked to only sleep for 4 hours between about 0100 and 0500 with no naps. To make sure you are able to adhere, and if you are not scheduled for any other supervised activities (for example, military classes or other research studies) we will ask you to report to the study testing facility (for example, Doriot Chambers, or other designated data collection space at USARIEM) and be monitored by study staff from about 2030 – 0015. You may be asked to report for supervision if you are not scheduled for any external supervised activity. You will be allowed to choose your own entertainment (i.e., use of cell phones and use of personal or provided video games, movies, internet). You will be released at about 0015 to return to your sleeping quarters, or place of residence and perform any pre-bed hygiene before going to sleep at about 0100.

Sleep Satiation and Sleep Recovery: On days 1-7 and 12-14, We will ask you to sleep about 7-9 hours each night between the hours of about 2300 and 0700 with no naps.

Diet Instructions (Days 1-3): You will receive individualized diet instructions from study staff to follow on days 1-3. Individualized diet instructions are developed using the resting energy levels measures. You will be asked to describe what you ate on days 1-3 to a study staff member during a food recall on days 2-4. No food will be provided to you.

Study Diets (Days 4-14): 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. You will eat meals that provide the amount of energy your body needs to maintain your weight. You will eat breakfast, lunch, dinner, and a snack at approximately the same time each day throughout the study. You will be asked to eat some meals with study staff (about 30-60% of meals) and return all food wrappers to study dietitians after consumption.

For days 12-14, you will randomly be assigned to eat protein foods and beverages in either a pattern that includes equal amounts of protein foods at all meals or a pattern that includes greater amounts of protein at dinner than other meals.

Individualized Exercise: Every day except Metabolic Testing Days (days 8,12, &15), you will run on a treadmill or ride a stationary bike for individualized study exercise. The level intensity assigned may range from easy to medium difficulty depending on your fitness level treadmill test result. However, you will keep same intensity for the entire exercise. We will monitor your heart rate during all exercises.

Blood Draw: We will take a single-stick blood draw (venipuncture) on day 4 and repeated blood samples on days 8, 12, and 15 (7 draws per day) from an IV catheter placed in your arm or hand on. Saline (salt water) will be attached to the IV catheter and slowly drip to keep the IV open for us to draw blood.

There will be 22 total blood draws, equal to just under 1 cup, during the study. Only trained staff will draw your blood.

Protein Stable Isotope Drinks: 6 times throughout the study (days 4, 7, 8, 11, 12, and 14), we will ask you to drink a stable isotope protein tracer dissolved in water. Protein tracers are similar to molecules that you already have in your body naturally and are not radioactive. The protein tracer on days 4, 8, and 12 will be deuterium oxide and the protein tracer on days 7, 11, and 14 will be ^{15}N-alanine.

Saliva Samples: On the morning of days 5, 6, 9, 10, 13 & 14, we will ask you to hold and chew on a cotton swab in your mouth for about 1 minute to collect your saliva (spit), total 6 samples will be collected for the study. We will ask you not to brush your teeth or eat or drink anything about 30 minutes before saliva sample collection.

Urine Collections: We will ask you to collect your urine for approximately 24 hours with a provided urine collection container 3 times throughout the study (days 7-8, 11-12 & 14-15). You will also be asked to empty your bladder before exercise, then collect your urine during (if needed) and immediately after you finish exercise (about 2hour) in a provided collection container on days 8, 12 & 15.

Muscle Samples: There will be 3 muscle samples (biopsies) during the study. A trained researcher will clean the skin with a medical cleaning solution and numb a very 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 (incision; less than 1/4 inch) in the skin and use a needle to remove a very 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. A sticky band-aid (steri-strip) will be used to close the cut. There will be one cut for each testing day (3 total) and the leg used will randomly alternate (i.e., right, left, right or left, right, left).

You may feel minor discomfort (not pain) 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 shot (or similar numbing medication). Your leg may feel sore for about a week. Only trained staff will take muscle samples. You will receive care instructions and OMSO will follow-up with you within 72 hours after each sample.

Ruck Marching & Carbohydrate beverage: During each Metabolic Testing Day (days 8,12 &15), you will complete a about 90 minutes rigorous walk on the treadmill while wearing a pack that is about 30% of your body weight (ruck marching). The exercise intensity will be approximately 55% of your maximal effort. Throughout the treadmill walk, you will wear a mouthpiece and a nose clip, or a mask covering

just your nose and mouth, connected to a machine that measures the oxygen you use and the carbon dioxide you breathe out. We will monitor your heart rate and observe you for safety.
We will provide you a sugar, fruit flavored beverage (i.e., like Kool-Aid) to drink at 4 specific times, once before you start (about 27oz) and 3 times (about 10oz at 20, 40, and 60 minute) during the ruck marching.

You will practice the ruck march during the baseline period, but you will not drink the sugar beverage during the practice.

HOW LONG WILL I BE IN THE STUDY?

This study will take about 18 to 27 days, including baseline, and will involve about 52 hours of working with study staff during lab visits.

WHAT PRECAUTIONS DO I NEED TO TAKE?

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

You <u>should</u> <u>not</u> participate in this study if any of the following applies to you:

- Metabolic or cardiovascular abnormalities, gastrointestinal disorders (e.g., abnormal blood clotting, kidney disease, diabetes, cardiovascular disease, anemia etc.) as determined by OMSO or home duty station medical support
- History of complications with lidocaine (or similar local anesthetic)
- Present condition of substance abuse (e.g., alcoholism, anabolic steroid use etc.) as self-report or determined by OMSO or home duty station medical support
- Cumulative blood donation of greater than 550mL within 8-wk of beginning scheduled study blood collection
- Cumulative blood donation of greater than 550mL within 8-wk after completing scheduled study blood collection
- Pregnant, trying to become pregnant, and/or breastfeeding (results of urine pregnancy test prior to body composition scans and self-report for breastfeeding)
- Unwilling or unable to consume study diets or foods provided due to personal preference, dietary restrictions, and/or food allergies
- Unwilling or unable to adhere to study physical restrictions or sleep prescriptions

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

- You must be willing to refrain from (stop using) alcohol, smoking/using any nicotine product (includes e-cigarettes, vaping, chewing tobacco), caffeine, and dietary supplements during the intervention periods of the study.

- You must adhere to study physical and sleep 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 days 4-14 and adhere to dietary guidance on days 1-3.

- During the sleep restricted portions of the study, please arrange to have someone else drive you home and be aware of the impact from drowsiness when driving, operating heavy machinery and engaging activities that might increase risk of injury.

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 20 volunteers to finish the study. All screening and enrollment 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.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source of Risk or Discomfort:	Risk or Discomfort:	How We Minimize Risk or Discomfort:
Dietary Intervention	Although rare, the foods that you will eat in this study may cause: gas, cramping, bloating, or constipation.	• The diet intervention is only temporary and any discomforts are temporary. • You will tell study staff if you have any known food allergies.
Sleep Restriction	Feeling tired, irritable, and/or not thinking clearly.	• The sleep intervention is only temporary and any discomforts are temporary. • You will walk back to the military quarters on post; and they will be put on study specific restrictions/profile. • If you come from off-post, you will be released in the care of someone else who will drive you home.
Body Composition	DEXA: Radiation, risk to fetus.	• Low dose of radiation, equal to 1/6th the amount of radiation received in a transatlantic flight. • Women who are pregnant or planning to become pregnant are excluded. • Females will be pregnancy tested before DEXA.
Venipuncture, Intravenous (IV) Catheter Placement and Blood Draws	Small risks include: feeling faint, irritation, bruising, swelling, infection, or allergic reaction Possible side effects related to saline drips include: volume overload (when your blood volume is too large for your heart to work properly), infection, or an 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. • Only qualified researchers will administer the slow saline drip and the saline drip is a relatively small amount (about 2 cups saline over about 1.5 hours).
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 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 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 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 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 Stable Isotope Tracer Drink	The tracers are not radioactive. There are no known risks or side effects directly related to drinking 15N alanine. Very rare, but possible side effects include: nausea when drinking large amounts of deuterium oxide.	• The amount of deuterium oxide provided is small and not expected to induce nausea. • Any rare, but potential nausea is only temporary and any discomforts are temporary.
Aerobic Exercise	Lightheadedness, Fatigue, Cardiovascular Risk, Musculoskeletal Strains or Soreness You may feel discomfort or fatigue in your muscles during and shortly after exercise. Mild to severe muscle soreness may continue for one to seven days.	• You are healthy and fit and will be excluded if not. • You will be monitored by study staff during exercise. • CPR-certified Staff. • You will stop exercising if lightheaded.
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?

If any unexpected health information is found during your participation, the findings will be documented and provided to you. You will be encouraged to make an appointment with your primary care provider (or OMSO for military) to follow-up. No diagnoses will be made by study personnel; therefore, the findings will not be reported to health providers.

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.

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 $46.00 for each completed study blood draw. There are 22 blood draws during the entire study. *This does not include the blood sample taken during your medical clearance*. If you complete all study blood draws, you will receive $1,012.00. If you do not complete the entire study, you will receive money for draws completed. You will not be eligible for any other form of compensation during this study.

Payment will be processed within two weeks of study completion/end and you will receive payment within approximately ten weeks of study completion/end. Payment will be made by direct transfer to your bank account.

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 (ORQC)
- USARIEM, Office of Medical Support and Oversight (OMSO)

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 completed. The data and samples collected from you will be retained and may be used when analyzing the results of this research. You will be asked to return the sleep watch and any study diet/wrappers and sleep 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

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.

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